A randomised clinical trial of a novel pharmacist-led glucocorticoid tapering intervention

Overview

Glucocorticoids (GCs, also known as steroids or prednisone/prednisolone) are frequently used in the treatment of many autoimmune inflammatory rheumatic diseases (AIRDs), including Rheumatoid Arthritis (RA), Polymyalgia Rheumatica (PMR) and Giant Cell Arteritis (GCA). While they can relieve symptoms, they are also associated with many side effects including reduced life expectancy, infection, weight gain, hypertension, diabetes, osteoporosis, cataracts, mood disturbance, thin skin, and easy bruising. In recognition of this, Australian Living Guidelines for RA recommend against the long-term use of GCs. However, studies have shown that once GCs are started, they are often difficult to stop, even when the joint disease of RA appears to be well-controlled. Reducing and stopping GCs is often difficult to achieve in the clinic setting, where there are often insufficient resources to provide comprehensive education and support. Currently, there are no proven interventions or guidelines for improving GC tapering and cessation in patients with AIRDS. However, the impact of GC-related adverse effects on patients is significant and improved tapering and cessation of these drugs will likely lead to an improvement in both physician-measured and patient reported outcomes. This study aims to develop a pharmacist-led intervention to support GC reduction and cessation, helping minimise associated side effects in AIRD patients, compared to usual care.

Lay Summary

This study aims to test the effectiveness and patient satisfaction of a pharmacist-led program to help patients with inflammatory diseases, such as Rheumatoid Arthritis (RA), Polymyalgia Rheumatica (PMR) and Giant Cell Arteritis (GCA), to reduce or stop taking glucocorticoids (GCs) over six months.

The study involved patients from two rheumatology clinics who were already using glucocorticoids and needed to lower or stop their dose as part of their regular treatment. Patients were randomly assigned to either a "control" group, which only received standard care from their rheumatologist, or an "intervention" group, which received extra support from the intervention pharmacist. This pharmacist helped patients reduce their glucocorticoid doses gradually by providing regular, 4-weekly, check-ins (either by phone or in-person) to track progress, offer advice, and address any issues such as side effects or flare-ups of their condition. Patients in both groups had their progress measured over six months, and their experience with care was recorded.

So far, 90 patients have enrolled in the study, with 53 completing the 6-month trial. Among those who have finished the study, 14 out of 24 (58%) in the intervention group and 21 out of 29 (72%) in the control group successfully tapered their GCs to the target dose set by their rheumatologist at the start of the study**.** All intervention group participants who did not meet their 6-month GC target dose were due to flares/relapses and 75% of those in the control group were similarly due to a relapse/flare of

their condition. The study is expected to conclude in July 2025, after which the results will be analysed and shared.

The goal of this research is to see whether the pharmacist-led approach helps patients reduce their glucocorticoid doses safely and whether it improves their overall care experience.

Scientific Summary

Objective:

To determine the efficacy and acceptability of a pharmacist-led GC tapering intervention for rheumatology patients.

Primary Outcome Measure: Achievement of target GC dose at 6 months*

*Target dose set by the usual rheumatologist at time of referral to study.

Secondary Outcome Measures:

1. Percentage reduction in GC dose at 6 and 12 months.
2. Incidence rate of disease relapse or flare.
3. Physician measured and patient reported GC adverse effects.
4. Barriers to GC tapering.
5. Patient's care experience (PREM).

Research design:

Patients were recruited to a randomised controlled trial from two public rheumatology outpatient services (Royal Adelaide Hospital and The Queen Elizabeth Hospital) to participate in a pharmacist-led GC tapering intervention every 4 weeks (via telehealth or phone consult).

Inclusion criteria included: Age >=18 years, clinical diagnosis of RA, SLE, Myositis, PMR, GCA or other AIRD made by a rheumatologist, and new or longstanding GC use requiring tapering to lower dose or cessation over the next 6 months as part of usual care.
Exclusion criteria included: Unable to provide informed consent, non-rheumatological indication for GC use.

Patients were invited to participate by their treating rheumatologist, rheumatology nurse or nurse practitioner during their usual clinic visit. Interested patients were then seen by the intervention pharmacist who provided further information on the study and obtained formal informed consent. The treating rheumatologist was asked to provide a GC taper and a target GC dose for 6 months' time. Patients were randomised in a non-blinded manner by the intervention pharmacist using the Sealed Envelope randomisation tool. All patients (control and intervention arm) had a baseline visit with the intervention pharmacist during which baseline measures were obtained and a personalised printed GC tapering protocol was provided, based on the instructions from their rheumatologist. Patients also

received GC education and information handouts from the pharmacist. All patients completed the CQRA-PREM-AU, a patient reported experience measure (PREM) at baseline and study end. Participants randomised to the intervention group received phone or face to face reviews with the pharmacist every 4 weeks. At these appointments the pharmacist provided support for patients as they tapered their GCs and recorded any patient reported adverse effects or barriers to tapering including relapse or flare. If there had been a change to their GC dosing between visits, the pharmacist provided an updated printed dosing schedule that reflected the treating rheumatologist's new tapering plan. These pharmacist visits were in addition to usual care with their rheumatologist. Patients in the control group, not receiving the intervention, received usual care from their rheumatologist only. All participants were reviewed by the pharmacist at 6 months (study end) for measurement of primary and secondary outcome measures. An exit participant satisfaction survey and patient reported outcome measure (PREM) were also completed at the 6-month final visit.

Results:

Ninety participants were recruited to this study between February 2024 until Jan 2025, with 44 randomised to the intervention arm and 46 to the control arm. Of those recruited, 66.6% were female with a median age of 69 (interquartile range, IQR 62.25-74). The majority of participants had a diagnosis of giant cell arteritis (GCA), polymyalgia rheumatica (PMR) or antineutrophil cytoplasmic antibody (ANCA) associated vasculitis, 35, 23 and 14 respectively. Fifty-three participants have completed the study (24 intervention and 29 control), with the remainder due to complete by the end of the July 2025. Of the 90 enrolled in the study, 4 elected to withdraw (3 from the intervention arm and 1 from the control arm).

Of the participants who have completed the study to date, 14/24 (58%) in the intervention group and 21/29 (72%) in the control group reached their target GC dose. Of those in the intervention group, all 10 participants who did not achieve their 6-month target GC dose experienced a relapse/flare, with their rheumatologist increasing their prednisolone dose. In the control group, 6/8 (75%) experienced a relapse/flare as the reason for not reaching their 6-month prednisolone dose target. Average CQRA-PREM-AU score in intervention vs control groups was 4 and 4.1 respectively, with a higher score (out of 5) equating to a better care experience.

Conclusion:

Recruitment to this randomised controlled trial of a pharmacist-led GC tapering intervention has completed recruitment, with all patients due to complete the final visit by July 2025. Formal analyses will be carried out with results to be disseminated through publication and presentation at scientific meetings.