

A randomised controlled trial to evaluate the clinical and cost-effectiveness of exercise in the Prevention of leg Ulcer Recurrence - PURE trial

What is the problem?

- Leg ulcers can have a negative impact on the patient's quality of life (QoL) and are costly to manage, accounting for approximately 2% of the annual healthcare budget in Western societies.
- Leg ulcers associated with chronic venous disease are known to recur after healing (e.g. [EVRA](#)).
- Rates of venous ulcer recurrence once healed are high (26-69% at 12M as estimated by [NICE 2021](#)).
- Compression therapy is recommended in the prevention of ulcer recurrence but adherence is poor – alternative/adjunct therapies are needed.
- [NICE](#) guidance (2021) states that 'lifestyle measures should be encouraged' (e.g. Exercise, limb elevation and lifestyle modification may be helpful in the prevention of recurrence).
- Exercise offers a low-cost intervention with the potential to reduce comorbidities and the burden of disease.

What is known?

- Small scale, poorly designed studies evaluating the role of exercise in the promotion of wound healing are [conflicting](#) – more research is needed.
- There is a paucity of data on the role of exercise in the prevention of leg ulcer recurrence. To date, there have been no RCTs evaluating the role of exercise in the prevention of leg ulcer recurrence.

Study aim: To compare the effectiveness of an exercise/behavioural reinforcement programme, in addition to standard care (compression therapy plus lifestyle advice), versus standard care alone, in the prevention leg ulcer recurrence.

Treatment arms

Intervention (Exercise + usual care): A progressive resistance exercise programme (PREG) supplemented by walking. Adherence support interventions will be provided to encourage adherence. Compression, limb elevation and lifestyle advice recommended. Participants will attend the intensive programme for 6M. Maintenance sessions will be attended during the 2-year follow-up period.

Control arm: Usual care - compression plus lifestyle advice. Lifestyle advice to comprise advice on smoking cessation and dietary aspects.

Follow-up: Two years

Setting: Participants with healed ulcers will be recruited via primary and secondary care.

Eligibility criteria

Inclusion: Patients who have had an ulcer which has recently healed (healed within the past 12 weeks); ABPI >0.8; able to participate in an exercise programme.

Exclusion: Patients with a fixed ankle; unwilling or unable to tolerate compression; absolute contraindication to prescribed exercise programme.

Outcomes

Primary

- Proportion/number of participants in each arm with an ulcer which recurs within 2-years.

Secondary

- Proportion of participants in each arm who remain ulcer free at 6, 12 and 18-months
- Time to ulcer recurrence
- Changes in physical activity outcomes (self-report and objective measures) at 12W, 6, 12, 18 and 24-months
- Generic and disease specific QoL at 12W, 6, 12, 18 and 24-months
- Psychological wellbeing (HADS) at 12W, 6, 12, 18 and 24-months
- Cost-effectiveness analysis
- Adherence to exercise and compression
- Acceptability of the intervention (using the Theoretical Framework of Acceptability)
- Treatment related adverse events