VenUS 6

Venous Leg Ulcer Study

A multi-centred, pragmatic, parallel group, randomised, controlled, three arm trial to assess the clinical and cost effectiveness of compression therapies for the treatment of venous leg ulcers

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VenUS 6 Study Design - Inclusion Criteria

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1) Has at least one venous leg ulcer

2) An ankle–brachial pressure index (ABPI) of ≥ 0.8 or use of locally-approved alternative assessments to rule out peripheral arterial disease

3) Is able to tolerate full compression

4) is aged ≥ 18 years

VenUS 6 Study Design - Exclusion Criteria

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1) Is unwilling to wear full compression
2) Lacks capacity or willingness to provide consent to participate in the trial
3) Has been previously recruited for the trial
4) Is currently participating in another venous leg ulcer study
5) Has leg ulcers of non-venous aetiology or significant peripheral vascular disease which contraindicates full compression
6) Has ulcers confined to the foot
7) Has known allergy to any trial product
8) Is deemed to be not clinically appropriate to take part in the trial (at clinician discretion)
9) Planned treatment to close/remove incompetent superficial veins (e.g. via endovenous ablation, sclerotherapy) within 28 days

VenUS 6 Study Design –Outcomes

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Primary Outcome:

- **Time to healing of the reference ulcer**

Collected by:	Collected how:
Images can be taken by treating nurse **OR** participant	Clinician completed: **Participant Event Form and Ulcer Healed Photography Form**.

- Digital image taken once a week for **4 weeks** once the reference ulcer has been recorded as healed by the treating nurse

- Photography guidance has been generated to standardise the process of taking digital images
- A camera will be provided to sites for use

VenUS 6 Study Design – Outcomes

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Secondary Outcomes

Outcome	Collected how?	Completed by who?
Clinical events *(e.g. reference ulcer/leg healing, recurrence, ulcer/skin deterioration, surgical treatment)*	Participant event form	Healthcare professional
Changes to treatment/ trial treatment	Participant visit log	Healthcare professional
Quality of Life and Ulcer-related pain	Participant self complete questionnaires (Baseline (in person), 1, 3, 6 and 12 month (postal))	Participant
Resource use	Participant self complete postal questionnaires	Participant
Treatment adherence and ease of use	Participant self complete postal questionnaires	Participant

VenUS 6 Study Timelines

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Participant Recruitment

- ❑ 675 participants (225 per group)
- ❑ 32 months recruitment period (6 months pilot; 26 months main study)
- ❑ Recruitment anticipated to be completed by 30th March 2023

Participant follow-up

- ❑ Minimum 4 months, maximum 12 months
- ❑ Anticipated last patient last visit 31st July 2023

VenUS 6 Study Sites

Open to recruitment: 22

In set up: 5

- Completed site initiation visit: 2
- Site initiation visit being arranged: 3

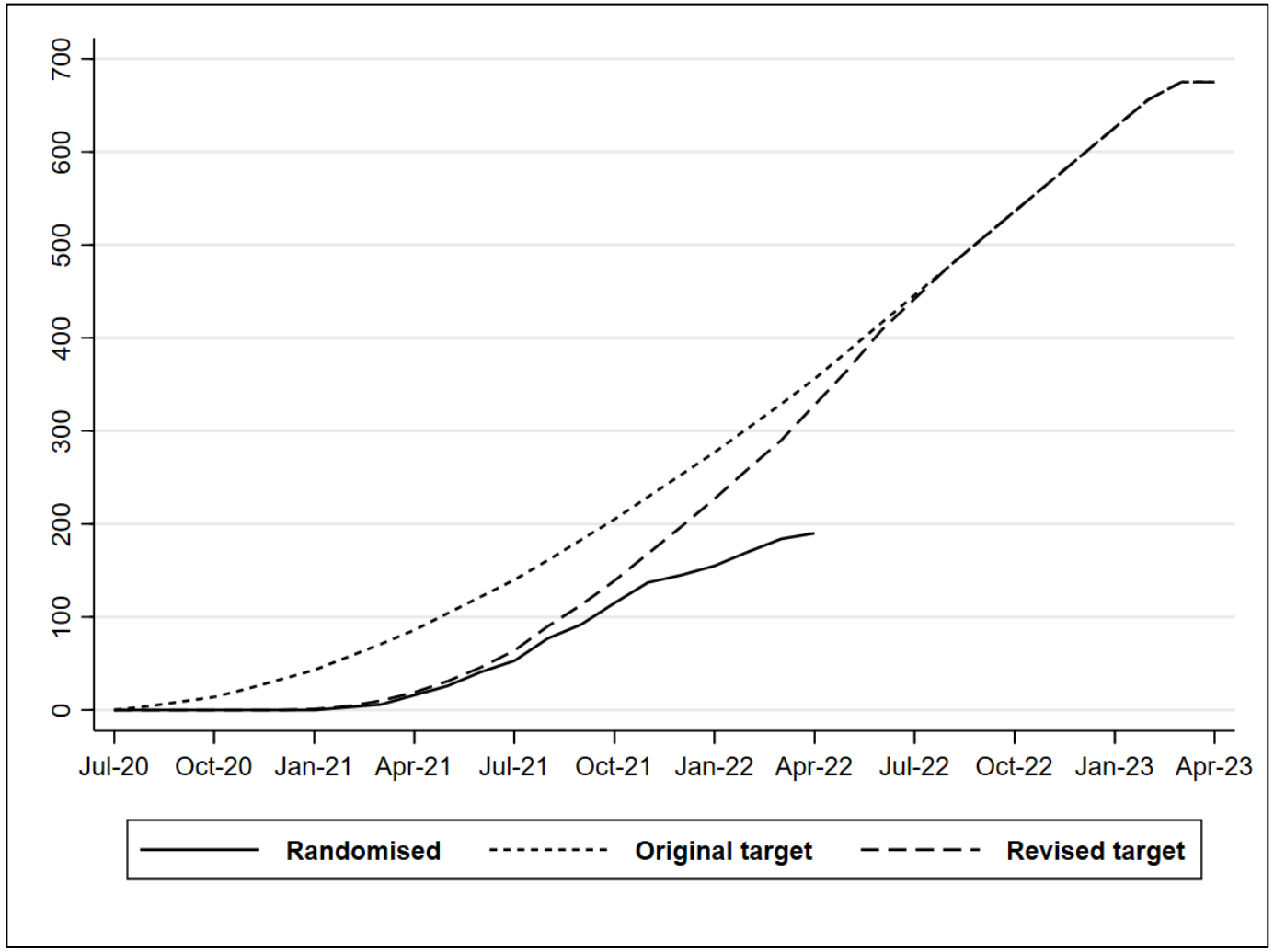
We're open to new sites

To express an interest or for further information please email: venus6-trial-group@york.ac.uk

VenUS 6 Recruitment

- Recruitment started: February 2021
- As of 11.05.2022, **216 (32%)** participants have been consented and recruited across 18 sites

- Recruitment is currently behind - running at 62% of target



VenUS 6 Contact Details

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Follow us on Twitter: **@_VenUS_6**

Find us at TVS – The Conference (Glasgow, 18&19th May) – Stand 13

Society of Tissue Viability