

Prevention Of primary Foot Ulcers in high-risk Diabetes patients (PrOFoUnD): A cluster randomised trial of 3D printed Insoles Versus Standard Care

North West Coast Clinical Network

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Emergent ICS CM Transformation Funding for programme

- Top sliced from CCG baselines
- All programmes encouraged to bid to develop improvements that could be scaled up
- 20 programmes competed
- Strong logic and evidence but smaller funding offer
- Decision to conduct RCT
- STP agreement

Diabetic Foot Ulcers

- 3.7m People have diabetes in England
- 10% will develop a foot ulcer at some time in their lives
- 85% of amputations begin with a foot ulcer
- The 5-year mortality rate after a major amputation is 70%
- Annually in England 58,000 patients with diabetes have an ulcer ¹
- Estimates that foot ulcer incidence is around 2% per year²
- Once a patient develops a primary ulcer they are twice as likely to develop further ulcer³

¹Kerr et al; (2019) *The cost of diabetic foot ulcers and amputations to the NHS. Research Health Economics. Diabetic Medicine* Vol 36. p995-1001.

²Abbot et al; (2002) *The NW Diabetes Foot Care Study: incidence of, and risk factors for, new diabetic foot ulceration in a community-based patient cohort. Diabetic Medicine* Vol 19(5)pp 377-384

³Lavery; et al. (2016) *WHS guidelines update: Diabetic foot ulcer treatment guidelines.) Journal Wound Repair and Regeneration. Date of publication 2016 Feb 1;volume 24(1):112-126.*

The cost and burden of diabetes foot ulcers to the NHS

- Annual cost of healthcare for foot ulcer and amputation in 2014/15 estimated to be between £837 million to £962 million¹
- Accounts for 1% spend of national NHS Budget and 90% of the foot care budget was spent on ulcer management¹
- Footcare expenditure greater than combined breast, prostate and lung cancer
- Reducing the prevalence of foot ulcers by a 1/3 would save the NHS £230 million¹

¹ Kerr et al; (2019) *The cost of diabetic foot ulcers and amputations to the National Health Service. Research Health Economics. Diabetic Medicine.* p995-1001.

SUMMARY OF DIABETIC FOOT CARE IN CHESHIRE AND MERSEYSIDE STP

Diabetic foot disease affects a large number of people and imposes a high cost on sufferers and NHS budgets. Experienced by 1 in 15 people with diabetes, foot ulcers have a severe effect on quality of life and are often prolonged. They can lead to lengthy spells in hospital and ultimately amputation. The longer patients wait for treatment, the longer and more severe the condition is likely to be and the higher the cost of treatment. Better care can improve outcomes and reduce costs.

There were 144,020 patients registered with diabetes in your STP population in 2016/17, and it is estimated that, at any given time, 3,240 of these had diabetic foot ulcers.

See diabetes prevalence
by CCG

See where foot ulcers
actually come from

The cost of caring for these patients in primary, community and outpatient settings across your CCGs is estimated to be £36,665,000 in 2017/18.

See how we have
calculated the costs

NICE recommends that all adult diabetes patients receive a foot assessment at least once a year. The percentage for your STP is 81%.

See how this varies
across your CCGs

However, a foot check is only useful if action is taken when risk is found. In many parts of the country there are no appropriate follow-on services to deliver this.

See what care structures
your CCGs have in place

NICE recommends that patients with active diabetic foot problems are referred within one working day to a specialist foot care service for triage within one further working day.

In the most recent National Diabetes Foot Care Audit, 92% of patients in your STP footprint waited more than 2 days and 58% of your patients waited at least 14 days.

See how your CCGs
perform on ulcer care

49% of ulcers were rated as severe and at least 39% were unhealed after 12 weeks. At least 15% had still not healed after 24 weeks.

<https://www.improvingdiabeticfootcare.com/>

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Hospital data for the three year period to March 2016 shows there were 5,988 spells with diabetic foot disease across your CCGs during this time, and patients stayed in hospital for an average of 16 nights.

See more detail on
hospital activity

1,349 amputations were undertaken in this period. 425 of these were major amputations.

Based on this level of activity, we estimate that hospital care on ulcers and amputations together with post amputation care will cost the CCGs in your STP footprint £19,774,000 in 2017/18.

View breakdown of
costs

So that gives an estimated total annual cost to your CCGs for diabetic foot care of £56,439,000.

There is strong clinical evidence that good foot care services can reduce the duration of ulcers and the rates of amputations and hospitalisations, thereby improving lives and saving money.

Find out what good foot
care services look like

A reduction of 10% across your CCGs would mean savings in the region of £5,644,000 in 2017/18. And UK experience shows that improvements and savings can start to be seen within the year changes are implemented.

Case studies

With the expected increase in the prevalence of diabetes, these savings could be worth £6,464,000 by 2030/31.

Find out how we
estimated the savings

College of Podiatry Diabetes Commissioning Toolkit v177130.1

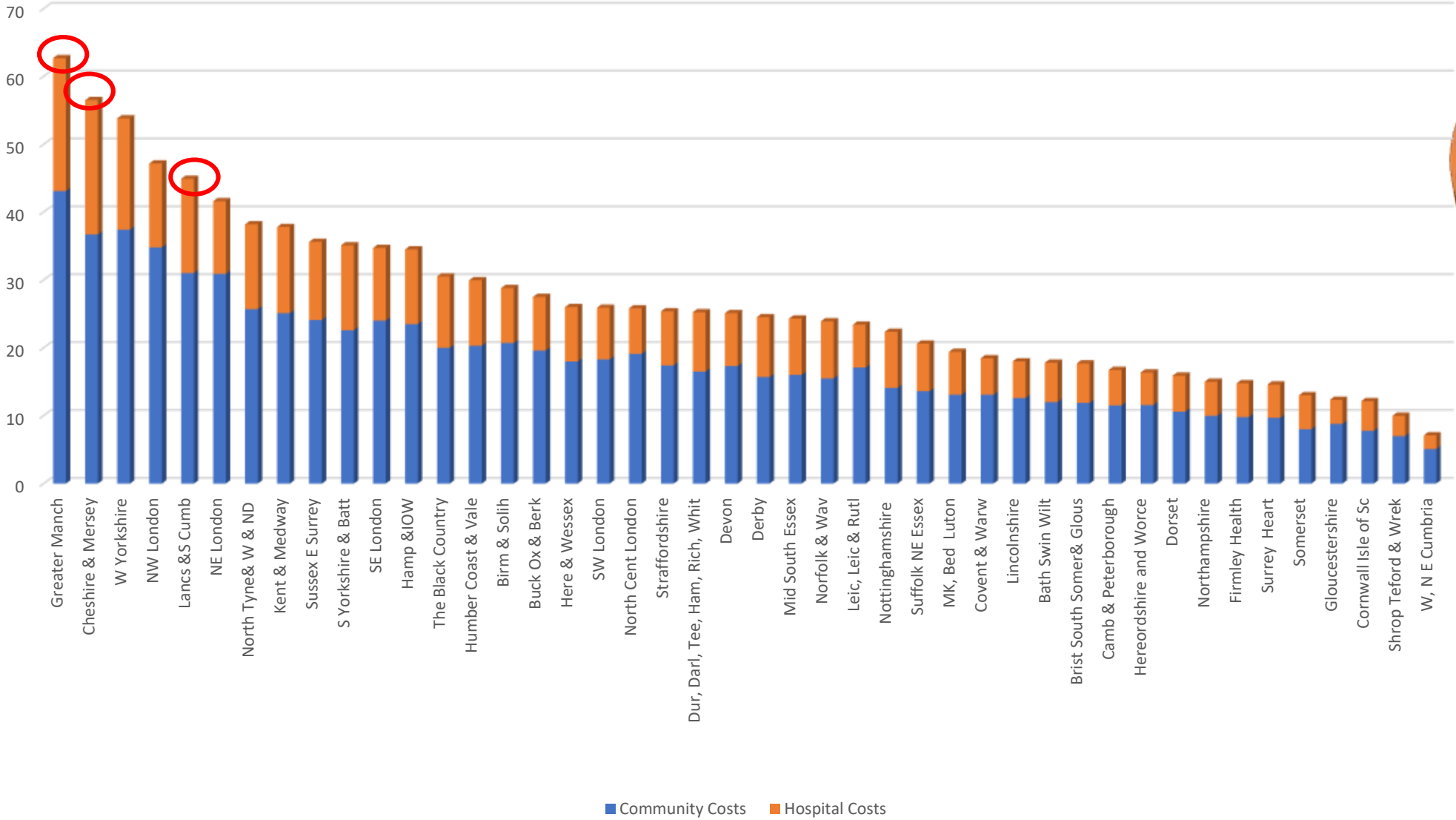
- Annual cost of approximately £1.17 Billion. Hospital based care £370 million and £800 million for community based footcare⁴
- Based upon 2016/17 data estimation of 70,535 ulcers annually
- Number of amputations over a 3 year period 25,535. Major amputations 7,133 and Minor 18,461

Data Sources

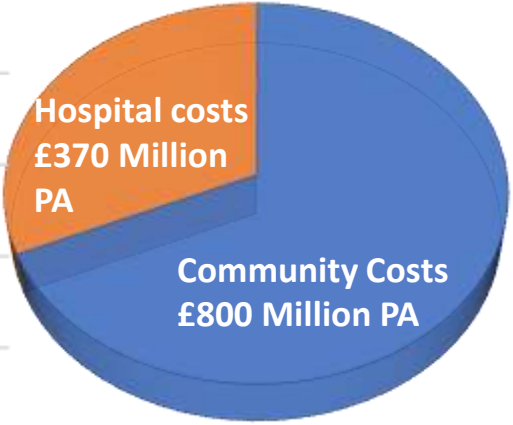
OOF 2015/16, National Diabetes Footcare Data 2014-16, Diabetes Footcare profiles 2017 NCVIN, HES data 2015/16, Diabetes prevalence models PHE.

⁴ *College of Podiatry Diabetes Commissioning Toolkit: Insight Health Improvement*

Diabetes Commissioning Toolkit data covering 2016/17 . Cost per £ Million STP for
Community and Hospital Ulcer and Amputation Care pa



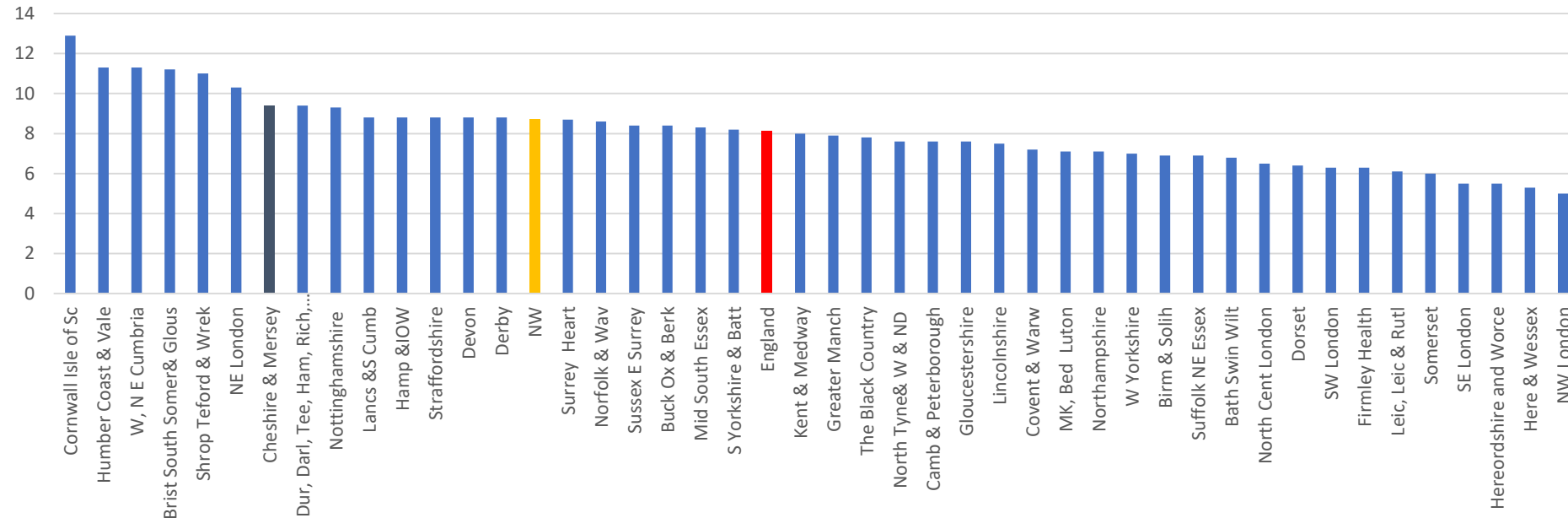
Total costs of Ulcer &
Amputation Management
PA



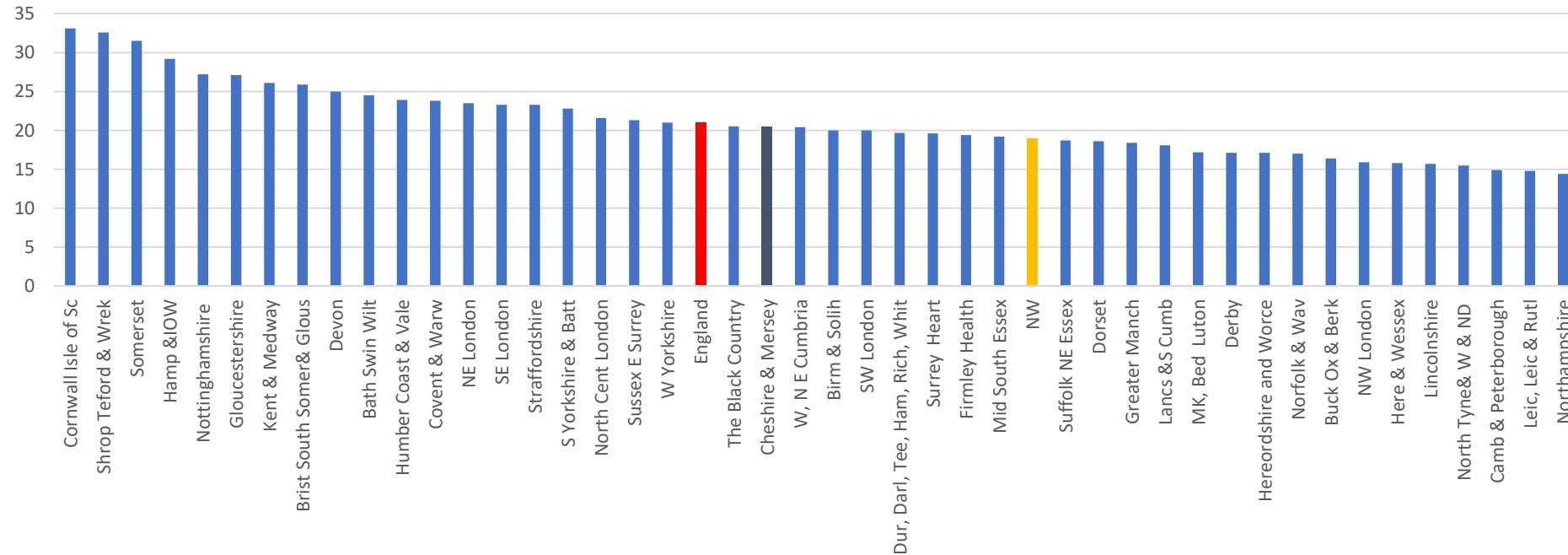
10% ROI Cost saving
if NICE practice adoption
£117 Million



Major Amputation Directly age/ethnicity standardised annual rate per 10,000 adults with diabetes



Minor Amputation Directly age/ethnicity standardised annual rate per 10,000 adults with diabetes



Diabetes Foot Ulcers in Cheshire & Merseyside HCP

- 3,240 ulcers at any one time
- £56.4 Million per year on amputations and foot ulcers
- £36.5m for community based care and £19.7m for hospital care (14% national expenditure on footcare in NW)
- Ulcers cost on average £214 per person per week
- Potential reduction in costs NICE costing model of 10% but could be as high as 40% in high risk groups
- Only 20% High risk patients receive any plantar pressure relief
- Estimated annual savings of £5.5 million each year if 10% reduction for C&M

3D Imprints orthotics

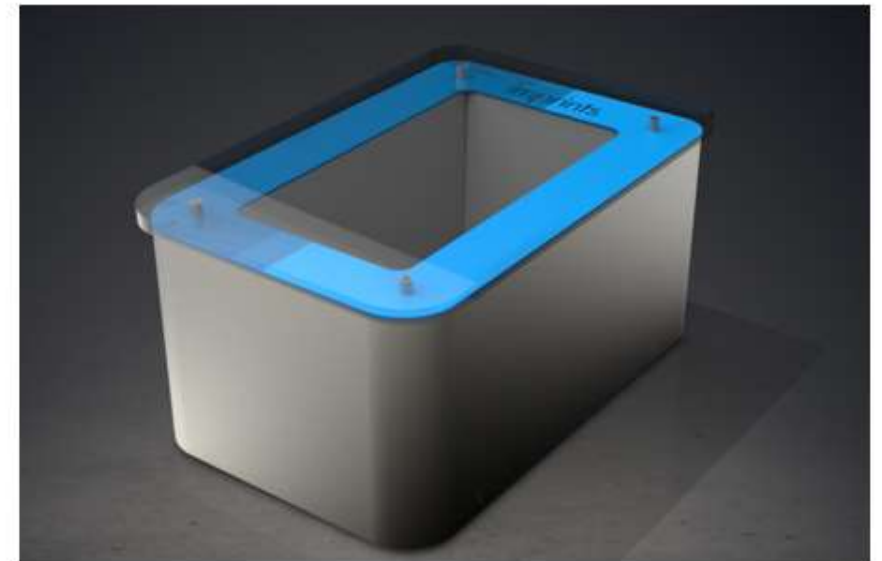
Bespoke, 3D Printed

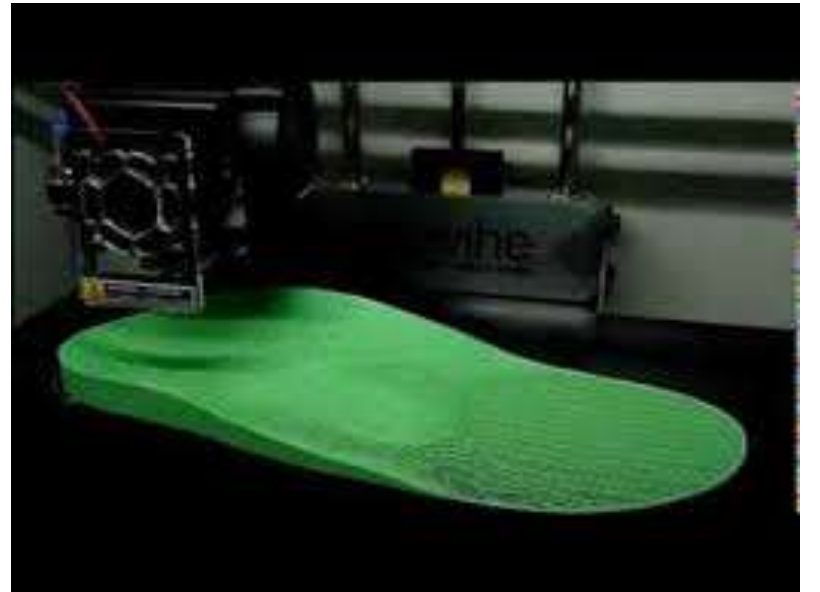
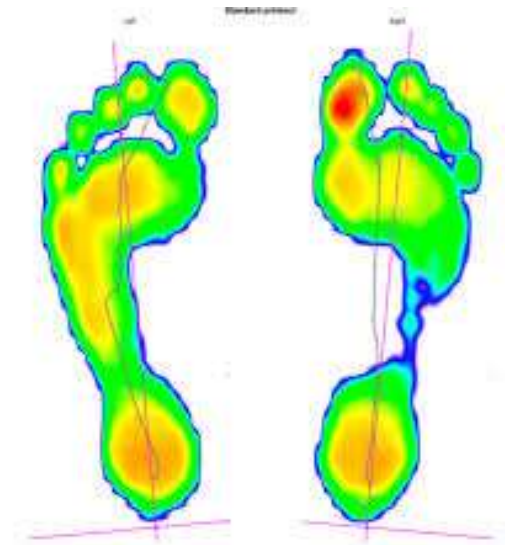
- Inputs: 3D foot scan & patient weight
- Captures **foot shape** and **load zones**
- Auto-design patient specific orthotic
- Variable density zones, form fitting
- Patient-specific pressure reduction (~21%)
- Manufactured using rubber material in 1-2hrs

→ **10x lower cost**



3D Foot Scanner





Primary objective

- To compare the rates of primary diabetic foot ulcers (DFUs) in high-risk diabetic feet using 3D printed insoles compared to standard care

Primary endpoint/outcome

- The incidence of DFU in patients with high-risk diabetic feet

Definition of Standard Care (at baseline, 12, 26, 38 and 52 weeks)

- Foot examination
- Routine podiatry treatment including debridement of callus
- Consider simple insoles or footwear referral as required
- DFU prevention education including footwear advice



**Feet pressure
measurement substudy in
a cohort of intervention
patients**



**The F-Scan: Ultra-thin, in-shoe
sensors capture timing &
pressure information for foot
function & gait analysis**

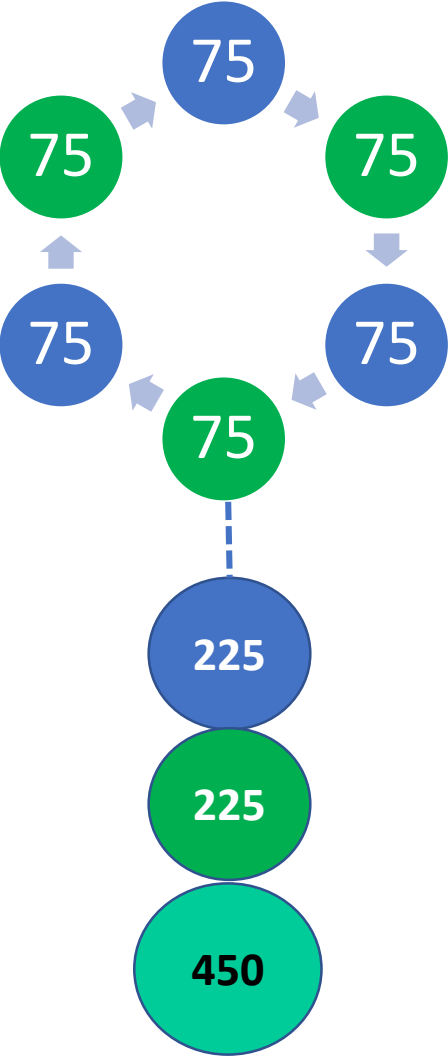
Secondary objectives

- Compare plantar foot pressures at baseline and 52 weeks of 3D insole use in patients who consent in one intervention site
- Compare patient satisfaction at baseline, 26, and 52 weeks
- Evaluate quality of life using NeuroQoL, EQ-5D-3L, and Quebec questionnaire
- Incidence of adverse events relating in the 3D insole group
- Assess protocol adherence with 3D insoles
- Determine cost-effectiveness over 52 weeks

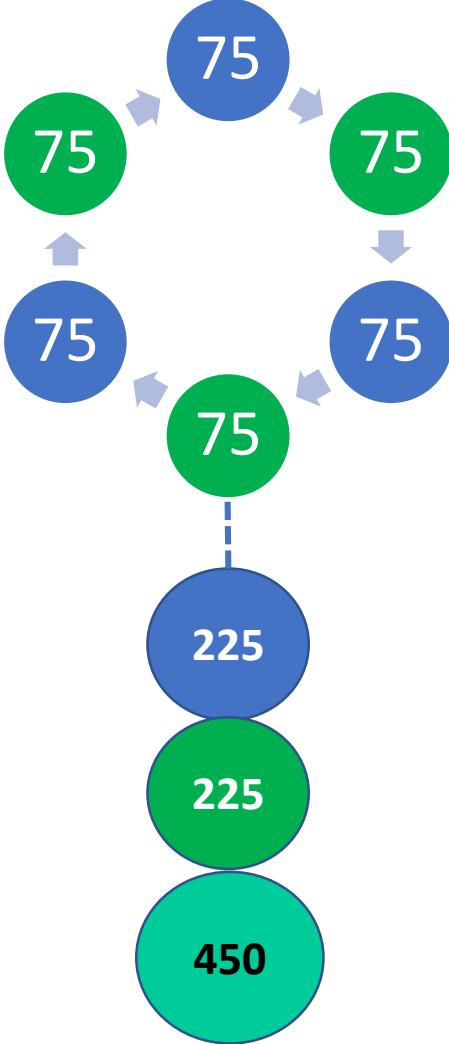
Study Design

- Prospective cluster randomised study
- We will recruit 900 adults with diabetes and high risk of foot ulcers




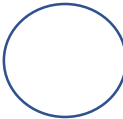
South Cheshire & Vale Royal



St Helens & Knowsley



900 patients
25% drop out rate
should result in
450 patients per
cohort meeting
study power
requirement (360)

-  Intervention Group
-  Control Group
-  Total subject per area
-  Total Cohort size

25%+ drop out

Inclusion criteria

- Adults with a diagnosis of diabetes
- Peripheral sensory neuropathy

with (one of the three)

1. Signs of abnormal loading as indicated by callus formation or hyperaemia

Or

2. limb ischaemia as evidenced by intermittent claudication /non-palpable pulses / history of vascular intervention

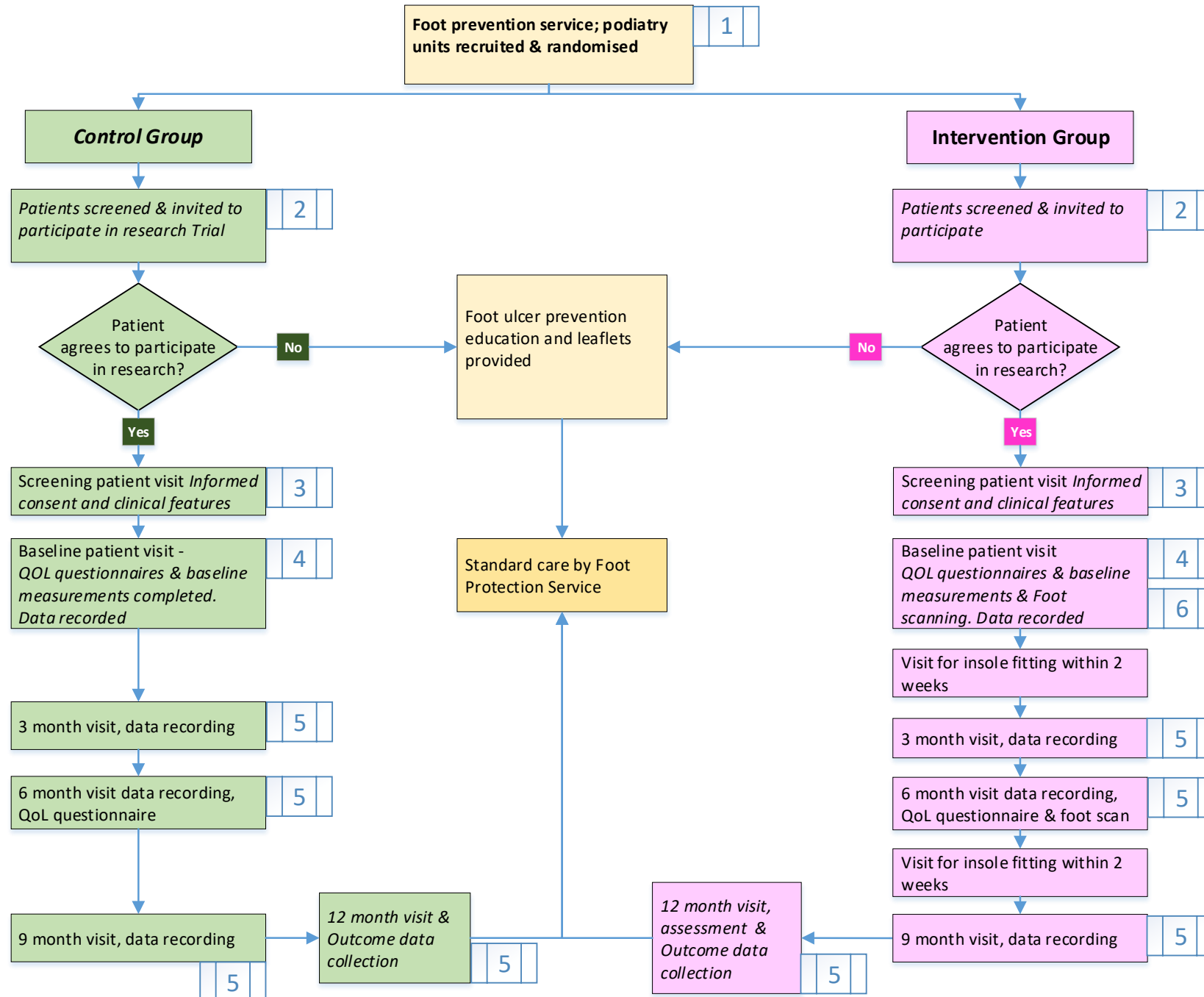
Or

3. On renal replacement therapy

Exclusion criteria

- Currently prescribed with or in need of therapeutic footwear
- Active or history of foot ulcer
- Active Charcot's neuroarthropathy
- History of major operation in the foot including amputation
- Local / systemic symptoms of infection, severe illness that would make 12-month survival unlikely
- Unable to provide informed consent
- Inability to follow the study instructions (as judged by the recruiting clinician)

PROFOUND Study Flow Chart



Progress to Date RCT

- Sponsor - Countess of Chester Trust R&D
- Co-Investigators agreed
- Health Research Authority – achieved Ethics Approval
- Adopted National Institute of Health Research (NIHR) portfolio
- Agreed Research Nurse & Administration support from Clinical Research Network
- Capacity & Capability R&D approved
- Identified Lead investigators at all sites – Senior podiatrists
- Established Operational group/ Research Advisory Group
- Site Visits undertaken – Site initiation calls in October

Timeline

