

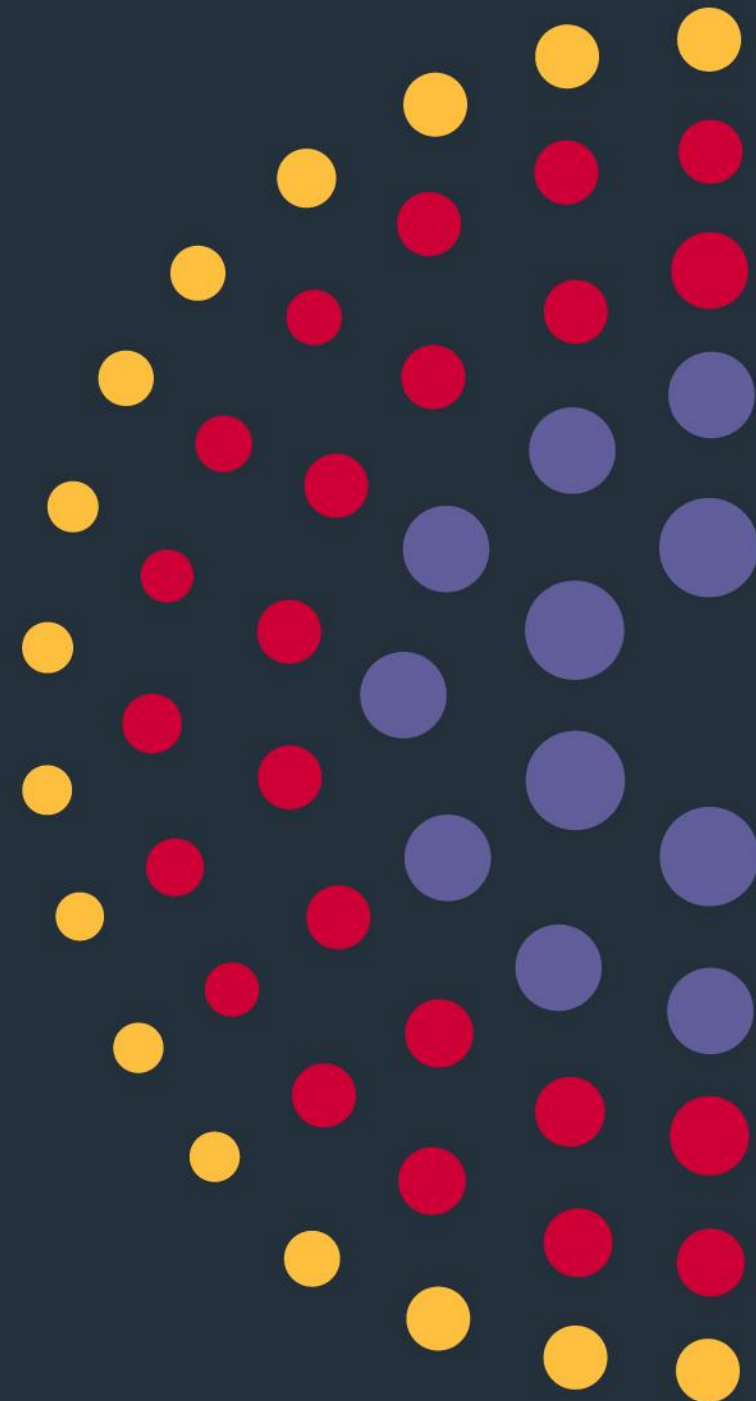
# Extracorporeal Shockwave Therapy for Diabetic Foot Wounds and Ulcers: A Pilot RCT

1<sup>st</sup> May 2019

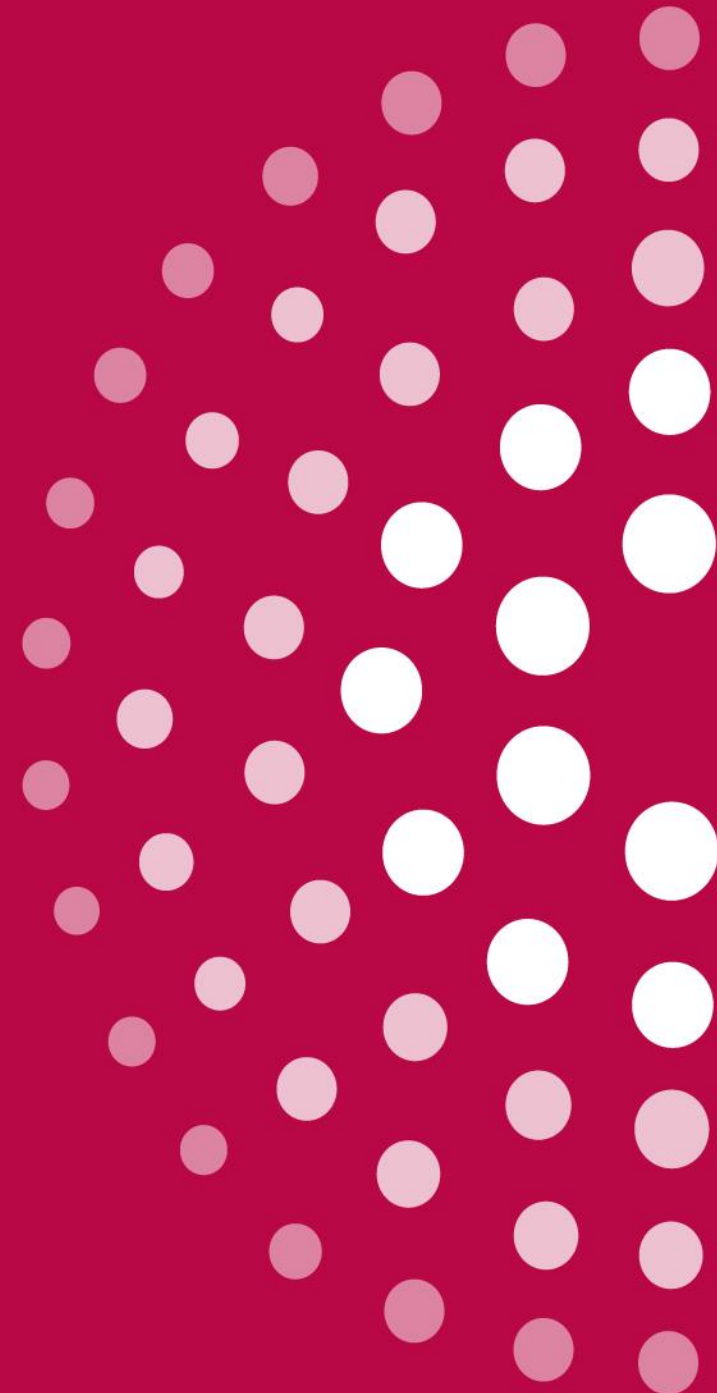
Hitchman, L.H. Smith, G.E. Chetter, I.C.

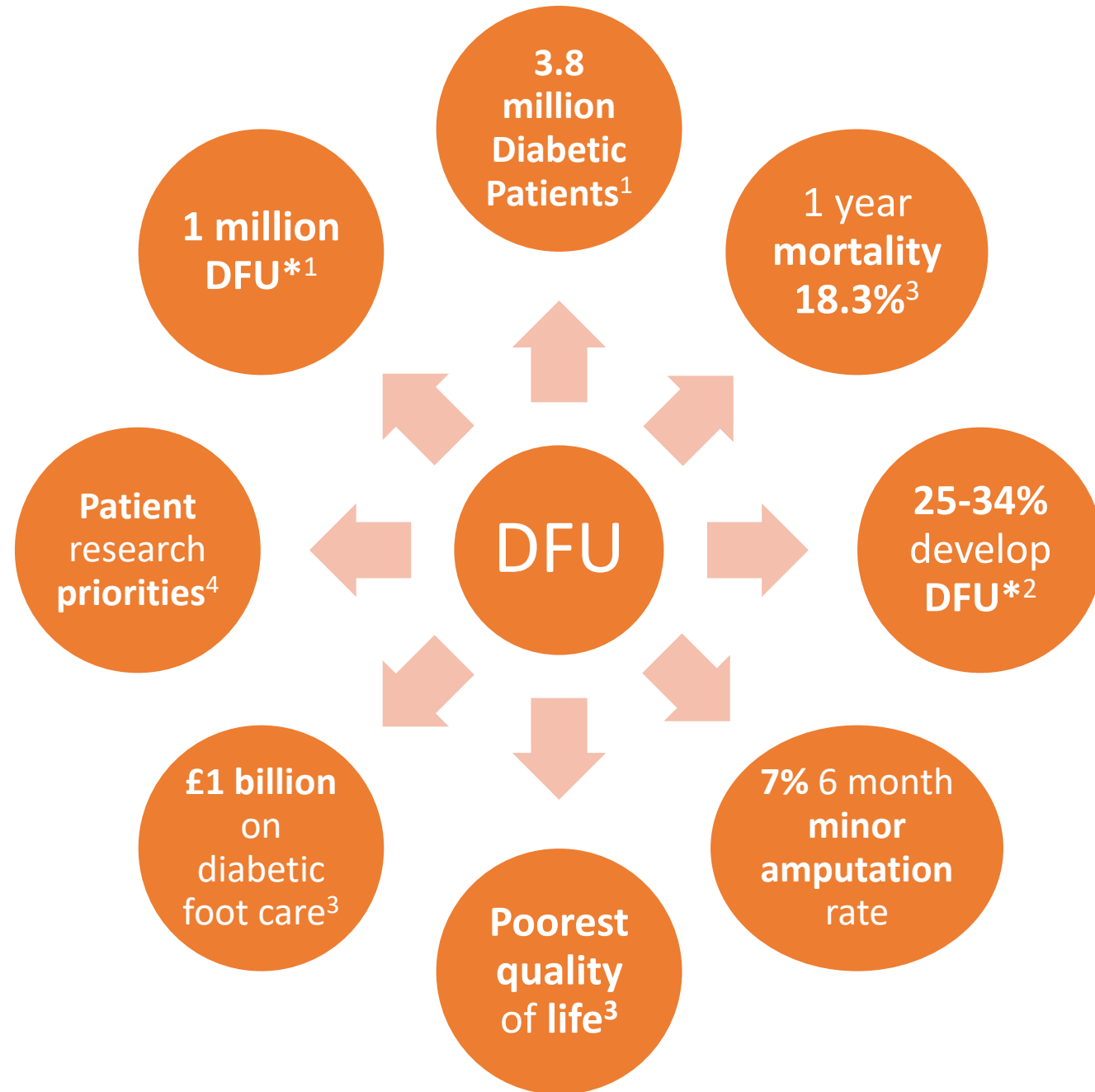
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# Background





## Extracorporeal Shockwave Therapy (ESWT)

- ✓ Low energy defocused shockwave
- ✓ Induce shearing forces
- ✓ Stimulate local inflammation
- ✓ Increase local cytokines and growth factors
- ✓ Possible bactericidal effect



## Current Evidence

### Snyder et al, 2018<sup>6</sup>

- Multi-centre RCT
- ESWT = 172 patients
- Control = 164 patients

% healed at 20 weeks:

**ESWT 35.5%**  
**Control 24.4%**  
**P=0.027**

### Jeppesen et al, 2016<sup>9</sup>

- Single centre RCT
- ESWT = 11 patients
- Control = 12 patients

% reduction at 7 weeks:

**ESWT 34.5%**  
**Control 5.6%**  
**p<0.01**

### Omar et al, 2014<sup>5</sup>

- Single centre RCT
- ESWT = 19 patients
- Control = 19 patients

% healed at week 20:

**ESWT 54%**  
**Control 33.3%**  
**P<0.05**

# Dosing Schedules

Study	Energy	Number of Shocks	Number of Treatments
Jeppensen et al, 2016 <sup>6</sup>	0.2mJ/mm <sup>2</sup> , 5Hz	500 + 250/cm <sup>2</sup>	6
Omar et al, 2014 <sup>5</sup>	0.11mJ/mm <sup>2</sup>	100/cm <sup>2</sup>	16
Wang et al, 2011 <sup>8</sup>	0.11mJ/mm <sup>2</sup>	≥500	6
Moretti et al, 2009 <sup>9</sup>	0.03mJ/mm <sup>2</sup>	100/cm <sup>2</sup>	3
Wang et al, 2009 <sup>10</sup>	0.11mJ/mm <sup>2</sup>	300 + 100/cm <sup>2</sup>	3
Snyder et al, 2018 <sup>7</sup>	0.23mj/mm <sup>2</sup>	500	6

## Systematic Review and Meta-analysis<sup>11</sup>:

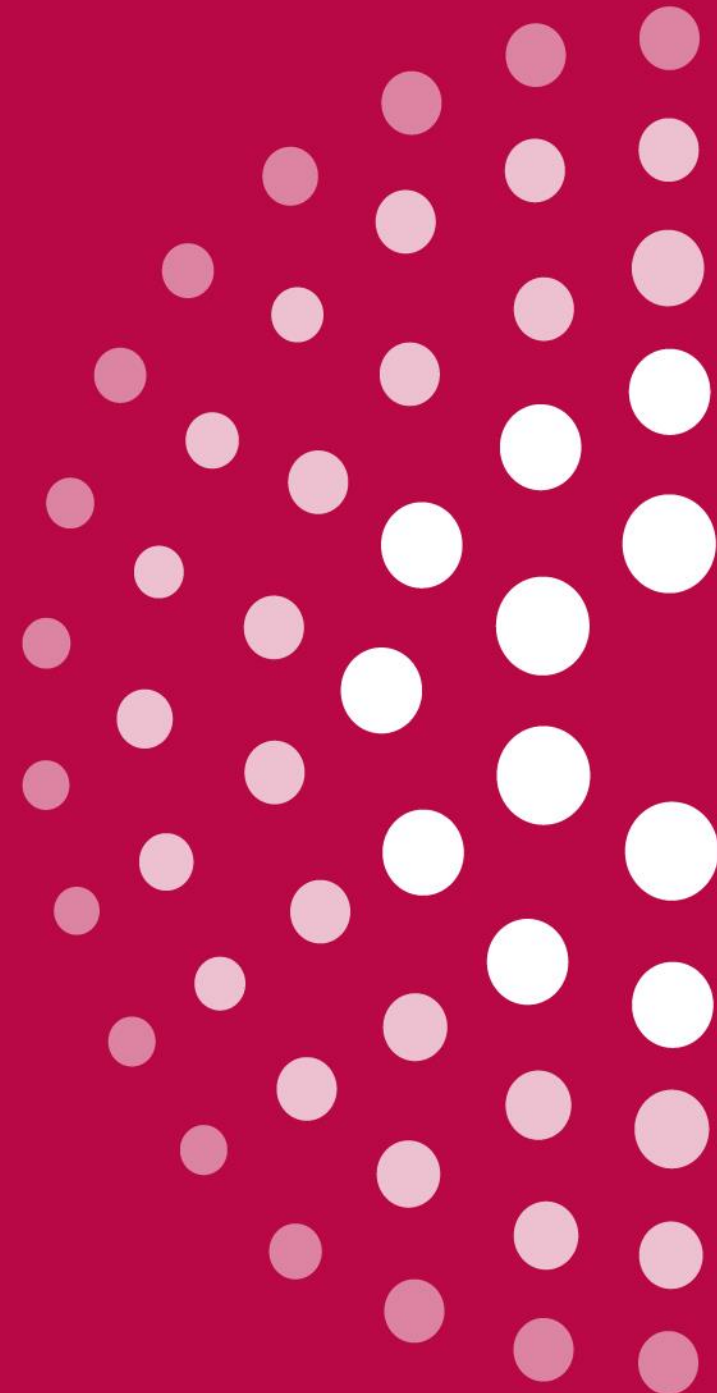
- ✓ ESWT superior to standard care for wound healing [OR 2.66 95%CI 1.03-6.87]
- ✓ ESWT superior to wound healing for time to healing [OR 2.45 95%CI 1.07-5.61]
  
- Heterogeneous data
  
- High risk of bias
  
- Need for further robust research

# Aims

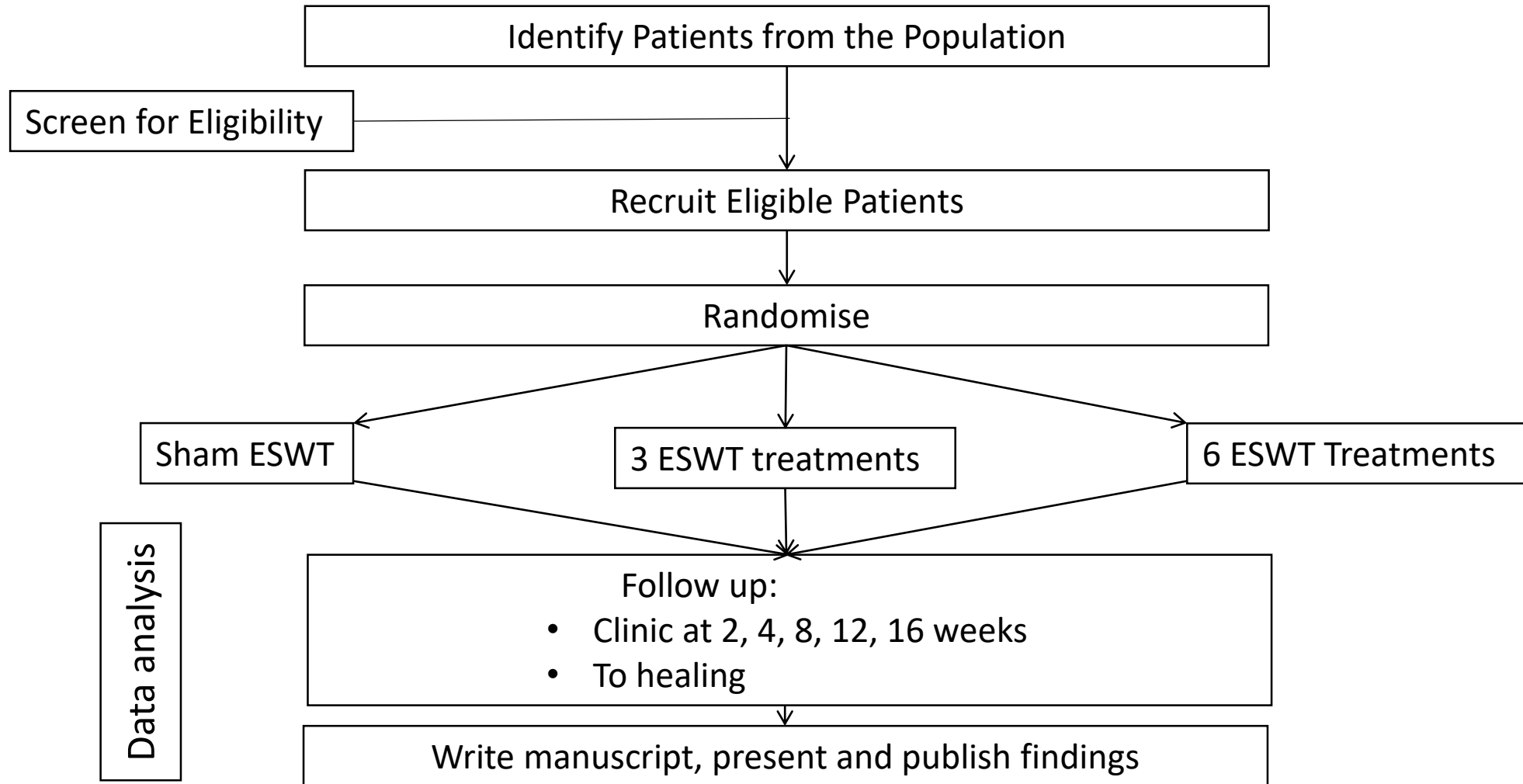
1. To assess whether ESWT reduces the time to healing compared to standard wound care
2. To assess whether there is a dose-response to ESWT



# Methods



## Design - A single centre pilot RCT



# Population

## **Inclusion Criteria:**

- Open foot wound
- Diagnosis of Diabetes Mellitus
- ABPI > 0.8
- Over 18 years old
- Capacity to give consent

## **Exclusion Criteria:**

- Planned re-vascularisation procedure
- Anticoagulation
- Active malignancy in the treatment area
- Pregnancy or breast feeding
- Palliative

## Intervention 1

### ESWT

- 100 shocks/cm<sup>2</sup>
- 0.11mJ/mm<sup>2</sup>
- 5Hz
- Minimum 500 shocks
- Plus standard wound care<sup>11</sup>
- **3 sessions over 1 week**

## Intervention 2

### ESWT

- 100 shocks/cm<sup>2</sup>
- 0.11mJ/mm<sup>2</sup>
- 5Hz
- Minimum 500 shocks
- Plus standard wound care<sup>11</sup>
- **6 sessions over 2 weeks**

# Comparison

- Sham ESWT
- Plus Standard Wound Care<sup>11</sup>

## Outcomes

### ◎ Primary Outcome - Time to wound healing

- Serial 2D photographs taken at wound reviews – blinded assessment

## ◎ Secondary Outcomes

- Clinical Outcomes:
  - Incidence of infection:
    - Clinical assessment and culture of wound swabs
  - Incidence of amputation
  - Changes in wound volume
    - 3D imaging
    - Assessed at 2, 4, 8, 12, 16 weeks
  - Recurrence Rate
  - Re-intervention Rate

## ◎ Secondary Outcomes

- Mechanism of Action:
  - Tissue perfusion
    - Doppler Flowmetry
  - Tissue integrity
    - Vapometer
  - Bacterial growth
    - Bacterial analysis



## • Secondary outcomes:

- Patient Outcomes:
  - Quality of Life
  - Pain

# Sample Size

④ 40 per group

④ 120 Total

# Progress

- ① Feasibility cohort study – recruiting
- ① PPI involvement in pilot design

## Summary

- 3 arm pilot exploratory RCT
- Open diabetic foot wounds
- Comparing
  - 3 treatments ESWT + standard care
  - 6 treatments ESWT + standard care
  - Sham ESWT + standard care
- To assess:
  - Time to healing
  - Dose response

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# Questions

