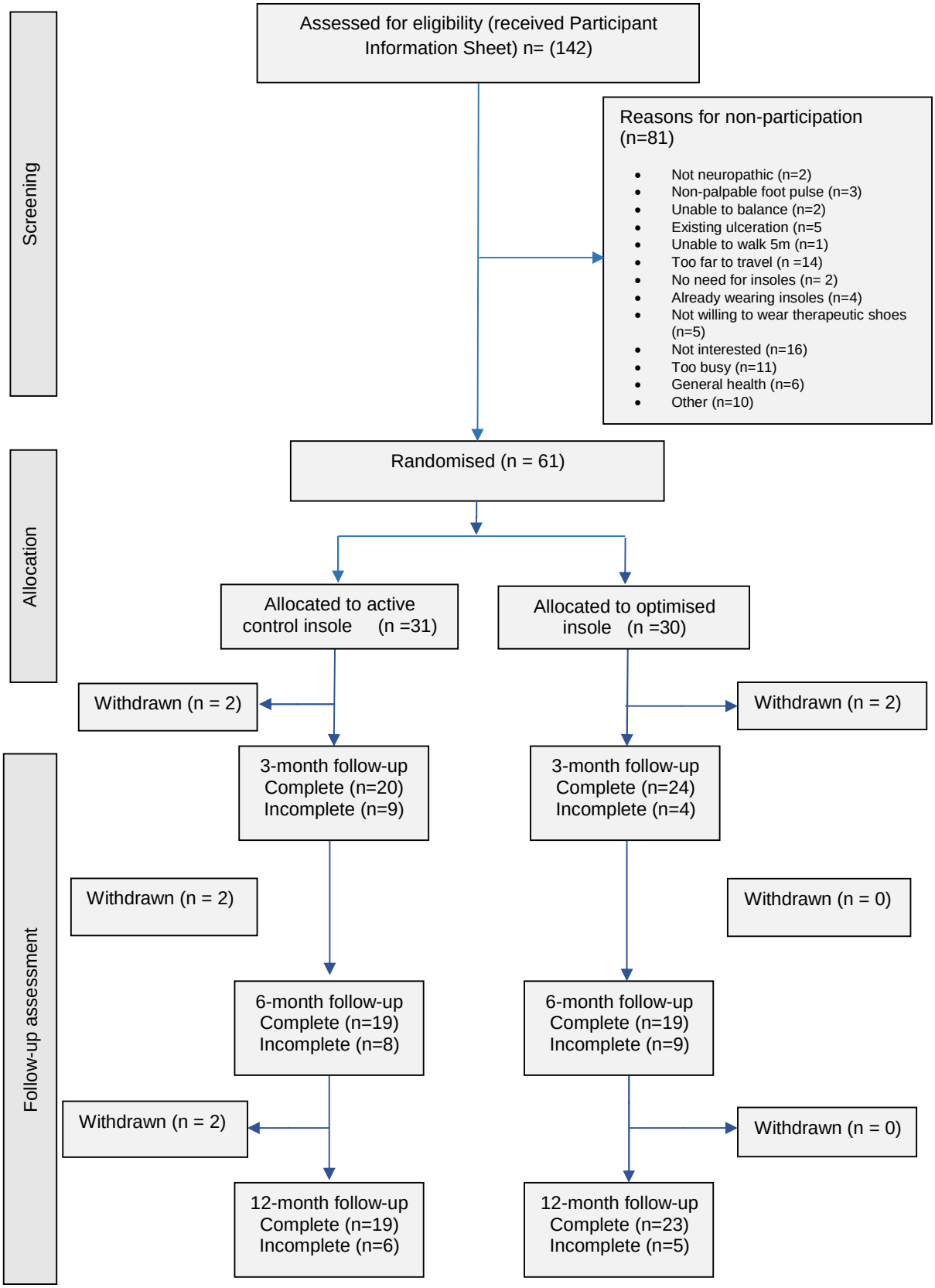
Participant flow



Baseline characteristics

		Active control insole group n=31	Optimised insole group n=30
Age (years)	Mean (SD)	67.9 (12.2)	70.2 (10.2)
	Median (IQR)	70.0 (60.0-73.0)	71.5 (67.6-74.8)
Gender, n (%)	Female	5 (16.1%)	3 (10.0%)
	Male	26 (83.9%)	27 (90.0%)
Height (cm)	Mean (SD)	177.2 (11.0)	176.1 (9.1)
	Median (IQR)	178.0 (171.5-183.5)	177.0 (171.0-183.0)
Weight (kg)	Mean (SD)	95.0 (14.1)	94.4 (18.6)
	Median (IQR)	94.0 (85.0-107.0)	92.0 (79.6-111.3)
BMI (kg/m^2)	Mean (SD)	30.4 (4.6)	30.4 (5.5)
	Median (IQR)	29.8 (37.7-32.2)	29.5 (20.3-35.8)
Ethnicity, n (%)	White	31 (100%)	30 (100%)
Smoker, n (%)	Yes	3 (9.7%)	2 (6.7%)
	No	28 (90.3%)	27 (90.0%)
	Missing	0 (0)	1 (3.3%)
Diabetes type, n (%)	Type 1	7 (22.6%)	2 (6.7%)
	Type 2	24 (77.4%)	28 (93.3%)
Duration of diabetes (years)	Mean (SD)	21.3 (9.7)	19.7 (14.9)
	Median (IQR)	20 (14.5-27.5)	17 (6.0-28.5)

Outcome measures

Number of patients screened from the target population and recruited to study by site

	Torbay (n)	Solent (n)	Exeter (n)	Total (n)
Screened	53	43	46	142
Not eligible	2	12	10	24
Not recruited	18	22	17	57
Total randomised	33	9	19	61
Proportion randomised/potentially eligible	62.3%	20.9%	41.3%	43.0%

Proportion of protocol deviations by site

Total	24.6% (n=15/61)
Torbay	21.2% (n=7/33)
Exeter	21.0% (4/19)
Solent	44.4% (4/9)

Proportion of self-completed checklists completed by site

Total	32.8% (n=20/61
Torbay	50.0% (n=10/20)
Solent	20.0% (n=4/20),
Exeter	30.0% (n=6/20).

Number of completed data sets for pressure and photograghs

Baseline	100% (n-61/61)
three months follow-up	72.1% (n=44/61)
six-months	60.7% (n=37/61)
12-months follow-up	67.2% (n=41/61)

Bang's Blinding Index for participant blinding by treatment group allocation

Follow up time point	Active control insole group	Optimised insole group
Three-months	0.2	0
Six-months	-0.26	-0.48
12-Months	0.16	-0.30

*Bang Index=number (*n*) of correct answers/total* n − n *of incorrect answers/total* n*. 1 indicates complete lack of blinding, −1 indicates opposite answers regarding treatment type, and 0 indicates perfectly conducted blinding (Bang, Ni & Davis, 2004).*

Plantar pressure change for region of interest-1 by treatment group allocation and follow-up time points

	Active control insole Group (n=31)				Optimised insole group (n=30)			
	Number* (n)	**MPPP kPa (sd)**	**MPPP Difference** kPa (sd)**	**MPPP Difference** %**	**Number* (n)**	**MPPP kPa (sd)**	**MPPP Difference** kPa (sd)**	**MPPP Difference** %**
Baseline without insoles	31	564.0 (223.0)	n/a	n/a	30	583.3 (220.9)	n/a	n/a
Immediately post randomisation	31	447.4 (181.9)	-116.6 (126.0)	-20.1%	30	370.2 (162.1)	-215.2 (137.6)	-36.9%
3-month follow-up	20	546.1 (229.6)	+11.7 (194.1)	+2.1%	24	495.9 (244.4)	-112.0 (313.7)	-19.2%
6-month follow-up	19	639.8 (332.3)	+45.8 (251.5)	+8.1%	18	625.3 (353.8)	-5.6 (320.5)	-1.0%
12-month follow-up	19	854.7 (538.9)	+242.2 (445.3)	+42.9%	22	596.2 (437.6)	-17.8 (404.0)	-3.1%

Incidence of foot ulceration over 12-months study

active control group	intervention group
22.5% (n=7/31)	33.3% (n=10/30

Proportion of questionnaires returned

	Nottingham foot questionnaire	International Physical Activity Questionnaire
baseline	98.3% (60/61)	98.3% (60/61)
3-month	72.1% (n=44/61)	72.1% (n=44/61)
6-month	62.3% (n=38/61)	62.3% (n=38/61)
12-month	68.9% (n=42/61)	68.9% (n=42/61)

Proportion of people adherent to wearing insoles by group

Time wearing insole/day	**Active control insole group (n=19)**	**Optimised insole group (n=25)**	**Total (n=44)**
<4 hours	9 (47.3%)	11 (44.0%)	20 (45.5%)
4-8 hours	7 (36.8%)	10 (40.0%)	17 (38.6%)
>8 hours	3 (15.8%)	4(16.0%)	7 (15.9%)

Themes from embedded qualitative study

Theme 1	Accepting the study
Theme 2	Behaviour and support during study procedures
Theme 3	Impact from study participation

Sample size scenarions

	MPPP diff (MCID)	sd	Effect Size	Correlation	LTFU	Unadjusted	Adjusted for LTFU
Base Case	**160**	**400**	**0.40**	**0**	**30%**	**265**	**379**
Vary MCID	180	400	0.45	0		210	300
	200	400	0.50	0		171	245
	220	400	0.55	0		141	202
Vary SD	160	420	0.38	0		293	419
	160	460	0.35	0		346	495
	160	500	0.32	0		413	590
Vary correlation	160	400	0.40	0.15	30%	260	372
				0.25		249	356
				0.35		233	333
				0.45		212	303
				0.55		185	265
				0.65		154	220

MPPP-mean peak plantar pressure, MCID-minimally clinical important difference, sd-standard deviation, LTFU-loss to follow-up

Adverse events

	Active control insole group	Optimised insole group	Total
Foot ulceration (probably attributable to intervention), n (%)	0 (0%)	1 (3.8%)	1 (3.8%)
Foot ulceration (not attributable to intervention), n (%)	7 (26.9%)	9 (34.6%)	16 (61.5%)
Falls (attributable to intervention), n (%)	0 (0%)	2 (7.7%)	2 (7.7%)
Foot rubs (attributable to intervention), n (%)	1 (3.8%)	0 (0%)	1 (3.8%)
Blisters (attributable to intervention), n (%)	0 (0%)	4 (15.4%)	4 (15.4%)
General musculoskeletal & postural pain (attributable to intervention), n (%)	1 (3.8%)	1 (3.8%)	2 (7.7%)
Total n, (%)	9 (34.6%)	17 (65.4%)	26 (100%)

% is expressed as a proportion of total AE's