REFORM Adverse Event Form

Centre number: ☐☐ Participant trial ID number: ☐☐☐☐☐

Participant's date of birth ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year) Male ☐ Female ☐

Date of onset of event ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

Classification of event Serious ☐ Non-serious ☐

Serious event: Death ☐ Hospitalisation required /prolonged ☐ Life or limb threatening event ☐

Persistent or significant Disability/incapacity ☐ Other medically important condition ☐

Event related to the intervention: advised footwear, trial insoles, exercise programme, use of equipment.

Aches/pain in the lower limb for longer than 48 hours ☐ Fall ☐ Injury due to exercise equipment ☐ Soft tissue injury ☐

Skin irritation/injury (including pressure sores, new callus/corn formation, blisters, ulcers) ☐

Other ☐ Please specify:

Description of event:

Please state outcome of event at time of this report *(cross one box only)*

Recovered fully ☐ Recovered partially ☐ On-going ☐

Died ☐ Date of death, if known: ☐☐ / ☐☐ / ☐☐☐☐

Relationship of the event to any of the research procedures *(cross one box only)*

Unrelated	Unlikely	Possibly	Probably	Definitely	Not able to assess
☐	☐	☐	☐	☐	☐

Expectedness Is this event expected? ☐ Yes ☐ No

Intensity *(cross one box only)* ☐ Mild ☐ Moderate ☐ Severe

Podiatrist's name: Podiatrist's Signature:

Date: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)