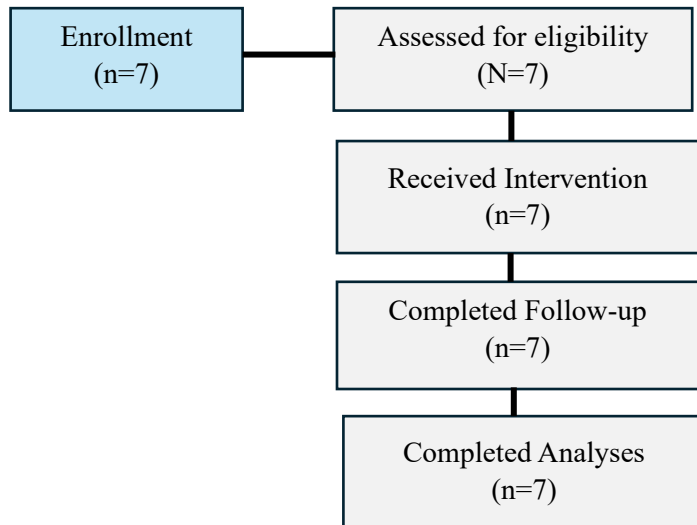


Participant Flow



Baseline Demographics and Clinical Characteristics

Table 1. Baseline Demographics and Clinical Characteristics

| Characteristic | Value |
|-------------------------|------------|
| Age (years) | 61 (7.7) |
| Sex | |
| Female | 4 (57.1%) |
| Male | 3 (42.9%) |
| BMI | 26.5 (5.7) |
| Ethnicity | |
| Not Hispanic or Latino | 7 (100%) |
| Uzbek | 7 (100%) |
| Race | |
| Unknown or Not Reported | 7 (100%) |
| AV Fistula Information | |
| Right forearm | 4 (57.1%) |
| Left forearm | 3 (42.9%) |
| Radial-cephalic | 7 (100%) |
| Fistula Depth 3 mm | 4 (57.1%) |
| Fistula Depth 4 mm | 1 (14.3%) |
| Fistula Depth 5 mm | 1 (14.3%) |
| Fistula Depth 6 mm | 1 (14.3%) |
| Fistula Diameter 8 mm | 1 (14.3%) |

| Characteristic | Value |
|------------------------|-----------|
| Fistula Diameter 9 mm | 3 (42.9%) |
| Fistula Diameter 10 mm | 2 (28.6%) |
| Fistula Diameter 11 mm | 1 (14.3%) |

Data are means (SD) or numbers (%).

Outcomes

Table 2 Feasibility Outcomes

| Primary Feasibility Outcomes | Number (%) | |
|---|------------|-----------|
| | Yes | No |
| Achieved blood flashback with device needle insertion | 6 (85.7%) | 1 (14.3%) |
| Absence of Serious Adverse Events | 7 (100%) | 0 (0%) |

No SAEs occurred.

Table 3 Needle Insertion Attempts

| Participant # | AVF Site | Insertions Attempted | Procedures Successful |
|---------------|-----------|----------------------|-----------------------|
| 01 | Left arm | 2 | 0 |
| 02 | Right arm | 1 | 1 |
| 03 | Left arm | 1 | 1 |
| 04 | Right arm | 1 | 1 |
| 05 | Right arm | 1 | 1 |
| 06 | Left arm | 1 | 1 |
| 07 | Right arm | 1 | 1 |
| Total | | 8 | 6 of 7 |

Table 4 Procedure Pain

| Pain of Manual Insertion Compared to Device | Participants (n=6) |
|---|--------------------|
| Less than Device | 0 (0%) |
| Same as Device | 1 (16.7%) |
| Greater than Device | 5 (83.3%) |

Adverse Events

Table 5 Adverse Events

| AE Name | Summary |
|---------------------------|-----------|
| Needle scratched the skin | 2 (28.6%) |

Percentage based on 7 participants