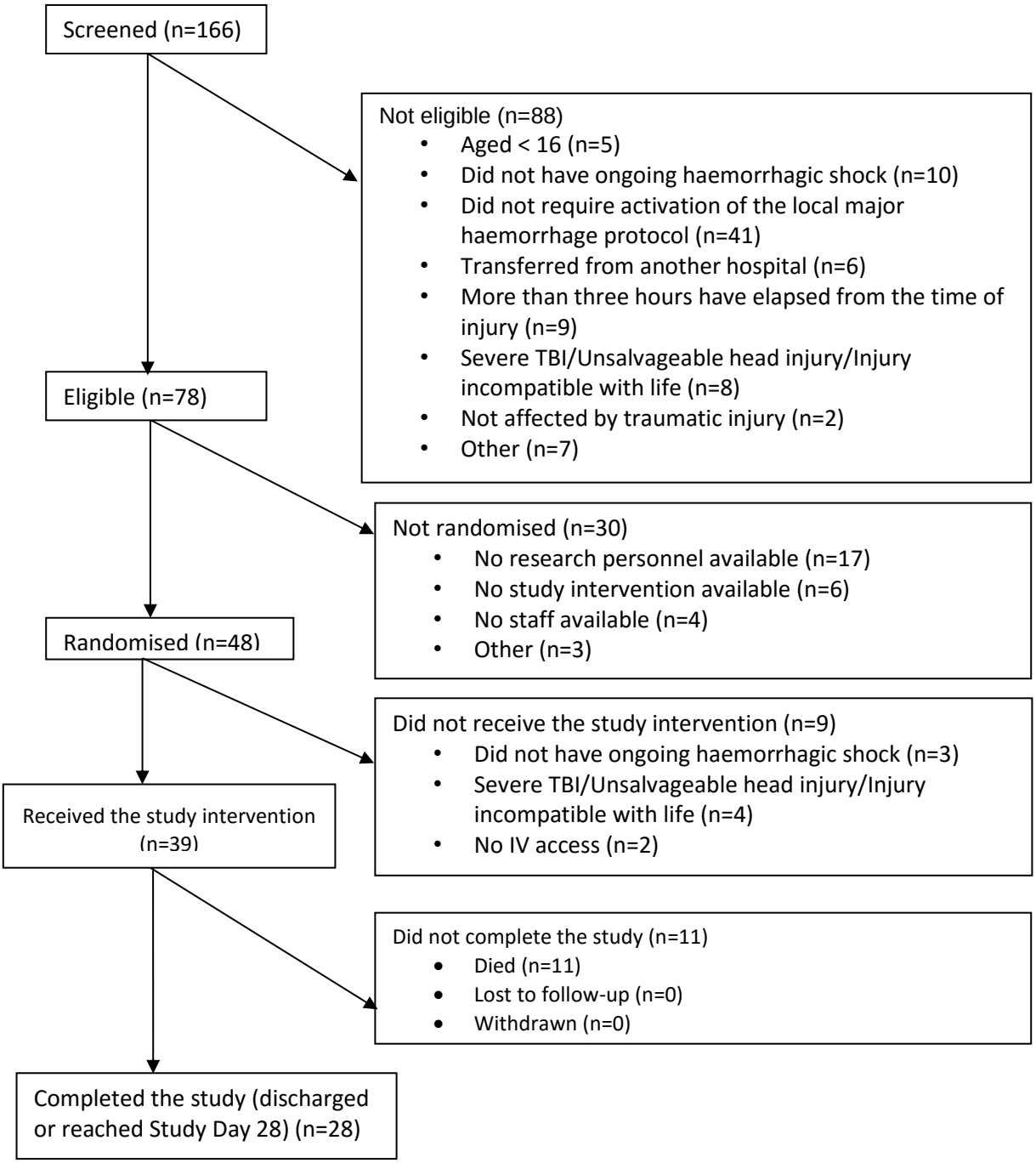
**Figure 1.**

**CONSORT flow diagram**