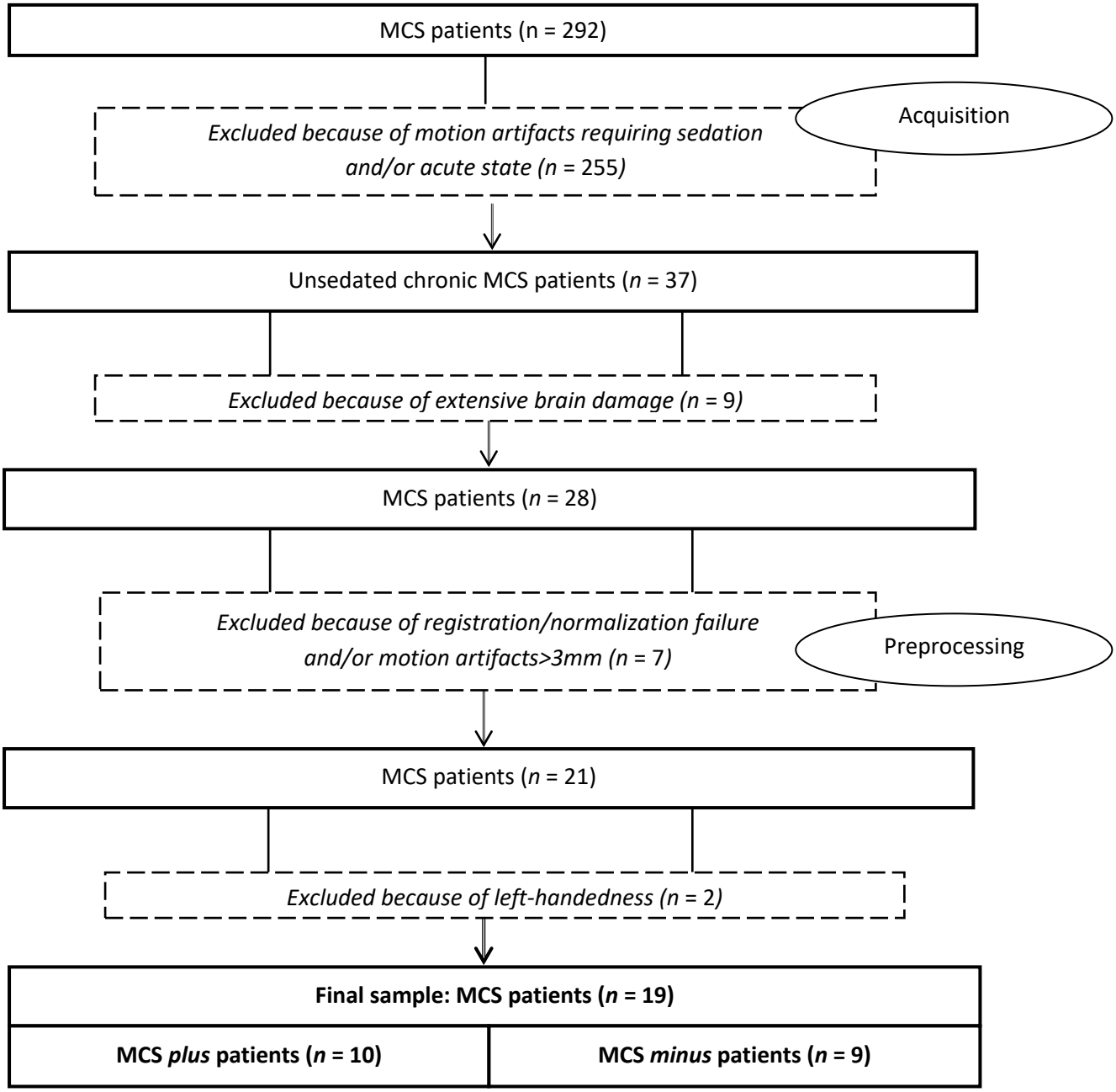Flowchart 1. Patient selection based on exclusion criteria.