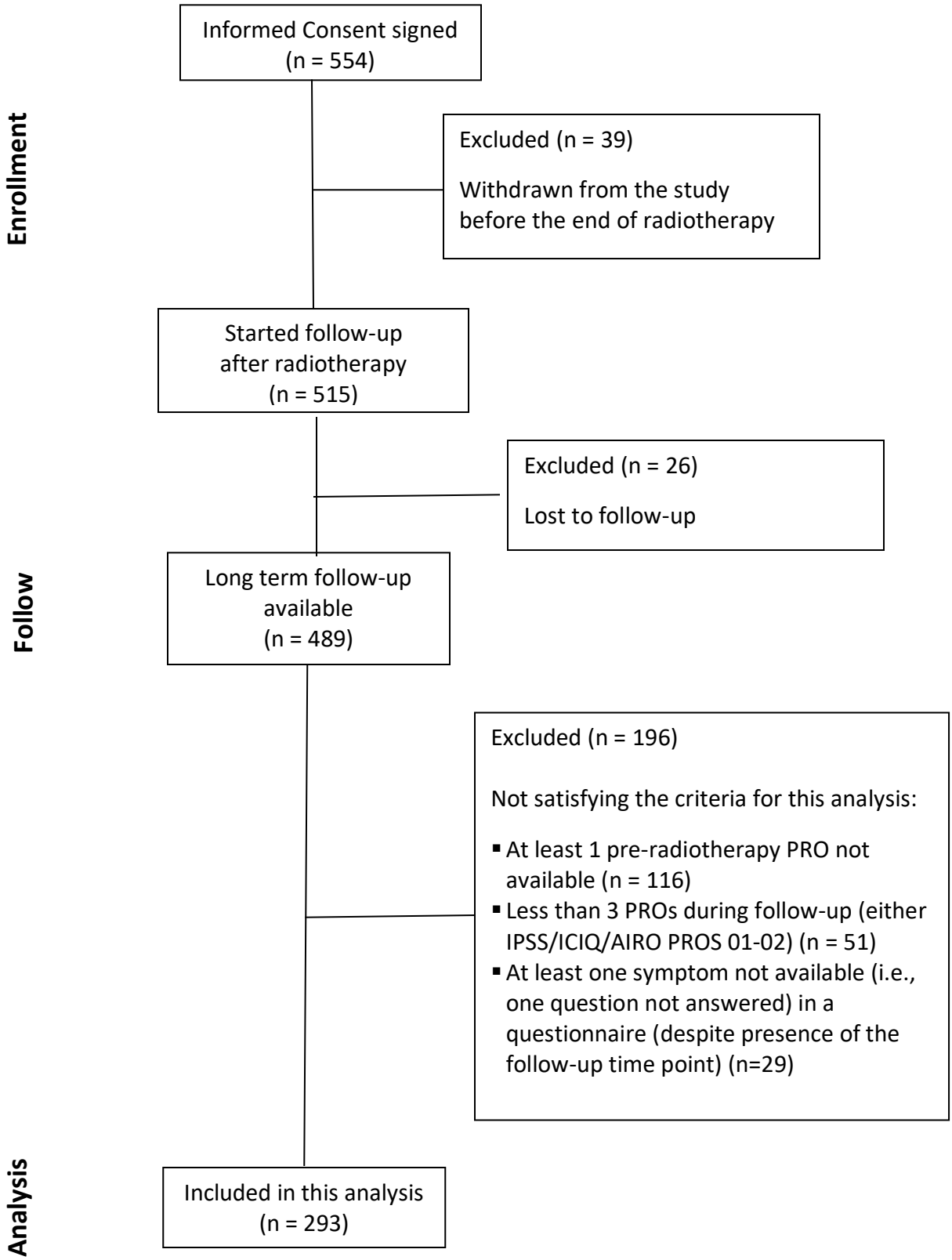CONSORT DIAGRAM: DUE01 STUDY