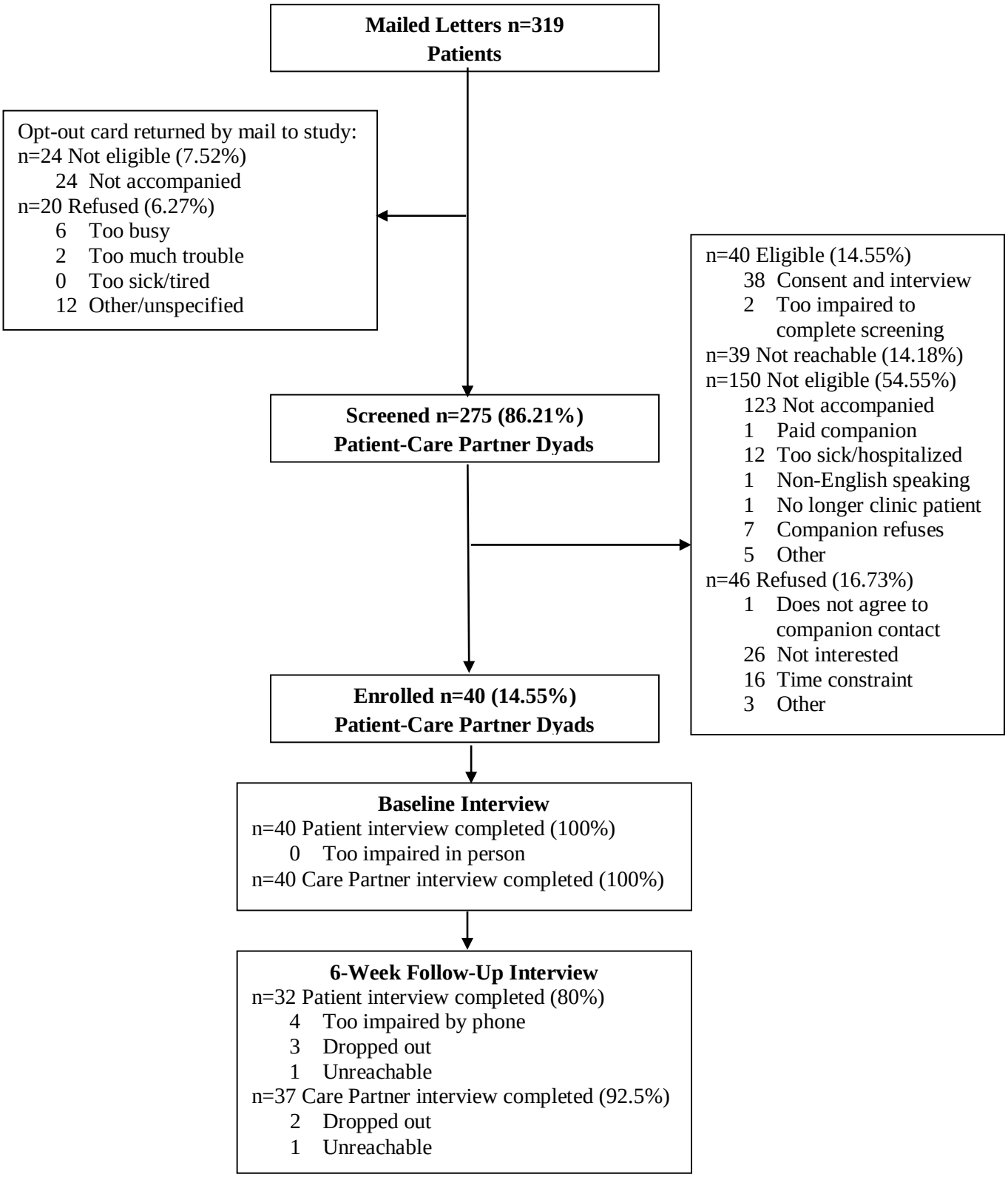Supplemental Appendix. CONSORT Diagram