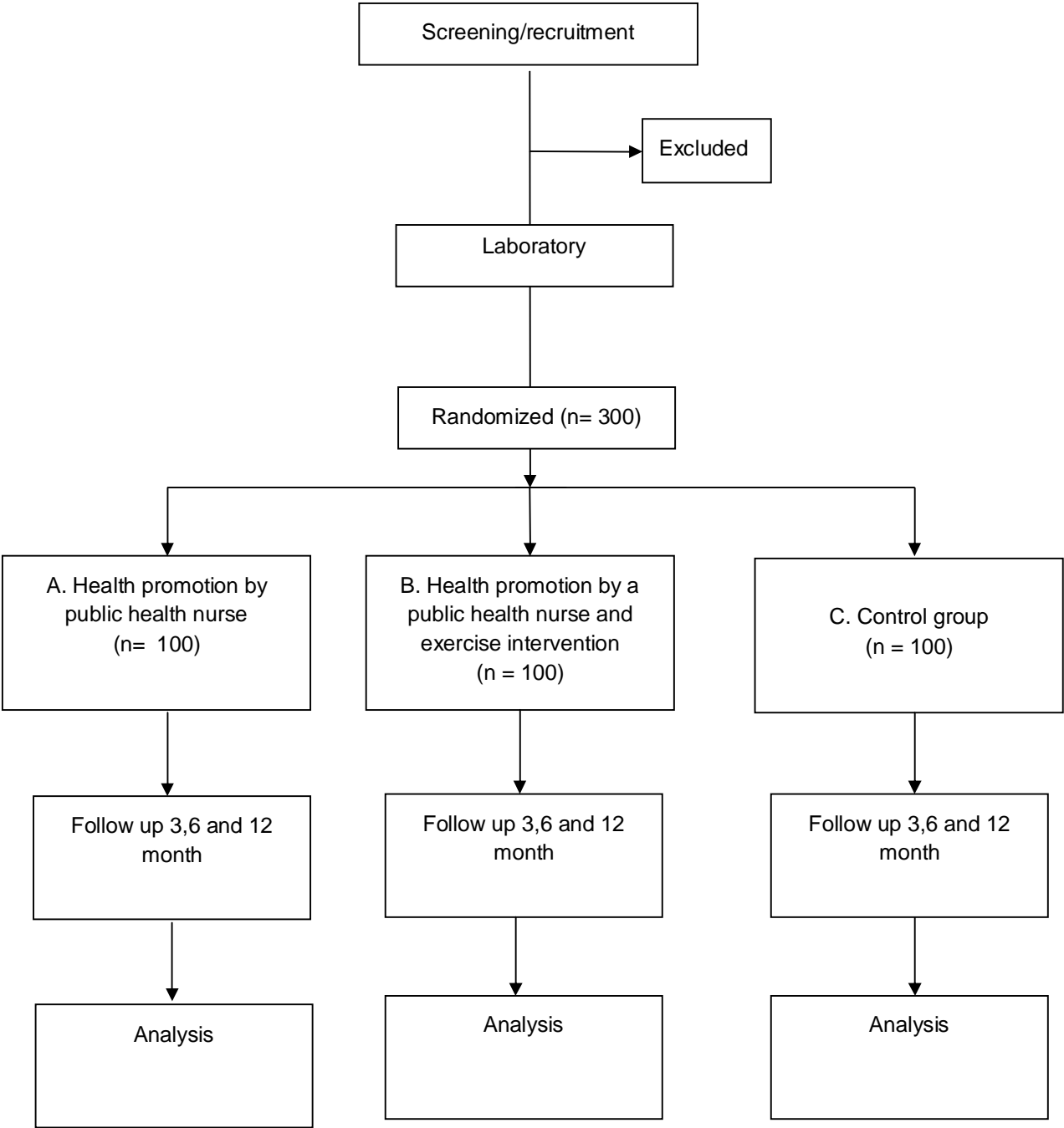


Figure1. Study design and flow chart



Enrollment

Allocation

Follow-Up

Analysis