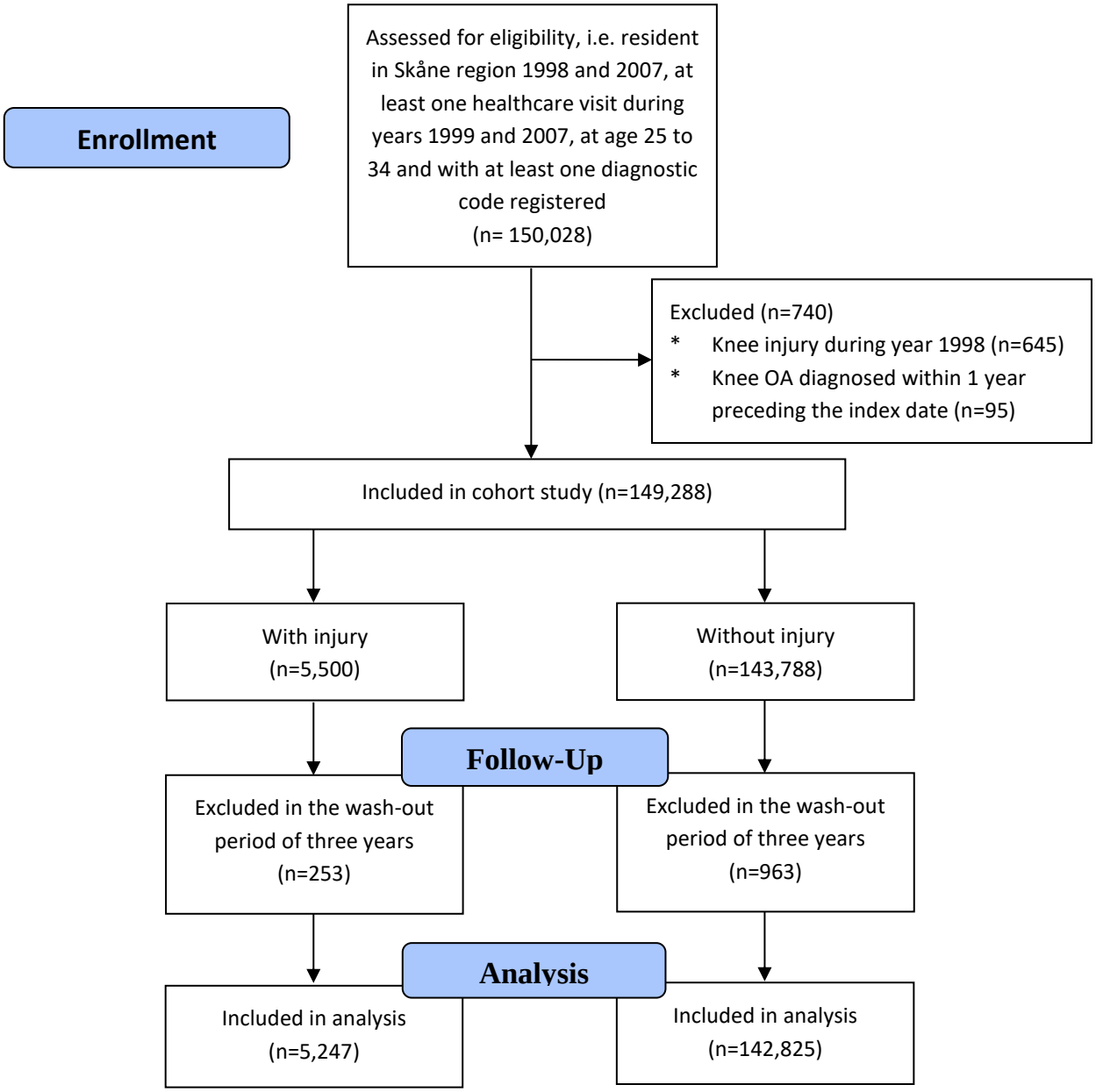Figure 1 Flow diagram of study inclusion and follow-up