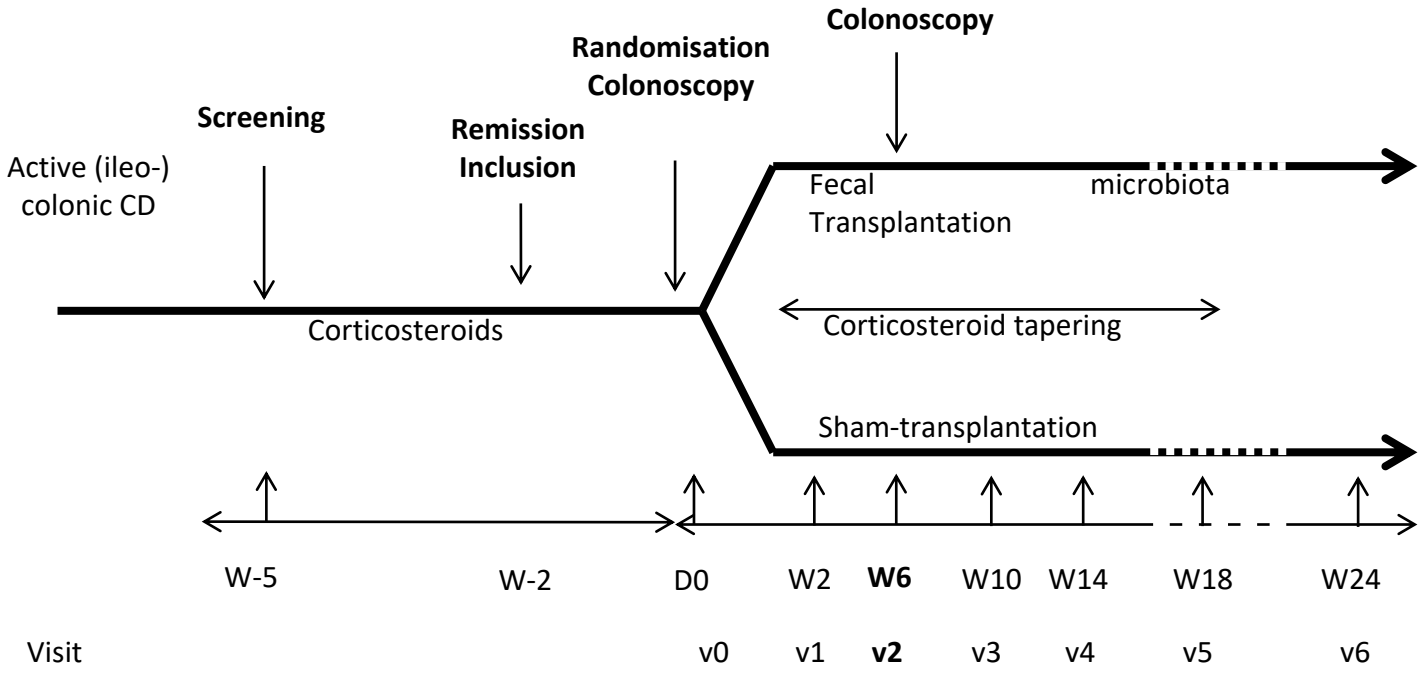

Additional file 1: Study design.