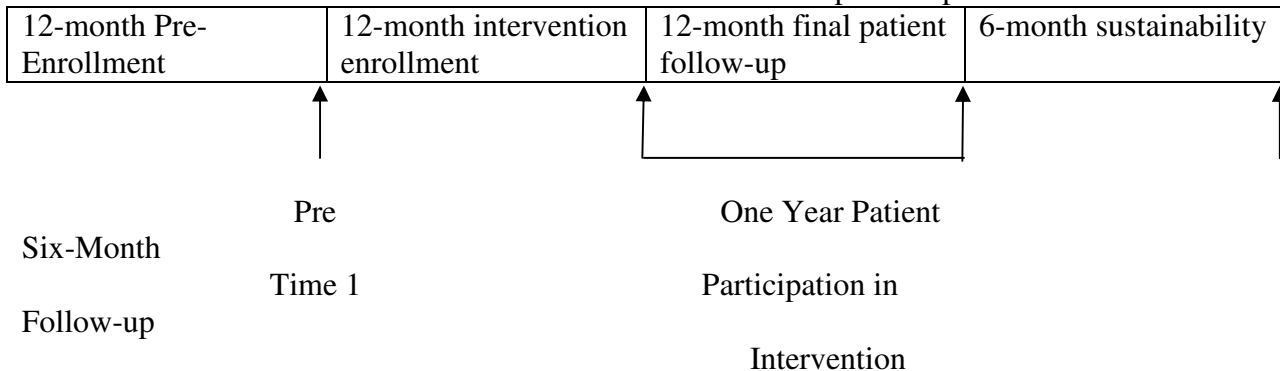


Intervention: Three sites with 500 intervention and 500 control patients per site



Control: Nine sites with 500 control patients per site

