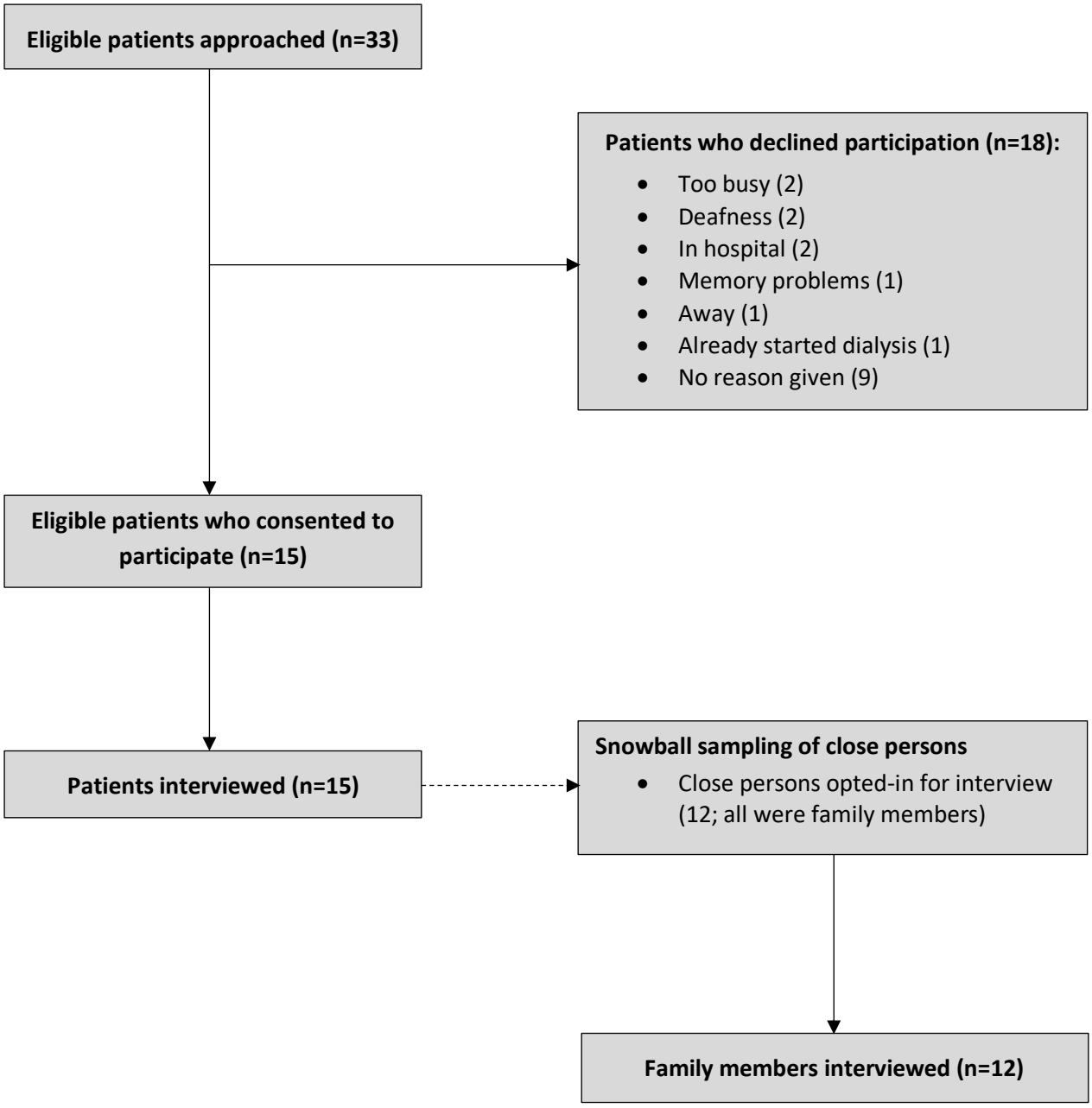Supplementary File S4. Study flow diagram