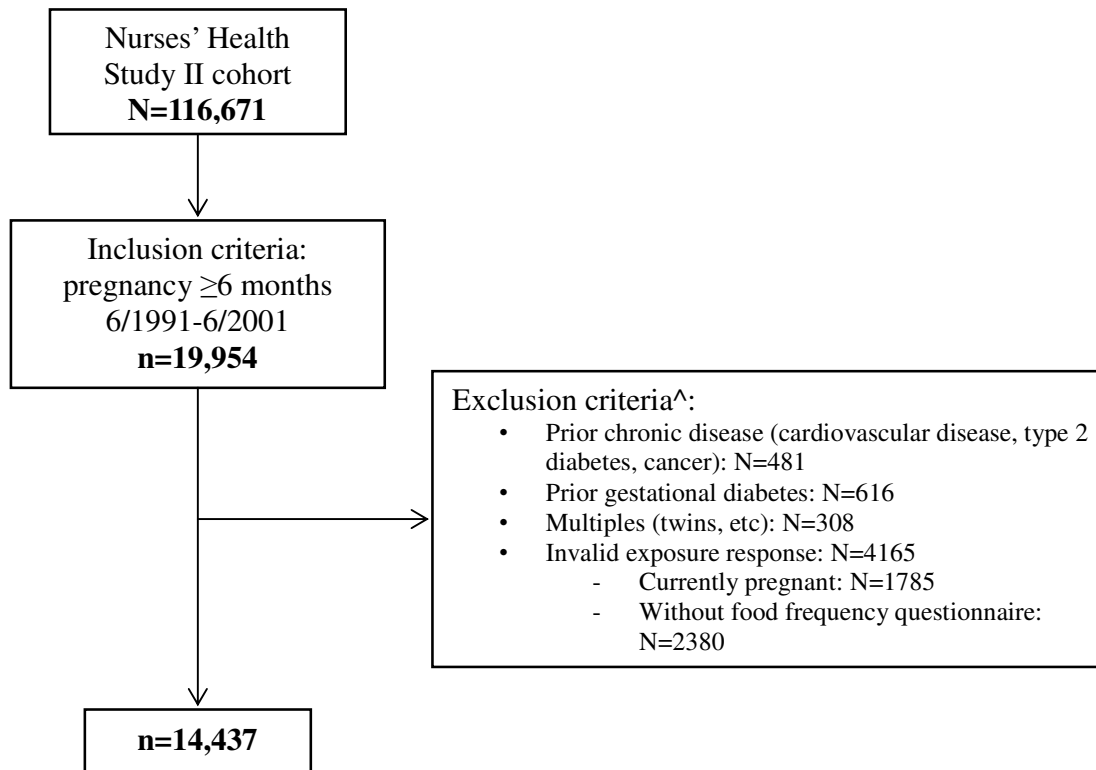


**Appendix 1:** Flow-chart of study participants [posted as supplied by authors]



<sup>^</sup>Exclusion criteria are not mutually exclusive and individual reasons may not total the number of excluded participants.