Application of the CONSORT Statement to a Randomized Trial of Low-Dose Aspirin in Preventing Cardiovascular Disease in Women

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Exemplar of CONSORT Assignment

**Analysis of Strengths and Weaknesses**

**Introduction**

The following analysis relates to the article by Ridker, Cook, Lee, Gordon, Gaziano, Manson, Hennekens, Buring (2005). The purpose of this Randomized Clinical Trial (RCT) was to determine if low-dose aspirin should be recommended as a strategy for prevention of cardiovascular disease for women age 45 or greater.

**Overall Strengths and Weaknesses**

There was a decrease in Cardiovascular events for women who received the aspirin as compared to women who received the placebo. In addition, the ischemic stroke risk decreased by 30%. The method of randomization was unclear, as well as the method for blinding (Author, 2016).

**Reliability and Validity**

The statistics used compared aspirin and placebo groups using the Relative Risk, P values, cumulative incidence rates, and 95% confidence intervals. There was no explanation of how the authors selected these methods in terms of time, e.g. pre-specified or commencement after the initiation of the trial (Author, 2018). This is a Level II trial, which is at a higher level of evidence if the researchers follow the protocols for a Level II trial, and overall these researchers did. The RCT had randomization, intervention and control groups, as well as manipulation of the independent variable, which provides strength in studying the cause-effect relationship. Following these Level II design requirements reduces the threats to internal and external validity LoBiondo-Wood & Haber, 2018).

**Ethics**

The Institutional Review Board did monitor the study, and informed consent was signed by those participating as subjects in this study .

**Topic, Summary**

This is an important topic and the need to determine whether low-dose aspirin should be utilized needs to be analyzed. Since this study was completed in 2005, much new information is available that renders the findings of this study lacking for generalization of the clinical applications to women in this age group.

References

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Note: CONSORT Checklist was completed for this Exemplar