

J2: Summary of Proposed Amendment:

ASCEND: A randomised 2x2 factorial study of aspirin versus placebo, and of omega-3 fatty acid supplementation versus placebo, for primary prevention of cardiovascular events in people with diabetes.

Reference: MREC 03/8/087

Substantial Amendment Code Number: CTSUASCEND3

Version: 8

Date: 2007-05-08

Amendment to request the use of posters/flyers for potential participants to be available in clinic waiting areas.

In a recent substantial amendment (CTSUASCEND2, version 8.0) the following new recruitment methods were approved for ASCEND:

- 1) an option for hospital collaborators, general practitioners or practice nurses to offer a standard "invitation pack" (containing patient information leaflet, screening questionnaire and freepost envelope) to potentially eligible participants when they are seen for routine care in their clinic

and

- 2) an option for potential participants to volunteer themselves if they hear about the study from some other route.

In order to enhance these more flexible recruitment methods, it is requested that the following new documents are approved for use in clinic waiting areas:

- a. poster V1_080507
- b. participant flyer V1_080507

These will be displayed in appropriate clinic waiting areas (e.g. hospital outpatient departments [where a local consultant has previously agreed to collaborate, and hospital trust R&D approval is in place], GP surgeries, mobile retinopathy screening units, Biobank clinics etc). The new documents give a brief description of the study and invite potentially eligible volunteers to contact the coordinating centre for more details.