Thank you very much for your valuable contribution to ASCEND. We are very grateful that you have been so generous with your time and commitment by agreeing to be part of the study. Without volunteers like you important questions about treatment cannot be answered and the care of people with diabetes cannot be improved. As you know, ASCEND aims to find out whether aspirin and omega-3 fatty acids (fish oils) help to prevent circulatory problems (such as heart attacks and strokes) in people with diabetes, but who did not have circulatory problems when they entered the study. You were allocated to either aspirin or a placebo (dummy) tablet, and to either omega-3 fatty acids or a placebo capsule for the course of the study, although we recognise that some participants have stopped their allocated treatment during the study. Even if you are no longer taking the study treatments the information you provide is still very valuable and important for the success of the study.

Study treatment

Once you have filled in and returned your Final Follow-up Questionnaire you should **stop** taking your ASCEND medication, if you have not already done so. We would be grateful if you could take any left-over study medication to your local pharmacy for safe disposal. Current UK guidelines do not recommend that people with diabetes, but who do not have heart and circulatory problems, are offered aspirin or omega-3 fatty acids but you may wish to discuss your ongoing treatment with your GP.

A letter has been sent to your GP, informing them of the end of your participation in the study.

Please tell us if you are admitted to hospital within 28 days of finishing the study treatments

If you are admitted to hospital for any reason during the 28 days after stopping your ASCEND medication and completing your Final Follow-up Questionnaire, please inform the coordinating centre.

Further follow-up questionnaires

Once you have completed and returned your Final Follow-up Questionnaire, you will no longer be sent the six monthly Follow-up

questionnaires. However, we shall be requesting some extra information from participants around the end of the study to assess whether aspirin, and or omega-3 fatty acids, have any effects on brain-power (cognitive function) and eye-sight. If you have not already been sent information about these two projects, you will receive these in the next few months. Completing these additional assessments is optional and, if you choose not to complete them, this will not affect your existing contribution to ASCEND.

Follow-up after the end of your participation in the study

Continuing to collect information about your health after the end of your participation in ASCEND could help to answer important questions such as whether aspirin has an effect on long term cancer risk. Since ASCEND started, several studies have suggested that aspirin might help to prevent come cancers such as bowel cancer, but this is difficult to study as any effects of aspirin on cancer risk might take many years to appear.

At the beginning of the study you agreed that the ASCEND investigators could be supplied with information about any serious illnesses by your own doctors or NHS registries. To allow any long term effects of aspirin or omega-3 fatty acids to be discovered, the ASCEND co-ordinating team will continue to request information about you from central registries, such as the Health and Social Care Information Centre (HSCIC) (now called NHS Digital). NHS Digital holds information nationally from the records that health and social care providers keep about the care and treatment they give. The information requested by ASCEND includes information about hospital attendances or admissions (called Hospital Episode Statistics), any new diagnosis of cancer and the causes of any death of a participant.

Your name, date of birth, NHS number and postcode are sent securely by secure electronic link to NHS Digital who have a record of all hospital attendances and admissions from the Hospital Episode Statistics (HES) dataset. This information is linked to individual participants in the study.

NHS Digital also provides information about cancer registrations on behalf of Public Health England and deaths, including date and cause of death, on behalf of the Office for National Statistics.

The information from NHS Digital is sent to the ASCEND investigators by a secure electronic link and your confidential data will not be shared with anyone else.

It is anticipated that this follow-up will continue for up to 20 years after the end of the treatment period. If you have any questions about this then please contact the study team (see contact details on page 1 of this leaflet). If you no longer wish to let the ASCEND team use such information or do not want them to continue to request this information about you in the future, please telephone, write to or email the trial team.

More information about how information about you is stored and processed by ASCEND is available on the study website.

Study results

The main study results will not be available until 2018. This is because the study team needs time to make sure all the questionnaires have been filled in and the study information is as complete as possible before analysing the results. We will write to you with the results of the study. The results will also be available on the ASCEND study website. If you do not want to receive a letter about the study results then please contact the study team.

ASCEND treatment allocation

It helps the study produce robust results if neither you, your doctors nor the study staff, know which treatment you were allocated until after the final analysis of the study results has been completed. If there is a medical reason for finding out which treatment (active or dummy) you were taking this can be done by calling the Freefone number 0800 585323. After the results are available, if you want to know whether you were on active or dummy treatments then please call the Freefone number. However, it will help the reliability of the results from the post treatment follow-up if as few participants as possible do find out.

British Heart Foundation

ASCEND

A Study of **C**ardiovascular **E**vents i**N** **D**iabetes

UNIVERSITY OF OXFORD

A randomised study of aspirin and of natural oils for the primary prevention of cardiovascular events in diabetes

INFORMATION ABOUT THE END OF YOUR PARTICIPATION IN THE STUDY

This leaflet contains important information about the end of your participation in the ASCEND study. Please read all the information contained in this leaflet carefully. If you have any further questions about this please contact the ASCEND team.

Please keep this information sheet for your own records.

THANK YOU FOR YOUR HELP

Contact details for the ASCEND coordinating centre

By phone:	Freefone service: 0800 585 323 (from outside UK: +44 1865 765615)
By e-mail:	ascend@ctsu.ox.ac.uk
By post:	ASCEND Clinical Trial Service Unit (CTSU) Richard Doll Building Roosevelt Drive OXFORD, OX3 7LF
Study website:	www.ctsu.ox.ac.uk/ascend

Co-ordinated by:
Clinical Trial Service Unit, University of Oxford
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Website: www.ctsu.ox.ac.uk/ascend

MRC Medical Research Council