Early ACTID Study
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Patient Information Sheet
Version 1, 3/06/09

ACTID Plus; a 5 year follow up of patients who took part in the Early ACTID study.

You are being invited to take part in a research study. Before you make a decision, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your friends, relatives or your GP if you wish. Please do not hesitate to ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Whether individuals who have had a 12 month diet or diet and exercise intervention continue to see benefits after this has finished is not known. This study aims to answer these questions.

In this study we will invite all patients who participated in the Early ACTID Study to attend a yearly appointment for 5 years from the time that they finished the Early ACTID study. At these visits we will carry out the same blood tests and measures that were done in the Early ACTID study.

Results from these tests will tell us whether participants who were given a 12 month diet or diet and exercise intervention continue to show benefits up to 5 years after completing these interventions.

Why have I been chosen?

We are asking you to take part in this study as you were involved in the Early ACTID study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

If you agree to take part we will arrange a visit where we will give you more information and ask you to sign a consent form. Prior to this visit, we will send you 12 simple questionnaires, an activity counter (a small black box that is worn on a belt and records your activity) and diaries to record your activity levels, sleep patterns and food. We will provide you with instructions on how to use these and ask you to fill the questionnaire and diaries in and wear the activity monitor for 7 days before this visit. These are the same questionnaires and diaries that you filled in for us whilst you were in the Early ACTID study.

Visit 1 – Consenting and measurement visit
This visit will take place on one morning with you having had nothing to eat and drink (except water) from 11pm the night before. After giving you further information about the study and an opportunity to ask questions, we will ask you to sign a consent form.

After this we will place a small fine plastic tube into a vein in your arm, similar to a normal blood test. We will then take 25 mls of blood (5 teaspoons) from this to measure kidney function, liver function, cholesterol, glucose, insulin and markers of inflammation. On completion of these tests we will give you something to eat and drink.

After you have had some breakfast, we will measure your blood pressure, weight, height, waist circumference and body fat and ask you some questions about your health. You will then spend an hour with the dietitian going over your food diaries. At the end this visit we will arrange your next visit.

The total time for this visit will be approximately 2 hours.

If it is more convenient for you we can arrange for you to see the dietitian at a separate visit.

Visit 2-5
These visits will take place 1, 2, 3 and 4 years after visit 1. Prior to the visit we will send you the 12 simple questionnaires, activity counter and diaries to record your activity levels, sleep patterns and food intake (food diary). Again we will ask you to fill in the questionnaires and diaries and wear the activity monitor for 7 days before this visit.

These visits will be the same as visit 2.

All of these visit will take place in the hospital where your were seen as part of the Early ACTID Study.

What will be done with the blood samples?

Blood taken at visits 2-6 will be tested for long term glucose control, kidney function, liver function, cholesterol, other fats and markers of inflammation. The glucose and insulin concentrations will enable us to work out how much insulin you can produce and how well this insulin is working.

Will I be told the results of all the tests?

A few weeks after visits 2-6 we will send you a letter explaining what the blood tests, activity monitor and diaries have found. We will also send a copy of this report to your doctor if your wish us to.

Are there any disadvantages/risks in taking part in the study?

Blood tests can sometimes be uncomfortable and may result in bruising.

What are the benefits of taking part in the study?

One benefit from entering the study is that you will be seen on 5 occasions by a dietitian and a nurse who specialises in diabetes. Furthermore, you will also have regular measures of your diet and exercise levels, something that is not routinely done.

What if something goes wrong?

As the tests we are proposing have very few risks associated with them, we do not anticipate that anything should go wrong. The research team are available in normal working hours and may be contacted at any time if you encounter any difficulties. You will be given details as to how to contact us.

Will taking part in the study remain confidential?

All information collected in the course of the study will be kept strictly confidential. If you agree, we will inform your GP of your participation in the study and the results of the tests.

What will happen to the results of the research study?

Results from the research programme will be published in medical journals and presented at conferences. We will provide you with a report of the research results on completion of the study which we expect to be at the end of 2014.

Who is organising and funding the study?

The principal investigator of this study is Dr Rob Andrews and it is being run between 3 departments at the University of Bristol, Exercise and Health Sciences, Henry Wellcome Laboratories for Integrative Neuroscience and Endocrinology and Primary Health Care. Doctors and nurses who specialise in the treatment of diabetes, dietitians and specialists in exercise are all involved in this study. The study is funded by a grant from the School of Primary Care.

Will there be money for travel expenses?

We have not received funding for this, however reasonable travel expenses will be reimbursed if required.

Who has reviewed the study?

The study has been reviewed by the School of Primary Care, NHS Research & Development and the appropriate Ethical Committee in accordance with local regulations.

Who do I contact for further information?

Rob Andrews, the principle investigator.

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What do I do now?

All you need to do is to complete and return the enclosed reply slip *in the prepaid envelope* telling us whether or not you are willing to take part in this study.

If you are able to help us one of the research team organising the study will contact you. He or she can answer any questions you may have and, if you wish, can arrange a time for you to come and meet us to discuss the study further.

Please discuss this information with your family, friends or GP if you wish.

Return Slip

Would you be interested in finding out more about this study? (Please circle) Yes No

If no, please state why. _____

If yes, please complete the details below:

Name _____

Address _____

_____

_____

Post code _____

Daytime Tel: _____

Evening Tel: _____

Best time to ring (Please circle) Morning Afternoon Evening

Thank you very much for your time.

Please return slip to:

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University of BRISTOL

NHS

ACTID Plus: follow up of the participants who took part in the Early ACTID study

Patient Written Consent Form

Name of researcher: <Research Nurse>

Study Number:	
Centre Name:	
Study Subject Number:	

If you agree with each sentence below, please INITIAL the box:

1. I have read and understood the patient information sheet for the above study (version 1, 3/6/09). I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided. ☐
2. I understand that my participation in this study is entirely voluntary and that I am free to withdraw from the study, at any time, without my medical care or legal rights being affected. ☐
3. I am willing to allow access to my medical records but understand strict confidentiality will be maintained. The purpose of this check is to ensure that the study is being carried out correctly. ☐
4. I agree to take part in the above study. ☐

Please print and sign below in the space provided and add today's date.

_____	_____	_____
Name	Signature	Date
_____	_____	_____
Name of person taking consent (if different from researcher)	Signature	Date
_____	_____	_____
Name of principal researcher	Signature	Date

I fully confirm that an appropriate person has taken consent and I take responsibility for the patient being fully informed about the trial.
N.B. Ensure the patient dates their own signature. 1 for patient, 1 for study, 1 to be kept with hospital notes.

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