Participant information sheet

Appendix 2.1: Initial participant information sheet

Participant information sheet [29/05/2013 version 3.0]

The MOVE-IT study: *A multi-centre randomised controlled trial comparing the effectiveness of enhanced motivational interviewing with usual care for reducing cardiovascular risk.*

You are being invited to take part in an NHS funded research study being carried out by Kings College London and St. Georges Hospital.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP. If you would like any more information, have any questions or something is not clear, please feel free to contact the research team, details are at the end of this letter.

You will be given this information sheet and a signed consent form to keep if you decide to take part in the study.

Why am I being asked to take part?

Your medical records suggest that there is over a 20% chance that you may develop heart disease in the next ten years. We would like to see if we could help you reduce this risk, so we are inviting you to take part in this research study.

Purpose of the study

Motivational interviewing (MI) is a therapy which involves talking about your thoughts and feelings to help you make positive changes to your life. This will be provided by a healthy lifestyle facilitator who aims to help people become more confident, willing, and committed to making changes to their lifestyle. There is evidence to suggest that MI helps people make short term lifestyle changes, we want to learn if these changes can be kept up in the long-term. We would also like to understand the differences between being seen individually or in a group. We would like to test whether motivational interviewing with additional coping skills can help people at high risk of developing heart disease make healthier lifestyle choices and stick to these over the course of two years.

Factors which may increase your chances of developing heart disease include cigarette smoking, poor diet and physical inactivity. If these lifestyle choices continue long-term this can increase the risk of other serious health problems, such as, high blood pressure, weight gain, stroke, and diabetes. This study will be looking at whether motivational interviewing, as described above, can help improve diet and physical activity, to reduce the risk of developing heart disease. Even though most of us are aware that we should be eating healthier and be more active, for many people it can be very difficult to achieve this in the long term for different reasons.

Do I have to take part?
No. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. If you would like to take part we will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, even after you have agreed to be contacted, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?
If you are happy to participate, one of the researchers would like to meet with you and take some measurements. This appointment would last approximately one hour and will involve:

- Measuring your height, weight and blood pressure.
- Taking a small sample (about 10 mls or two spoonfuls) of blood from your arm to check your cholesterol and blood glucose.
- Answering some questions about your health.
- At the end of the appointment you will be given a small pedometer to wear on your hip for 7 days, and then post back.

You will then be randomly placed into one of three categories. You will have an equal chance of being in any of the categories. The categories are:

1. Usual care
    - If you are placed in this category you will not attend the motivational interviewing sessions, but will continue to see your GP as normal.

If you are placed in the individual or group categories you will be given an appointment to see a healthy lifestyle facilitator. The healthy lifestyle facilitators are specially trained in motivational interviewing and will deliver the sessions at your GP practice or a local community venue.

2. Individual motivational sessions
    - During the study you will receive 10 therapy sessions over 12 months, with each session lasting 30 minutes. At first there are 6 weekly sessions and then one session at 3, 6, 9 and 12 months.

3. Group motivational sessions
    - During the study you will receive 10 therapy sessions over 12 months, with each session lasting 90 minutes. At first there are 6 weekly sessions and then one session at 3, 6, 9 and 12 months.

Everybody will continue to have their usual care from their GP. Everybody will meet with the researchers after 1 and 2 years to repeat the measurements taken in the first appointment.
The aim of this study is to understand how useful motivational interviewing is in reducing the risk of heart disease. To help us understand what happens during the therapy sessions we would like to audiotape some of these. Any sessions that are taped will be written down and your identity

will be kept anonymous throughout this process. During the course of the study we will contact you to discuss your thoughts and experiences of the therapy that you have received.

What are the possible disadvantages or risks of taking part?
We do not expect there to be any disadvantages of participating in the study. The therapy is based on eating more healthily, increasing physical activity, and gradual and sustainable weight loss. As we would request permission for a blood sample this may cause some discomfort.

What are the possible advantages of taking part?
We cannot promise the study will help you, but you may receive motivational interviewing. There are potential health benefits for participants in the study, as it has been shown taking part in research usually is related to better outcomes. The results of our research could also help to develop new treatments for people at risk of heart disease.

Will my information be kept confidential?
Yes. We follow ethical and legal practice and all information about you will be handled in confidence. The data you give us will be made anonymous.

What will happen to the results of the research study?
The research data will be stored in a locked filing cabinet and in a locked room. Patients can only be identified by a unique and anonymous study number. Electronic data will be password protected and any direct quotations will be anonymised.

What will happen to my collected data if I withdraw from the study?
If you decide to leave the study any research data and blood previously collected with your agreement would be kept and used in the study. We would not collect any more information from you or expect you to take part in any other research activities.

Who is funding the research?
The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) is funding this study. The NIHR is the organisation which conducts research for the NHS. Any of your travel expenses for the study may be refunded.

Who has reviewed the study?
The research proposal has been reviewed by staff in the Academic Department of Psychological Medicine at King's College London and by the local Research Ethics Committee at Dulwich, London.

Future research
We have funding for this research for 4 years in total but would like to continue collecting information about your health for an additional 5 years if you agree. This is to see if the motivational interviewing is helpful in the long-term. We would like to request your permission

to continue to collect health data from your medical notes and to contact you after the 4 year study is over.
We would like to retain your blood samples for up to 5 years after the study ends for further analysis.
We would also like to invite a number of people for further interviews to tell us about their experience of the study.
You can record your decision about these on the consent form.

Contact for further information

If you have any questions or require further information about this study now or at any time during the study, you are very welcome to get in touch with the research team on Tel. 020 7848 5759/5785.
If you have any questions concerning your rights as a study participant you may wish to read the following leaflet: Getting Involved in Research: A guide for consumers, available at:- http://www.invo.org.uk/pdfs/guide_for_consumers.pdf or contact the Consumers in NHS Research Support Unit, Tel: 01962 872247.

Appendix 2.2: Additional participant information sheet

Additional participant information sheet [15/09/2015 version 1.0]

The MOVE IT study: *A multi-centre randomised controlled trial comparing the effectiveness of enhanced motivational interviewing with usual care for reducing cardiovascular risk.*

Thank you again for your participation in MOVE IT. We are inviting you to take part in a related research study, the PROTECT study, which is also taking place at King's College London. The PROTECT study is a national study looking for factors that might increase the chances of developing memory problems in later life. The reason we are inviting you is because the results of both studies can be shared. This would mean that the information we have collected in the MOVE IT study can be linked with information from PROTECT, allowing for new research questions about memory loss to be studied which may benefit patients in the future.

Before you decide whether or not you wish to take part in further research, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP. We will be contacting you by phone shortly after you receive this letter, to answer any questions you may have.

If you decide to consent to the additional two points outlined in the enclosed consent form please keep a copy of this information sheet along with one copy of the consent form for your reference, and return a signed consent form to the research office in the freepost envelope provided.

Why am I being asked to consent?

1) You can take part in the PROTECT study if you are over the age of 50 years, resident in the UK and have not been diagnosed with dementia.

2) We are also asking you to consent for the MOVE IT study to access your Hospital Episodes Statistics data, which tells us how often you have used hospital services over a period of 6 years beginning one year before you started participating in the MOVE IT study

Purpose of request for consent

1) The PROTECT study details can be found in the enclosed leaflet and online at http://www.protectstudy.org.uk/

2) The reason we have asked to access your Hospital Episodes Statistics data is for us to be able to accurately estimate the economic costs of healthcare services provided to those participating in the MOVE IT study. This will contribute to our assessment of the cost-effectiveness of the MOVE IT intervention.

Do I have to take part?

No. It is up to you to decide. If you decide to take part in the PROTECT study, we will ask you to initial the box and sign the enclosed consent form to confirm you are willing for your data to be shared between the two studies.

If you decide not to take part, we will still ask you whether you are happy for us to access your Hospital Episodes Statistics data. You are welcome to consent to one of the two additional points on the consent form, rather than both. We will not take any further action until we receive your signed consent form.

Contact for further information

If you have any questions or require further information about data sharing, you are very welcome to get in touch with the research team on Tel. 020 7848 5759/5785.

If you have any questions concerning your rights as a study participant you may wish to read the following leaflet: Getting Involved in Research: A guide for consumers, available at:- http://www.invo.org.uk/pdfs/guide_for_consumers.pdf or contact the Consumers in NHS Research Support Unit, Tel: 01962 872247.

Appendix 2.3: Participant information sheet – Focus groups

Participant information sheet – Focus Groups [26/02/2016 version 1.0]

The MOVE-IT study: *A multi-centre randomised controlled trial comparing the effectiveness of enhanced motivational interviewing with usual care for reducing cardiovascular risk.*

Thank you once again for your participation in the MOVE IT study. You are receiving this information sheet as we would like to invite you to take part in a focus group in which we want to find out more about your individual experience of the MOVE IT programme.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP. If you would like any more information, have any questions or something is not clear, please feel free to contact the research team, details are at the end of this letter.

You will be given this information sheet and a signed consent form to keep if you decide to take part in the study.

Why am I being asked to take part?
You are a participant of the MOVE IT study, and you were randomised to receive healthy lifestyle sessions in either a group or one-to-one format. You may have received all 10 sessions, or some number of sessions before deciding not to continue.

Purpose of the study
The MOVE IT study aim was to reduce weight and increase physical activity in people at high risk of developing heart disease, and to assess whether resultant health benefits would remain over the course of two years. We have not as yet assessed whether the intervention has been successful. An important part of a study which assesses a lifestyle intervention such as MOVE IT is to consider the processes which may have resulted in any observed change. This study will use focus groups to find out more information about what parts of MOVE IT were helpful, which parts were not helpful and how it might be better tailored to people who decided against participating.

Do I have to take part?
No. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. If you would like to take part we will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, even after you have agreed to be contacted, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?
If you are happy to participate, we will arrange a focus group date and time which is suitable for you and a small group of other participants. The group will last approximately one hour and thirty minutes and will involve:

- Attending King's College London in Denmark Hill.
- Meeting in a group of approximately 5-10 participants.
- The focus group will be run by 1-2 facilitators.
- Refreshments will be provided.
- We will also compensate for travel expenses to and from the venue, as well as providing a £10 shopping voucher to thank you for your participation.

To help us accurately record the discussions which take place during the focus group, we will audiotape the whole session. Any sessions that are taped will be written down and your identity will be kept anonymous throughout this process.

What are the possible disadvantages or risks of taking part?
We do not expect there to be any disadvantages of participating in the study.

What are the possible advantages of taking part?
We would like to hear your views and experiences on the MOVE IT programme, which you may not have had the opportunity to express until now. The results of this research, in gaining a better understanding of how MOVE IT helps people, could also go on to guide the development of similar treatments in the future.

Will my information be kept confidential?
Yes. We follow ethical and legal practice and all information about you will be handled in confidence. The data you give us will be made anonymous.

What will happen to the results of the research study?
Study materials, such as your consent form, will be stored in a locked filing cabinet and in a locked room. Patients can only be identified by a unique and anonymous study number. Electronic data will be password protected and any direct quotations will be anonymised.

What will happen to my collected data if I withdraw from the study?
If you decide to leave the study any research data and blood previously collected with your agreement would be kept and used in the study. We would not collect any more information from you or expect you to take part in any other research activities.

Who is funding the research?
The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) is funding the MOVE IT study. The NIHR is the organisation which conducts research for the NHS. Any of your travel expenses for the study may be refunded.

Who has reviewed the study?
The research proposal has been reviewed by staff in the Academic Department of Psychological Medicine at King's College London and by the local Research Ethics Committee at Dulwich, London.

Future research

When joining the MOVE IT study, you will have consented to whether you are happy or not happy to participate in future research. Whenever you are invited to further research you will be asked to give consent and you are under no obligation to participate if you do not wish to.

Contact for further information

If you have any questions or require further information about this study now or at any time during the study, you are very welcome to get in touch with the research team on Tel. 020 7848 5759/5785.

If you have any questions concerning your rights as a study participant you may wish to read the following leaflet: Getting Involved in Research: A guide for consumers, available at:- http://www.invo.org.uk/pdfs/guide_for_consumers.pdf or contact the Consumers in NHS Research Support Unit, Tel: 01962 872247.