Participant Information Sheet
‘Lifestyle Matters’ for maintenance of health and wellbeing
A Randomised Controlled Trial

Invitation
We would like to invite you to take part in a research study. Before you decide whether you want to take part, we need you to understand what the research is for and what you would be expected to do. Please read the following information carefully. If you do not understand anything or have any questions, please contact us. Please take time to decide whether you wish to take part.

What is the study about?
Lifestyle Matters is a programme of group meetings, for people aged 65 years and over. The programme is based on the idea that what we do in our everyday lives is important for health and wellbeing. We want to find out whether attending the Lifestyle Matters programme can help people maintain a healthy, happy and fulfilling life.

What is the Lifestyle Matters programme?
Small groups of 12 people attend weekly meetings led by a trained facilitator for a period of 4 months in which they undertake a range of activities. The activities covered in these meetings will be decided by the group with assistance provided by the group facilitator. The types of activities that people chose to get involved in during the pilot study included computing (at the local college), tai chi, aromatherapy, using public transport and dining out together.

Why have I been invited?
We have invited people who are aged 65 years or more and who live in certain areas of Sheffield/Bangor. The study is concerned with anyone who would like to get a little bit more out of life. You may have experienced a change in physical ability, the consequences of bereavement, a recent or longstanding illness or a fall. You may just feel you want to do more with your life.

Do I have to take part?
It is up to you to decide whether you would like to take part in the study or not. If you decide to take part you are still free to withdraw at any time without giving a reason. Your future care will not be affected if you choose not to take part. If you withdraw during the course of the study any data we’ve collected from you will be retained and may be used for reports and publications.

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How do I give my permission to take part in the study?
You will be asked to sign a ‘Consent Form’. This is a form you sign to say that you understand why the study is being done, that you understand what you are expected to do and what the researchers will do with the information they will collect.

Who will see the information that I give to you?
The information we will collect from you will be seen by a number of different people and organisations. These are listed below:
The Research Team
The information you give us and any data collected will be seen by authorised individuals from the University of Sheffield, Bangor University and Sheffield Hallam University.

The NHS Information Centre for Health and Social Care (NHS IC)
With your consent, we will share your name, postcode and date of birth with the NHS Information Centre, Medical Research Information Service. The information we share will be used by The Health and Social Care Information Centre and other central UK NHS bodies in order to provide us with information about your health status.

The UK Data Archive
A requirement of the study is to share the data we collect, with the rest of the research community so that the data can be used to help inform other research and policy development. We will do this by sending the data we collect to the UK Data Archive [www.data-archive.ac.uk](http://www.data-archive.ac.uk). No recognisable information will be used and your confidentiality will be maintained. We will ensure that any data sent to the UK Data Archive is done so using their secure electronic system for transferring data.

What will happen to me if I agree to take part?
If you agree to take part in the study we will invite you to meet one of our researchers for a brief assessment. They will ask you to complete some questionnaires about your health, wellbeing and attitude. The researcher will go through this information sheet with you and answer any questions you may have. You will then sign a consent form. To find out if 'Lifestyle Matters' makes a difference we need to compare people who take part in group meetings with people who don’t. This means that some people will take part in the programme and others won’t. To be fair, a computer programme will randomly select which people will take part in the Lifestyle Matters programme.

What will I have to do if I am selected to attend the Lifestyle Matters programme group?
You will be asked to choose which day (Mon-Fri) and time (AM or PM) you would like to attend. As soon as we have enough people to run a group we will contact you with the date...
and time of your first meeting. The meeting will take place in a local community venue. The programme involves weekly meetings over a period of 4 months. After 6 months you will be asked to complete some questionnaires asking you about your health and wellbeing. These are the same questionnaires that you completed at the start of the study. There are a number of ways in which you can complete the questionnaires including by post, by telephone or face-to-face with a Research Assistant. If they are posted to you we will include a pre-paid envelope for you to return the questionnaires so you will not have to pay any postage. You will be asked to complete the same questionnaires again, 18 months later.

When you have completed the Lifestyle Matters programme you may also be asked if you would like to take part in an interview with one of our research team. We are not interviewing everyone who has taken part. The interview will ask you about your experience of the programme. It will take approximately 1 hour and will be conducted in a location that is convenient for you. The interview will be audio recorded and the recording typed up into a document which you will be asked to read through and check for accuracy.

**What will I have to do if I am NOT allocated to the Lifestyle Matters group?**

If you are allocated to the group not attending the programme you do not need to do anything at first. After 6 months you will be asked to complete some questionnaires asking you about your health and wellbeing. These are the same questionnaires that you completed at the start of the study. There are a number of ways in which you can complete the questionnaires including by post, by telephone or face-to-face with a Research Assistant. If they are posted to you we will include a pre-paid envelope for you to return the questionnaires so you will not have to pay any postage. You will be asked to complete the same questionnaires again, 18 months later.

**Apart from the questionnaires at 6 and 24 months will you contact me in any other way during the course of the study?**

Yes, a Progress Update will be sent to you at 7 months, 14 months and 21 months which will tell you about what is happening in the study.

**Will you be observing the group meetings?**

We will be video recording a small number of the group meetings to look at how the facilitator works with the group. The video tapes will be watched by members of the research team.

**Are there any expenses or payments involved?**

You will not receive any payment for taking part in the study.
Will my taking part in the study be kept confidential?
Yes. All information about you will be handled in confidence, except if there is an issue of safety, in which case we will let you and your GP know. The information you give us will be ‘anonymised’; this means that we won’t use any recognisable information such as your name or any other personal information in reports or publications. Identifiable data collected for the study will only be looked at by authorised persons from the research team and the NHS Information Centre for Health and Social Care (NHS IC).

Why do you want to tell my GP that I am taking part in the study?
We want to make sure your GP is aware of the study in case they think it affects your medical care. Your GP will not be given any of the information we collect unless you give your permission.

What if there is a problem?
If you have any cause to complain about how you have been approached or treated during this study you can contact either the Trial Manager Kirsty Sprange, in Sheffield on (0114) 222 2969 or the Trial lead in North Wales, Gill Windle on (01248) 383968, or, you can use the University complaints procedure and contact Dr. Philip Harvey, ‘Registrar and Secretary’ of the University of Sheffield, by post (Registrar and Secretary’s Office, Firth Court, Western Bank, Sheffield, S10 2TN), telephone (0114 222 1100) or e-mail (registrar@sheffield.ac.uk).

You can also make a complaint through the National Health Service (NHS) complaints procedure. This can be done by contacting [the Patient Services Team on telephone 0114 271 2400 at participating hospitals (Sheffield Teaching Hospitals or NHS Sheffield) or you can contact the South Yorkshire and Humberside Independent Complaints Advocacy Service (ICAS) on telephone 0300 456 8349] [the Concerns Team, Ysbyty Gwyned Hospital on telephone East 01978 725543, Central 01248 385337 or West 01248 384194]. You will not be compromised in any way because you have taken part in a research study.

What are the possible risks and benefits of taking part in this research?
Previous research suggests that this type of programme can enhance physical health and general wellbeing in older adults. Benefits might include; increased confidence, learning new skills, meeting new people, engaging in daily activities and increased quality of life. If you have an existing medical condition we would recommend that you let the research team know. This will help reduce any risk in taking part in group meetings and activities.

What will happen to the results of the study?
Firstly the results of the study will be used to develop current health and social care services and practice. Secondly results will be presented at appropriate conferences and published as reports in scientific journals. You will not be identified in any presentation, report or
publication. We will ensure you receive a summary of the results and that you are invited to any local events about it. You will also be able to access the results of the study on the University of Sheffield website at: www.shef.ac.uk/lifestylematters.

Who is organising and funding the study?
The study is organised by the Universities of Sheffield and Bangor with the support of the local authorities and the NHS. The study has been funded by Lifelong Health and Wellbeing Research for Healthy Ageing, Medical Research Council (MRC). You can find further information about this initiative at the following website www.mrc.ac.uk/Ourresearch/ResearchInitiatives/LLHW/index.htm

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by XXXXX Research Ethics Committee.

Contacts for further information:
You can contact the Lifestyle Matters research team using any of the following methods:

- Tel: XXXX XXX XXXX Calls and answerphone messages will be monitored between 9.00am and 4.00pm Mon to Fri
- X.XXXX@XXXXXX Emails will be monitored between 9.00am – 4.00pm Mon to Fri
- Lifestyle Matters Study Team, (Sheffield or Bangor address)

This information sheet is for you to keep.
Thank you for your time and help.