Lifestyle Matters

For maintenance of health and wellbeing

RESEARCH PROTOCOL
(Version 4.0, 20.09.12)

Sheffield CTRU:	**J10-027**
REC:	**12/YH/0101**
ISRCTN:	**67209155**
Funder:	**LLHWB/MRC**
Authorised by:	**Prof Gail Mountain**

Sheffield Clinical Trials Research Unit (CTRU)

Lifestyle Matters for maintenance of health and wellbeing

Contents

Definition of terms

Term	Definition
6CIT	6 Item Cognitive Impairment Test
BRS	Brief Resilience Scale
CI	Confidence Interval
CRF	Client Report Form
CSRI	Client Services Receipt Inventory
CTRU	Clinical Trials Research Unit (Sheffield University)
DMEC	Data Management and Ethics Committee
ESRC	Economic and Social Research Council
GCP	Good Clinical Practice
GLM	General linear model
GSE	General Perceived Self Efficacy Scale
IRAS	Integrated Research Application System
LOCF	Last observation carried forward
LLHWB	Lifelong Health and Wellbeing Cross-Council Programme
MRC	Medical Research Council
NHS IC	NHS Information Centre
NICE	National Institute for Health and Clinical Excellence
NRES	National Research Ethics Service
ONS	Office of National Statistics
PHQ-9	Patient Health Questionnaire
PROMS	Patient Reported Outcome Measures
QALY	Quality Adjusted Life Years
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SF-36	Short-Form 36
TMG	Trial Management Group
TSC	Trial Steering Committee

General information

Sponsor
Professor Jon Nicholl, Dean of School, School of Health and Related Research (ScHARR), University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA.

Persons authorised to sign the protocol & amendments
Prof Gail Mountain, Professor of Health Services Research (assisted living research), Rehabilitation and Assistive Technologies Group, School of Health and Related Reseach, 30 Regent Court, University of Sheffield, S1 4DA. Tel 0114 222 2982; Email: g.a.mountain@sheffield.ac.uk

Partner Institutions

Prifysgol Bangor University
Dr Gill Windle (**Site Investigator**), Research Fellow; Dementia Services Development Centre, Institute of Medical and Social Care Research, Prifysgol Bangor University, 45 College Road, Bangor, Gwynedd, Wales, LL57 2PX; Tel: (01248) 383968; E-mail: g.windle@bangor.ac.uk

Professor Robert T. Woods, Professor of Clinical Psychology with Older People, Dementia Services Development Centre (DSDC) Wales, Ardudwy, University of Wales, Holyhead Road, Bangor, Gwynedd LL57 2PX Tel: (01248) 382463; Email: b.woods@bangor.ac.uk

Sheffield Hallam University
Dr Sarah Cook, Reader in Occupational Therapy, Centre for Health and Social Care Research, Sheffield Hallam University, Montgomery House, 32 Collegiate Crescent, Collegiate Campus, Sheffield, S10 2BP. Tel: 0114 225 5672; Email: s.p.cook@shu.ac.uk

Ms Claire Craig, Senior Lecturer in Occupational Therapy, Sheffield Hallam University, City Campus, Howard Street, Sheffield S1 1WB, UK Tel: 0114 225 2586; Email: c.craig@shu.ac.uk

Trial Manager
Mrs Kirsty Sprange, Trial Manager, Clinical Trials Research Unit (CTRU), ScHARR, University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA. Tel: 0114 222 2696; Email: k.sprange@sheffield.ac.uk

Trial Statistician
Professor Stephen Walters, Professor of Medical Statistics and Clinical Trials, ScHARR, The University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA. Tel: (+44) (0)114 222 0730; Email: s.j.walters@sheffield.ac.uk

Trial Management Group

Prof Gail Mountain (PI) Professor of Health Services Research (assisted living research), ScHARR, University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA. Tel: 0114 222 2982; Email: g.a.mountain@sheffield.ac.uk	**Dr Danny Hind (Chair)** Research Fellow and Assistant Director, Clinical Trials Research Unit, ScHARR, The University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA. Tel: 0114 222 0707; Email: d.hind@sheffiled.ac.uk
Mrs Kirsty Sprange Trial Manager/Research Associate, Clinical Trials Research Unit, ScHARR, The University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA. Tel: 0114 222 2969; Email: k.sprange@sheffield.ac.uk	**Prof Stephen Walters** Professor of Medical Statistics and Clinical Trials, ScHARR, The University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA. Tel: 0114 222 0730; Email: s.j.walters@sheffield.ac.uk
Dr Gill Windle Research Fellow, Dementia Services Development Centre, Institute of Medical and Social Care Research, Prifysgol Bangor University, 45 College Road, Bangor, Gwynedd, Wales, LL57 2PX. Tel: 01248 383968; E-mail: g.windle@bangor.ac.uk	**Prof John Brazier** Professor in Health Economics, HEDS, ScHARR The University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA Tel: 0114 222 0726; E-mail: j.e.brazier@sheffield.ac.uk
Dr Sarah Cook Reader in Occupational Therapy, Centre for Health and Social Care Research, Sheffield Hallam University, Montgomery House, 32 Collegiate Crescent, Collegiate Campus, Sheffield, S10 2BP. Tel: 0114 225 5672 Email: s.p.cook@shu.ac.uk	**Prof Bob Woods** Professor of Clinical Psychology with Older People, Dementia Services Development Centre (DSDC) Wales, Ardudwy, University of Wales, Holyhead Road, Bangor, Gwynedd LL57 2PX. Tel: 01248 382463; Email: b.woods@bangor.ac.uk
Ms Kath Horner Health Improvement Principal, NHS Sheffield 722 Prince of Wales Road, Sheffield, S9 4EU Tel: 0114 305 1049 Email: kath.horner@nhs.net	**Ms Claire Craig** Senior Lecturer in Occupational Therapy, Sheffield Hallam University, City Campus, Howard Street, Sheffield S1 1WB, UK Tel: 0114 225 2586 Email: c.craig@shu.ac.uk

Mr Tim Chater Data Manager / Information Systems Co-ordinator, Clinical Trials Research Unit, ScHARR, University of Sheffield, 30 Regent Street, Sheffield, S1 4DA. Tel: 0114 222 0876 Email : t.chater@sheffield.ac.uk	**Ms Lauren O'Hara** Trial Support, Clinical Trials Research Unit, ScHARR, The University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA. Tel: 0114 222 0880; Email: l.e.ohara@sheffield.ac.uk
Mrs Margaret Spencer Older person representative (Sheffield c/o Clinical Trials Research Unit, ScHARR, The University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA.	

Trial Steering Committee

Dr Pip Logan (Chair) Associate Professor in Community Rehabilitation, Faculty of Medicine & Health Sciences, Room B108a Medical School, Queen's Medical Centre, Nottingham, NG7 2UH Tel: 0115 823 0235 Email: pip.logan@nottingham.ac.uk	**Dr Jennifer Wenborn** Clinical Research Fellow in Occupational Therapy University College London c/o R&D Department, North East London NHS Foundation Trust, 1st floor, Maggie Lilley Suite Goodmayes Hospital Barley Lane Ilford IG3 8XJ Tel: 07903 021667 Email: j.wenborn@ucl.ac.uk
Dr Linda Sheppard Technical Adviser Centre for Clinical Practice, National Institute for Health and Clinical Excellence, Level 1A City Tower, Piccadilly Plaza, Manchester M1 4BD Tel: 0161 870 3119 Fax: 0845 003 7785 Email: linda.sheppard@nice.org.uk	**Older persons advocacy group representative (tbc)**
Dr Fiona Goudie Consultant Clinical Psychologist Clinical Director - Strategic Development Sheffield Health and Social Care FT Fulwood House, Old Fulwood Rd, Sheffield S10 3TH Tel: 0114 2263949 Blackberry: 07792 170361 Email: fiona.goudie@shsc.nhs.uk	

Data Management and Monitoring Committee

Dr Mona Kanaan (Chair) Statistician, Department of Health Sciences, Seebohm Rowntree Building, University of York, Heslington, York, YO10 5DD Tel: 01904 321375 Email: mona.kanaan@york.ac.uk	**Prof Avril Drummond** Professor of Healthcare Research, Facility of Medicine and Health Sciences, University of Nottingham, A Floor, South block link, Queen's Medical Centre (QMC), Nottingham NG7 2HA Tel: 0115 8230493 Ext 30493 Email: Avril.Drummond@nottingham.ac.uk
Dr Claire Ballinger Research Design Service South Central Southampton General Hospital Southampton SO16 6YD Tel: 023 8079 4778 Email: c.ballinger@soton.ac.uk	

Trial Summary

Trial Design: A pragmatic, two-arm, parallel group, individually randomised controlled trial, intended to determine the population benefit of an occupational therapy based intervention in people aged 65 years or older.

Setting: Weekly group meeting intervention carried out in the community.

Recruitment: GP practice mail out, signposting by local authority and primary care staff, signposting by voluntary sector organisations and community engagement.

Intervention: Groups of 10-12 participants randomised to the intervention arm will receive 16 weekly facilitated meetings at a local community venue. The group will be assisted by the facilitators to select, explore and engage with activities that are relevant to them. Didactic sessions relevant to the needs of the specific members are woven into the programme to enhance participants' knowledge of how to overcome barriers to active engagement. Each participant will also be offered monthly 1-1 sessions with one of the facilitators where they will be encouraged to pursue personal goals.

Sample size: 268 participants or couples (a couple counts as one participant). To account for loss to follow-up, the impact of different facilitators and intervention type, 134 participants are required for each arm of the trial. The sample size would then have over 90% power to detect a 10-point difference in the SF-36 Mental Health scores 6 months post randomisation.

Measurement of Outcomes: The primary outcome measure is the SF-36 Mental Health dimension at 6 months post randomisation; Secondary outcome measures are other SF-36 dimensions; EQ-5D; Brief Resilience Scale (BRS); General Perceived Self Efficacy (GSE) Scale; PHQ-9; de Jong Gierveld Loneliness Scale; Health and Social Care Resource Use and Wellbeing Question of the Integrated Household Survey 2011. All outcomes will be measured at baseline, 6 and 24 months.

Follow-up: Follow-up will occur at 6 and 24 months post randomisation.

Planned analyses: Analyses will compare the two arms of the trial to establish whether the intervention is beneficial. Statistical analyses will be performed on an intention-to-treat basis. The primary analyses will compare the mean SF-36 Mental Health dimension scores at 6 months between the two arms using a linear marginal model (GLM) with robust standard errors. Secondary outcomes between the intervention and control group will be compared at 6 months and 24 months post randomisation using marginal GLM with robust standard errors both with and without adjustment for covariates.

A cost effectiveness analysis will be undertaken of the incremental cost per Quality Adjusted Life Years (QALYs) of the Lifestyle Matters intervention compared with treatment as usual. QALYs will be calculated using the SF-6D preference-based index derived from the SF-36 administered at baseline, 6 and 24 months

1. Introduction

The trial will be conducted by the Universities of Sheffield and Bangor and will examine the impact of a complex lifestyle intervention 'Lifestyle Matters' upon the mental wellbeing and quality of life of people 65 years or older (1). This will include how self efficacy and resilience can be supported and sustained in later life. The success of the intervention is based on positioning the older person as an expert in facilitating improved confidence, and associated behavioural change. The intervention focuses on enabling participants to undertake new or neglected activities in the community, make lifestyle choices, undertake personal goal setting and be active in their own personal and group development. The overall goal is to promote long term change and associated psychological benefit.

Rationale

Mental wellbeing in later life is strongly associated with healthy, active ageing which in turn helps to prevent mental illness (2–4). Mental wellbeing is promoted by participation in meaningful activities/ occupations and by active engagement with life (5–7). However far more investment has been made into research into interventions to prevent mental illness than into those designed to improve wellbeing (8). This programme will provide high quality evidence for an intervention designed to improve and sustain wellbeing, thereby redressing the imbalance.

A systematic review of evidence to support NICE guidance on interventions to promote good health and wellbeing in older people confirmed that a US health promoting intervention (Lifestyle Redesign®) provided robust effectiveness and cost effectiveness evidence (9,10). The intervention was able to significantly enhance the physical and mental health, occupational functioning and life satisfaction of community living older adults (11,12). Furthermore, approximately 90% of the post intervention therapeutic gain was retained at follow up six months later (13).

A pilot study was conducted in 2003/4 with adults aged between 60 and 92 years to determine how the US intervention might be transferred into a UK context (14). This examined the acceptability of such a programme to older people living in the UK (including how to recruit participants and programme structure and content). It also explored the key competencies and experience necessary to deliver the programme, the supervision requirements for facilitation, and the health and wellbeing measures that might be appropriate for application in a future large scale study with this population. The results of the pilot resulted in a UK intervention 'Lifestyle Matters.' The pilot study found that individual benefits were experienced by participants who ranged from those at the point of retirement to individuals aged 80 years and over. The pilot also stimulated local community resources in ways that had not been anticipated; e.g. by encouraging the library and leisure centre to respond more flexibly to the needs of older people and by enabling participants to continue to meet following organised programme cessation. Therefore the resources of older people were harnessed and use of community facilities was encouraged rather than fostering reliance upon statutory services (15).

Lifestyle Matters is recommended for implementation within NICE guidance (2008) and can be located on the NHS evidence site for Quality, Productivity and Prevention (QIPP) where it is stated that 'results of replication are not yet determined' (16). The systematic review which underpinned the NICE Guidance rated the pilot study as being 'sound qualitatively' but we remain reliant upon the results of a US study to provide population based evidence for an intervention that is highly dependent upon cultural context (10).

Despite support with implementation and the extensive need that exists among older people there has been a patchy response nationally to the NICE Guidance with only a few sites active in rolling out the intervention. The Lifestyle Matters intervention can be feasibly delivered by either health or social care and by the statutory or third sector and therefore 'falls' between different providers, tending not to be prioritised. Also the only evidence to support implementation of a UK based programme (e.g. the skills and competencies of service providers and UK costs for commissioners of services) is limited to that identified through the pilot study.

The proposed programme of research provides the opportunity to determine whether this intervention is clinically and cost effective in a UK context. The results will support commissioners and providers with decisions about implementation. The questions being posed through this research are important given the increasing numbers of older people, pressure on the public purse and the associated need to support good health in the extended lifespan.

2. Aims and objectives

The primary aim of this research programme is to identify how mental wellbeing, self efficacy and resilience can be supported in people aged 65 years or older by;

1. Evaluating (through a randomised controlled trial) the clinical and cost effectiveness of a psycho-social intervention to promote healthy ageing (Lifestyle Matters).
2. Examining the underlying mechanisms that can promote self efficacy and resilience.
3. Determining the long term sustainability of the intervention.

Research questions

1. Is mental wellbeing as measured by the SF-36 (mental health dimension) significantly increased in participants allocated to receive Lifestyle Matters compared to participants allocated to a control group? (17)
2. Does the intervention have any lasting impact upon mental wellbeing?
3. What is the incremental cost effectiveness (using cost-effectiveness analysis and cost-utility analysis) in terms of cost per QALY of the Lifestyle Matters intervention compared with a treatment as usual control condition?
4. What is the nature of the underlying mechanisms appear to promote self efficacy and resilience?

3. Trial Design

The study is a pragmatic, two-arm, parallel group, individually randomised controlled trial, to determine population benefit in people aged 65 years or older. It will adhere to the MRC framework for the evaluation of complex interventions (18). It has been selected to:-

a) Determine population benefit, thereby significantly adding to the body of existing knowledge derived from a number of existing feasibility studies
b) Enable comparisons with the results obtained from the US study (11)
c) Improve the existing evidence base as recommended in NICE guidance (9)

We will conduct a fidelity and process evaluation within the RCT to explore the mechanisms underpinning the intervention, and specifically to identify the dimensions that appear to enhance the resilience of individual participants, encourage positive changes in behaviour (and particularly in self efficacy) and promote effective intervention facilitation. A period of trial follow-up to 24 months will allow for definitive examination of potential longer term benefits of the intervention.

4. Selection and withdrawal of participants

Selection of participants will be based on the following inclusion and exclusion criteria:

Eligibility criteria:

1. Aged 65 years and over
2. Display reasonable cognitive function as evidenced by a score of 0-7 on the Six Item Cognitive Impairment Test (6CIT) (19).
3. Living independently or in sheltered accommodation, alone or with others.
4. Are able to converse in English. Groups will be facilitated in Welsh if there is demand in Bangor.

Individuals with mobility problems will be actively supported to attend.

Exclusion criteria:

1. Aged 64 or under
2. Score 8 or more on the Six Item Cognitive Impairment Test (6CIT). We will signpost these individuals to relevant services with their agreement.
3. Living in residential accommodation.
4. Not able to converse in English or Welsh.

Withdrawal of participants

Participants will be free to withdraw from the trial at anytime without giving a reason. If someone does withdraw during the study period data already collected prior to withdrawal will be retained and used for the purposes of the study as stated in the Participant Information Sheet. If a participant wishes to withdraw they will be asked to notify one of the research team or the group facilitators. Reasons for withdrawal will be recorded where provided and a **Study Withdrawal Letter** will be sent to the participant. The participants' record in the data management system will be flagged to indicate their withdrawal and prevent any further contact being made by the research team. At this point they will receive no further contact from the University.

5. Recruitment

The trial will target people aged 65 years and over. To achieve this a variety of recruitment methods will be used including:

- targeted mass mail-outs using GP databases;
- advertisement at local venues including libraries, pharmacies, supermarkets;
- direct referral and/or advertisement by:
    - statutory and community services;
    - community groups;
    - health and social care professionals; and,
- third sector organisations such as AgeWell, Age UK and 50+

There will be three waves of recruitment, one for each 4 month cycle of the intervention. Each cycle will concentrate upon a specific geographical location. This approach will enable a focussed effort to recruit participants and provide a local venue from which the intervention will operate therefore maximising accessibility for participants.

A range of marketing materials will be used to advertise the study to potential participants providing information on how to contact the research team for further details. All materials will be made available in English and Welsh. A breakdown of the recruitment process is shown in figure 2.

Targeted GP mail-outs will include a **[1] GP letter**, a copy of the **[2] brief study description** and a **[3] response card** for registration of interest. The same documents will be provided to signposters and referrers to hand out to potential participants. A potential participant can register an interest either by returning the **[3] response card**, by contacting the study team directly or through a third party, for example a signposter, a friend or relative. Once we receive a potential participants contact details a unique screening number will be allocated. The screening process occurs in two stages:

Stage 1: The first stage is First Contact Screening which is conducted by telephone and asks the participant to confirm their age, current accommodation and establishes whether they are able to converse in English or Welsh. The information collected is entered onto a **[5] Screening - First Contact Form**. If they are eligible to proceed an eligibility interview is arranged (stage 2). The potential participant is sent a **[6] Participant Information Sheet letter** and a copy of the **[7] Participant Information Sheet** to read in their own time approximately one week before their eligibility interview. If they are still eligible after stage one they progress to stage 2.

Stage 2: The second stage is Eligibility Screening which is conducted at a face-to-face eligibility interview with the potential participant in a place convenient to them. The potential participant will be asked to confirm the responses provided during stage 1 and will then be taken through the 6CIT. The responses collected will be entered onto a **[8] Screening - Eligibility Form**. Potential participants will also have the opportunity to ask questions about the study.

Non-eligibility process

If a potential participant is not eligible for the study during stage 1 based on their age, current accommodation or language capabilities this will be explained to them at the time of their First Contact Screening Interview. The potential participant will be thanked for their time and no further contact will be made. Reasons for non-eligibility during stage 1 will be recorded on the **[5] Screening - First Contact Form.**

If a potential participant is found not eligible during stage 2 based on a significant score of 8 or more on the 6CIT the following procedure will apply. The researcher will thank the individual and inform them that a member of the research team will be in touch presently. The researcher will then inform an appropriate health professional on the trial, either Gail Mountain (Sheffield) or Bob Woods (Bangor). They will then make direct contact with the participant and arrange a home visit where possible to discuss the 6CIT score, its implications and to signpost the individual to appropriate services. Responsibility can be delegated to another member of the research team who is a qualified health professional.

If the potential participant cannot be contacted or an appointment arranged within one week of the original eligibility interview, a **[9] 6CIT non-eligibility letter** will be sent to the participant. This will include an explanation of why it is not appropriate for their participation in the study, advice on what they should do including signposting to appropriate services and a copy of the score they obtained which they can take to their GP. The letter will also include contact details if they wish to discuss the contents of the letter further. Non-eligibility will be recorded on the **[8] Screening - Eligibility Form**.

PHQ-9 Depression scale

If an individual is found to have a significant score on the PHQ-9 depression scale or concerns are raised by the researcher during baseline or at the 6 and 24 month assessment the relevant health professional, Gail Mountain (Sheffield) or Bob Woods (Bangor) will be notified. They will then risk assess the individual based on the PHQ-9 score and scores on the other measures and decide whether any intervention is required. This will consist of a telephone call to advise the participant on accessing appropriate services. If they are unable to contact the participant by telephone a **PHQ-9 Letter** will be sent to the participant. Responsibility can be delegated to another member of the research team who is a qualified health professional.

Consent and recruitment options

At the end of the Eligibility Interview if the individual is eligible and still interested in participating they will have 3 options.

Option 1: The participant agrees to consent to the study. The researcher will then go through the **[7] participant information sheet** and invite them to ask questions. When all questions and concerns have been addressed they will then be asked if they still wish to continue and consent to the trial or if they would like more time to consider their decision. If they agree to consent to the trial the researcher will go through the **[10] participant consent form** with the participant and carry out the baseline assessment, details for

which are provided in Section 7. The researcher will then complete the consent and additional information sections of the **[11] Recruitment – Consent and randomisation form** including participant availability to attend weekly groups and any specific health issues. The form will then be handed to the clerical team who will enter the participant's details onto the randomisation system which allocates them a group and randomisation number. This information is then recorded by the Clerical team in the randomisation section of the **[11] Recruitment – Consent and randomisation form** and on the Lifestyle Matters secure database**.** The clerical team will then follow the appropriate procedure for notifying participants of their allocation as described in Section 6.

Option 2: If the potential participant requests time to consider their decision the researcher will agree with that person how further contact should be arranged. They can either agree a date for the researcher to make contact or for the potential participant to contact the researcher. This will ensure that the individual does not feel pressured to have to contact the researcher should they decide not to participate in the trial.

Option 3: The potential participant may wish to withdraw their interest in taking part in the study at this stage. The researchers will record the outcome on the **[11] Recruitment – Consent and randomisation form.**

Challenges

A particular challenge identified during the pilot study was harmonising the time of intervention delivery with the routines of potential participants. We propose to offer participants within each recruitment wave, a range of sessions covering a variety of days and times. By doing so, we hope to optimise recruitment so that fewer participants are lost to the study post randomisation due to session timings.

To ensure that we are optimising recruitment in both Sheffield and North Wales and meeting local policy requirements, all marketing materials and participant report measures will be available in both English and Welsh translations. Essential study documentation approved by the NHS REC will be translated by the University of Bangor and supported by the Language Awareness Infrastructure Support Service (LLAIS). All documents will be forward-back translated (English-Welsh-English) with the back translation being compared to the original English for harmonisation and to clarify anomalies. This will ensure that the meaning is standardised for both research sites. A number of the patient reported outcome measures are already available in Welsh translations including the SF-36, EQ-5D, BRS and de Jong Gierveld Loneliness scale.

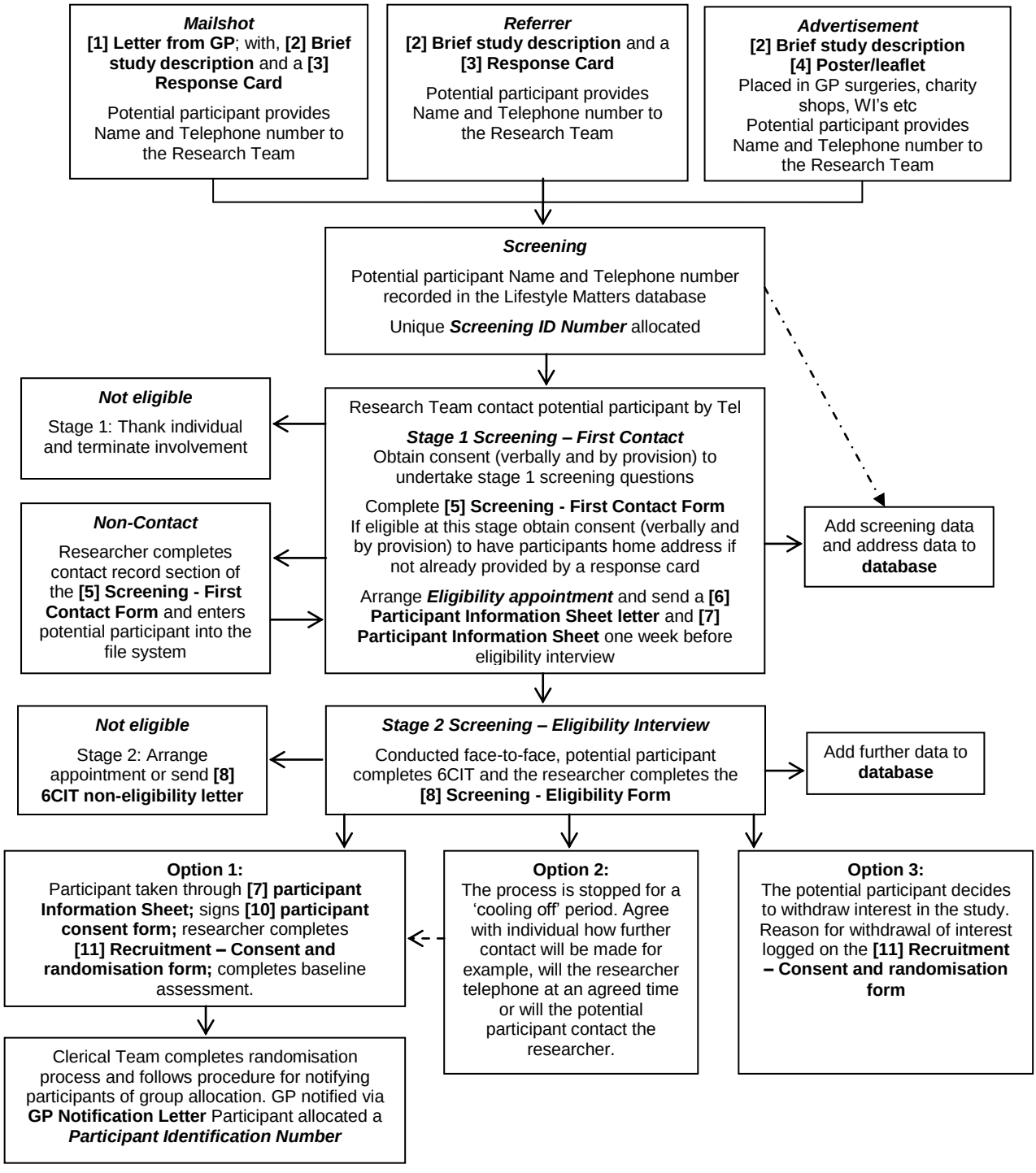

Figure 2: Participant recruitment pathway

6. Randomisation

The Sheffield Clinical Trials Research Unit (CTRU) and Bangor University will oversee randomisation (see figure 3). To ensure assessors are blinded to group allocation the Trial clerical teams in Sheffield and Bangor will enter the participant's details onto a remote web-based randomisation system which will allocate a participant identification number. Details entered onto the system will include confirmation of signed consent. Participants will then be randomly allocated to either the intervention (n=134) or usual care (n=134) arm of the trial. In the event of a couple in the same household both consenting to take part the pair will be randomised as a couple and not separately i.e. to both get the intervention or to both get usual care. This outcome will be recorded on the participant's **[11] Recruitment – Consent and randomisation form** and in the Lifestyle Matters database.

The randomisation schedule will be generated by the CTRU prior to the start of the study. The randomisation sequence will be computer generated, stratified by site and random permuted blocks of variable size will be used to ensure enough participants are allocated evenly to each arm of the trial at each site (Sheffield and Bangor). Participants will then be informed by telephone of their randomly allocated group and what this means for their future involvement in the trial. The participant's GP will also be notified of their involvement in the study via the **GP notification letter**.

Participants randomised to the control arm of the trial will be telephoned by a member of the clerical team who will inform them of their group allocation. Participants will then have the opportunity to ask any questions they may have about their future involvement in the study. A **Control Group Allocation Letter** confirming their allocation will also be sent out for the participant to keep as a record.

Participants allocated to the intervention arm of the trial will first be sent an **Intervention Group Allocation Letter**. This letter will confirm their group allocation and include details of the group facilitator(s). It will also inform the participant they will be contacted by telephone within one week of receiving the letter by one of the facilitators to discuss what will happen next.

Design measures to avoid bias

The Trial Steering Committee (TSC), the study statisticians, health economists and the Research Assistants collecting data at 6 and 24 months will be blinded to treatment allocation whilst the trial is ongoing, but the Trial Manager, Trial Support Officer and participants will not be blinded. Analysis will be by intention-to-treat. Where individuals are lost to follow-up or data is missing, imputation methods will be employed, which will be described in the statistical analysis plan.

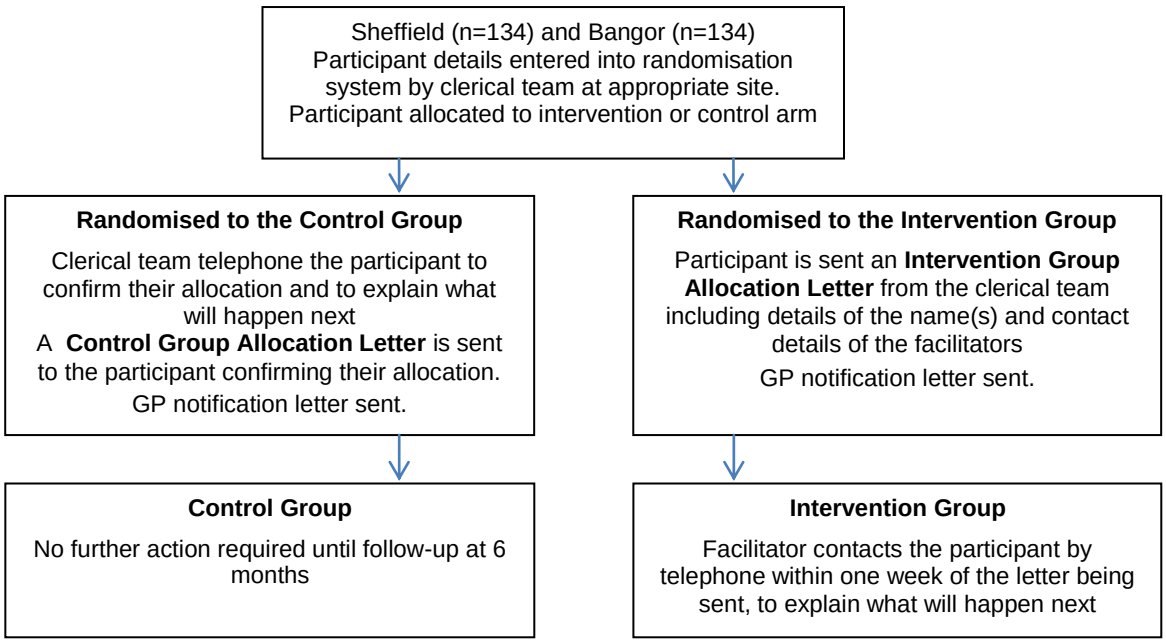

Figure 3: Participant randomisation and allocation pathway

7. Assessments and procedures

A summary of the Lifestyle Matters trial is shown in Figure 4.

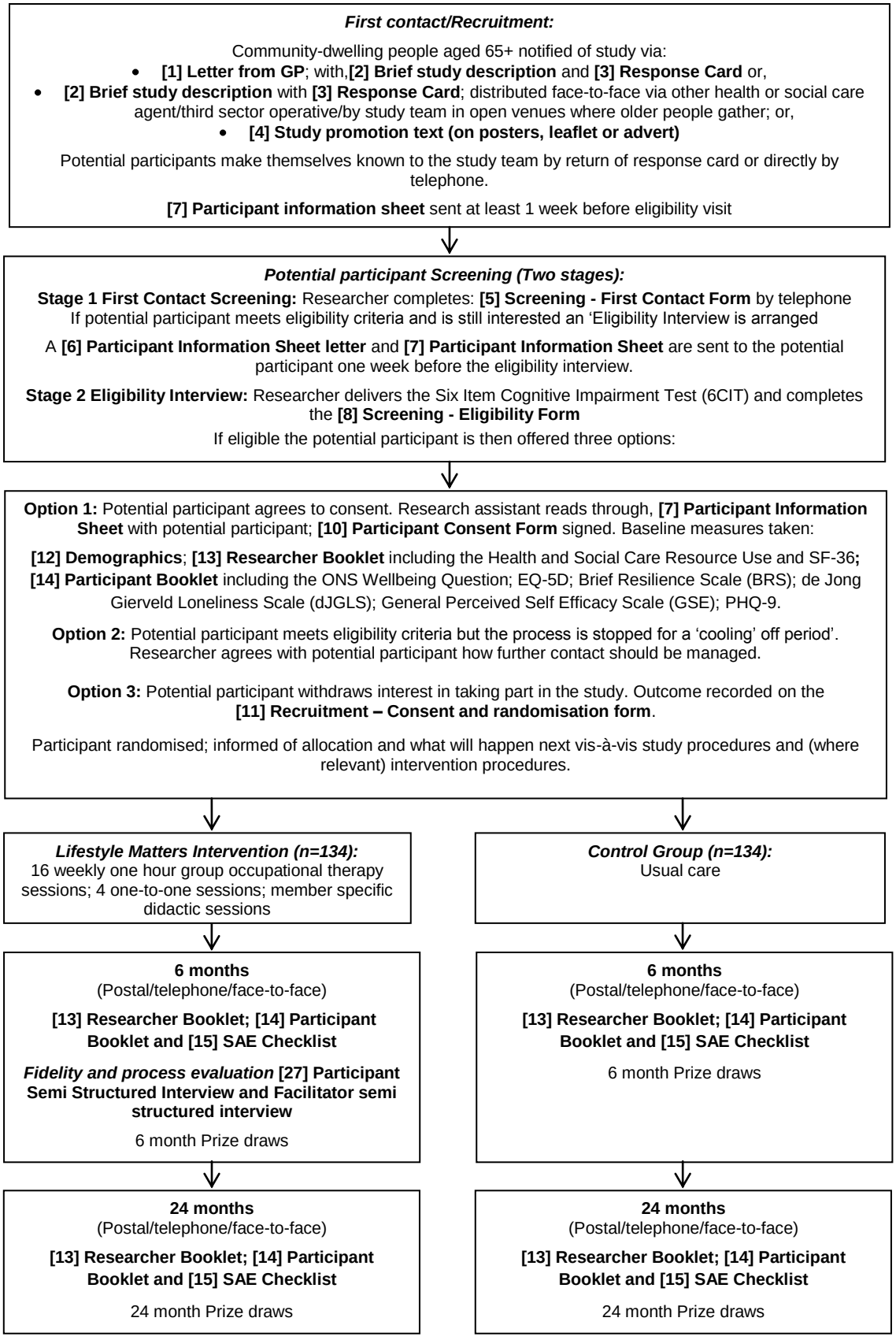

Figure 4: Summary of Lifestyle Matters

The two arms of the study are as follows and a breakdown of the participant pathway can be found in figure 5:-

Intervention group - Four months Lifestyle Matters Programme

Participants randomised to receive the intervention will be invited to attend 16 weekly facilitated sessions of 10-12 participants over 4 successive months at a local community venue and in the community as agreed between group members. Each participant will also be offered a monthly one-to-one session where they can pursue their individual goals, supported by one of the facilitators.

The content of the intervention includes (but is not limited to) the following themes/ sub themes which are fully documented in a published manual (1). The group are encouraged to pursue the themes appropriate to them as described fully in the manual (20):

[a] Beginnings – a celebration of achievements (*activity and health; the ageing process and activity; personal time, energy and activity; goals, realising hopes and wishes; pulling activities together; how is activity related to health*).

[b] Maintaining and improving mental wellbeing *(sleep as an activity; keeping mentally active, memory)*

[c] Maintaining physical wellbeing *(nutrition; pain; keeping physically active)*

[d] Occupation in the home and community *(transportation; opportunities for new learning; experiencing new technologies)*

[e] Safety in and around the home *(keeping safe in the community; keeping safe at home)*

[f] Personal circumstances (*dealing with finance; social relationships and maintaining friendships; dining as an activity; interests and pastimes; caring for others, caring for self; spirituality*)

[g] Endings

Intervention facilitation will be conducted by relevant NHS Agenda for Change Band 4 staff, e.g. health trainers, health champions and occupational therapy support workers recruited to the study. This differs from the US study in that the intervention will be delivered by staff who are not registered occupational therapists (as tested in the UK pilot study) (11). Two facilitators will deliver the programme at each site to every group. This is a requirement of the programme but will also provide cover for annual leave and sickness absence.

Trained occupational therapists will be supervising the lesser qualified facilitators and providing supervision on a regular basis. A short 2 day training programme for facilitators was developed during the pilot study (now also on CD-ROM). Both the facilitators and occupational therapist supervisors will receive the two day training programme by the original author (Claire Craig) and be provided with the CD-ROM. Further guidance on programme delivery will also be provided by an **OT Supervisors protocol** (not submitted to REC). The PI Gail Mountain and Fidelity Lead Sarah Cook will also maintain contact with occupational therapy supervisors to ensure any issues with either facilitators or participants are addressed.

Control group

This will be usual care. Usual care is defined as accessing health and social care acute and community services as appropriate to meet needs. Those allocated to the control group will also receive a **Lifestyle Matters information leaflet** at the end of the study period at 24 months to try and prevent 'resentful demoralisation' as a consequence of non involvement. The information will be derived from the published manual and will include signposting to local groups and services.

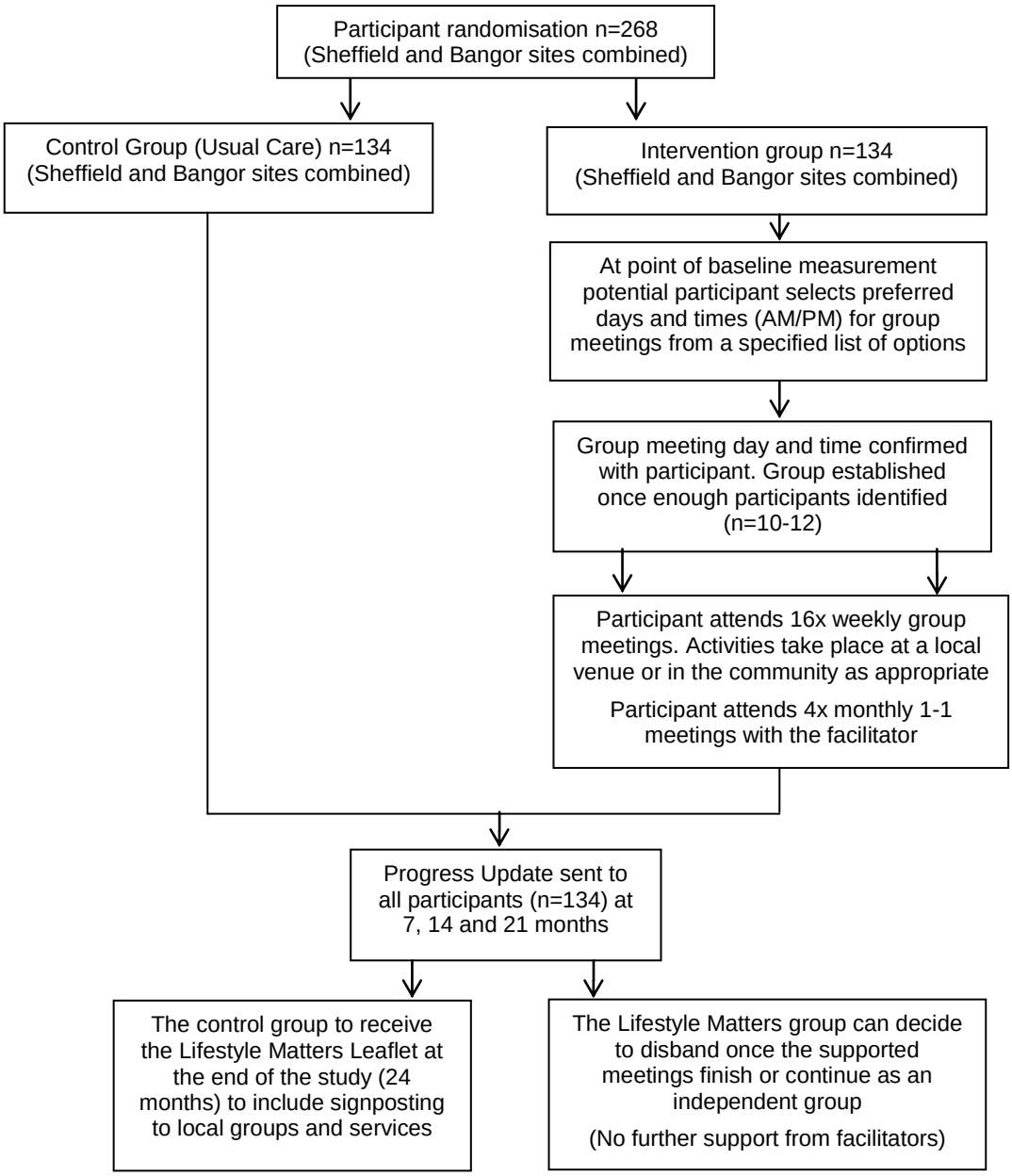

Figure 5: Participant Pathway

Outcome Measures

Participants in both the intervention and control groups will be asked to complete the same series of outcome measures at the same time points. The method of delivery will meet the individual needs of each participant, for example assistance may be provided by

telephone or through a face-to-face visit by a member of the research team. This will be identified as part of eligibility screening and recorded on the **[8] Screening - Eligibility Form**.

Measures taken at baseline:

- **[12] Demographics**
- **[13] Researcher Booklet**
    - **SF-36**
    - **Health and Social Care Resource Use**
- **[14] Participant Booklet**
    - **ONS Wellbeing Question from the Integrated Household Survey 2011**
    - **EQ-5D**
    - **Brief Resilience Scale**
    - **De Jong Gierveld Loneliness Scale**
    - **General perceived Efficacy Scale (GSE)**
    - **PHQ-9**

All measures will be delivered during a face-to-face visit with the participant. The Researcher will first deliver and complete the **[12] Demographics** questionnaire followed by the **[13] Researcher Booklet** on behalf of the participant. The participant will then be asked to complete the **[14] Participant Booklet**. This will be self-completed by the participant with assistance provided by the researcher where asked for or where a need is identified.

Measures taken at 6 and 24 months follow-up:

- **[13] Researcher Booklet**
    - **SF-36**
    - **Health and Social Care Resource Use**
- **[14] Participant Booklet**
    - **ONS Wellbeing Question from the Integrated Household Survey 2011**
    - **EQ-5D**
    - **Brief Resilience Scale**
    - **De Jong Gierveld Loneliness Scale**
    - **General perceived Efficacy Scale (GSE)**
    - **PHQ-9**
- **[15] SAE Checklist**

Follow-up at 6 months will be delivered during a face-to-face visit with the participant. The Researcher will first deliver and complete the **[13] Researcher Booklet** and **[15] SAE checklist** on behalf of the participant. The participant will then be asked to complete the **[14] Participant Booklet**. This will be self-completed with assistance provided by the researcher where asked for or where a need is identified.

At 24 months the Researcher will deliver and complete the **[13] Researcher Booklet** and **[15] SAE checklist** by telephone. The **[14] Participant Booklet** will be sent by post to the

participant for self completion. This will include a **[16] Participant booklet letter** with instructions and a pre-paid envelope.

Any participant who requires assistance understanding or completing the Participant Booklet will be able to contact the research team who will provide assistance in response to individual need, for example requests for large print. Further assistance can also be provided either by telephone or though a face-to-face visit as appropriate.

Due to the length of time, 24 months between baseline and final assessment at 24 months, the 6CIT may be conducted again to record any changes in cognitive function. This will only be undertaken if resources allow.

Procedures for participant follow-up

Recruitment:

Once we have received a potential participants name and telephone number, telephone contact will be attempted a minimum of 3 times at two day intervals (week days only). Messages will be left where appropriate. To improve follow-up rates if the potential participant has returned a **[3] Response card** this will indicate a preferred day and time to contact them. If we are unable to contact them the following actions can be implemented. Wrong telephone numbers will be checked in the telephone book. If the potential participant was signposted to the study by a referrer we may ask the referrer if they could approach the individual again to confirm their interest and ascertain a suitable time to contact them. If a response card is received without the required information to contact a participant e.g. telephone number, a **Participant Contact Letter** will be sent.

A folder system with five sections representing the days of the week (excluding weekends) will be implemented to manage and monitor all telephone calls and contacts. If a potential participant does not answer a contact call the date, time and, reason for non-contact and outcome will be logged on the **[5] Screening - First Contact Form**. The system will provide a full record of participant contact and will act as a reminder for the Research Team when the next contact is due.

Progress update for participants

Each cycle of participants will be sent a **[17] Progress Update Card** at 7, 14 and 21 months providing an update on study progress. This will include details of participant and group numbers and areas. The purpose of this follow-up is to keep participants engaged throughout the study and will act as a reminder prior to the **[14] Participant booklet** being sent out at 24 months.

Participant Prize Draw

Due to the long follow-up timescale for this study (24 months) it was agreed we will be offering a small incentive to help keep participants engaged in the trial and to improve data collection particularly at 24 months. For each of the 3 cycles at each site a prize draw will be conducted at 6 months follow-up and again at 24 months follow-up. All participants allocated to either arm of the study (Intervention or usual care) will be entered into the

prize draw. Separate prize draws will be held for participants taking part in Sheffield and in North Wales. This means that each participant will have the opportunity to be entered into two prize draws during the course of their participation in the study.

In order to be entered into each of the prize draws at 6 months and again at 24 months participants will be expected to complete and return to the study team all the questionnaires collected during follow-up. Participants will be informed of the prize draw when they are notified of their group allocation post randomisation. Information about the **Prize draw rules** will be included along with the **Control group allocation letter** and the **Intervention group allocation letter**. Participants will be free to opt out of the prize draw by contacting the study team. Contact details are provided with the prize draw rules.

Participants lost to follow-up

Participants will be considered lost to follow-up if they stop attending the group sessions for 4 successive weeks unless facilitators have reported to the research team an intended or prolonged absence. Two telephone calls and one **[18] Group Attendance Reminder letter** will be used to try and contact the participant. If unsuccessful and the participant fails to return to the group before the end of the 16 week cycle they will be considered lost to follow-up from the last week they attended. All attendances and absences will be recorded using the **weekly registers** for the group sessions. It is expected that participants may miss one or two group sessions throughout the 4 month cycle for example through illness or holidays.

Participants will also be considered lost to follow-up if they fail to return their completed questionnaires at 6 months and at 24 months. This will be determined as no response within 4 weeks of sending the participant booklet. Contact will be attempted in two stages. Firstly a **[19] Participant Booklet Reminder letter** will be sent to the participant including another **[14] Participant booklet** and asking if they need any assistance in completing the questionnaires. If a response, defined as a return of the completed questionnaires or a written or telephone contact, has not been received within 2 weeks of sending the reminder letter, the research team will try to make contact by telephone. This is the second stage and will be attempted twice. If after this action no response has been elicited from the potential participant they will be considered lost to follow-up.

We will also be accessing the NHS Information Centre (NHS IC) service to obtain regular updates on health status of participants within the cohort. This is achieved by comparing the personal details of the study participants with national records of registered deaths. This will eliminate unnecessary contacts and therefore distress to relatives. We will obtain permission to share participant's personal information with the NHS IC including name, address and date of birth.

The trial will be considered closed once all questionnaires have been collected or when participants have failed to respond to reminders.

Safety assessments

As part of the recruitment process participants will be asked to state any current medical conditions which may affect their ability to take part in the intervention. The facilitators will undertake ongoing monitoring of participants and their involvement in group activities. Locations for intervention delivery will also be assessed for health and safety including:

- appropriate access
- appropriate facilities
- implementation of fire procedures including fire exits
- availability of first aid equipment
- access to a telephone for emergency calls.

Adverse Events (AEs) are not anticipated as a consequence of the intervention. Serious Adverse Events (SAEs) will be recorded for all participants, the categories will include:

- death;
- hospitalisation (initial or prolonged);
- disability.

All events will be reported in accordance with the sponsor's Standard Operating Procedure for Managing and Recording Adverse Events. SAEs will be collected during each follow-up at 6 and 24 months using the **[15] SAE checklist** provided in Appendix 1. At each follow-up, participants will be asked if they have experienced any event or illness since we last contacted them that has:

- required unscheduled hospitalisation; or,
- resulted in persistent or significant disability/incapacity.

The details of Serious Adverse Events will be confirmed with the participant's general practitioner before classification. The Chief Investigator (Gail Mountain) will be responsible for assessing each event reported for causality and category and reporting details of the events to the Dean of ScHARR and the University Research Office. They will also notify the Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC) of all SAEs and submit an annual safety report to the REC.

8. Ancillary sub-studies

Fidelity assessment and process evaluation sub study

A fidelity assessment and process evaluation will collect and analyse data from both participants and facilitators. Data collection tools, such as the semi-structured interview topic guides will collect data for both the fidelity assessment and the process evaluation as part of the same interview. The data collection tools used with participants has formed part of the submission to the Ethics Committee. Tools intended for the facilitator assessment have not been submitted. Table 1 provides an overview of the fidelity assessment and the ways in which this is going to be evaluated. We will seek permission to video record a number of group meetings so that the content of the interventions can be examined for fidelity.

Fidelity checks

Fidelity checks will assess how well the Lifestyle Matters programme is delivered according to the intervention protocol and the published manual. A lead with a remit to check fidelity at the beginning of the study and at further points throughout has been identified (Sarah Cook). Checks will adhere to an intervention fidelity framework based on that identified by the Behaviour Change Consortium (20) and NICE guidance on behaviour change (21). This provides quality assurance parameters based on intervention design, training, delivery, receipt and enactment.

The efficacy of facilitator training and supervision will also be evaluated using a number of methods. All programme and facilitator training will be provided by the same individual Claire Craig, author of the LM programme manual. A **training delivery observation checklist** (not submitted to REC) will be used to assess training delivery and will be administered by the fidelity lead (Sarah Cook) and the Trial Manager (Kirsty Sprange) during one training session. Facilitators will complete **reflective diaries** (not submitted to REC) which may or may not be shared during OT supervision. Facilitators will also complete a **weekly facilitator record** of group meetings which will include reflections on the content of the session, how they felt about it and goal achievement. A **Supervisor protocol** (not submitted to REC) will be provided as a guidance document for those involved in supervising facilitators.

Facilitator delivery of the intervention programme will also be assessed and monitored using a **programme delivery checklist** (not submitted to REC) administered by the fidelity lead (Sarah Cook) and the PI (Gail Mountain). Observations will be undertaken during week 4 of the intervention cycle and again at week 10. They will be video recorded and coded at a later date. In addition facilitators will be expected to complete **goal setting sheets** as part of the programme for each participant as part of their weekly recording procedures.

A number of tools will be used to monitor participant engagement and adherence to the LM programme including an **attendance register for each weekly meeting** and an **attendance register for individual 1-1 sessions**. Receipt of the intervention will be monitored using a **[20] participant semi-structured interview topic guide** to explore perceptions and attitudes towards the programme. Interviews will be conducted with a purposive sample of around 10% of participants allocated to the intervention across both sites and from all 3 cycles to elicit the range and nature of issues that influence their experiences of the interventions and perceived advantages and disadvantages. They will be conducted face to face in a location convenient to the participant. We will also interview at least one intervention facilitator at both sites using a **facilitator semi-structured interview topic guide** (not submitted to REC) during the 1st and 3rd cycle of the intervention to elicit their experience of the Lifestyle Matters training and programme delivery.

The following patient related outcome measures from the **[14] Participant booklet**, the Brief Resilience Scale, de Jong Gierveld Loneliness scale and the General Perceived Self

Efficacy (GSE) Scale will be used to evaluate the impact of the LM programme upon resilience, self-efficacy and loneliness. Data will be collected at baseline, 6 months and 24 months.

Process evaluation

A qualitative sub-study will evaluate the impact of the Lifestyle Matters programme upon older people's health and wellbeing and to identify factors which may mediate or moderate the effectiveness of the intervention. This will include identifying the mechanisms perceived to promote self-efficacy and resilience, evaluating the implementation of the intervention and eliciting participant's experiences of the intervention.

Method

Semi-structured interviews will be used with both participants and facilitators. A **[20] participant semi-structured interview topic guide** and a **facilitator semi-structured interview topic guide** will explore to what extent they considered the Lifestyle Matters groups to have made an impact on wellbeing and their experience of the lifestyle matters intervention. Interview themes will include:

- how older people experience the programme and its delivery;
- what issues promote the effectiveness of intervention facilitation,
- the skills and competencies required to facilitate the programme;
- the barriers and facilitators to its uptake and continued use;
- and the effect of the Lifestyle Matters programme on the social behaviours of older people.

All interviews will be of approximately 60 minutes duration, be conducted in a convenient location and audio recorded with the consent of the interviewee. Transcripts of interviews will undergo respondent validation. This will be achieved by asking participants to read through the transcript of their interview and comment on its accuracy. For the purposes of reporting, confidentiality will be assured by removing all identifiable or recognisable information.

Participant interviews

In total around 10% of participants attending the intervention from across all 3 cycles and both sites will be interviewed to ensure a balanced representation of participants. Interviews will be conducted at the end of each cycle (week 17). Purposive sampling will be used with the aim of including a maximum range of participant characteristics such as age, gender, ethnicity etc. Information detailing the sub-study will be provided in the **[7] participant information sheet** and permission obtained through the **[10] participant consent form.**

Table 1: Fidelity assessment strategy for Lifestyle Matters

Goal	Description	Fidelity
Trial Design		
Comparable treatment	All participants have received the same programme tailored to the needs of the group/setting.	• 16 weekly meetings will be offered to all participants with delivery of a minimum of 8. • 4 1-1 meetings will be offered to all participants. Uptake and attendance recorded by the facilitator as part of their weekly records.
Risk to implementation	Plan for potential issues that could affect the delivery of the lifestyle matters programme.	• A range of recruitment strategies including between 1 and 6 GP surgery mail outs for each geographical area, referrals from the third sector and posters/leaflets. • Offer a pre-arranged set of days and times for meetings from which participants can choose. • Undertake 3 recruitment cycles. • Recruit from three geographically separate areas, one per cycle, to prevent saturation.
Monitoring provider training		
Standardised training Facilitator skill acquisition	All facilitators receiving the same training programme tailored to the group/setting. All facilitators understand and engage with the intervention programme training in a similar way.	• Observation of a training session by the fidelity lead (Sarah Cook) and the Trial Manager (Kirsty Sprange) using a content checklist and evidence of skill transference as demonstrated through role playing activities and reflective exercises. • Training delivered by the same trainer. • Manual and CD-Rom provided to all trainees. • CD-Rom provided to OT Supervisors. • Completion of training exercises by facilitators.
Monitoring intervention delivery		
Standardised delivery	All facilitators using the same techniques and content from the programme.	• Observation using a content checklist by the Fidelity Lead (Sarah Cook) and the PI (Gail Mountain). • The number of opportunities for completing goal setting are recorded (both for individual and group). 75% of opportunities have the goals recorded. • Range of materials from the Lifestyle Matters programme received by all participants. • Reflective diaries. • Weekly facilitator record from group meetings. • **[20] Participant semi-structured interview topic guide.** • **Facilitator semi-structured interview topic guide**. • All participants receive certificate of attendance and achievement. • All participants receive typed notes from group discussions. • Facilitators meet the Band 4 job description criteria.
Minimise drift in skills/delivery	Adherence to training content and delivery over the 3 cycles of the intervention	• Observation using a content checklist by the Fidelity Lead (Sarah Cook) and the PI (Gail Mountain). • OT supervisor protocol provided. • OT supervisor record of a minimum of 8 face-to-face sessions with facilitator. Each facilitator will attend between 8 and 16 sessions in total.
Monitoring receipt of intervention		
Participant attendance and engagement	Recording the numbers of participants attending the programme each week All participants taking part in the group meetings and activities Impact of intervention on participant in terms of wellbeing	• **Registers** completed by facilitator for weekly meetings and 1-1 meetings where arranged. • The number of opportunities for completing goal setting are recorded (both for individual and group). 75% of opportunities have the goals recorded. • **[20] Participant semi-structured interview topic guide.** • **Facilitator semi-structured interview topic guide.** • PROMS.

Adapted from Bellg et al (2004) (20)

Facilitator interviews

A **facilitator semi-structured interview topic guide** will also be conducted with at least one facilitator at each site. Because the facilitators will ideally remain the same throughout the whole study the facilitator structured interviews will be conducted at the end of cycle 1 and cycle 3. This will identify any changes in the facilitator's experience of delivering the intervention between cycle 1 when they first receive and implement their training through to the third cycle when a more practised and proficient delivery would be expected. Should there be a need for a replacement facilitator to take over a group they will also be included in the interviews.

Analysis

Analysis of the semi structured interviews will commence at the end of each data collection period (intervention cycle). The same methods of analysis will be applied to both the participant and facilitator interviews. Interviews will be transcribed verbatim. Qualitative data will be interpreted using Framework Analysis in order to analyse each respondent's data within an overall framework that is related to the intervention process. This will follow the five stages of Framework analysis including familiarization, identifying a thematic framework, indexing, charting, mapping and interpretation.

The thematic framework will be identified by two people, the Trial Manager (Kirsty Sprange) and either the Fidelity Lead (Sarah Cook) or the PI (Gail Mountain) and an index will be developed. The index will then be used to recode the transcripts and the data will be charted and mapped for interpretations to develop explanations to understand the processes underlying the programme. Results will also be used to explore potential explanations for the quantitative findings and identify if there are other emerging factors influencing uptake and impact of the intervention.

9. Statistics

Sample Size

The primary outcome for the study is the mean SF-36 mental health (MH) score 6 months post randomisation. The SF-36 MH dimension is scored on a 0 (poor) to 100 (good health) score. A previous general population survey of 3,085 Sheffield community residents aged 75 or more has demonstrated that the SF-36 can successfully be used as an outcome measure and the indications were that it was appropriate and sensitive (22). From this general population survey the mean SF-36 MH score was 68.3 with a standard deviation of 19.9 (22). Differences between groups of between 5 and 10 points on the SF-36 MH score can be regarded as "*clinically and socially relevant*" (23).

The Lifestyle Matters pilot study suggested that improvements of 7 to 14 points on the SF-36 MH are achievable depending on baseline functioning (24). If we assume a standard deviation of 20 points for the SF-36 MH score at six months post randomisation, a mean difference in MH scores between the two groups of 8 or more points is clinically and practically important. To have an 80% power of detecting this 8 point mean difference in MH scores at four months as statistically significant at the 5% (two-sided) level will require

99 participants per study arm (200 in total). However, the Lifestyle Matters intervention is a group or facilitator-led intervention. Therefore the success of the intervention may depend on the facilitator delivering it so that the outcomes of the participants in the same group with the same facilitator may be clustered. If we assume an average cluster size of 10 subjects per Lifestyle Matters facilitator group and an intra cluster correlation of 0.01, then the sample size must be inflated by a design effect of 1.09 to allow for this clustering giving a revised sample size estimate of 107 participants per group. A couple will count as one participant. If 20% leave the study prematurely and are lost to follow-up then we will need to recruit and randomise 134 per arm (n=268 individuals or couples (since a couple will count as one participant) in total). The same sample size would have over 90% power of detecting a 10-point mean difference in MH scores post intervention.

Analysis

As the trial is a pragmatic parallel group randomised, with a usual (control) treatment arm, data will be reported and presented according to a revised CONSORT statement (25). Statistical analysis will be performed on an intention-to-treat-basis. All exploratory tests will be two-tailed with alpha = 0.05. Baseline demographic (e.g. age, gender, number and proportion of sample who are couples) and health related quality of life data (SF-36) will be assessed for comparability between groups.

The outcome data to be collected is hierarchical or multi-level in nature with individual participants nested or clustered within couples; who are nested or clustered within Lifestyle matters facilitation group who are then nested within a treatment group. The statistical analysis, of the outcome data, will take into account the hierarchical or clustered nature of the data by using multi-level mixed effects linear regression model. Mixed effects models are characterised by containing both fixed and random effects. We shall assume a fixed effect for the randomised treatment group but random effects for the couple and Lifestyle matters facilitation group. Individual participants who are not part of couple will be treated as clusters of size one; similarly participants randomised to the control usual care group will be treated as clusters of size one (or two if they are a couple).

The primary analysis will compare mean SF-36 Mental Health dimension (MH) scores at six months post randomisation between the intervention group and control groups using a random-effects or multi-level mixed effects linear regression model to allow for the clustering of the outcomes within couples and lifestyle matters facilitation groups (26,27). A 95% confidence interval (CI) for the mean difference SF-36 mental health dimension scores between the intervention and control groups will also be calculated. An adjusted analysis will also be performed alongside this unadjusted analysis which will include baseline covariates, such as age, gender and quality of life in the multi-level mixed effects linear regression model.

For the primary outcome, the SF-36 MH score at six months follow-up, missing data will be imputed through a variety of methods, including Last Observation Carried Forward (LOCF), regression and multiple imputation.

Secondary outcome measures: (6 and 24 months post randomisation)
Secondary outcomes such as the other dimensions of the SF-36, EQ-5D, BRS, GSE, de Jong Gierveld Loneliness Scale at six months follow-up will be compared between the intervention and control group using a multi-level mixed effects linear regression model both with and without adjustment for covariates. A 95% CI for the mean difference in this parameter between the treatment groups will also be calculated.

Participants will be followed up at 24 months post randomisation. Mean SF-36 (MH), other SF-36 dimensions, BRS, GSE, PHQ-9, EQ-5D, de Jong Loneliness Scale dimension scores at 24 months follow-up will be compared again using multi-level mixed effects linear regression model with and without adjustment for covariates. A 95% CI for the mean difference in this parameter between the treatment groups will also be calculated.

Health Economics
A trial based economic evaluation will be undertaken of an intention to treat comparison of the costs and outcomes of the two trial arms. A cost effectiveness analysis will be undertaken of the incremental cost per Quality Adjusted Life Years (QALYs) of the Lifestyle Matters intervention compared with treatment as usual. QALYs will be calculated using the SF-6D preference-based index derived from the SF-36 administered at baseline, six and 24 months (28). The QALY gain from the intervention will be estimated using a standard area under the curve calculation. A sensitivity analysis will be undertaken using utility values from the EQ-5D. The total cost consequences of the intervention will be estimated at the individual participant level and will include the costs of providing the four month Lifestyle Matters intervention and the subsequent consequences for the use of routine health and social care services.. A detailed costing of the weekly facilitated sessions will be undertaken including recruitment (though postal invitation), administration, hire of local community venues, facilitator salaries, refreshments participant travel if required and any materials used. Care will be undertaken to exclude all research costs. Resources will be costed using local price data to estimate a total cost per session. The number of participants attending each session will be recorded and an average level of capacity used to estimate an average cost per attendance. Finally, this estimate will be applied to the actual number of sessions each participant attended.

A potentially important benefit of the intervention is that it may result in important cost savings to the NHS. The use of services by trial participants will be collected in detail using a Health and Social Care Service Use Questionnaire that will be administered by telephone or face to face. Interviewer administration is essential in order to obtain accurate and useable data on the use of all NHS and Personal and Social Services. Service use will be costed using National Reference Cost Data (29). Missing data will be dealt with using multiple imputation for SF-6D and resource use data. The central analysis of mean incremental costs per QALY will be subjected to a full sensitivity analysis of key parameters including the measure used to estimate QALYs and number participants at the weekly sessions. A full probabilistic sensitivity analysis will be performed to examine the probability of cost effectiveness of the intervention for the NHS at different values for a

QALY. There will also be a supplementary cost consequences analysis that will include the other outcome measures.

10. Trial Monitoring

The following groups have been recruited to oversee the study:

Trial Steering Committee (TSC)

The TSC meet every 6 months and is composed of an independent Chair, Dr Pip Logan, Associate Professor in Community Rehabilitation, Faculty of Medicine & Health Sciences at the University of Nottingham. Dr Logan has experience in delivering RCTs and of trial monitoring. The Committee includes lay expert elders and research delivery and content experts. The TSC acts in accordance with the CTRU Standard Operating Procedure GOV002 Trial Steering Committee.

Role of the TSC:

- advise the PI or CI on all aspects of the trial;
- provide overall supervision of the trial protocol, case report form and statistical analysis plan;
- monitor trial progress;
- review relevant information from other sources but related to the trial;
- consider recommendations of the Data Monitoring and Ethics Committee;
- review outputs and final reports.

Data Monitoring and Ethics Group (DMEC)

The DMEC will meet annually and is composed of a Chair, a Statistician and a content expert. All members will be independent of the trial. The DMEC will act in accordance with the CTRU SOP GOV003 Data Monitoring and Ethics Committee.

Role of the DMEC:

- review the study protocol pertinent to their duties as a DMEC;
- review study materials, including patient information, consent and data capture forms;
- determine the schedule of meetings during the trial, at least one of which should be face-to-face where possible;
- monitor patient safety;
- advise the trial steering committee (TSC) where it believes the study protocol should be altered.

Trial Management Group (TMG)

The TMG meet on a monthly basis and consists of key individuals directly involved in the development and delivery of the trial including the PI, CI, Study Manager and collaborators. There is also lay representation from older persons. The TMG act in accordance with the CTRU SOP GOV001 Trial Management Group.

Role of the TMG:

- accountable to the TSC for implementation of the trial;
- identify and resolve issues on the intervention and associated research in a timely manner;
- consider and act on recommendations of the TSC, DMEC and Research Ethics Committee.

11. Data Management

The University of Sheffield Clinical Trials Unit (CTRU), undertake data management and ensure the trial is conducted according to Good Clinical Practice (GCP) Guidelines and local standard operating procedures.

Data collection and record keeping

Data will be collected and retained in accordance with the Data Protection Act 1998. Anonymised trial data will be entered into a validated database system (Prospect) developed and hosted by the Sheffield CTRU. The data will be stored securely on a central server. A Data Management and Monitoring Protocol (DMMP) will be implemented to provide a verification function to check data collection and entry. Access will be controlled by the use of assigned logins and encrypted passwords. The system will be regularly backed-up for security. Output for analysis will be generated in a format and at intervals agreed between the Sheffield CTRU, and the Chief Investigator. Trial documents (paper and electronic) will be retained in a secure location during and after the trial has finished. Each site will be responsible for ensuring records are archived appropriately.

Hard copy data will be stored in a secure location, for example a locked cabinet within a secure room. Electronic data will be held on a secure server with access granted to authorised persons only. Data will not be shared with any unauthorised persons.

Archiving

Data will be archived for 5 years in accordance with the University of Sheffield CTRU's standard operating procedures and Commission Directive 2005/28/EC Article 17 and will also be made available to the wider research community through deposition in the UK Data Archive.

Confidentiality

The trial will follow ethical and legal practice. A unique screening and participant identification number will be allocated to each participant. Any information provided by a participant will be handled in confidence, except were there is an issue of safety, in which we will notify the participant's GP. Consent will be sought from the participant to be able to contact their GP in such an event. Research participants will be protected by the removal of any recognisable, personal, confidential or sensitive data.

Data sharing

A requirement of the LLHWB Cross-Council Programme, MRC funding was data resulting from the study is shared with the wider research community through the UK Data Archive.

The UK Data Archive was established by the Social Science Research Council in 1967 and is currently funded largely by the ESRC, the JISC and the University of Essex. Collaborators include the MRC Data Support Service, the ESRC National Centre for Research methods and the Office for National Statistics. From 2005 the archive was designated a Place of Deposit by the National Archives. The archive currently manages the Economic and Social Data Service, a portal for national and international survey and qualitative data.

The UK Data Archive is compliant with the Data Protection Act 1998 and other relevant legislation including the Freedom of Information Act 2000 and the Statistics and Registration Services Act 2007. Use of data is restricted and requires user registration. Users are required to sign a legal and contractually binding End User License agreeing to certain conditions including maintaining confidentiality of participant personal and sensitive data. A summary of the End User licence can be obtained from their website http://www.esds.ac.uk/aandp/access/summary.asp.

Quality control in the UK Data Archive is managed through a range of data processing standards dependent on anticipated future use of the data (30). Procedures include validation and content checks. The UK Data Archive also enforces a Data Preservation Protocol to ensure the authenticity, reliability and logical integrity of resources.

The participant information sheet and consent form includes information about the UK Data Archive and state the intention to share final data.

Data access

The source of data will be:

- Participant Screening Interviews
- Patient Reported Outcome Measures
- Qualitative interviews

The sponsor will permit monitoring and audits by the relevant authorities, including the Research Ethics Committee. The Chief Investigator will also allow monitoring and audit by these bodies and the sponsor and they will provide direct access to source data and documents.

Access to data including data collection, entry and analysis will be required by all authorised staff associated with the trial including its collaborators. This will include named individuals at the University of Sheffield, University of Bangor and Sheffield Hallam University staff. The NHS Information Centre for Health and Social Care will also have access to participant information for the purposes of service provision. Relevant regulatory authorities may also request access to data.

Quality assurance

A Data Management and Monitoring Protocol (DMMP) will be designed for the purposes of overseeing the progress of the trial in line with Good Clinical Practice guidelines. The DMMP will outline all monitoring activities to be carried out during the lifetime of the trial.

The trial will also operate within a series of quality standards (SOPs) and guidelines at site. Responsibility for adherence to the DMMP will lie with the CTRU for both sites.

The following oversight committees will also be in operation for this trial:

- Trial Steering Committee (TSC)
- Data Monitoring and Ethics Committee (DMEC)
- Trial Management Group (TMG)

12. Publication

The trial protocol will be published on an open access source. A number of academic outputs will be produced as the data is analysed throughout the trial. Journals will be selected based on the highest possible impact. We will also publish results of the recruitment process, establishing and delivering the intervention.
Other stakeholder specific outputs in relevant formats will also be produced for commissioners, health and social care practitioners, third sector and user advocacy organisations. A website will be established to promote the work of the trial.

All knowledge transfer activity including translation will be informed by input from trial collaborators, the Trial Steering Committee (TSC) and Trial Management Group (TMG) to ensure the study is meeting the needs of the commissioners and audience.

13. Finance

Research funding has been secured from the Lifelong Health and Wellbeing (LLHW) Cross-Council Programme. Funding partners for the LLHW are the Arts and Humanities Research Council, Biotechnology and Biological Sciences Research Council, Engineering and Physical Sciences Research Council, Economic and Social Research Council, Medical Research Council, Chief Scientist Office of the Scottish Government Health Directorates, National Institute for Health Research /The Department of Health, The Health and Social Care Research & Development of the Public Health Agency (Northern Ireland), and Wales Office of Research and Development for Health and Social Care, Welsh Assembly Government. An application may be made for local service support costs if deemed necessary.

14. Ethics approval

Ethical approval will be sought from the National Research Ethics Service (NRES) via the Integrated Research Application System (IRAS) system and from the NHS and relevant local authorities in Sheffield and Bangor.

The study will only commence once approval has been received from the ethics committee and Local NHS and Authority R&D including copies of the approved patient information sheet and consent form.

15. Indemnity / Compensation / Insurance

The University of Sheffield has in place insurance against liabilities for which it may be legally liable and this cover includes any such liabilities arising out of this research project.

16. References

1. Craig C, Mountain. G. Lifestyle Matters: an occpational approach to healthy ageing. Bicester: Speechmark; 2007.

2. Department of Health. National service framework for older people [Internet]. 2001. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4003066

3. Welsh Assembly Government. National Service Framework for Older People in Wales [Internet]. 2006. Available from: http://wales.gov.uk/topics/olderpeople/publications/nationalserviceframeworkolderppl/?lang=en

4. Friedli. L. Mental health, resilience and inequalities. 2009.

5. Age Concern. Promoting mental health and well-being in later life. A first report from the UK Inquiry into Mental Health and Well-Being in Later Life. 2006.

6. Rowe J, Kahn. R. Successful Ageing. New York: Pantheon; 1989.

7. Government Office for Science. Foresight (2008) [Internet]. 2008. Available from: http://www.bis.gov.uk/assets/biscore/corporate/migratedD/ec_group/116-08-FO_b

8. Department of Health. New Horizons: a shared vision for mental health [Internet]. 2009. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_109705

9. National Institute for Health and Clinical Excellence. Guidance on occupational therapy and physical activity interventions that promote good health and wellbeing in older people. 2008.

10. Windle G, Hughes D, Linck P, Russell I, Morgan R, Woods B, et al. Public health interventions to promote mental well-being in people aged 65 and over: systematic review of effectiveness and cost-effectiveness [Internet]. 2008. Available from: http://www.nice.org.uk/nicemedia/live/11999/42401/42401.pdf

11. Clark F, Azen S, Zemke R, Jackson J, Carlson M, Mandel D, et al. Occupational Therapy for Independent-Living Older Adults. Journal of the American Medical Association. 1997;278(16):1321–6.

12. Hay J, LaBree L, Luo R, Clark F, Carlson M, Mandel D, et al. Cost-Effectiveness of Preventive Occupational Therapy for Independent-Living Older Adults. Journal of the American Geriatrics Society. 2002;50(8):1381–8.

13. Clark F, Azen S, Carlson M, Mandel D, LaBree L, Hay J, et al. Embedding Health-Promoting Changes Into the Daily Lives of Independent-Living Older Adults: Long-Term Follow-Up of Occupational Therapy Intervention. Journal of Gerontology: Series B Psychological Sciences. 2001;56(1):60–3.

14. Mountain G, Et al. Occupational therapy led health promotion for older people: feasibility of the lifestyle matters programme. British Journal of Occupational Therapy. 2008;71(10):406–13.

15. Mountain G, Craig. C. The lived experience of redesigning lifestyle post-retirement in the UK. Occupational Therapy International. 2011;18(1):48–58.

16. Department of Health. Quality and Productivity [Internet]. 2010. Available from: http://www.dh.gov.uk/en/Healthcare/Qualityandproductivity/index.htm

17. Hays R, Sherbourne C, Mazel. R. The rand 36-item health survey 1.0. Health Economics. 1993;2(3):217–27.

18. Medical Research Council. A Framework for development and evaluation of RCTs for Complex Interventions to Improve Health [Internet]. 2008. Available from: http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003372

19. Brooke P, Bullock R. Validation of a 6 item cognitive impairment test with a view to primary care usage. International Journal of Geriatric Psychiatry. 1999;14:936–40.

20. Bellg A, Borrelli B, Resnick B, Hecht J, Minicucci D, Ory M, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. Health Psychology. 2004;23(5):443–51.

21. National Institute for Health and Clinical Excellence. Public Guidance 6. 2007.

22. Walters S, Munro J, Brazier J. Using the SF-36 with older adults: a cross-sectional community based survey. Age & Ageing. 2001;30:337–43.

23. J W, Et al. SF-36 Health Survey Manual and Interpretation Guide. Boston MA: The Health Institute, New England Medical Centre; 1993.

24. Mountain G, Et al. An Occupational Approach Towards Health and Well-being in Later Life - Final Research Report. 2006.

25. Schulz K, Altman D, Moher. D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. British Medical Journal. 2010;340(c332).

26. Walters. S. Quality of life outcomes in clinical trials and health care evaluation: a practical guide to analysis and interpretation. Chichester: Wiley; 2009.

27. Walters S. Therapist effects in randomised controlled trials: what to do about them. Journal of Clinical Nursing. 2010;19(7-8):1102–12.

28. Brazier J, Roberts J, Deverill M. The estimation a preference-based single index measure for health from the SF-36. Journal of Health Economics. 2002;21(2):271–92.

29. Netten A, Curtis. L. Unit Costs of Health and Social Care. Personal Social Services Research Unit, University of Kent; 2000.

30. UK Data Archive. UK Data Archive Preservation Policy [Internet]. 2010. Available from: http://www.data-archive.ac.uk/media/54776/ukda062-dps-preservationpolicy.pdf

Appendix 1: [15] SAE Checklist