An investigation of the relationship between social factors in older age and levels of physical activity, set in the rural context

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
16/04/2014		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/05/2014	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
05/08/2021	Other			

Plain English summary of protocol

Background and study aims

We know that staying physically active in later life leads to important health benefits and that, similarly, staying socially active leads to important health gains. Research is increasingly showing that loneliness is a very serious issue in older age, leading to poor health and wellbeing. It is important to note, however, that loneliness and the number of contacts one has are not the same things. Loneliness is a feeling which can be felt even if one has many contacts. There is not much research linking loneliness with physical activity. This is interesting to look at as it may be that loneliness is linked to lower levels of physical activity, and that this explains, in part, why loneliness affects health so badly. It is interesting to explore these issues in a rural context because rural areas have the fastest growth in numbers of older residents. What is also important is to explore these issues in areas where individuals may suffer from deprivation, as this has been proven to make staying physically active and well more difficult in older age. Thus, exploring this relationship in deprived rural areas may help inform initiatives to maintain the health and wellbeing of a large section of the ageing population living in rural areas, in the near future. This study therefore investigates the relationships between loneliness, social activity and levels of physical activity and physical inactivity for older adults in a rural areas.

Who can participate?

Individuals over the age of 65 will be able to participate in this study. We will pick three rural areas (villages or hamlets housing less than 10,000 individuals) in Wiltshire that are classified as deprived with respect to income, employment, health and disability, education, access to housing, crime and quality of living environment. In these areas we will ask NHS practices to randomly select individuals from their patient lists and send them an invitation to participate. The GP will make sure that these individuals are living independently in their own homes, and are not diagnosed with dementia or Alzheimer's or are particularly vulnerable for other reasons (as judged by the GP).

What does the study involve?

Participants will be visited on two occasions. On the first, participants will be asked to complete the first half of a questionnaire and perform some simple functional tests. These tests will

include three brief exercises: balancing on two feet, walking across four meters, and standing up from a chair five times. A date will be set for the second visit, and then the participant will be asked to keep a 7-day activity diary and wear an accelerometer (matchbox-sized electronic devices which measure physical activity) for the following 7 days. During the second visit, the 7-day activity diary and accelerometer will be collected and the participant asked to complete the second half of the questionnaire. At the end of this visit, participants will be invited to take part in face to face interviews at a later date. They are free to decide if they wish to do so. Each visit will last about 1.5 hours.

What are the possible benefits and risks of participating?

Participants may benefit from taking part because they will be given a summary of the study findings and of their personal data. This will give participants an understanding about what activities in their weekly schedule provide them with the greatest physical activity. These methods have been used effectively and without issues in previous studies with older adults, therefore there are no expected risks for the participants. However, participants may feel a slight demand on their time when it comes to filling in the activity diary each day for 7 days.

Where is the study run from?

This study will be run from the University of Bath. The main researcher and a research assistant will personally drive to each of the three villages to meet with participants.

When is the study starting and how long is it expected to run for?

The study will start at the end of May 2014 by sending out invitations to participants. We hope to start visiting participants in June and hope to have collected enough responses by September 2014. The study will continue running after this, allowing time for conducting the follow-up interviews. The study will be completely finished by December 2015.

Who is funding the study?
The Economic Social Research Council (ESRC) (UK)

Who is the main contact? Miss Jolanthe de Koning jdk21@bath.ac.uk Mobile: 07735474831

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 16433

Study information

Scientific Title

An observational cross-sectional study of the relationship between social factors in older age and levels of physical activity, set in the rural context

Acronym

SHARP (Staying Healthy and Active in Rural Places)

Study objectives

The health benefits of physical activity, social participation and the avoidance of loneliness in older age are well established. The relationship between loneliness and physical activity is less understood however, and an understanding of this could guide programmes aiming to increase older adults' health and wellbeing. Less is known about older adult health promotion in rural areas whilst older people in these areas experience particular economic, service and health-related disadvantages.

This study investigates the relationships between loneliness, social activity and levels of physical activity in older age in a rural living context.

We aim to recruit 75 older adults living in rural villages or hamlets in Wiltshire and classified as deprived when summarising the following factors: income, employment, health and disability, education, access to housing, crime and quality of living environment. We will identify and ask GPs working in NHS practices in three such sites to send invitations on our behalf to patients aged 65 years and over from their patient lists.

Participants will be asked to complete a questionnaire, perform a simple functional tests, keep a 7-day activity diary and wear accelerometers (matchbox-sized electronic devices which measure physical activity) for one week. These tasks will be completed over two visits to participants' homes, 1 week apart, each lasting approximately 1.5 hours. Participants will be invited to participate in qualitative interviews at a later stage. Only participants who have consented for this sub study will be contacted and invited.

These methods have been used effectively and without issues in previous studies with older adults.

We will provide participants and GPs with feedback regarding the overall study findings, and participants with their individualised physical activity profiles. Research outcomes will contribute to a guidance document focussed on the promotion of active ageing in rural areas.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Central, 04/04/2014, ref: 14/LO/0456

Study design

Randomised; Observational; Design type: Cross-sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Primary Care; Subtopic: Not Assigned; Disease: All Diseases

Interventions

Activity diaries

Participants will be asked to complete an activity diary for each of the 7 days between the first and the second visit. They will be provided with diaries to fill in which have been designed and piloted to be filled in with ease by older participants (e.g., with logical left to right flow of questions, large font size and examples). The information gathered from the activity diaries will be important for the study because it will allow the researchers to explain the reasons for increases in physical activity measured by the accelerometers (matchbox-sized device worn on participants' belts).

Basic physical function tests

A brief set of test for physical function will be completed by the participant; the Short Physical Performance Battery (SPPB; Guralnik et al., 1994). This test includes home-based assessments of leg strength, walking speed and balance. It is a test which can be applied safely to older participants by non-clinicians, causes no discomfort and takes 10-15 minutes to complete. The SPPB has been used safely in other studies of older adults (e.g., Davis et al., 2011). The researchers will undergo a training session led by a researcher with extended experience of applying this test.

Physical activity measurement

A matchbox-sized activity measuring device (accelerometer) will be given to the participants on the first visit, and it's function and instruction for use explained. Participants are to wear it on their belt for 7 days, and complete three questions in the activity diary each day about the times they put on and took off the device and reasons for taking it off if they did so. The researchers will collect it during the second visit. This does not cause the participant any discomfort.

Questionnaire

A questionnaire divided over two visits, 7 days apart. The first half of the questionnaire will include questions about:

- 1. General personal and social information (such as age, gender, marital status, number of children, pets etc)
- 2. Wellbeing: general, across 'life', 'health and fitness', 'feelings' and 'social life', and relating to depression
- 3. Participants' perceived physical activity levels and their confidence
- 4. General health and mobility
- 5. Perceptions of the physical environment

The second half of the questionnaire will include questions about:

- 1. Getting out and about in the local area: how often participants go to a selection of places and their transport to these places
- 2. Social behaviour, and motivations for social behaviour
- 3. The amount of moderate-intensity physical activity achieved, and participants confidence and intentions to do so
- 4. Socioeconomic status and perceived wealth inequalities across the neighbourhood

Follow Up Length: 18 month(s); Study Entry: Single Randomisation only

Intervention Type

Behavioural

Primary outcome measure

Moderate to vigorous intensity physical activity, measured using data from waist-mounted accelerometers collected over 7 consecutive days

Secondary outcome measures

- 1. Loneliness, measured using questionnaire responses. Questionnaires will be interviewer-administered. Timepoint(s): First visit, at the start of the 7 days
- 2. Social isolation/integration, measured using questionnaire responses. Questionnaires will be interviewer-administered. Timepoint(s): First visit, at the start of the 7 days
- 3. Social participation, measured using questionnaire responses. Questionnaires will be interviewer-administered. Timepoint(s): Measured over 7 days
- 4. Weekly frequency of journeys out of the house, measured using the accounts on the 7-day activity diaries (response categories in the diary structured like a questionnaire of a mixture of closed and open-ended questions)

Overall study start date

21/05/2014

Completion date

20/12/2015

Eligibility

Key inclusion criteria

- 1. Aged 65 and over
- 2. Living independently in their own homes in a rural area

The former inclusion criterion was chosen because the World Health Organisation (WHO) defines older adults as individuals over the age of 65. The latter was chosen due to our focus on increasing knowledge about what could keep rural-dwelling older people healthy and living independently in their own homes for as long as possible. To do this, the sample needs to be limited to older adults who are still, at present, living in the community, not in residential homes.

Target Gender: Male & Female; Lower Age Limit 65 years

Participant type(s)

All

Age group

Senior

Sex

Both

Target number of participants

Planned Sample Size: 75; UK Sample Size: 75. Across three General Practices in Wiltshire, 450 invitation letters will be sent from which we expect to get 75 positive responses (n=25 in each site).

Key exclusion criteria

- 1. Diagnosed with dementia or Alzheimer's
- 2. Living in residential care settings
- 3. Having any condition/circumstance which the GP deems will lead to undue stress with the receipt of a questionnaire including items on loneliness (e.g., end-stage palliative illness or recently bereaved)

The first exclusion criterion was chosen to ensure that participants are able to give informed consent and able to provide answers for the primary and secondary variables; recalling loneliness and out of house activities, as well as recalling significant life events and transitions in the qualitative stage of the project. This criteria also allows the questionnaire to be kept more brief, as a Mini Mental State construct to assess participants' ability to answer a questionnaire will not need to be included.

The second exclusion criteria was chosen because this study aims to identify lifestyle factors which could enable older adults to remain independent for as long as possible. To do this, it is necessary to focus on those who are still living independently.

The third exclusion criterion will ensure that only participants for whom the protocol contains no risk of harm will be recruited.

The GPs in each of the three NHS practices will be responsible for following the inclusion and exclusion criteria, so that confidential patient information will not be passed onto researchers.

Date of first enrolment

Date of final enrolment 20/12/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Department for Health Bath

United Kingdom BA2 7AY

Sponsor information

Organisation

University of Bath (UK)

Sponsor details

The Avenue Claverton Down Bath England United Kingdom BA2 7AY

Sponsor type

University/education

Website

http://www.bath.ac.uk/

ROR

https://ror.org/002h8g185

Funder(s)

Funder type

Research council

Funder Name

Economic and Social Research Council (ESRC) (UK)

Alternative Name(s)

ESRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Results in De Koning J, Stathi A, Richards S. SHARP: Staying Healthy and Active in Rural Places. Determinants of active ageing in rural England.. 2015. Poster session presented at 11th Annual Scientific Meeting of the UK Society for Behavioural Medicine, Newcastle, UK.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Questionnaire results	09/04/2021	05/08/2021	Yes	No
HRA research summary			28/06/2023	No	No