

Lifestyle Matters

Submission date 22/03/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/03/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/10/2017	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In later life, mental wellbeing can be improved through taking part in meaningful activities and occupations as part of everyday life. This study will evaluate whether a group activity programme called Lifestyle Matters can help improve and sustain physical and mental wellbeing in people aged 65 and older.

Who can participate?

People aged 65 and over who are living independently in Sheffield and North Wales.

What does the study involve?

Participants are randomly allocated to one of two groups. One group continues with their usual care, accessing health and social care services as appropriate to meet their needs. Participants in the other group attend 16 weekly meetings at a local community venue and are also offered monthly one-to-one sessions where they are encouraged to pursue personal goals. All participants are assessed at the start of the study and again 6 and 24 months later. A small number of participants are interviewed at the end of the programme to evaluate the impact of the Lifestyle Matters programme upon their health and wellbeing.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

University of Sheffield (UK)

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

December 2011 to November 2015

Who is funding the study?

Medical Research Council (UK)

Who is the main contact?

Kirsty Sprange
k.sprange@sheffield.ac.uk

Study website

<http://www.shef.ac.uk/lifestylematters>

Contact information

Type(s)

Scientific

Contact name

Mrs Kirsty Sprange

Contact details

University of Sheffield
School of Health and Related Research
Regents Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA
+44 (0)114 222 2969
k.sprange@sheffield.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

11912

Study information

Scientific Title

Lifestyle Matters for maintenance of health and wellbeing

Study objectives

To ascertain whether taking part in an occupational therapy based lifestyle intervention, Lifestyle Matters, can improve mental wellbeing, self efficacy and resilience in people aged 65 years and over. The aims of this research are to:

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Yorkshire Research Ethics Committee, 07/03/2012, ref: 12/YH/0101

Study design

Pragmatic two-arm parallel-group randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

GP practice

Study type(s)

Prevention

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

All Diseases

Interventions

268 participants will be randomly allocated to one of two groups. 134 participants allocated to the intervention group will receive an occupational therapy based lifestyle intervention called 'Lifestyle Matters'. Groups of 10-12 participants attend 16 weekly facilitated activity based meetings at a local community venue and in the community. The groups are assisted by trained facilitators to enable participants to select, explore and engage with activities that are relevant to them. Didactic sessions relevant to the needs of specific members are also 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 the facilitators where they are encouraged to pursue personal goals.

The 134 participants allocated to the control group will continue with usual care. Usual care being defined as accessing health and social care acute and community services as appropriate to meet needs.

Intervention Type

Behavioural

Primary outcome measure

The SF-36 Mental Health (MH) dimension at 6 months post-randomisation

Secondary outcome measures

1. SF-36 Mental Health (MH) dimension at 24 months post-randomisation
2. Other dimensions of the SF-36 at 6 and 24 months post-randomisation
3. PHQ-9 at 6 and 24 months post-randomisation
4. EQ-5D at 6 and 24 months post-randomisation

5. General Perceived Self-Efficacy Scale (GSE) at 6 and 24 months post-randomisation
6. de Jong Gierveld loneliness scale at 6 and 24 months post-randomisation
7. ONS Wellbeing Question from the Integrated Household Survey 2011 at 6 and 24 months post-randomisation
8. Brief Resilience Scale at 6 and 24 months post-randomisation
9. A health and social care resource use questionnaire to collect participants' use of health, social care and community services for health economic analysis

Overall study start date

01/12/2011

Completion date

30/11/2015

Eligibility

Key inclusion criteria

1. Aged 65 years or older
2. Display reasonable cognitive function as measured by a score of 07 on the Six Item Cognitive Impairment Test (6CIT)
3. Living independently or in sheltered accommodation, alone or with others
4. Are able to converse in English or Welsh

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Planned Sample Size: 268; UK Sample Size: 268

Key exclusion criteria

1. Aged 64 years and under
2. Score of 8 or more on the Six Item Cognitive Impairment Test (6CIT)
3. Living in residential/nursing home accommodation
4. Unable to converse in English or Welsh

Date of first enrolment

01/08/2012

Date of final enrolment

19/04/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Sheffield

Sheffield

United Kingdom

S1 4DA

Sponsor information

Organisation

University of Sheffield (UK)

Sponsor details

Health Services Research

School of Health & related Research (SchARR)

Regents Court

30 Regent Street

Sheffield

England

United Kingdom

S1 4DA

+44 (0)114 222 2000

abc@email.com

Sponsor type

University/education

Website

<http://www.sheffield.ac.uk/>

ROR

<https://ror.org/05krs5044>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council [MRC] (UK) - Lifelong Health and Wellbeing ref: G1001406/1

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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

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?
Protocol article	protocol	21/09/2013		Yes	No
Results article	results	01/07/2017		Yes	No
Results article	long-term results	24/09/2017		Yes	No