ISRCTN96478815 https://doi.org/10.1186/ISRCTN96478815

Does taking up a new activity benefit our thinking skills?

Submission date
20/02/2018

Recruitment status
No longer recruiting

Registration date
22/02/2018

Overall study status
Completed

Last Edited
19/08/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
As we age, we may experience general declines in our thinking, memory and reasoning skills (cognitive ageing). There is, however, large variation in the degree of decline experienced. Keeping intellectually, socially or physically engaged have all been proposed as potentially protective. These factors have been incorporated in interventions for cognitive ageing, though are often developed and tested in lab-based settings that may not translate to realistic environments. This study tests a range of activities within existing community-based programmes as potential interventions to reduce cognitive ageing in old age. The activities selected vary in their social, intellectual or physical demands, so the key question relates to how these different aspects of engagement might relate to benefits across different types of thinking skills.

Who can participate?
People aged 65 and over in Edinburgh and the Lothians (Scotland).

What does the study involve?
Participants attend two screening visits. During their first visit, participants complete some assessments of memory, attention and other cognitive functions. Participants also complete some questionnaires related to their background, current health and well-being, and some physical tests that measure blood pressure, grip strength and lung capacity. A saliva sample are also collected. The saliva sample is tested for different genes later on. The saliva sample stored for gene testing are kept completely anonymous as these tests are of no importance for your health as an individual. Participants are then randomly allocated into one of six activities that could be any of the following: computer classes, participation in social clubs, bingo, exercise or sport classes, gardening, dance or drama groups, musical instrument or language classes, and woodcraft. Participants need to be randomly assigned to each group to ensure that any changes observed as a result of taking up a new activity are not because of initial differences between participants. The activity duration will be around 2 hours per week and will run for between 10-12 weeks. Participants return for another testing session and are asked repeat the cognitive and health measures taken at the first session. After completing this second assessment, you will be

given the opportunity to complete a second new activity, or return to complete some further tests after about 3 months. You do not need to decide on that just now as you'll be given fuller details at the time.

What are the possible benefits and risks of participating?
Participants may or may not get a direct benefit from taking part in this study though all participants will attend a new activity free of charge. The outcomes of the study will, however, help to better understand how taking up new activities might benefit thinking skills. It is not thought that there are many disadvantages. It is highly unlikely that participation in this study will cause participants to become bored, tired or distressed; however, if this happens, participants can stop at any time. If participants become distressed for any reason, they may discuss this with any of the researchers.

Where is the study run from?
This study is being organised The Ageing Lab at Heriot-Watt University (UK).

When is the study starting and how long is it expected to run for?
June 2017 to March 2020

Who is the main contact?
Dr Alan Gow (A.J.Gow@hw.ac.uk).

Contact information

Type(s)
Scientific

Contact name
Dr Alan Gow

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
The Intervention Factory: Advancing community-based activities as interventions for cognitive ageing

Study objectives
Primary study objective: To develop and test the efficacy of a series of real-world activities as potential interventions to reduce or delay cognitive ageing. Specifically, examination of the effects of interventions on cognitive ability at both general and domain-specific levels (memory, processing speed, reasoning), exploring whether different intervention types have different effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. School of Social Sciences Ethics Committee, Heriot-Watt University, 12/05/2017, ref: 2017-453
1. South East Scotland NHS Research Ethics Committee, 22/12/2017, ref: REC reference number: 17/SS/0153, SSA reference number: 17/SS/0157, IRAS project ID: 238302

Study design
Single-centre interventional randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
https://healthyageing.hw.ac.uk/images/downloads/IF_Information_Sheet-December_2017_Version_2-18_December_2017.pdf

Health condition(s) or problem(s) studied
Cognitive ageing

Interventions
Participants meet with a researcher at Heriot-Watt University on two occasions. During their first visit, participants complete some assessments of memory, attention and other cognitive functions. Participants also complete some questionnaires related to their background, current health and well-being, and some physical tests that measure blood pressure, grip strength and

lung capacity. A saliva sample are also collected. The saliva sample is tested for different genes later on. The saliva sample stored for gene testing are kept completely anonymous as these tests are of no importance for your health as an individual. The researcher explains each assessment, and are able to ask any questions as you go along. The testing sessions last about 2.5 hours, and there are time for breaks.

On completion of their baseline assessments, participants are randomised to one of six intervention groups: language classes, social groups, handicraft/woodcraft classes, bingo, exercise classes and computer classes. All interventions run for 10-12 weeks and all are based within existing community-based settings.

All interventions are community classes that run in Edinburgh and surrounding areas. The research team is not involved in the interventions (these are for example, classes run by Adult Education or similar organisations). Participants attend these groups as if they were regular attendees; the classes are not constituted for the purposes of the study. Participants are assigned to one of the six activity groups after their baseline assessments, which must constitute a new activity for them. After completing their new activity for ~10-12 weeks, participants return for follow-up assessments.

Intervention Type
Behavioural

Primary outcome measure
Cognitive ability is measured using the Mini-Mental State Examination, the Clock Drawing Task, psychometric tests (from the Wechsler Adult Intelligence Test (WAIS)-IV, Wechsler Memory Scale (WMS)-IV at baseline and three months.

The main analyses will be mixed model analysis of variance. Briefly, the cognitive domain scores will be computed as described in the WAIS-IV and WMS-IV manuals. To investigate the effect of the interventions on cognitive performance, 6 x 2 mixed model ANOVA will be conducted with the between factor Group (five intervention groups and the placebo control) and within factor Time (pre-test, post-test) for each of the cognitive ability domains separately.

Secondary outcome measures
1. Mental wellbeing is measured using the Warwick-Edinburgh Mental Wellbeing Scale at baseline and three months.
2. Quality of life is measured using the WHO Quality of Life Scale at baseline and three months.
3. Anxiety and depression are measured using the Hospital Anxiety and Depression Scale at baseline and three months.
4. Physical function is measured at baseline and three months, comprising: blood pressure is measured using a digital sphygmomanometer; lung function is measured using a spirometer; grip strength is measured using a handheld dynamometer; balance, chair stands and walk speed are measure using the Short Portable Physical Performance Battery.

Overall study start date
12/05/2017

Completion date
31/03/2020

Eligibility

Key inclusion criteria
1. Aged 65 or over
2. Resident in Edinburgh or the Lothians

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
300

Total final enrolment
336

Key exclusion criteria
1. Younger than 65 years old
2. Not resident in Edinburgh or the Lothians
3. Diagnosed with a memory/cognitive impairment or dementia

Date of first enrolment
01/06/2017

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Heriot-Watt University
Department of Psychology
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EH14 4AS

Sponsor information

Organisation
Heriot-Watt University

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Sponsor type
University/education

Website
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ROR
https://ror.org/04mghma93

Funder(s)

Funder type
Charity

Funder Name
Velux Stiftung

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal, not anticipated before 31/12/2019, in addition to inclusion in a PhD thesis due for submission 31/08/2020. The first publication will comprise an empirical paper describing the main cognitive intervention findings; additional publications linked to the PhD thesis will comprise comparison of benefits according to age group, baseline cognitive status, and personality characteristics.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Alan Gow (A.J.Gow@hw.ac.uk), as raw or computed data in anonymised format for the purposes of scrutiny of published results or agreed new analyses. Participants consent to data being retained for future analyses coordinated by the research team, but not for these to be uploaded to a public repository; all requests for data will be via the Principal Investigator Dr Alan Gow.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		23/04/2021	23/04/2021	No	No
Interim results article		06/12/2021	19/08/2022	Yes	No
HRA research summary			28/06/2023	No	No