Cognitive and biological correlates of loneliness in stroke population (#57469)

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1) Have any data been collected for this study already?
It's complicated. We have already collected some data but explain in Question 8 why readers may consider this a valid pre-registration nevertheless.

2) What's the main question being asked or hypothesis being tested in this study?
To what extent are executive functions and inflammatory biomarkers associated with the experience of loneliness in healthy individuals and those who have had a stroke?
H1. Higher loneliness scores will be associated with lower scores on measures of general cognitive performance (e.g., processing speed, memory and verbal fluency).
H2. Higher loneliness scores will be associated with biomarkers that are indicative of higher inflammatory/stress responses (e.g., C reactive protein, blood pressure and Feretinin).
H3. The hypothesised relationships in H1 and H2 will be stronger in stroke survivors than in the healthy population.

3) Describe the key dependent variable(s) specifying how they will be measured.
Self-reported loneliness is the key dependent variable. Loneliness will be measured by three items on the WEMWEBS: I've been feeling interested in other people, I've been feeling close to other people, I've been feeling loved. Each item is measured on a Likert scale from 1 – 5 (1- "none of the time", 2 – "rarely", 3 – "some of the time", 4 – often, 5 – "all of the time"). Each item will be reverse scored, so that higher scores would reflect a proxy measure for greater levels of loneliness.

4) How many and which conditions will participants be assigned to?
Testing H1 and H3 (cognitive processing and stroke):

IVs

1. Demographics (gender, level of deprivation, marital status)
2. Social contact (2 items measuring frequency of social contact)
2a. Item 1 – contact with family ("how often do you meet with family"). Likert scale response range from 1 ("three or more times a week") to 7 ("never"). There is an additional response "N/A - lives with family", which is coded as 8.
2b. Item 2 – contact with friends ("how often do you meet with friends"). Likert scale response range from 1 ("three of more times a week") to 7 ("never"). There is an additional response "N/A -does not have any friends", which is coded as 8.
3. Cognitive factors (There are four cognitive measures available, which are listed below. The primary measure for our purposes is 'Processing speed'. Therefore, processing speed will be the only cognitive factor tested initially. Subsequently, we may run further analyses using the other cognitive factors in order to compare how different dimensions of cognitive performance compare to each other in relation to loneliness.)
3a. Processing speed (Performance on Letter Cancelation – Speed score (seconds))
3b. Immediate memory (List learning task – recall score (number of words correctly recalled)
3c. Delayed memory (List learning task – delayed recall score (words of words correctly recalled))
3d. Verbal fluency (Animal naming – number of animals named in 1 minute)
4. Illness/brain injury (no ill-health condition (healthy) vs. stroke).
5. Cognitive factors * brain injury interaction (This tests H3).

Testing H2 and H3 (biomarkers and stroke):

IVs

1. Demographics (gender, deprivation, marital status)
2. Social contact (as described above).
3. Biomarkers (Three biomarkers have been identified in the dataset, which have been previously associated with inflammatory responses (listed below). Each biomarker will be modelled separately to test its relationship to loneliness. In addition, the biomarkers may also be combined into a composite measure and the same analyses performed again).
3a. C reactive protein levels (mg/L).
3b. Blood pressure (systolic/diastolic)

3c. Fibrinogen levels (ug/L)
4. Illness/brain injury (no ill-health condition (healthy) vs. stroke).
5. Biomarkers * brain injury interaction (This tests H3).

5) Specify exactly which analyses you will conduct to examine the main question/hypothesis.
Data will be analysed using ordinal regression and a Bayesian estimation approach (see, McElreath, 2020; https://doi.org/10.1201/9780429029608). As such, we will build models incrementally towards the full model (which will include all fixed and varying effects that the design permits – Barr et al., 2013). Priors will be set using a 'weakly informative' approach (https://github.com/stan-dev/stan/wiki/Prior-Choice-Recommendations). The three loneliness items from the WEMWEBS scales will be modelled in one multivariate model using the mvbind function. The full model for testing H1 and H3 is specified below using the brms syntax (Burkner, 2017; doi:10.18637/jss.v080.i01). The model for testing H2 and H3 would be identical except that biomarker measures would replace cognitive factors.

Hypothesis 1 & 3
Full model: brm(mvbind(item1, item2, item3) ~ 1 + Demographics + Social contact +
Cognitive factors + Brain injury + Cognitive factors * Brain injury), family=cumulative("probit")

Hypothesis 2 & 3
Full model: brm(mvbind(item1, item2, item3) ~ 1 + Demographics + Social contact +
Biomarkers + Brain injury + Biomarkers* Brain injury), family=cumulative("probit")

6) Describe exactly how outliers will be defined and handled, and your precise rule(s) for excluding observations.
n/a. We do not have any exclusion criteria.

7) How many observations will be collected or what will determine sample size? No need to justify decision, but be precise about exactly how the number will be determined.
Data has already been collected through the 1970 British Cohort Study (BCS). The BCS is a longitudinal birth cohort study that follows over 17,000 people born in England, Scotland and Wales who were born within a single week of each other in 1970. Participants in the BCS undertake surveys at specific time intervals at the age of 5, 10, 16, 26, 30, 34, 38, 42 and more recently at ages 46-48. In the most recent survey, cognitive performance, biomarkers and levels of loneliness were measured and over 48 participants have had a stroke within the last 4 to 6 years. Further information regarding the survey is publicly available through UKdataservice.org.

8) Anything else you would like to pre-register? (e.g., secondary analyses, variables collected for exploratory purposes, unusual analyses planned?)
The database also measures other potential variables of interest. The below variables may be included in the analysis should it be warranted at a later date.

Biomarkers:
Glycated haemoglobin
Tryglycerides
CMV IgG result
CMV IgM result
CMV avidity result
Red blood count

Certain biomarkers may be grouped together, which may allow for a better measurement of inflammatory response rather than single biomarkers in isolation.

Social functioning score (RAND-36, 2 Items):
Items 20 and 32 are used to score the measure of social functioning. Each of the two items has 5 response choices. However, a high score (response choice 5) on item 20 indicates the presence of limitations in social functioning, while a high score (response choice 5) on item 32 indicates the absence of limitations in social functioning. To score both items in the same direction, responses 1 through 5 for item 20 should be recoded to values of 100, 75, 50, 25, and 0, respectively. Responses 1 through 5 for item 32 should be recoded to values of 0, 25, 50, 75, and 100, respectively. The two recoded items should be averaged together to form the social functioning scale. If the respondent is missing one of the two items, the person's score will be equal to that of the non-missing item.
a. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?
b. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?