Title: The Emotional, Physical and Cognitive Benefits of Purposeful Green Space Activities on Seniors

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NCT# NCT04913363

PROTOCOL

Background

1. Provide the scientific background, rationale and relevance of this project.

INSTRUCTIONS

- This should include a referenced systematic evidenced-based review when possible.
- If this study involves qualitative research explain the major constructs of your study.
- Do not state in this section what you plan to do in this study. This information should be entered later under "What will be done in this protocol?"
- Do not include the bibliography in this section.
- For studies submitted under the Expedited review criteria, this section need not be more than a few paragraphs.
- For those studies where data will be analyzed collaboratively by multiple sites doing a similar study for which there is no common protocol (Collaborative Site Analysis Study) include a description of the common scientific goals/ procedures/data points.
- If this is an update to current templates from Protocol Builder make sure the information throughout the protocol includes the most current information.

Answer/Response:

The onset of COVID-19 and the subsequent lockdown imposed on the public brings about a novel set of mental health risks arising from being spatially constricted and the absence of a physically present support network. Prior to the onset of the pandemic, 13.8 million older adults in America lived alone; 28% of the older adult population. Isolated older adults will have likely seen family connections dramatically reduced due to mobility restrictions and social distancing. This impact has also been felt at Jefferson Area Board of Aging (JABA) facilities across Charlottesville and the wider county areas as the Centers closed in mid-March due to COVID-19. They re-opened in early September, with smaller numbers and trying to make use of outdoor spaces, and large rooms to allow social distancing. JABA estimate that only a third of their service users have returned since reopening in September. It is vital that we understand the impacts of this enforced isolation on mental and social health in order to generate novel measures for mitigating its effects and fostering a higher quality of life in these trying times, and indeed, beyond. Further to this, as we begin to lift state, federal and self-imposed restrictions, we want to understand how to safely bring older adults back into social, outdoor spaces that are optimized to have a beneficial impact on their health and wellbeing. This is a national concern as the Center for Disease Control (CDC) has indicated adults over 65 should engage in developing a care plan as well as providing guidance for coping with stress/anxiety at this time.

One way of allowing increased social activity in a safe environment would be to utilize outdoor green spaces. Research has shown cognitive, social and physiological health benefits of green space interventions in older adults, but what is less understood is how

different activities may deliver positive health benefits to those returning to green social spaces. Adults aged over 45 years have lower levels of distress if they are physically active in greener surroundings, but exposure to green space among those who do no or little activity has no impact on mental health. With social connections severely restricted due to COVID-19, it is important to understand how safe interventions utilizing nature contact/exposure can support mental health and social interactions. This issue is also wider than the current pandemic, with global standards existing for urban spaces to align with the Sustainable Development Goals (SDGs) which include the aim, by 2030, of providing universal access to safe, inclusive and accessible public green spaces, particularly for women and children, older people and people with disabilities. Research on this is limited at present, but evidence suggests exposure to green space can improve sense of belonging and interconnectedness with others in younger cohorts; by logical extension this should follow in other populations, but there is no consensus as to the impacts of nature contact on social connections in older adults.

Our team have developed and piloted a protocol in younger adults (in the UK) to understand how activity type may impact mood. Specifically, we looked at how a 'default activity' in green space (walking in a park) compared to a 'cerebral activity' (citizen science; learning about green space with little to no physical exertion) and 'physical activity' (digging and planting, with little cerebral exertion) to understand green 'dosing'. Using this framework, we seek to understand how different activities might impact older adults in our local community.

Objectives/Hypothesis

INSTRUCTIONS:
If this study involves biomedical research clearly state the objectives and hypotheses and clearly define the primary and any secondary outcome measures. If this study involves qualitative research clearly state your research hypothesis or question.

This section should not include information already included in other sections such as background information or information from the procedures section.

Answer/Response:

Building on pilot work from our team exploring green space activity type, this study aims to focus specifically on older adults in Charlottesville and the surrounding areas. We aim to understand how green space activity type may influence belonging, loneliness and mood and how this may impact on willingness to return to JABA centers. Our research questions are as follows;

1. What types of green space activities have a beneficial impact on loneliness, belonging and mood in seniors who are JABA center members?
2. Does the inclusion of these activities encourage JABA service users to continue participation at their JABA centers?

To investigate these questions, we will utilize 2 study components. The first, titled 'activity sessions' refers to a participant group who will undergo a series of activities (on separate days) including walking, citizen science and planting in order to understand pre- and post-activity wellbeing. The second component, titled 'survey-only', refers to a different participant group who are remotely surveyed on their current wellbeing, experiences during COVID and barriers on returning to JABA. All participants will be JABA service users.

Study Design: Biomedical

1. Will controls be used?

Answer/Response: Yes

►IF YES, explain the kind of controls to be used.

Answer/Response: There are two controls. First, during the activity sessions, participants will act as their own control, crossing over to take part in each activity. Second, we also will conduct a survey remotely in which participants will respond to questions regarding their current wellbeing. These will be compared to those of the participants who undergo the activity sessions.

2. What is the study design?

Example: case series, case control study, cohort study, randomized control study, single-blind, double-blind, met-analysis, systematic reviews, other. You may also view the IRB-HSR Learning Shot on this topic to help you answer this question. https://hrpp.irb.virginia.edu/learningshots/Writing_protocol_June09/player.html

Answer/Response: For the activity sessions, the study is a repeated measures study design. For the survey only group, the study is a single cohort study.

3. Does the study involve a placebo?

Answer/Response: No

►IF YES, provide a justification for the use of a placebo

Answer/Response: N/A

Human Participants

Ages: 65 and over
Sex: Not controlling for sex, but would prefer 50:50 if possible
Race: all

Subjects- see below

INSTRUCTIONS: For question 1-4 below insert an exact #. Ranges or OPEN is not allowed. This # should be the maximum # you expect to need to enroll (i.e. sign consent) If you are only collecting specimens the number of participants should equate to the # of specimens you need. If you are collecting only data from a chart review the

number should designate the number of subjects whose medical records you plan to review. Age/ Sex/Race criteria should designate the demographics of participants from whom you will obtain the specimen/data.

1. **Provide target # of subjects (at all sites) needed to complete protocol.**

   INSTRUCTIONS: If this is NOT a database protocol, this number should be the same as the number of subjects needed to obtain statistically significant results.

   Answer/Response:
   60

2. **Describe expected rate of screen failure/ dropouts/withdrawals from all sites.**

   Answer/Response:
   We would expect around 10% attrition, so a final sample of 54 (n = 27 per group) is expected

3. **How many subjects will be enrolled at all sites?**

   INSTRUCTIONS: This number must be the same or higher than the # from question # 1 in order to account for the # of screen failures, dropouts, withdrawals described in question # 2.

   Answer/Response:
   60

4. **How many subjects will sign a consent form under this UVA protocol?**

   INSTRUCTIONS: If the protocol does not have a consent form- the number listed here should reflect such things as the number of subjects from whom specimens will be obtained, the number of charts to be reviewed etc.

   Answer/Response: 60

Inclusion/Exclusion Criteria

INSTRUCTIONS:

- The inclusion and exclusion criteria should be written in bullet format.
- *This item applicable if the study will require consent (verbal or written).* Unless there is a scientific reason for not recruiting a certain type of vulnerable population(e.g. not enrolling fetuses, neonates or children in a study regarding Alzheimer's) list the following vulnerable populations under either Inclusion or Exclusion criteria below: pregnant women, fetuses, neonates, children, prisoners, cognitively impaired, educational or economically disadvantage, non- English speaking subjects .
- If you will not enroll subjects who do not speak English because certain procedures cannot be carried out if the subject does not speak English (e.g. a survey is not validated in other languages) insert the following as an Inclusion Criteria: Willingness and ability to comply with scheduled visits and study procedures.
- If this is a collection of only retrospective* specimens or data, the inclusion criteria must include a start and stop date for when specimens/ data will be collected.
- The stop date must be prior to the version date of this protocol.

- *Retrospective: all specimens are in a lab at the time this protocol is approved by the IRB. All data exists in medical records or records from previous studies at the time this protocol is approved by the IRB.

1. List the criteria for inclusion

Answer/Response:

- 65 years old or older
- A (previous) JABA center user
- Able to walk unassisted for up to 20 minutes
- Willing to comply with COVID-19 regulations

2. List the criteria for exclusion

Answer/Response:

- Under 65 years
- Never used a JABA center
- Unable to walk unassisted for up to 20 minutes
- Unwilling to comply with COVID-19 regulations

3. List any restrictions on use of other drugs or treatments.

INSTRUCTIONS: List only those drugs or treatments that are prohibited while on study, not those listed as an exclusion criteria.

Answer/Response:

None

Statistical Considerations

1. Is stratification/randomization involved?

Answer/Response: No

►IF YES, describe the stratification/ randomization scheme.

INSTRUCTIONS:
The stratification factors and/or the randomization plan should be identified. If there is no randomization component or important patient characteristics that will be used in treatment allocation or data analysis, a statement to this effect should be included.

Stratification factors: These are pretreatment patient characteristics which could be balanced across treatment arms by design or may be used to determine starting dose or treatment allocation.

If randomization is going to be used, the details of the randomization plan should be described.

The description should include:
--the method and timing of randomization

--the type of randomization scheme that will be used in the study
--whether or not the randomization masked/blinded/if so, then to whom is it masked/blinded
--who has access to the randomization scheme

Answer/Response: N/A

►**IF YES, who will generate the randomization scheme?**

_____ Sponsor
_____ UVA Statistician. Insert name Answer/Response:
_____ UVA Investigational Drug Service (IDS)
_____ Other: Specify Answer/Response:

2. What are the statistical considerations for the protocol?

The objectives section and the statistical section should correspond, and any objective for which analysis is unfeasible should be deleted. Also, the estimates and non-statistical assumptions of the statistical section should be supported by discussion in the background section.

The answer to this question should include:
--Study Design/Endpoints
--Recap of study objectives and endpoint definitions. An assessment of how study objectives will be assessed by identifying & defining which endpoints will be used to assess each component of the study objectives.
--The study design should include contingencies for early stopping, interim analyses, stratification factors (If applicable), and any characteristics to be incorporated in analyses.
--The power/precision of the study to address the major study endpoint(s), the assumptions involved in the determination of power/precision.
--If statistical hypothesis testing is included then specify the null and alternative hypotheses, the test statistic, and the type I and II error rates
--If precision of an estimate, then provide a definition for precision
--If other, then specify

Answer/Response:
This is a pilot study aimed at ascertaining impacts of outdoor activities on both wellbeing as well as understanding barriers to returning to JABA centers.

3. Provide a justification for the sample size used in this protocol.

Include sample size calculations or statistical power estimation. If not applicable, please provide explanation.
Also include the anticipated accrual rate, the accrual goal for the study, including accrual goals by strata if appropriate, adjustments for drop-outs etc. and study duration.

Answer/Response: In collaboration with JABA, an n of 60 across the two study components is a realistic number of participants to be able to recruit.

4. What is your plan for primary variable analysis?

Include primary outcome(s)/predictor variable(s), statistical methods/models/tests to be employed, or descriptive summaries as appropriate. If not applicable, please provide explanation.

Answer/Response: We will use the following outcome measures across the study.

- Loneliness; measured by the UCLA Loneliness Scale, a 3-item scale that captures feelings of loneliness. (Activities and survey-only)
- Belonging; measured by the General Belonging Scale (GBS), a 12-item scale capturing social acceptance/inclusion and social rejection/exclusion. (Activities and survey-only)
- Acute Mood; pre and post measures of mood will be taken using the UWIST Mood Adjective Checklist (MACL), an acute measure of hedonic tone, stress and arousal. (Activities only)
- Restoration; Psychological restorative qualities of the setting measured by the Perceived Restorativeness Scale, a three point scale determining the restorative quality of activity spaces. (Activities only)
- Physical Activity; In addition to the arousal measure of the MACL, we will use the 10 point scale of the OMNI Perceived Exertion scale, to understand how physically exerted participants feel between activities. To understand baseline physical activity, we use the international physical activity questionnaire (IPAQ) to compare between studies (Activities and survey-only).
- Accelerometer; we will use accelerometers to measure participant movement throughout the activities to correlate with physical activity measures. (Activities only). Specifically, we will look to understand if increased movement, as measured by the accelerometer, correlates with increased feelings of exertion post-activity (across all three activities).

For measures taken in both the activities and survey-only, we will use an independent t-test using condition (activity or survey) to compare. For activities that use pre- and post-assessments, we will make change scores for each and use this in a one-way ANOVA, using activity type (three levels; walking, citizen science, planting) as the grouping variable.

5. What is your plan for secondary variable analysis?

Include the following:
--Secondary outcome(s)/predictor variables, statistical methods/models/tests to be employed, or descriptive summaries as appropriate. If not applicable, please provide explanation.
--For phase III studies, the power/precision of the study to address the secondary objective(s).

Answer/Response: N/A

6. Have you been working with a statistician in designing this protocol?

Consultation with a professional statistician is highly recommended to ensure good science of the study and facilitate the review process.

Answer/Response: No

IF YES, what is their name?
Answer/Response:

7. Will data from multiple sites be combined during analysis?
Answer/Response: No

INSTRUCTIONS: IF YES, answer the following questions

7(a). Does the study involve randomization?
Answer/Response:

IF YES, will randomization be done at each site or among sites?
Answer/Response:

7(b). Has the sample size calculation considered the variation among sites?
Answer/Response:

7(c). When combining the data from multiple sites to assess the study results, is the effect of the treatment to be tested (or the association to be tested) assumed to be the same across sites or vary among sites? What is the modelling strategy?
Answer/Response:

7(d). Is there a common protocol used in all sites?
Answer/Response:

IF NO, how will differences among sites, such as those related to the implementation, inclusion criteria, patient characteristics, or other sites characteristics, be considered to assess the study results?
Answer/Response:

Study Procedures-Biomedical Research

1. What will be done in this protocol?

INSTRUCTIONS:
This should include everything that will be done as part of this protocol. Do not repeat information that is included in other sections such as Background or Hypothesis sections.

This section should include an indication of which research interventions if any offer a prospect for direct benefit and which interventions (invasive measurements, collection of blood, tissue, data, surveys, etc.) are being done solely to answer a research question and generate generalizable knowledge. If the interventions done solely for research purposes are associated with greater than minimal risk they need to be justified. Describe and justify any control and experimental arm and include method, dose, and duration of drug administration. Reference any claim of clinical equipoise if applicable.

If you are obtaining specimens or data, provide information regarding the type of specimen/data, amount of specimen needed and how the specimen/data will be obtained and what analysis will be done with the specimen/data.

Special note for studies with waiver of consent/waiver of documentation of consent: Include a statement regarding how subjects will be recruited. For other studies this information is captured in Recruitment does not need to be duplicated in this section.

Answer/Response:

There are two components to this study, so we describe each separately. *Activity sessions*

There will be three activity sessions, the protocol for each is largely the same. For the walking and the citizen science sessions, participants will be transported (Jaunt bus) to a nature preserve to conduct this session. Alternatively, if participants wish to transport themselves, they are welcome to – this will be confirmed after obtaining consent. The planting session is held at the JABA center. Upon arrival at the given site, participants will be given their initial pre-activity survey to complete (pen and paper) and are given an accelerometer to wear throughout the study session. Following this, they will undertake their activity; this will include a short nature walk, a guided citizen science walk or a session planting and tending to greenery in raised beds. At the end of the sessions (up to 30 minutes), participants will complete the post-activity survey and remove their accelerometer. After payment ($10 supermarket voucher per session), participation ends.

Survey Only

Participants are mailed a study information sheet and the the survey with a return envelope. They are asked to complete the survey and return it to the research team.

1. **If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.**

Example: If the subject will be taking an investigational drug, will they need to be put back on an approved drug when they have completed the study? If yes, explain how this will be accomplished and who will cover the cost. If the subject has a device implanted will it be removed? Again- who will cover the cost of the removal?
Instructions: Answer NA if this study does not involve a study treatment.

Answer/Response: N/A

Bibliography

INSTRUCTIONS: Provide a current bibliography supporting the hypothesis, background and methodology including references to papers and abstracts that have resulted from previous work by the investigator and references to the work of others.

1. Administration on Aging (AoA). *2017 Profile of Older Americans*. https://acl.gov/sites/default/files/Aging%20and%20Disability%20in%20America/2017OlderAmericansProfile.pdf (2017).
2. CDC. Coronavirus Disease 2019 (COVID-19). *Centers for Disease Control and Prevention* https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/managing-stress-anxiety.html (2020).
3. Artmann, M. *et al.* The role of urban green spaces in care facilities for elderly people across European cities. *Urban For. Urban Green.* **27**, 203–213 (2017).
4. Neale, C. *et al.* The impact of walking in different urban environments on brain activity in older people. *Cities Health* **0**, 1–13 (2019).
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6. Tilley, S., Neale, C., Patuano, A. & Cinderby, S. Older People's Experiences of Mobility and Mood in an Urban Environment: A Mixed Methods Approach Using Electroencephalography (EEG) and Interviews. *Int. J. Environ. Res. Public. Health* **14**, 151 (2017).
7. Astell-Burt, T., Feng, X. & Kolt, G. S. Mental health benefits of neighbourhood green space are stronger among physically active adults in middle-to-older age: evidence from 260,061 Australians. *Prev. Med.* **57**, 601–606 (2013).
8. United Nations. *New Urban Agenda*. http://habitat3.org/wp-content/uploads/NUA-English.pdf (2017).
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10. Neill, C., Gerard, J. & Arbuthnott, K. D. Nature contact and mood benefits: contact duration and mood type. *J. Posit. Psychol.* **14**, 756–767 (2019).
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13. Roe, J. *et al.* The Urban Built Environment, Walking and Mental Health Outcomes Among Older Adults: A Pilot Study. *Front. Public Health* **8**, (2020).
14. Aspinall, P., Mavros, P., Coyne, R. & Roe, J. The urban brain: analysing outdoor physical activity with mobile EEG. *Br J Sports Med* **49**, 272–276 (2015).
15. Neale, C. *et al.* The Aging Urban Brain: Analyzing Outdoor Physical Activity Using the Emotiv Affectiv Suite in Older People. *J. Urban Health* **94**, 869–880 (2017).

16. Roe, J. *et al.* Green Space and Stress: Evidence from Cortisol Measures in Deprived Urban Communities. *Int. J. Environ. Res. Public. Health* **10**, 4086–4103 (2013).
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