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| **COVID-19 RISK ASSESSMENT** | |
| **Study Title:** | BEET-Winter |
| **ISRCTN:** | N/A |
| **Sponsor Reference:** |  |
| **IMP/Intervention:** | Beetroot Juice |

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| **Intervention** | **Risk identified** | **Likelihood** | **Mitigation** | **Comments/monitoring approaches** |
| Care home set-up | Care homes may have no research experience | Medium | EOI’s have been sent to homes previously involved in UoN research  Research training can be given to homes who have no previous experience of research | Review on a monthly basis to ensure that the required number of homes have been recruited |
| Care home set-up | Care homes may have an outbreak of COVID-19/winter flu | Low | Homes with current outbreaks of infection will not be included in the trial | Review on a monthly basis. Send further EOI’s as necessaey |
| Care home training | Face to face visits for training purposes are currently prohibited due to COVID-19 | Low | Training will be completed via a virtual platform  Homes will have a dedicated email inbox to which they can submit queries  Research team to create frequently asked questions (FAQ) document | Review on a monthly basis. If there are a large number of queries, training to be reviewed |
| Potential residents | Residents may have COVID-19 | Medium | Residents with COVID-19 are unable to take part in the trial, if they develop COVID-19 during the trial data will be collected | Review on a monthly basis |
| Potential participants | Residents may not like the taste of beetroot juice | Medium | Residents to taste test the beetroot juice before taking part in the trial | Review numbers recruited on a monthly basis |
| Site Monitoring | Monitors are not able to visit sites in person due to social distancing | High | Homes to be monitored remotely | Review on a monthly basis |
| Second wave | There may be a second wave of the pandemic which will impact on the staff’s ability to collect trial data | Medium | Plan to try to continue if possible  If necessary pause recruitment and re-assess the situation monthly | Review on a monthly basis |

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| **Chief Investigator:** | Prof Philip Bath |
| **Date of initial risk assessment:** | 07/09/20 |
| **Risk Assessment Contributors** |  |
| **Name:** | **Job title:** |
| Diane Havard | Senior Clinical Trial Manager |
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| **Date of risk assessment review:** | **Undertaken by:** | **Action:** |
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