

Consultee Information Sheet (Version 2.1 10/12/2020)



The aim of the study is to see if we can reduce winter infections such as colds, 'flu, and COVID-19 in care home residents using a natural food supplement over 2 months.

We feel your relative/friend is unable to decide for himself/herself whether to participate in this research. To help decide if he/she should join the study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration form provided. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns

or you think your relative/friend should be withdrawn.

If you decide that your friend/relative would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice.

We will understand if you do not want to take on this responsibility".

Your relative's GP will be informed of their participation in the trial.

The supplement is nitric oxide that comes in the form of concentrated beetroot juice. The juice is provided in a small bottle (70ml) and is drunk once-a-day for two months. The only ingredients



Consultee Information Sheet (Version 2.1 10/12/2020)



in the juice are crushed beetroot with 2% lemon juice from concentrate. There are no other additives, preservatives or other allergens, and there is no risk of cross-contamination during manufacturing.

Half the care homes in the study will have active juice (juice with naturally occurring nitrate) and the other half will receive inactive juice (juice with nitrate removed).

Neither your relative nor their care home will know which sort of juice your relative will receive. The active and inactive juice look and taste the same and we will ask your relative to taste the juice before the study to make sure they can take it.

The inactive juice has the same ingredients as the active juice but with the nitrates removed. This is done using a process by which the juice is filtered through a special resin. This process does not add any other ingredients to the juice and also avoids the risk of allergens and other cross contamination. (Information from James White Drinks Ltd)



Concentrated beetroot juice is widely used by athletes to help their performance. It has been tested in many studies and lowers blood pressure a little. In lab studies, nitric

oxide is shown to be anti-microbial (anti-viral, anti-bacterial, anti-fungal) – a feature that could be key in fighting infections. Beetroot juice (both active and inactive) will also contribute to one of your relative's 'five-a-day',

Due to its wide use, we do not think your relative will be harmed by taking part in the study.

The most common effect is that urine may go red or pink coloured. Less commonly, poo (stools/faeces) may also go red or pink coloured. The colour is different from having blood in poo.



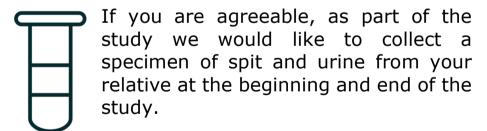
Consultee Information Sheet (Version 2.1 10/12/2020)

On rare occasions, beetroot may cause a rash or stomach cramps (usually because the individual has a food allergy or intolerance).

The care home staff will look out for all of these side effects, but if you have any concerns please speak to the care home.



We will train and support the staff in your relative's care home to give this supplement as part of normal day-today care.



We will use this to test the levels of nitrate/nitrite in their body. The results will be recorded, and the samples will be disposed of immediately.



Your relative's care home should already be using best practice standard-of-care for limiting spread of infections, including COVID-19. These measures include social distancing,

good hygiene (handwashing) and use of Personal Protection Equipment (masks/visors etc).

The juice supplier James White Drinks Ltd has confirmed that they employ strict control measures including restriction of non-essential personnel on site, social distancing, frequent cleaning and disinfecting, good hygiene practice (handwashing) and use of PPE where appropriate (masks and gloves).



If you have a concern about this study, please speak to the care home staff who will do their best to answer your questions. If this does not deal with your concern, please contact Professor



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Philip Bath, whose contact details are given below.

interests. This study has been reviewed and given the go-ahead by the National Research Ethics Service Committee.



Just tell us and you can withdraw your relative from the study. You don't have to give a reason. We will still use the information we have already gathered but won't bother your relative any

further. And it won't affect any other aspect of your relative's care.

If you want to know more about how the University of Nottingham uses your information in research please go to https://www.nottingham.ac.uk/utilities/privacy.aspx. A copy can be supplied on request.



It will take 6 months to complete the study. A report on the findings will be sent to you if you wish, your relative's care home and published in medical journals.

The research is being organised by the University of Nottingham, is led by Professor Philip Bath and is funded through the University.

Research in social care is looked at by an independent group of people called a Research Ethics Committee to protect your relative's



If you have any further questions, please contact us:

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