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Title of Study: Are high-dose Vitamin B6 supplements beneficial for autistic individuals?

PARTICIPANT INFORMATION SHEET

We would be grateful if you could assist us by participating in our study, which will take about 4 hours of your time in total, split into several online and lab-based sessions.

What will I be asked to do?

You will be first be asked to complete some online questionnaires about yourself. Following this, we will arrange a time for you to visit the Psychology Department at University of Reading. During this lab visit we will use a recently invented device to collect a very small blood sample (about 6 drops) from the tiny capillary blood vessels in the skin of your arm. You can choose to self-administer the device, if you prefer this. The device is designed to make providing blood samples for research studies and other purposes much less painful and stressful than the traditional method using a needle. If you would like to watch some videos of this procedure and an explanation of how it works, here is a link: <https://yourbiohealth.com/en-us/virtually-painless-blood-collection-devices-for-clinical-trials-and-wellness-testing> Note that if you have more than averagely hairy arms it may be necessary to shave a small area.

Following the capillary blood sample, you will undertake a series of short visual perception tests. These all involve sitting at a computer desk in a darkened lab and reporting what you see by pressing one of two or four keys on the keyboard.

At the end of the session you will be given a bottle of tablets to take daily for the next 30-35 days, and we will arrange a time and date for you to return to the lab to repeat the above tasks. The bottle will either contain B6 tablets or a placebo, but which it is won't be known to you or the experimenters. During the session, because some people have difficulty swallowing tablets and capsules, we will show you a technique that makes swallowing them easier. At the end of the study we will tell you which tablets you took, and if you were in the placebo condition you will be offered the chance to take the Vitamin B6 tablets.

Because of the form of Vitamin B6 the study is investigating, the tablets you will take need to be kept in a cool and dry environment, and not exposed to light. The storage temperature needs to be 20 degrees centigrade or below, without high humidity. A kitchen fridge is ideal for this, but a freezer is too cold. Most importantly, the bottle should be kept closed to stop the tablets being exposed to light.

Prior to the second visit, you will be asked to fill in the online questionnaires again.

Once the study is complete and we have analysed the data we will contact you to explain more about the study and summarise the findings.

Taking part in this study is completely voluntary; you may withdraw at any time without having to give any reason. Please feel free to ask any questions that you may have about this study at any point.

We will analyse the blood samples for Vitamin B6 content. Vitamin B6 is vital for many different processes in the body, including in the brain where it is involved in making neurotransmitters. It is possible that taking part in this study will reveal that you are Vitamin-B6 deficient (Pyridoxal-5'-phosphate concentration < 20 nmol/L). If this occurs, we will contact you and suggest that you contact your GP. We will not be able to offer individual medical advice ourselves, because we are not medically qualified. However, generally speaking, the symptoms of a severe Vitamin-B6 deficiency include swollen tongue, dermatitis (especially cracked skin around the mouth), mental confusion, and depression. These symptoms are only likely to occur when the blood concentration falls much lower than the threshold we are using to define deficiency, and fortunately, Vitamin-B6 deficiency is treatable by taking Vitamin-B6 supplements.

Why have I been invited to participate in this study?

A number of studies of high-dose B6 supplementation in autism were carried out from the late 1960's through to the 1990's. The results of these were mixed and are hard to interpret clearly because of flaws in the way they were carried out. We believe it is now timely to carry out a, modern, definitive study to clarify whether high-dose Vitamin B6 is beneficial.

Who can take part in the study

You must be over 18 years of age and under 60 and have a diagnosis of autism. You should not be taking, or have recently taken on a regular basis, any multivitamin or supplement that contains more than 2 mg Vitamin B6 (other dietary supplements are OK). You should not be taking any medication that is a GABA agonist – our researchers will check this with you. You must have no medical history of peripheral neuropathy. You should not be taking, or have taken in the last 2 weeks, the antibiotic cycloserine (Seromycin); this would have been prescribed to you either for tuberculosis, or rarely, a urinary tract infection.

Are there any benefits to taking part?

It is possible you may experience positive effects of the supplement, but we cannot be confident of this at this stage. It is also possible that – as is the case with many interventions – some individuals will respond to Vitamin B6, while others will not, depending on individual differences in physiology and metabolism. You will receive £30 to compensate you for your time, which will either be transferred to your bank account, or provided in the form of an Amazon voucher. Travel expenses will also be covered.

Are there any risks or disadvantages to taking part?

The Vitamin B6 tablets used in the study contain 100 mg of Vitamin B6 as Pyridoxal-5'-Phosphate (PLP). This is a high dose, equivalent to approximately 50 times the typical daily intake. The vast majority of people experience no ill effects when taking a high dose of Vitamin B6. However, for a very small number of individuals it can trigger peripheral neuropathy. The first signs of this are a tingling sensation in the fingers and toes. If you experience this, then you must stop taking the tablets and contact the researchers; the tingling will soon stop. Although the reason why peripheral neuropathy occurs in rare individuals is not well understood, it is known that it is even less likely to occur when B6 is given as PLP rather than the more commonly available form – pyridoxine. This is why our study is using PLP instead of pyridoxine.

Capillary blood sampling is done by briefly pressing a device on your arm, which will then remain there for several minutes. When it is pressed on, tiny needles very briefly pierce your skin and are then withdrawn. Capillary blood is drawn from the holes in the skin by a vacuum. You may experience a sensation of pressure or suction, and you may have a small mark on your arm that lasts several days. It is possible that slight bruising will occur, but this does not usually happen.

What will happen to my data/how will it be protected?

Your personal data that we have to gather for practical reasons, such as bank details, will be held securely in confidence. Personally identifying data will be kept in a separate file from the study data, with the two being linkable if necessary using an allocated ID number that will be present in both data files. Anonymised data collected from this study will be preserved and made available, so that data can be re-used by others. Personal information such as your name and bank details will not be included in, or linkable to, these publicly shared data files.

Who can I contact about data privacy and storage?

The organisation responsible for protection of your personal information is the University of Reading (the Data Controller). Queries regarding data protection and your rights should be directed to the University Data Protection Officer at imps@reading.ac.uk, or in writing to: University of Reading, Information Management & Policy Services, Whiteknights House, Pepper Lane, Whiteknights, Reading, RG6 6UR, UK.

The University of Reading collects, analyses, uses, shares and retains personal data for the purposes of research in the public interest. Under data protection law we are required to inform you that this use of the personal data we may hold about you is on the lawful basis of being a public task in the public interest and where it is necessary for scientific or historical research purposes. If you withdraw from a research study, which processes your personal data, dependant on the stage of withdrawal, we may still rely on this lawful basis to continue using your data if your withdrawal would be of significant detriment to the research study aims. We will always have in place appropriate safeguards to protect your personal data.

If we have included any additional requests for use of your data, for example adding you to a registration list for the purposes of inviting you to take part in future studies, this will be done only with your consent where you have provided it to us and should you wish to be removed from the register at a later date, you should contact David Field (d.t.field@reading.ac.uk).

You have certain rights under data protection law which are:

- Withdraw your consent, for example if you opted in to be added to a participant register
- Access your personal data or ask for a copy
- Rectify inaccuracies in personal data that we hold about you
- Be forgotten, that is your details to be removed from systems that we use to process your personal data
- Restrict uses of your data
- Object to uses of your data, for example retention after you have withdrawn from a study

Some restrictions apply to the above rights where data is collected and used for research purposes.

You can find out more about your rights on the website of the Information Commissioners Office (ICO) at <https://ico.org.uk>

You also have a right to complain the ICO if you are unhappy with how your data has been handled. Please contact the University Data Protection Officer in the first instance.

Who has reviewed this study?

This application has been reviewed by the University Research Ethics Committee and has been given a favourable ethical opinion for conduct (**UREC NUMBER: 23/27**).

Where can I get more information/who I can contact about this study?

If you have any questions or concerns about the research, please feel free to contact Dr David Field.

Email: d.t.field@reading.ac.uk , Tel: +44-(0)118-378-5004.

Thank you for your help.
