Participant Information Sheet

Study Title: The relationship between iron status, cognitive performance, subjective mood and fatigue in women of reproductive age

Subject ID:

Principal Investigator: Hannah Avery

Sponsor: Supported by Bayer Consumer Care AG, Basel, Switzerland

BPNRC Study Code: 9BM1

Number of participant points/payment: £30

You are being invited to take part in this research study. Before you decide it is important for you to read this leaflet so you understand why the study is being carried out and what it will involve.

Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether you would like to take part or not.

What is the purpose of the study?

Iron deficiency is the most prevalent nutritional deficiency worldwide with one in four estimated to be affected by iron deficiency anaemia. Women of reproductive age are at greatest risk for iron deficiency and anaemia due to iron losses during menstruation and childbirth as well as the increased need for iron throughout pregnancy. However, iron deficiency without anaemia is at least twice as common as iron deficiency anaemia with females aged 11-49 at the biggest risk of all. Despite this, it is commonly left undiagnosed. Those who are iron deficient non-anaemic can still suffer from the same common consequences of iron deficiency anaemia; these include unexplained fatigue, mood changes and decreased cognitive performance. Previous studies have found a significant relationship between iron status and cognitive performance in anaemic women however, studies assessing cognition, mood and fatigue in women of varying iron status including those who are iron deficient non-anaemic are lacking. The aims of this study are to improve knowledge concerning women's health and to determine whether there is a relationship between iron status, cognitive performance, subjective mood and fatigue in women of reproductive age (18-49 years).

Why have I been invited?

You have indicated that you are interested in taking part in the study and are a healthy female (as assigned at birth) aged 18-49 years.

Do I have to take part?

After reading through this information sheet you can choose whether to take part or not. You should not take part if you:

- Are not female (as assigned at birth) aged 18-49 years
- Are not proficient in English

- Have any pre-existing medical condition/illness
- Have any blood disorders (excluding anaemia) or any known active infections
- Have a current or past breast cancer diagnosis and/or a mastectomy
- Smoke or use any nicotine replacement products e.g. vaping, gum, patches
- Are pregnant, trying to get pregnant or breast feeding
- Are currently taking any prescription medication (excluding the contraceptive pill)
- Have regularly used dietary/herbal supplements within the last month (defined as more than 3 consecutive days or 4 days in total)
- Have used iron supplements within the past 4 months
- Have donated more than 300ml of blood in the past 3 months
- Have a history of significant head trauma or suffer from frequent migraines that require medication (more than or equal to 1 per month)
- Have any learning difficulties, dyslexia, or colour blindness
- Have a visual impairment that cannot be corrected with glasses or contact lenses
- Have a BMI <18.5kg/m^2 or >40 kg/m^2
- Are currently taking part in any other clinical or nutritional intervention studies or have in the past 4 weeks
- Have any health condition that would prevent fulfillment of the study requirements
- Do not have a bank account (required for payment)

If you are unsure about your eligibility, then please contact the research team and we can discuss any issues or ambiguity.

What will happen if I take part?

In the first instance, you will receive a 5-minute phone call from the research team at an agreed time to check your initial eligibility for the study. During this conversation, the researcher will discuss the exclusion criteria with you and assess whether you are eligible to attend for a full screening appointment. The researcher will also gather menstrual cycle information from you during this phone call as you will need to attend the screening visit the week before the start of your period.

You will then need to attend the laboratory on two separate occasions.

Appointment 1: Screening/Training (approx. 3 hours)

The first appointment is a screening and training visit, during which you will be asked to give your informed consent to participate. Once you have completed the consent form you will be asked to provide demographic (DOB, ethnicity, etc.) and health data (including measurement of blood pressure and height and weight) to confirm your eligibility. You will be asked to complete questionnaires based upon caffeine consumption, food frequency, and your exercise regime. You will also complete a menstrual cycle questionnaire as you will be required to attend the laboratory for your testing visit between days 7-14 of your cycle.

A finger-prick blood sample and a venous blood sample will then be taken, which will be analysed to determine your iron status.

You will then be trained on a selection of computerised mental performance and mood tasks. Appointment 1 will last approximately 3 hours and will take place at an agreed time.

Instructions for Appointment 1: There are no dietary or medication restrictions for this appointment. Please bring with you any details of medications (inc. contraception) that you are

currently taking so we can document details about them (name, dosage etc.). NOTE: You are encouraged to check with the research team that these do not exclude you from the study prior to attending this appointment.

Appointment 2: Testing (approx. 1 hour)

This appointment will take place between days 7-14 of your menstrual cycle at an agreed time in the morning. You will arrive at the laboratory having not consumed any food or drink other than water for 12 hours prior. Upon arrival at the lab, the research team will check that you still comply with inclusion/exclusion criteria and that you are in good health and are well-rested. Changes to medication and/or illness between appointments will be reviewed if applicable.

You will then complete the computerised assessments of mood and cognitive function.

Instructions for Appointment 2: You must fast for the 12 hours prior to Appointment 2. You should refrain from alcohol for 24 hours prior to this visit. Oral antihistamines should not be used within 48 hours of a visit. Non-prescription medications (e.g. paracetamol, ibuprofen etc.) and local (spray) antihistamines should not be used within 24 hours of your appointment. You should reschedule the visit if you are feeling unwell or require medication. If unsure, please contact the researcher.

Will my participation involve any physical discomfort?

Venous blood samples may cause you some minor physical discomfort and possibly minor bruising. These samples are taken using standard techniques with minimal discomfort and will only be carried out by trained phlebotomists. You are advised to avoid heavy lifting or strenuous exercise after taking part to minimise bruising.

You will be required to remain seated at a desk for the duration of the cognitive and mood assessments. Prolonged computer testing may cause some minor discomfort and you may feel tired at times. It is therefore important that the correct eyewear is brought along to the testing session and that you inform the researcher of any back/arm/wrist problems you may have. If at any point during the testing session you wish to discontinue, please inform the investigator and your session can be re-scheduled, if desired.

Will my participation involve any psychological discomfort or embarrassment?

Completion of the mood measures may cause some discomfort or embarrassment. However, this is likely to be minimal and you are free to leave any questions that you do not wish to answer blank.

You may find some of the cognitive tasks difficult to complete which you may find embarrassing or stressful. You will be given thorough training on how to complete each task and opportunity to practice these tasks until you are able to perform well on each one. You are, however, free to withdraw from the study at any point.

Will I have to provide any bodily samples (i.e. blood, saliva)?

Yes you will be required to give a finger prick blood sample and a venous blood sample at Appointment 2. Should the blood tests reveal that you are iron deficient anaemic following the study, the researcher will recommend to you that you seek further medical advice from your GP. Do bear in mind though that a single test may not always provide an accurate reflection of your health status.

How will confidentiality be assured?

You will be assigned a number that will be used for identification purposes throughout the study. Only the research team will have access to any identifiable information; paper records will be stored in a locked filing cabinet and electronic information will be stored on a password-protected computer. Any

personal details will be kept separate from data and will be treated in accordance with the Data Protection Act.

Who will have access to the information that I provide?

The principal investigator (Hannah Avery) and their research team will have access to the information that you provide. Should the research be presented or published in any form, then that information will be generalized and your personal information or data will not be identifiable.

How will my information be stored / used in the future?

The data collected in this study will be used for a Postgraduate Psychology Thesis. It is intended that the results of the study will eventually be published in a peer-reviewed journal and may also be presented at conferences. After the final report has been completed, all study related materials will be archived in accordance with the Good Clinical Practice guidelines, for a minimum of 15 years. At no time will you or your data be personally identifiable.

Has this investigation received appropriate ethical clearance?

Yes, this study has received ethical approval from the Northumbria University Faculty of Health and Life Sciences Ethics committee. If you require confirmation of this, please contact the Chair of this Committee, stating the title of the research project and the name of the principal investigator:

Chair of Faculty of Health and Life Sciences Ethics Committee,

Northumberland Building,

Northumbria University,

Newcastle upon Tyne,

NE1 8ST

Will I receive any financial rewards / travel expenses for taking part?

You will receive £30 to cover your out of pocket expenses and potential loss of earnings. You will be paid by BACS transfer into your bank account; therefore, you will not receive your payment until after you have completed the study. We apologise for any inconvenience this may cause. Payment may take up to four weeks to reach your account.

How can I withdraw from the project?

You are free to withdraw from the study at any time. If you choose to withdraw from the study, the investigators will attempt to follow-up with you, check how you are feeling and request your reason for withdrawing, however you do not have to disclose this reason. The investigator also has the right to terminate your participation in the study. Your right to withdraw at any time is not affected by the receipt or offer of any financial compensation or other inducements for participation. If you wish to withdraw, simply contact one of the researchers or the principal investigator.

If I require further information who should I contact and how?

If you need more information, would like to discuss your participation, or experience any problems as a consequence of taking part in the study you should contact Hannah Avery (hannah.l.avery@northumbria.ac.uk) or alternatively, a member of the research team on **0191 243 7252** (Office hours).