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Participant Information Sheet – Medical (Extended)

Project Title: The MENOCOG Trial:

Feasibility, acceptability, and safety of creatine monohydrate supplementation for cognitive function and mood in postmenopausal women with dementia risk: a randomised, double-blind, placebo-controlled, parallel-group feasibility trial.

Project Summary:

Do you feel like your memory and thinking has been getting worse over the past 6 months? If so, you are invited to take part in a research study that aims to find out whether creatine supplementation can improve memory and mood in postmenopausal women with dementia risk.

The study is being conducted at the NICM Health Research Institute, Western Sydney University by Lauren Dewsbury (PhD candidate), under the supervision of Associate Professor Genevieve Steiner-Lim and Associate Professor Mike Armour.

Over 60% of people with Alzheimer's disease worldwide are postmenopausal women. It is quite common for women to feel that their memory and thinking is getting worse during the menopause transition. This is called subjective cognitive decline. Research shows that experiencing subjective cognitive decline can increase the risk of developing mild cognitive impairment (MCI) and Alzheimer's Disease later in life in susceptible people.

Creatine can help to support cellular energy production which is important for brain health. For this reason, we want to test whether creatine can improve cognition and mood in women with subjective cognitive decline and other factors related to increased dementia risk.

The MENOCOG Trial will test whether creatine supplementation is feasible, acceptable, and safe for use by women with subjective cognitive decline in a 12-week randomised, double-blind, placebo-controlled, parallel group trial.

How is the study being paid for?

This study is being funded by the Dementia Centre for Research Collaboration and NICM Health Research Institute at Western Sydney University.

What will I be asked to do?

This study is a decentralised clinical trial meaning all the screening and tests will be conducted online. You will be asked to complete an online pre-screening survey to find out whether you are eligible to take part. If you meet all the pre-screening requirements, you will be invited to a telephone screening call to confirm your eligibility with a member of our research team. If eligible, you will be invited to enrol into the trial. Once you are enrolled, you will be randomly allocated to the group that receives the creatine supplement or the group that receives the placebo treatment. The study will be double blinded

which means that neither you or the research team will know which group you are in until the trial has finished.

The people in the creatine group will take a sachet containing a powdered creatine supplement (5 g) mixed into liquid with food two times daily for 12 weeks, each morning and evening.

Once you are enrolled in the trial you will complete online assessments every month for 3 months (4 testing sessions in total) and speak with someone from the research team on the phone to monitor your safety. When the trial is finished, you will be invited to a brief telephone call to talk about your experience in the trial. A follow up testing session and phone called will be conducted 4 weeks after the trial ends (Week 16).

The online assessments will involve a cognition test, and survey questions about your sleep quality, mood, and daily functioning. You will be asked to have your blood tested at your local pathology collection centre (we will help you locate your closest centre).

You will be invited to provide a saliva sample using a home collection kit that we will analyse to test for the presence of a certain gene called *Apolipoprotein ε4* that is involved in dementia risk. We are collecting this information so we can see how having this gene might impact the response to the treatment being tested. This is optional and you can choose whether you would like to provide this sample or not. Once you are enrolled in the trial, a sample kit will be mailed to you, along with a return postage sachet for you to return your sample to us. Samples will be sent overseas for analysis, however, all samples will be deidentified to protect your privacy and confidentiality.

During DNA analysis, we could discover information that may impact your future health. If such information is discovered, you can elect for us to contact you about this so you can receive more information. The research team would then provide you with details of the Human Genetics Society of Australia so you can locate a clinical geneticist in your state that can go through this information with you. If you choose to receive the information, the results of the research would be passed directly to the clinical geneticist. In order to confirm the information, the clinical geneticist will need to collect a fresh sample of DNA and send it to a diagnostic laboratory for confirmation of the result. The clinical geneticist would also refer you to a genetic counsellor prior to the participant receiving the information.

How much of my time will I need to give?

Screening will be conducted remotely (online and via telephone) and will take around 45 minutes. If you are enrolled in the trial, your monthly online assessments will take no longer than 60 minutes to complete. There will also be a brief monthly telephone call from the research team (approximately 10 minutes) to check in with you and see how you are going.

The total interactions with the research team over the trial will be around 1.5 hours and total time required for your participation (including online assessments) to be approximately 5 hours over the course of the 16 weeks.

What benefits will I, and/or the broader community, receive for participating?

- To thank you for your time, you will receive a $30 gift card per assessment completed (up to $150 for the study across the 5 assessments).
- If you are in the creatine supplement group, you may experience improvements in memory, mood and cognition from the study intervention.
- This research may provide early evidence to support the use of creatine supplementation to support memory, mood and thinking in postmenopausal women with subjective cognitive decline.
- We are happy to send the results of your assessments and cognitive tests to your GP if you would like.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

We don't expect that taking part in this project will cause you any harm. There are some risks associated with the study and we have done all we can to minimise any potential discomfort you might experience.

Some risks with taking part in the study include:

a) You may experience some mild side effects like stomach upset, nausea or water retention when taking a creatine supplement.
b) You may receive test results that are negative or distressing to you (for example, regarding your memory during cognitive tests). If this happens, we will support you with resources to contact Lifeline for free on 13 11 14. We may also encourage you to seek assistance that day from your general practitioner. If you are experiencing challenges related to your memory and thinking, we will encourage you to contact the National Dementia Helpline on 1800 100 500. Webchat options are available at dementia.org.au/helpline/webchat; as well as email options at helpline@dementia.org.au.
c) There is a chance that we could find the presence of severe mental distress or signs of a mental health disorder during pre-screening. If this happens, we will refer you to your general practitioner for further support regarding a mental health care plan and provide you with some resources and helpful links via email.
d) You may feel some discomfort during the blood sample collection. We can assure you that your blood will be collected by a suitably qualified venepuncturist at their preferred local pathology collection centre.
e) You may feel unsure about the intended use of your blood and DNA collection. We can assure you that your samples will be protected, and analysis in this and future studies, will be targeted to research study hypotheses. Please note the collection of your DNA is optional.

The research team will give you a call monthly to check in and see how you are feeling throughout the trial. Any adverse events should be reported directly to the research team as they occur and will be managed by the study doctor.

How do you intend to publish or disseminate the results?

Your information will be protected and stored confidentially. Only the research team will have access to your information and the results from your assessments. The data that we collect during the study will be deidentified and connected to a unique code. This means we won't know who the data belongs to, and there will no identifiable information used to ensure that your privacy and confidentiality is maintained. Please note that some of the data that is collected during your baseline testing session may be used in future studies.

The results of the study will be written into a thesis, published in scientific journals, and/or discussed/ displayed in conference presentations. A plain-language summary of the study findings will be shared with you and with the wider community through channels like social media. In any case, only group information and trends will be presented. No reference will ever be made to individual results, or individual participants.

Will the data and information that I have provided be disposed of?

Please be assured that only the researchers will have access to your information and test results. However, sometimes additional studies or analyses may be carried out and your deidentified data may be used in other related projects for an extended period. Future related projects may include follow-up projects to the current study, that may have a larger sample size or different doses of the study drug, for example. Please note that the minimum retention period for data collected during clinical trials is 15 years for adults following completion of the trial. We intend to keep a copy of the deidentified dataset indefinitely for future research purposes.

Can I withdraw from the study?

Taking part in the study is entirely voluntary and you are not obliged to be involved. If you do decide to participate, you can withdraw at any time without giving a reason. Whatever your decision, it will not affect your relationship with the medical and research team. The information gained during the study may be published and stored for research use but no information about you will be used in any way that reveals your identity. If you choose to discontinue, any information, such as your test results, will be retained to ensure the results of the research project can be measured and analysed properly.

It is important that you communicate this decision to withdraw to Lauren Dewsbury on 0422 774 769 or via email, menocog@westernsydney.edu.au. If you withdraw from the study, the research team will not collect any additional information from you.

Can I tell other people about the study?

Yes! You can tell other people about the study by providing them with the research team's contact details or sharing the link to the study web page. They can contact us directly to discuss their participation in the research project and obtain an information sheet.

What if I require further information?

Please contact a member of our investigator team should you wish to discuss the research further before deciding whether or not to participate.

For all enquiries, please contact:

Ms Lauren Dewsbury; Phone: 0422 774 769; Email: menocog@westernsydney.edu.au

Privacy Notice:

Western Sydney University staff and students conduct research that may require the collection of personal and/or health information from research participants.

The University's Privacy Policy and Privacy Management Plan set out how the University collects, holds, uses and discloses personal or health information. Further details about the use and disclosure of this information can be found on the Privacy at Western Sydney webpage.

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee The Approval number is H16573.

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Explanation of Consent

What will happen with my information if I agree to it being used in projects other than this one?
Thank you for considering being a participant in a university research project. The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.

This request is in line with current University and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.

You have been asked to agree to extended consent.

Extended consent: When you agree to extended consent it means that you agree that your data, as part of a larger dataset (the information collected for this project) can be re-used in projects that are

- an extension of this project
- closely related to this project
- in the same general area of this research.

While the outcome of this research may inform future research projects, the actual data collected will not be utilized in future projects.

To enable this, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available will have information in it that makes you identifiable. The re-use of the data will only be allowed after an ethics committee has agreed that the new use of the data meets the requirements of ethics review.

The researchers want to keep the data for fifteen years for possible re-use. After this time the data will be securely destroyed.

You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the National Statement on Ethical Conduct in Human Research – see Sections 2.2.14 - 2.2.18.

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

NICM Health Research Institute
Western Sydney University
Locked Bag 1797
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Australia

Ms Lauren Dewsbury
Telephone: 0422 774 769
Email: menocog@westernsydney.edu.au

Consent Form – Medical (Extended)

This consent form is not project specific. Participants baseline data may be used in future studies.

Project Title: Feasibility, acceptability, and safety of creatine monohydrate supplementation for cognitive function and mood in postmenopausal women with dementia risk: a randomised, double-blind, placebo-controlled, parallel-group feasibility trial.

This study has been approved by the Human Research Ethics Committee at Western Sydney University. The ethics reference number is: H16573.

I hereby consent to participate in the above-named research project.

I acknowledge that:

I have read the Participant Information Sheet (or where appropriate, have had it read to me) and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.

The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

I consent to participating in this 16-week trial. I understand that screening will be conducted remotely (via phone or zoom) and is expected to take up to an hour. I understand that monthly online assessments will take 60 minutes to complete each month and there will also be a brief monthly telephone call from the research team (approximately 15 minutes). I understand that I will receive a text message and surveys to complete around each appointment.

I understand that the screening interview will involve a member of the research team asking me a series of questions about my general health (including my mental and cognitive health), and that I will be asked to complete a brief cognitive test and a brief depression test.

I understand that I will need to undergo blood tests at two timepoints and provide a saliva sample at the beginning of the trial. I understand that my de-identified biological samples may be sent overseas for analysis by a third party.

☐ I consent to providing a saliva sample for my DNA analysis

☐ Please share information with me or my nominated healthcare provider that is relevant to my current or future health

I understand that if I am eligible to be enrolled in this study that I will be randomly allocated to either the active treatment or the placebo group. I understand that this allocation is unknown (blinded) to both myself and the research team. I understand that after my involvement in this study that I will not have continued access to the study intervention.

I understand that my involvement is confidential, and that the information gained during the study may be published and stored for other research use but no information about me will be used in any way that reveals my identity but will only be used after additional ethical review.

I understand that I can withdraw from the study by contacting a study investigator at any time, without affecting my relationship with the researcher/s now or in the future.

I consent for my data, including biological samples and information provided to be used in this project and other related projects for an extended period of time as detailed in the participant information sheet.

Signed:	
Name:	
Date:	

Return Address:

Ms Lauren Dewsbury, Western Sydney University, Locked Bag 1797, Penrith NSW 2751

Or digitally to menocog@westernsydney.edu.au

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