Re:Cognition Health Brain and Mind Experts

45 Queen Anne Street, London, W1G 9JF
clinicaltrials@re-cognitionhealth.com
re-cognitionhealth.com
+44(0)20 3355 3536 (tel.)
+44(0)20 3432 7378 (fax)

MAIN PARTICIPANT INFORMATION SHEET

Short Trial Name:	Clinical trial of MK-1942 for mild to moderate Alzheimer's Disease dementia
Full Trial Name:	A Phase 2a/2b Randomized, Placebo-Controlled Clinical Study to Evaluate the Safety and Efficacy of MK-1942 as Adjunctive Therapy in Participants with Mild to Moderate Alzheimer's Disease Dementia
Protocol Number:	MK-1942-008
EudraCT Number:	2021-006336-94
IRAS Number:	1006261

We are inviting you to take part in a clinical trial

- We would like to invite you to take part in a clinical trial with the drug MK-1942. This trial is for people who have mild to moderate Alzheimer's disease dementia.
- Taking part in this trial is voluntary. It is up to you to decide whether or not to take part. You can discuss it with friends, relatives and your GP if you wish.
- You do not need to take part in this trial to be treated for your Alzheimer's disease dementia.
- You can stop taking part in the trial at any time without giving a reason, by telling your trial doctor your decision.
- Take your time and read this document carefully. If this information sheet contains words that you do not understand, please ask your trial doctor or trial staff and they will help explain what is meant.
- Thank you for reading this information sheet. If you decide to take part, we will ask you to sign a consent form to give your permission after you understand all of the information. You will be given this information sheet and consent form to keep.

How to contact us

If you have any questions about this trial, please contact your trial doctor at:

Dr. Emer MacSweeney
Re:Cognition Health
45 Queen Anne Street, London,
W1G 9JF
Tel: 020 3355 3536
clinicaltrials@re-cognitionhealth.com

Important things that you need to know

- If you take part in this trial, you will visit the trial doctor about 9 times over 6 months. These will be in addition to any usual visits that you make to your own doctor. Most visits will last between 1 and 7 hours.
- There is a 1 in 2 chance of getting placebo. A placebo or "dummy" treatment looks like a trial drug, but it has no active ingredients.
- Your GP will be informed if you take part in this trial. This is so they know which other medicines they may give you safely.
- This research has been looked at and approved by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This trial has been reviewed and approved by Scotland A REC.

Contents

1 What is a clinical trial?

A clinical trial is a type of research study designed to learn more about how our bodies respond to drugs or other treatments.

Most new treatments must be tested in clinical trials before they can be approved by health authorities. These health authorities want to be sure that the new treatments are safe and that they work. If a new treatment has not been approved by health authorities, it is known as experimental.

Researchers look at the results of many clinical trials to understand which drugs work and how they work. It takes lots of people in many trials all around the world to advance medical science.

2 Who is sponsoring this trial?

This trial is being sponsored by the pharmaceutical company Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, New Jersey, USA ("MSD"). Re-Cognition Health will be paid by MSD for the costs associated with running this trial.

3 Why is this trial being done?

This trial is testing MK-1942 in people with mild to moderate Alzheimer's disease dementia.

MK-1942 is experimental. It has not been approved for treatment of Alzheimer's disease dementia.

This trial will compare MK-1942 to placebo. A placebo looks like a trial drug, but it has no active ingredients.

This trial is being done to:

- Test the safety of different doses of MK-1942.
- See how well different doses of MK-1942 work, compared to placebo.

4 Who can be in this trial?

You can be in this trial if you have mild to moderate Alzheimer's disease dementia.

There may be reasons why you cannot be in this trial. The trial doctor or staff will discuss these reasons with you.

About 408 participants will take part in the trial from approximately 11 countries.

5 What drug will I get?

Sometimes we don't know what the best way is to treat participants. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see which one is better. To try to make sure the groups are the same to start with, each participant is put into a group by chance (randomly).

The drug you get will depend on which group you are placed in. This trial has 3 groups:

- **Group 1:** will get a lower dose of MK-1942 (5 mg per dose).
- **Group 2:** will get a higher dose of MK-1942 (8 mg per dose for 1 week and then 15 mg per dose).
- **Group 3:** will get placebo.

A computer will decide which group you are put in. You have an equal chance of being placed into each group. You have a 1 in 2 chance of getting placebo only.

You, your trial doctor, and the trial staff won't know what drug you are getting. In case of a health emergency, they can find out. This is called 'blinding'. Blinding is important to make sure the trial results are valid.

MK-1942 and the placebo are capsules. Participants in all groups will take the capsules twice each day (in the morning and evening).

6 How long will I be in the trial?

You could be in the trial for about 6 months and will visit the trial site about 9 times.

- **Screening:** First, the trial staff will see if you can be in the trial. This is called the screening phase and will last about 12 weeks. During this time, you will visit the site one or more times.
- **Treatment:** If you can be in the trial, the next step is the treatment phase. You will be in the treatment phase about 12 weeks and will visit the trial site about 7 times.
- **Follow-up:** After you stop getting the trial drug, you will enter the follow-up phase. You will be in the follow-up phase about 2 weeks and will visit the trial site once.

The trial doctor or staff may also contact you between visits to check on your health and ask about any side effects you may have.

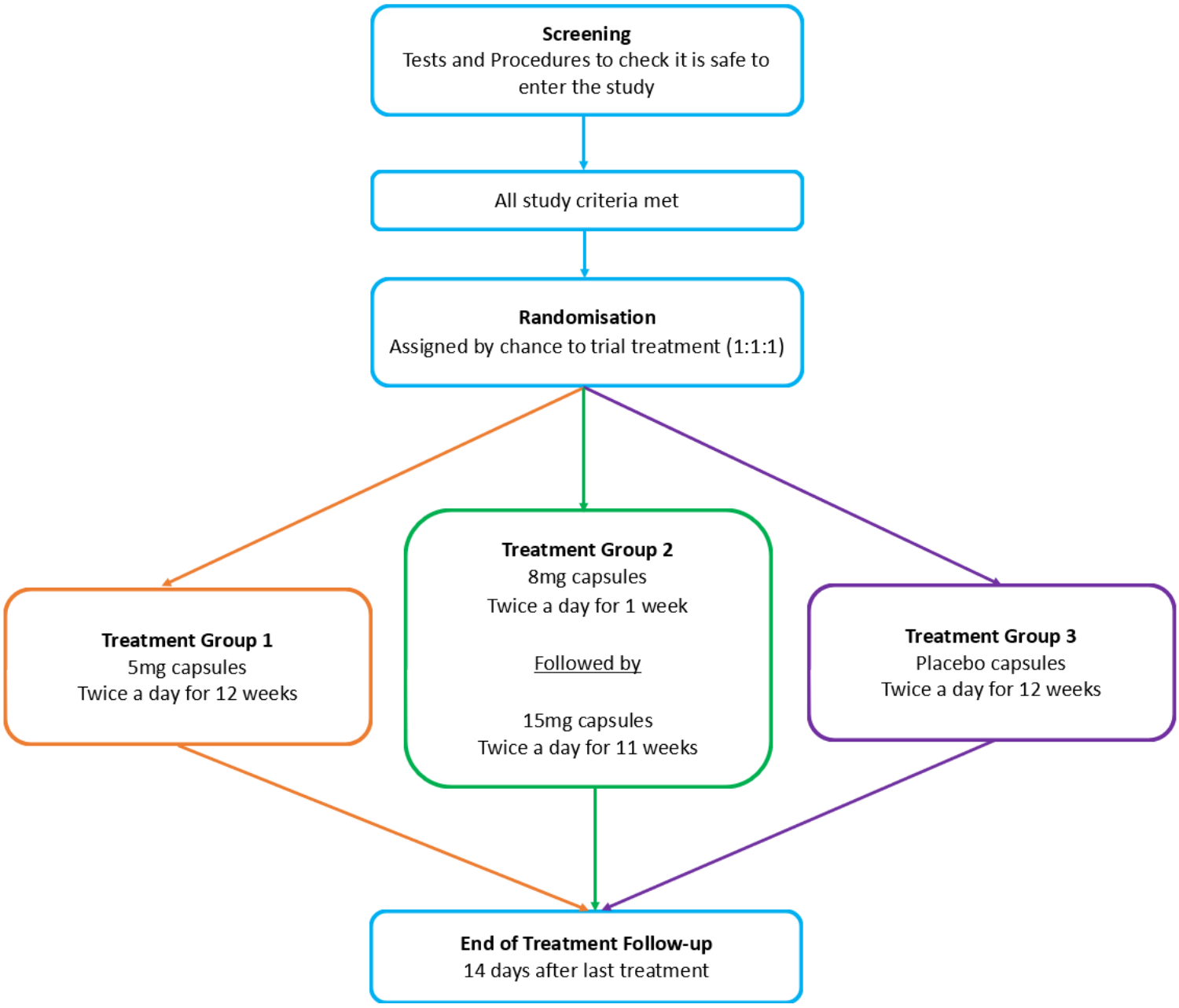
If you have a side effect that might be caused by the trial drug, the trial doctor may ask you to have additional trial visits until the side effect is resolved. This is to ensure safety. The additional visits may mean that you will stay in the trial longer.

7 What happens at trial visits?

You will be given a card that identifies you as a participant taking part in this trial. You should carry it with you at all times. This card contains important information about the trial.

The diagram below shows the design of the trial:

Trial Design:

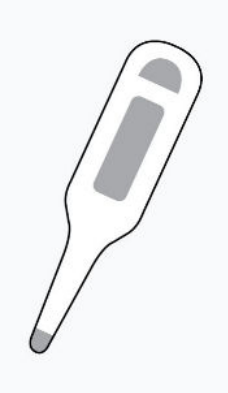


Screening Visit

If you decide to participate in this trial, you will be invited to come to a screening visit. During this visit your trial doctor will check if it is safe, and if it is possible for you to take part in this trial. It is possible that the results from the screening visit will require that you come back to the trial site for more visits to confirm that you can take part.

Below is a summary of what will be performed for this visit:

- Discuss your medical history and how you are feeling.
- Discuss the medications you have taken before the trial and your current medications.
- Answer questions about your race and ethnicity.
- Answer questions about whether you have had suicidal thoughts and behaviours:
  - These are standard questions for Alzheimer's disease dementia clinical trials.
- Answer questions or make drawings that help test how well you think, reason, remember, and make judgments:
  - Some of these question and answer sessions may be audio recorded. You will be told whenever you are being recorded.
  - The audio recordings will be reviewed by experts at a third-party vendor outside of the trial site. These experts are not judging you or your answers. They are reviewing how the trial team performs the tests.
  - The recordings will be "encrypted" – a technical process that prevents anyone from listening unless they are authorised. The encrypted audio is saved on secure servers that are password protected. The Sponsor will not have access to the recordings.
  - The recordings will be destroyed after they are no longer needed for the trial. The maximum storage period is estimated to be about 25 years.
- Have a scan of your brain using an MRI or allow the trial team to have a copy of a recent MRI that was done as part of your medical care outside the trial. If an MRI is not possible, this may be a CT scan.
- Perform a physical exam.
- Perform a neurological examination.
- Check your vital signs (blood pressure, heart rate, temperature, breathing rate, height and weight).
- Have an exam of your heart function, called an electrocardiogram (ECG).
- Collect blood (approximately 2 teaspoon/8.5mls) and urine samples:
  - For safety tests

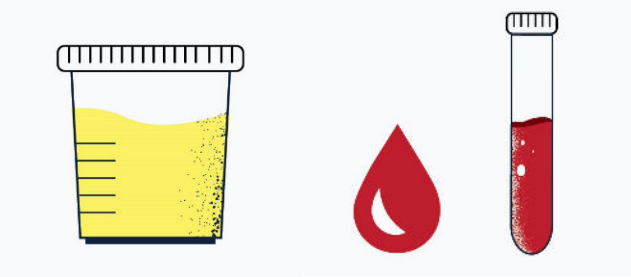


Treatment Visits

If you are able to take part, you will be invited back to see your doctor who will re-check that you are still able and willing to take part in the trial. You will then be placed in a treatment group. When you return for your trial visits, your trial doctor or staff may do any or all of the following to measure if the trial drug is working and/or to monitor your health.

Below is a summary of what will be performed during the treatment visits:

- Review the medications you have taken and your current medications.
- The trial doctor and staff will give you the trial drug or placebo and watch you take it.
- The trial doctor and staff will give you a supply of capsules and inform you how to take them daily.
    - Once you start taking the trial capsules daily, when you visit the site, the trial team will review any remaining capsules and packaging to be sure you are taking the trial capsules correctly.
- Answer questions about whether you have had suicidal thoughts and behaviour.
- Answer questions or make drawings that help test how well you think, reason, remember, and make judgments:
    - Some of these question and answer sessions may be audio recorded. You will be told whenever you are being recorded.
- Review your medical history since your last visit.
- Perform a physical examination.
- Check your vital signs (including blood pressure, heart rate, temperature, breathing rate) at every visit.
- Check your weight.
- Have an exam of your heart function, called an electrocardiogram (ECG).
- Collect blood (approximately 1-10 teaspoons/5 - 49.5mls) and urine samples:
    - For safety tests
    - For genetic and biomarker analysis



Follow-up Visit

After you stop taking the trial drug, you will visit the trial site about 2 weeks later for a follow-up visit.

Below is a summary of what will be performed during the follow-up visit:

- Review the medications you have taken and your current medications.
- Review your medical history since your last visit.
- Collect blood (approximately 1 teaspoon/5mls)
    - For safety tests
- Answer questions about whether you have had suicidal thoughts and behaviour.
- Answer questions that help test how well you think, reason, remember, and make judgments:
    - Some of these question and answer sessions may be audio recorded. You will be told whenever you are being recorded.

Your trial partner

You will also agree to have someone be your partner for this trial. This will be someone who knows you well. Your partner will sign a separate consent form.

Your partner will help with some trial activities, including:

- Come with you to trial visits.
- Help you to take the trial capsules correctly.
- Let the trial doctor and team know about side effects they think you may be having to the trial drug or placebo.
- Answer questions about:
    - Your current and past health, behaviour, and symptoms.
    - How well they think you are thinking, reasoning, remembering, and making judgments.
    - How well they think you are managing activities of daily life.
    - Their own general health, wellbeing, and quality of life.

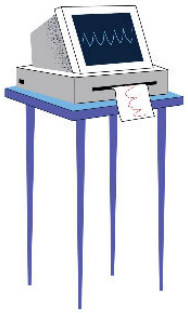
8 What if my blood test results are not normal?

If your blood test results are not normal, your doctor may ask you to have more tests to see if the trial drugs are affecting your liver. These tests include for HIV and hepatitis. You will be informed of these results. A positive viral Hepatitis result will be reported to the local health authority.

If you do not want to have these added tests, you may need to stop taking the trial drug for your own safety.

Some of your blood and urine sample will be collected by your trial doctor or delegate and labelled with your participant number, gender and year of birth in a way which will not identify you. The sample will be processed at the trial site and then shipped securely by courier to the UK, United States of America and Canada for testing, storage or distribution to other testing laboratories.

9 What can I expect during procedures and tests?



- **Blood samples:** drawing blood from your arm may cause pain, bruising, dizziness, and rarely, infection.
- **Electrocardiogram (ECG):** This may cause minimal discomforts during the attachment and removal of the ECG stickers to and from the skin.
- **Fasting:** The risks include dizziness, headaches, stomach discomfort, or fainting.

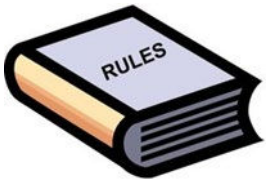
Imaging and Radiation Risks

- **Computed Tomography (CT) Scan**: You may be required to have a CT scan of your brain at screening if you cannot undergo an MRI scan. The scan would be considered additional to your standard care. The dose from each CT scan of your brain is about the same as you would receive from one year's natural background radiation in the UK. The ionising radiation from the CT scan may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study may increase the chances of this happening to you to about 50.01%, an increase of 0.01%, and in some cases much less. You may find the CT scanner mildly claustrophobic.
- **Magnetic Resonance Imaging (MRI):** Participants may be asked to have an MRI scan. Unlike CT it uses radiowaves and magnetic fields instead of X-rays. For most participants, the risks or side effects associated with undergoing MRI are minimal. However, because the MRI scanner uses strong magnets, you cannot have any metal implants in your body to have an MRI scan. You will be asked questions to make sure you can safely have an MRI scan. There may be some anxiety and claustrophobia associated with the MRI scanner and you will be asked to lie still for around 30 minutes during each scan. As part of the MRI scan, a contrast agent is injected into your vein. The risks associated with the contrast agent include mild nausea, headache, hives and temporary low blood pressure, although such reactions are very rare. Prior to trial entry, your trial doctor will run tests to determine if your kidneys are working properly to make sure the contrast agent is safe for you. As images are taken, a loud banging noise will be produced. Earplugs or headphones will be available if needed.

10 Will genetic and biomarker testing be used on my samples?

- Yes, your samples will be used for genetic and other biomarker testing. Your blood samples contain genes (which are made up of DNA or deoxyribonucleic acid), RNA (ribonucleic acid) and other biomarkers such as proteins. DNA chains are the building blocks for the cells in your body. RNA is involved in the building process. Other biomarkers can help tell us what is going on in your body. This research can help in discovering ways that the trial drugs work, how your body responds to or resists them and how they affect your disease. We will look at differences in your DNA, RNA and other biomarkers together with other information collected in this trial.
- Yes, your samples will be used to study the link between CYP2C19 and APOE4 and response to the drugs and your disease. CYP2C19 is the code for a gene that determines how well your body manages to clear drugs you are taking from the system. APOE4 is a type of a gene called APOE that is linked to a higher risk of developing Alzheimer's disease. It may also be the case that drugs work better or may be less likely to cause side effects depending on whether or not you carry the APOE4 gene variant. Your DNA will be taken from your sample, to find out your CYP2C19 and APOE4 status.
- This research may include whole exome or whole genome sequencing. Whole exome sequencing looks at only the coding sections of your DNA, and whole genome sequencing looks at your whole genome or all of your DNA, which contains your complete set of genes. These results are for research only.
- Your genetic and biomarker samples will be kept for up to 15 years. This allows the Sponsor to fully study biomarkers and answer questions from health authorities about the way the drugs work in this trial. Your samples may be sent to locations outside the UK for testing and/or storage.
- You will also be asked to take part in optional future biomedical research. You will be given a separate form that will describe this research. If you agree to participate, your samples will be kept for up to 20 years.

11 What do I need to do during the trial?



Any medication used during the trial, including over the counter products, must be discussed with the trial doctor prior to use.

You must tell the trial staff if you have to take any other medication during your participation in the trial and inform them straight away of any changes in your health.

When you are not visiting the trial site, you will need to:

- Take the trial drug by following the directions:
    - One capsule twice each day (in the morning and evening)
- Keep the trial drug out of reach of children.
- Bring the remaining capsules and packaging to all trial visits.
- Be willing to speak to the trial doctor or staff as needed.
- Not eat or drink 1 hour before and 1 hour after you take the trial drug. This is called fasting. The trial doctor and staff will give you instructions.
- Not eat grapefruit or drink grapefruit juice when you are in the trial.
- Not drink alcohol for 24 hours before a trial visit.
- Not drive or operate heavy machinery when you are on the trial drug, unless the trial doctor confirms that it is not making you dizzy.

12 What do I need to know about the trial drug and side effects?

You may get some of the side effects, but you are unlikely to get all of them.

For MK-1942:

What is known about this trial drug?

MK-1942 is being developed by the Sponsor to treat Alzheimer's disease and depression. Single doses of MK-1942 up to 12 mg and multiple doses up to 50 mg twice daily have been given to 116 healthy men and women. In addition, MK-1942 or placebo has been given to 27 people with Alzheimer's disease and 4 people with depression. Placebo is a capsule or solution that looks the same as MK-1942, but has no active ingredient.

What side effects could the trial drug cause?

The following side effects were seen more than once in people who were given MK 1942:

- Dizziness
- Feeling tired
- Headache
- Fast and deep breathing
- Common cold
- Sore throat
- Stuffy nose
- Nausea
- Vomiting
- Diarrhoea

- Constipation
- Blood in the urine
- Stomach pain
- Hot flush
- Sweating more than usual
- Abnormal dreams
- Fuzzy thinking
- Disturbance in attention
- Eyesight problems including tunnel vision, blurriness, abnormal staring, and delayed vision
- Ringing in the ears
- Muscle twitching
- Difficulty balancing
- Walking abnormalities
- Abnormal measures of liver function

All the side effects were mild to moderate in intensity. Participants who experience dizziness should avoid driving and using heavy machinery.

MK-1942 was tested in laboratory animals as required before testing in people. Animal studies do not always predict what will happen when MK 1942 is given to people.

The following side effects were seen in at least 1 of the types of animal studies that were conducted with MK-1942:

- Vomiting
- Loose stool
- Decreased weight gain/body weight
- Decreased food intake
- Decreased activity
- Sleepiness
- Changes in the liver
- Changes in the testes (male sex glands)
- Changes in the stomach
- Decreased weight of an organ that helps control the immune system
- Changes in blood pressure
- Increased breathing rate
- Decreased body temperature
- Changes in the electrical activity of the heart
- Changes in the amounts of sugar, salts, fats, and proteins in the blood
- Increase in the amount of fluoride, a mineral that strengthens teeth and bones, in the urine
- Malformation of the foetus skeletons
- Malformation of the foetus organs
- Decrease in foetal body weights
- Weight loss and decreased body weight gain in pregnancy
- Changes in the amount of stool during pregnancy
- Decrease in food consumption during pregnancy

These side effects in animals were seen when MK-1942 was given at amounts that are higher than the amount of drug that is expected to be in your body.

With any drug, there is the potential for an allergic reaction. The most commonly reported symptoms associated with allergic reactions are:

- Rash
- Hives
- Itching
- Dizziness
- Fainting

- Nausea
- Facial flushing
- Fever
- Muscle aches
- Chest tightness
- Shortness of breath/difficulty breathing
- Cough

Rarely, a more severe allergic reaction may occur and may result in death. Additional symptoms may include:

- Swelling of the face, lips, throat, and tongue
- Low blood pressure
- Loss of consciousness

For Placebo: Placebo looks like a trial drug but it has no active ingredients that are known to cause side effects.

You should tell your doctor if you suffer these or any other symptoms.

Are there any other side effects?

Yes, there are other side effects that have been reported. You can ask your trial doctor or staff about these.

There may be other side-effects or risks that are not yet known.

If you become concerned while taking part in the trial you should contact your trial doctor on the number listed at the beginning of this form.

13 Are there any risks to pregnancy?

There may be pregnancy risks. No one knows if the trial drug may affect an unborn or a nursing baby. If you are pregnant, trying to become pregnant or breast-feeding, you cannot be in the trial.

For women:
You cannot be in this trial if you are able to have a baby.

For men:
If your partner is pregnant, breast-feeding, or able to have a baby, you must use acceptable birth control, or you must not participate in sexual activities that could cause her to get pregnant.

14 What are the possible benefits of taking part?

If the drug works and if your Alzheimer's disease dementia gets better, you may receive a health benefit (this means it may help you). If the drug does not work, or if you get the placebo, you may not receive a health benefit.

Information learned from the trial may help other people in the future.

15 What if relevant new information becomes available?

The trial doctor or staff will let you know in a timely manner if new important information might affect your choice to be in the trial. Examples of new information may include information about the trial drug and side effects, or a new treatment that may become an option during the trial.

16 What happens if I am injured in the trial?

If you experience an injury, you should contact the trial doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

For any injury sustained while on the trial, compensation will be in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). A copy is available to you on request.

Compensation will be considered where the injury resulted from:

- A drug being tested or administered as part of the trial protocol;
- Any test or procedure you received as part of the trial.

Any payment would be without admission of liability. (Please ask if you wish to receive more information on this). The Sponsor would not be bound by these guidelines to pay compensation where the injury resulted from a drug or procedure outside the trial protocol or where the protocol wasn't followed.

17 Expenses and payments

All trial medication and trial-related tests will be provided at no cost to you. You and your trial partner will be paid stipend payments for trial site visits and telephone calls. Stipend payments are offered as recompense for your dedicated time, inconvenience during each visit and for successful completion of questionnaires.

You and your trial partner will get paid between £80 and £160 depending on what is performed at the trial visits. A stipend payment of £20 will be paid per follow-up phone call. The trial doctor or staff will discuss stipend payments with you.

You and your trial partner will be reimbursed for your transportation, parking, meals, or other reasonable expenses related to your participation in this trial.

If you withdraw from the trial early, you and your trial partner will be reimbursed for the expenses and stipend payments for the portion of the trial that you and your trial partner completed.

18 What are my options if I am not in the trial?

If you decide not to join the trial your doctor can discuss with you other treatments.

Other treatments for preventing or treating Alzheimer's disease dementia may include:

- Your current care.
- Other medications to treat your symptoms that are available in your country. Your trial doctor can discuss the specific options.
- Non-medication therapy, such as memory and cognitive training.
- Taking part in another clinical trial.
- Receiving no treatment at this time.

If you have questions about other treatments and their potential benefits and risks at any time, ask the trial doctor. You do not need to join this trial to be treated for your Alzheimer's disease dementia.

19 What if I want to stop taking the trial drug, stop the procedures, leave the trial or the trial stops?

You can choose to withdraw from the trial at any time without giving a reason, by telling your trial doctor that you would like to stop the trial drug, stop any trial procedures or leave the trial, so this can be done safely. You will not be penalised or lose any benefits that you had before starting the trial and your continued health care will not be affected.

You may be able to stay in the trial, even if you stop taking the trial drug, if you:

- Give the trial doctor and staff information,
- Agree to have trial visits or procedures or
- Let the trial doctor access your health records.

The trial doctor can discuss this with you and help you with your decision.

If you decide to stop taking the trial drug and decide not to continue, the trial doctor or staff will contact you and your GP about every 2 weeks or more often to check on your health.

If you no longer want to be contacted directly your trial doctor or staff will contact your GP to check how you are. You will also be asked if we can look at your medical records. If you decide that you do not want the trial doctor or staff to contact your GP or look at your medical records, the trial team will look at publicly available sources (e.g. internet searches).

If requested, any stored blood samples that can still be identified as yours will be destroyed. Please note that we may not be able to destroy samples immediately upon request if the sample is required to maintain the scientific integrity of the trial.

If you decide to leave the trial early, for any reason, any health information, samples, and trial data that has been collected before your request to leave will still be used for research and will not be deleted. Once you leave the trial, no further new samples will be collected for the trial. If you do not agree for follow-up information to

be collected, no further new health information and trial data will be collected.

Once your participation in the trial ends, you will not be provided with the trial drug.

What happens if I become unable to give informed consent?

At each trial visit the trial doctor will discuss with you whether you want to continue to participate in the trial.

It is your decision whether you want to continue to participate in the trial if you become unable to give informed consent yourself. You will need to document your decision in the trial consent form. Your trial doctor will discuss this with you.

Can I be taken out of the trial?

Yes, your trial doctor or the Sponsor may have to withdraw you from the trial. If this happens, the trial doctor or staff will tell you why. Some reasons could be:

- You may need other treatment;
- You may have health issues that require you to leave the trial.
- You are not able to follow the trial plan.
- The trial may be stopped.
- For any other reason. If this were to happen you will be told why and your continuing care will be arranged.

What happens if the trial doctor is not able to contact me?

If you remain in the trial, and the trial doctor is not able to reach you, or your medical doctor, the trial doctor or staff will search publicly available sources (e.g. internet searches) to find your updated contact information, to get back in contact with you, and/or to find information about your health status.

By law, your trial doctor is able to look at government General Register Office records to see if your name is listed on the register.

If you would like to take away your permission to any type of follow-up, you must do so by contacting the trial doctor or staff.

20 How will my privacy be protected? How will my information be used?

The trial doctor and staff will use your health information (including but not limited to ethnicity, medical history, month and year of birth), and information from your trial visits (trial data and samples) in this trial. This health information may come from your GP or others involved in your general care. Your GP will be informed of important information about your health.

The trial staff will share your health information with the following groups:

- Health authorities involved in the conduct of trials and the regulation of medicines, both in the United Kingdom and other countries and;
- The Sponsor and those working for, or with, the Sponsor; groups or individuals contracted by the Sponsor; and service providers such as vendors and laboratories
- Whenever the Sponsor is mentioned, this means those working for or with the Sponsor, which may include affiliates of the Sponsor located in the UK or other countries.

These groups may:

- Carry out visits to the trial site and view your medical records in order to check that information about the trial is correct;
- View your medical records remotely from outside of the trial site if required.

The same level of restriction and oversight will be in place regardless of where your medical records are viewed from. The trial site has a strict policy on access to your medical records. At no point will any of your medical records be stored outside of the trial site.

If you think that you have been harmed by being in the trial, your information may be given to the Sponsor's insurer to resolve your claim.

Your health information, samples and trial data will be key-coded (pseudonymised) using your month and year of birth to help protect your identity before it is sent to the Sponsor. The trial doctor will retain your personal identifiable information at the trial site. Only your coded information will be sent to the Sponsor.

You will not be identified by name in any publication or presentation about this trial.

The Sponsor may use your health information and trial data, in a way that will not identify you to:

- See if the trial drug works and is safe;
- Compare the trial drug to other drugs;
- Develop new tests related to the trial drug or disease/condition under trial;
- Make reports to health authorities related to the trial drug or tests developed related to the trial drug or disease/condition under trial.
- Allow outside researchers to use health data provided it does not identify you.
- Allow other research partners, vendors, or laboratories to use health data to develop new tests related to the trial drug or disease/condition under trial and include the data in reports to health authorities or publications.

The Sponsor may share your coded information with research partners and service providers that assist in the trial and analyse the results.

The trial data may also be shared with health authorities and ethics committees. The Sponsor will use your health information and trial data for scientific research use only (legitimate interests according to data privacy laws).

The Sponsor may transfer your coded health information and trial data, to other countries outside the UK (including to the United States of America (USA)) where privacy laws may offer less protection and rights to personal data. However, the Sponsor will ensure adequate safeguards are in place to protect your data and will abide by UK data privacy laws. Trial data will be sent to the Sponsor and other affiliates in the USA for central analysis. These transfers occur on the basis of the Sponsor's Binding Corporate Rules (the procedures that the Sponsor has put in place), which can be found on the Sponsor's website (https://www.msdprivacy.com/uk/en/cross-border-privacy-policy-rules.html).

There is always a risk that personal data can be compromised. The Sponsor has therefore put in place the required technical and organisational controls to protect your personal information and ensure compliance with the relevant data privacy legislation.

You have certain rights to your information. However, your rights to access, restrict, correct or delete your information for the purposes of research are controlled by law as we need to manage your information in specific ways in order for the research to be reliable and accurate.

The Sponsor may decide to transfer, licence, or sell this trial and other similar trials for the trial drug to another company. If this happens, the other company would take on the responsibilities that are described in this information sheet.

When the trial is finished, Re-Cognition Health is required to keep information relating to the trial for about 25 years. The health authority or Re-Cognition Health can require that that this period is longer, if necessary.

The Sponsor will act as data controller and will manage access to data that will not personally identify you.

Please contact the data protection officer at your trial site if you have any questions about the use of your information or would like to exercise your data protection rights. The Sponsor will not be able to identify you from the information held and therefore ask the trial site to respond to requests relating to a specific individuals' data.

You have the right to make a complaint with the Information Commissioner's Office (ICO).
Contact Details below:
https://ico.org.uk
Tel: 0303 123 1113

21 What will happen to the results of the research?

Information about you will be collected and analysed as part of this trial. The information will be collected and combined with information from other trial participants. The results will be published in the scientific press and may be submitted to health authorities in the UK and abroad to allow the medicine to be used by other doctors.

Results obtained from planned genetic and biomarker research will not be provided back to you, your GP or the trial doctor.

Based on regulatory requirements and the Sponsor's policy, your coded information will be kept for at least 25 years. This allows the Sponsor to fully study biomarkers and answer questions from health authorities about the way the drug works in this trial.

A description of this trial will be available on the following websites:
https://www.ClinicalTrials.gov
https://www.clinicaltrialsregister.eu

These websites will not include information that can identify you. At most, the websites will include a summary of the results. You can search the websites at any time.

22 What if there is a problem?

If you have a concern about any aspect of this trial, you should contact your trial doctor whose details are in the "How to contact us" section at the beginning of this information sheet. If you remain unhappy and wish to complain formally, you can do this through Re-Cognition Health by contacting compliance@re-cognitionhealth.com

If you would like to discuss the trial with someone independent (not the trial team), please contact your General Practitioner (GP).

Please contact the trial doctor:

a) If you suffer an illness or a possible trial related injury;
b) If you feel different in any way;
c) If you are admitted to hospital for any reason; or
d) If you are seen at accident/emergency department for any reason

Thank you for reading this information sheet.

Re:Cognition Health Brain and Mind Experts

45 Queen Anne Street, London, W1G 9JF
clinicaltrials@re-cognitionhealth.com
re-cognitionhealth.com
+44(0)20 3355 3536 (tel.)
+44(0)20 3432 7378 (fax)

Trial Site Number:	**1804**
Protocol Number:	**MK-1942-008**
Participant Identification Number for this trial:	

CONSENT FORM

Title of Trial: **A Phase 2a/2b Randomized, Placebo-Controlled Clinical Study to Evaluate the Safety and Efficacy of MK-1942 as Adjunctive Therapy in Participants with Mild to Moderate Alzheimer's Disease Dementia**

Name of Principal Investigator: **Dr Emer MacSweeney**

Please Initial Boxes

1.	I confirm that I have been given, have read and understood the information sheet and consent form dated 30-JAN-2023 (Version .00b). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3.	I understand that health information and trial information about me may be shared with individuals from Re-Cognition Health, health authorities, the Sponsor and those working for it, for the specific purposes described in the information sheet, both during and after the trial period. I give permission for these individuals to have access to my information.	
4.	I understand that relevant sections of my medical records may be looked at remotely by the Sponsor and those working for it, if required. I give my permission for these individuals to review my medical records remotely from outside of the trial site.	

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5.	I agree to my General Practitioner (GP) being informed of my participation in the trial.	
6.	I agree to provide samples for use in this trial under the conditions described in the information sheet.	
7.	I understand that my coded data will be transferred outside of the United Kingdom as described in the information sheet. I understand that data protection laws outside the United Kingdom may not be as comprehensive.	
8.	I understand I may have to leave the trial without my consent, if I need other treatment, do not follow the trial plan, have a trial-related injury or for any other reason as described in the information sheet.	
9.	I understand if I decide to leave the trial early, for any reason, any health information, samples, and trial data that has been collected before my request to leave will still be used for research and will not be deleted.	
10.	I agree for my GP to provide follow-up information about my health status to my trial doctor if required.	
11.	I agree to being audiotaped as part of my participation.	
12.	I agree to take part in the above clinical trial.	
13.	If I become unable to give informed consent myself, I agree to continue to take part in the clinical trial.	

Name of Participant (Please Print)	Signature of Participant	Date (dd/mm/yyyy)

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CONSENT OBTAINED BY (MUST BE A PHYSICIAN OR NAMED DELEGATE):

By signing below, I confirm I have reviewed the information in this form and the risks of all drugs with the participant.

Name of Physician Or Named Delegate (Please Print)	Signature of Physician Or Named Delegate	Date (dd/mm/yyyy)

COMPLETE BELOW SECTION, ONLY IF APPLICABLE. IF NOT APPLICABLE, LEAVE BLANK.

Name of WITNESS (if applicable) (Please Print)	*Signature of WITNESS*	*Date (dd/mm/yyyy)*

By signing the consent form, the witness confirms that all the information contained in the Participant Information Sheet/Consent Form has been read in its entirety to, and apparently understood by the participant and that informed consent was freely given

When completed, 1 for participant; 1 (original) for Investigator file; 1 to be kept in medical records