

Assessing the effect of caffeine on attention in patients with and without dementia

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| Submission date 03/06/2014 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 06/06/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 16/01/2019 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Dementia with Lewy bodies (DLB) is a common form of dementia in which tiny clumps of abnormal protein (the Lewy bodies) form in the brain over time. People that have this condition experience memory loss, difficulty concentrating and problems with visual perception (recognising objects and making judgements about where they are in space). The aim of this study is to find out whether caffeine (taken as coffee) improves the attention of people diagnosed with DLB. Attention is assessed according to how alert a person is, how they respond to a particular stimulus and how they react to that stimulus. The standard medical treatment for DLB is a drug called Rivastigmine which, as well as improving attention, also alleviates other symptoms such as hallucinations. Rivastigmine is known to improve a DLB patients ability to respond to a particular stimulus while caffeine improves alertness and responsiveness. Caffeine should therefore improve attention when taken alone and also in combination (synergistically) with Rivastigmine.

Who can participate?

Patients with dementia with Lewy bodies

What does the study involve?

The study compares the effect of drinking regular instant coffee with decaffeinated instant coffee on tests of attention. The coffee is served at a safe temperature as measured by a thermometer. Each participant first does a series of tests designed to assess memory and responsiveness. Following on from this initial testing day, each participant is given a supply of decaffeinated tea or coffee depending on preference and asked not to consume caffeine containing food or drink (tea, coffee, chocolate etc) for the next 7 days. They are also asked to fill in a daily questionnaire recording any caffeine consumption, their sleeping patterns and any hallucinations. On day 7, the participant redoes the tests done on day 1. On day 8, each participant is given either caffeinated or decaffeinated coffee, asked to wait for an hour and then sit through the tests done on day 1. On day 9, the participant is given the alternative type of coffee, asked to wait an hour again and do the same series of tests once more.

What are the possible benefits and risks of participating?

The ingestion of coffee whether caffeinated or decaffeinated poses no risks, as the caffeine

dose is the same or lower than a standard cup of coffee from a high street coffee shop. In the unlikely event that a participant finds the psychology attention tasks too stressful, they are reminded that they are free to withdraw from the study and/or refuse to complete any of the tests if they wish. Caffeine withdrawal can occur in participants who consume as little as 100mg of caffeine a day. Withdrawal symptoms can include headache, fatigue, decreased energy, decreased alertness, drowsiness, depressed mood, difficulty concentrating, irritability, and foggy/not clearheaded. In addition, flu-like symptoms, nausea, vomiting, and muscle pain/stiffness are possible symptoms. Should a participant develop these symptoms and find them too distressing then they are free to withdraw from the study. There is no published evidence to suggest any difference or benefit from using a gradual as opposed to an abrupt caffeine withdrawal in terms of withdrawal symptom severity, frequency or duration. As caffeine has been studied for over 100 years it is known that whilst withdrawal may cause unpleasant symptoms, it is not harmful. Participants are required to attend for testing on four days which can potentially inconvenience them due to the time and cost of travel. This will be minimised by offering money to cover travel expenses.

Where is the study run from?
North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
July 2014 to July 2016

Who is funding the study?
North Bristol NHS Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Assessing the effect of caffeine on attention in patients with and without dementia: A double blind, randomised, cross over trial

Study objectives

Caffeine ingested via coffee will improve performance on psychological and functional tasks of attention compared to placebo in patients with dementia with Lewy bodies

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES committee South West - Exeter, ref: 14/SW/1018

Study design

Double-blind randomised cross-over trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Dementia with Lewy bodies, Parkinson's disease dementia, Alzheimer's dementia, vascular dementia, frontotemporal lobe dementia

Interventions

A double blind crossover trial will compare instant coffee (a cup containing 1 standard sachet of approximately 4g Starbucks VIA Ready Brew Italian Roast with 250ml of hot water) with decaffeinated instant coffee (a cup containing 1 standard sachet of approximately 4g Starbucks

VIA Ready Brew Decaff Italian Roast with 250ml of hot water) with or without artificial sweetener as per patient preference but consistently given across the trial. The dose has been chosen on the basis it will contain 135mg of caffeine which from trial data should be high enough to induce a therapeutic effect without risk of significant side effects. The sachets come in a standard weight and are the same flavour therefore using sachets should allow a reproducible dose within the caffeinated group and reproducible flavour between the caffeinated and decaffeinated group. The coffee will be served at a temperature range of between 50 - 60°C which will be confirmed by measurement with a thermometer. This will ensure that the drink is hot but not too hot for safe consumption.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Caffeine

Primary outcome measure

Attention, measured by neuropsychological tests

Secondary outcome measures

1. Ability to complete a timed walk
2. Ability to complete a timed walking while talking task
3. The measure of habitual caffeine intake by patients with dementia and its correlation with hallucinations and sleeping patterns

Overall study start date

01/07/2014

Completion date

01/07/2018

Eligibility**Key inclusion criteria**

1. Patients with dementia with Lewy bodies or Parkinson's disease dementia fulfilling standard diagnostic criteria who retain capacity to consent to research, in keeping with the Mental Capacity Act 2005
2. Patients on or off cholinesterase inhibitors or memantine as long as stable on medication for 3 months or more
3. An adequate level of communication in written and verbal English

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Patients with alternative neurodegenerative diseases or other condition likely to interfere with test performance (e.g. chronic pain, stroke)
2. Patients on medication likely to interfere with cognitive performance that has been changed in the last 3 months
3. The tests of attention in this trial require a working knowledge of English, good vision and the ability to walk independently (with or without walking aids) and we will therefore exclude patients without sufficient English language skills, those with poor vision and those who cannot walk independently.
4. Patients taking caffeine containing medication or foodstuffs with greater than 15mg caffeine over a day who do not wish to cease ingestion
5. If a patient loses capacity to consent during the trial they will be withdrawn

Date of first enrolment

01/07/2014

Date of final enrolment

01/07/2016

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

North Bristol NHS Trust

Bristol

United Kingdom

BS10 5NB

Sponsor information**Organisation**

North Bristol NHS Trust (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.nbt.nhs.uk/>

ROR

<https://ror.org/036x6gt55>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

North Bristol NHS Trust

Alternative Name(s)

NBT

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---|--------------|------------|----------------|-----------------|
| Abstract results | results presented at ABN Annual Meeting | 01/12/2016 | | No | No |
| HRA research summary | | | 28/06/2023 | No | No |