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

Submission date
03/06/2014

Recruitment status
No longer recruiting

Registration date
06/06/2014

Overall study status
Completed

Last Edited
16/01/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 though 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

Protocol serial number

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

Study type(s)
Treatment

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(s)
Attention, measured by neuropsychological tests

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust (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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes