ISRCTN11610863 https://doi.org/10.1186/ISRCTN11610863

Feasibility study of electronic pen to help early diagnosis of dementia

Submission date
07/09/2023

Recruitment status
No longer recruiting

Registration date
16/10/2023

Overall study status
Completed

Last Edited
16/10/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary
Background and study aims
There are currently over 800,000 people with dementia in the U.K. Improving ability to diagnose dementia in its earlier stages and accurately can help ensure patients access appropriate treatment and support.
Researchers at a number of universities across Europe (including Newcastle University) have developed a pen system which assesses changes in movement and ability to write and draw. We are looking to study whether the pen system may help identify dementia and different types of dementia

Who can participate?
Those referred to North Tyneside memory clinic and local age matched individuals as controls.

What does the study involve?
Completing a series of basic drawing tests using the electronic pen on a touch sensitive tablet.

What are the possible benefits and risks of participating?
The pen is similar to a normal writing pen but it contains some sensors which detect movement. Previous studies of the pen conducted in the U.K., Netherlands and Ireland have not reported any adverse events.
There will be no direct benefit to participants. However, the study will allow us to assess whether the pen system could be used in a memory clinic setting and help identify dementia. If the study is successful then there may be potential for the pen to improve diagnosis of dementia and different types of dementia

Where is the study run from?
North Tyneside General Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2022 to June 2024

Who is funding the study?
1. Innovate UK
2. Manus Neurodynamica Ltd (UK)

Who is the main contact?
Dr Christopher Davison, Christopher.davison@nhct.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Christopher Davison

ORCID ID
http://orcid.org/0000-0001-6509-7059

Contact details
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH
-
Christopher.davison@nhct.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
303834

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52890, IRAS 303834

Study information

Scientific Title
Evaluation of Neuromotor Pen in early identification of dementia and differential of dementia subtypes: a feasibility study

Study hypothesis

We are testing a novel, user-friendly and inexpensive pen system to aid in the differential diagnosis of dementia. It is hypothesized that the pen system can be developed to differentiate between dementia, MCI and normal subjects as well as potentially differentiating dementia subtype

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/10/2022, South East Scotland REC2 (2ndFloor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 131 5369000; ruth.fraser4@nhslothian.scot.nhs.uk), ref: 22/SS/0039

Study design
Non-randomized; Interventional; Design type: Screening, Process of Care, Device

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Condition
Dementia

Interventions
Patients and carers will be consented to perform a series of written/drawing tests using the NMP taking between 5 and 15 minutes. These will be incorporated into memory clinic assessment with patients consent. Rating of acceptability of testing will be tested with a basic questionnaire and rating scales. Results of tests will be compared to tests results from the memory clinic assessment so not to add significant extra time to assessments and to compare with normal practice.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Neuromotor Pen

Primary outcome measure
The level of agreement between the pen system and clinical diagnosis. The assessment by a specialist clinician will be conducted as part of routine assessment of suspected dementia

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
17/10/2022

Overall study end date
01/06/2024

Eligibility

Participant inclusion criteria
1. Capacitated individuals attending memory clinic for assessment of possible dementia
2. Carers may be invited to act as controls
3. Willing and able to provide written informed consent
4. Aged 18 years or older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Participant exclusion criteria
1. Lack of capacity
2. Significant visual impairment
3. Significant upper limb physical functional impairment
4. Under 18 years old
5. Unable to communicate in English

Recruitment start date
19/12/2022

Recruitment end date
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Tyneside General Hospital
Rake lane
North Shields
United Kingdom
NE29 8NH

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
North Tyneside General Hospital
Rake Lane
North Shields
England
United Kingdom
NE29 8NH
+44 1912934087
peta.heslop@nhct.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.northumbria.nhs.uk/

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Manus Neurodynamica Ltd

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.3	11/07/2023	03/10/2023	No	No