ISRCTN25427954 https://doi.org/10.1186/ISRCTN25427954

Project CYGNUS: A feasibility study of gathering health information in people with memory problems

Submission date 27/03/2017	**Recruitment status** No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/04/2017	**Overall study status** Completed	☐ Statistical analysis plan ☐ Results
Last Edited 22/05/2019	**Condition category** Mental and Behavioural Disorders	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims
Alzheimer's disease (AD) is a common cause of dementia. People with dementia have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worse over time as they age. Recently, there have been failures in developing medications to try and cure AD. This means new efforts are needed to support those suffering without the hope of a cure. New projects are being undertaken that are focused on aiding studies of new AD treatments. While these research goals are important, they are part of a strategy that will not impact patients for over 15 years. The aim of this study is to explore how the information collected at Memory Assessment Services when patients are referred and diagnosed with AD and/or dementia and additional information collected from patients and their study partners over a one year follow-up period could be used to improve patient treatment and care.

Who can participate?
Adults over the age of 18 who are referred to a Memory Assessment Service and their partner, family member or close friend.

What does the study involve?
Participants are visited in their own homes (or in a clinic if they prefer) where they are asked a series of questionnaires about living with dementia. Participants are either patients who have been referred to memory assessment services or study partners who are those who have consented to support the patient through the study and are happy to answer a set of questionnaires aimed at carers of people living with dementia. This takes place every three months for one year. Participants are also asked if they would like to use a wearable device that collects data about activity and sleep over two or 12 weeks (depending on the device they use).

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
This study is being run from the University of Manchester (UK) and takes place in NHS Mental Health Trusts across England (UK).

When is the study starting and how long is it expected to run for?
April 2016 to March 2018

Who is funding the study?
Innovate UK (UK)

Who is the main contact?
1. Ms Francine Jury (Public)
francine.jury@manchester.ac.uk
2. Professor Derek Hill (Scientific)

Contact information

Type(s)
Public

Contact name
Ms Francine Jury

Contact details
Room 3.306
Jean McFarlane Building
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PY
+44 161 306 7491
francine.jury@manchester.ac.uk

Type(s)
Scientific

Contact name
Prof Derek Hill

Contact details
Ixico PLC
4th Floor
Griffin Court
15 Long Lane
London
United Kingdom
EC1A 9PN

Additional identifiers

Protocol serial number
30502

Study information

Scientific Title
Project CYGNUS: A feasibility study of gathering health information in people with memory problems

Study objectives
The aim of this study is to explore how the information collected at Memory Assessment Services at the point of referral and subsequent diagnosis and additional information collected from the cognitively impaired participants and their study partners over a one year follow-up period could be used to improve patient treatment and care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Central Research Ethics Committee, 23/04/2016, ref: 16/LO/0354

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Dementias and neurodegeneration, Primary sub-specialty: Dementia; UKCRC code/ Disease: Neurological/ Other degenerative diseases of the nervous system

Interventions
Participants receive five home visits at three month intervals over 12 month periods. This involves being asked a series of questionnaires relating to outcomes for people living with dementia (the standard scales for dementia). The questions are answered by either the participant or by their study partners who have consented to support the participant through the study and are happy to answer a set of questionnaires aimed at carers of people living with dementia.

Participants are also asked if they would like to take part in a sub-study. This includes either using a wearable device to collect continuous data on activity and sleep over two or 12 weeks (depending on the device) or using mobile data collection which involves using a web/mobile app to collect self-reported data on a more regular basis from home (this is done weekly).

There are 2 wearable devices are:
The Withings device: This device is worn for 12 weeks and collects sleep and activity data. It is a commercial device which requires other technology to use such as a smartphone or tablet that

can download an app to collect self-reported data on a more regular basis from home (this is done weekly).
The Axivity AX3 device: This device is worn for 2 weeks and does not required any other technology. It collects raw data over two weeks which is then downloaded.

The data collected is reviewed to examine the feasibility of collecting quality and actionable patient and carer reported outcomes.

Intervention Type
Other

Primary outcome(s)
Information about Memory Assessment Services are measured using patient and carer reported outcomes (PRO) (Quality of Life, Activates of Daily Living, etc) at baseline, three, six, nine and twelve months.

Key secondary outcome(s))
Feasibility to collect quality and actionable patient and carer reported outcomes is measured using web-based and mobile technologies continuously or at weekly increments.

Completion date
31/03/2018

Eligibility

Key inclusion criteria
Cognitively Impaired Participants:
1. Aged 18 years or older
2. Referred to a Memory Assessment Service with suspected Dementia by GP
3. Able to understand written and spoken English with the assistance of a carer/ study partner
4. Have capacity to consent

Study Partners:
1. Aged 18 years or older
2. Partner, Family Member or Close Friend is a participant in CYGNUS in the cognitively impaired participant group
3. English speaking/able to understand study documents

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Cognitively Impaired Participants:
1. Aged younger than 18 years
2. Currently resident in a care or nursing home
3. Do not have capacity to consent

Study Partners:
1. Aged younger than 18 years
2. Do not have capacity to consent
3. Previously referred to memory assessment service themselves

Date of first enrolment
01/04/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Manchester
Room 3.306
Jean McFarlane Building
Oxford Road
Manchester
United Kingdom
M13 9PY

Sponsor information

Organisation
Ixico PLC

ROR
https://ror.org/00paezp73

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the dataset is collected on a proprietary data platform at Ixico PLC and used for platform development. Paper based data collection could be made available on request from June 2018 but there would be a cost for retrieval for data archives.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes