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The Angela project

Submission date	Recruitment status	[X] Prospectively registered
10/07/2017	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
08/08/2017	Completed	[X] Results
Last Edited	Condition category	[ ] Individual participant data
03/02/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Dementia in younger people (YPD) affects up to 42,000 people in the UK. The first signs of young onset dementia often differ from later onset. The average time to diagnosis is over four years, as clinicians often do not immediately recognise the symptoms. In addition, in some areas of the country specialist treatment, care and support is limited or not available. The Angela project is a three year project that aims to develop guidelines that will improve diagnosing dementia in younger people and improve the experience of receiving a diagnosis. It aims to gather good examples of post-diagnostic age-appropriate and condition-appropriate support that will help spread good practice more evenly across the UK. To develop the best practice guidelines, two panels are asked for their opinions. One consists of a panel of leading experts and the other consists of younger people with dementia and their family members/supporters. Examples of clinical case notes of YPD diagnosed in the last year will be compared to a 'quality indicators' template. This will show where there are gaps in the way younger people with dementia are currently diagnosed. Concerning post-diagnostic support is explored as well as well as services. The aim of this study is to produce guidance for improved diagnosis and post-diagnostic support that will help YPD get the right help and support much earlier.

Who can participate?
Adults who are diagnosed with dementia before their 65th birthday or their carer of any age who is affected by a diagnosis of dementia.

What does the study involve?
This study involves two work steams. The first workstream involves asking participants to be a member of a panel where they are presented with online questions about referral, assessment and diagnostic processes where they are asked to respond. They are then invited to a second round which review an anonymous summary of statements based on the information they provided. A facilitator provides an anonymous summary of the experts' views as well their reasons for their judgements in a final consensus. In the second workstream, participants fill out the 'improving support and service use' survey either using the internet, by paper, by a phone call or face to face. All participants are asked to provide free-text descriptions of services, support, advice, information or interactions that they have found helpful over the duration of their experience with dementia, from the diagnostic process onwards. Services described may be directed at the younger person with dementia, the primary carer, the 'care dyad' or the wider family. Participants are also asked to provide information on service use, quality of dementia

care they have received and satisfaction with services. In the end of the survey, respondents may optionally provide their contact details to take part in a follow-up interview. Those who express willingness and are purposively selected are contacted to arrange a face-to-face or skype /telephone interview. Interviews seek to understand the psycho-social, practical and physical needs experienced by participants and will then consider how the services and support identified as positive, contributed to these needs being met. Commissioners and service providers are identified from the study sites and the results of the survey. It is expected that key individuals from areas with limited through to extensive service provision are selected to obtain a range of perspectives and achieve a good geographical spread. Details of the project are sent to potential participants. The interviews focus on barriers and facilitators to the commissioning or provision of good services for younger people with dementia and their families. It is anticipated that each interview will be of approximately 30 minutes duration.

What are the possible benefits and risks of participating?
There are no direct benefits with participating however participants may find it participating a positive experience as they can express their views, and contribute to improving dementia diagnosis in the future. There are no direct risks however participants may experience distress or upset during interviews. Participants who have a significant level of distress may be referred to an appropriate health or social service.

Where is the study run from?
This study is being run by the University College London (UK) and takes place in different hospitals across nine NHS trusts (UK).

When is the study starting and how long is it expected to run for?
December 2016 to December 2019

Who is funding the study?
Alzheimer's Society (UK)

Who is the main contact?
Dr Janet Carter

Study website
https://www.ucl.ac.uk/psychiatry/the-angela-project

Contact information

Type(s)
Public

Contact name
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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32710

Study information

Scientific Title
The Angela Project: Improving diagnosis and post-diagnostic support for younger people living with dementia and their caregivers

Study objectives
The aim of the ANGELA Project is to develop guidelines that will improve the accuracy of clinical diagnosis for young onset dementia and the post-diagnostic care that younger people with dementia and their family members/supporters receive.

Objectives:
1. Develop guidelines for best practice in diagnosis and recommendations to improve current UK practice by:
-Establishing a consensus about the diagnostic assessment for young onset dementia via a Delphi study with young onset dementia experts and a Delphi study with younger people with dementia and supporters
-Conducting a case note audit

2. Provide guidance on best practice regarding post-diagnostic support that meets the needs of people with young onset dementia and their families/supporters across the care pathway by:
-Identifying practical examples of positive post-diagnostic services and support across the care pathway and gaining an in-depth understanding of the needs they meet
-Acquiring an overview of current service use, costs and satisfaction with care within England
-Understanding access to health, social and voluntary services by people with young onset dementia at diagnosis and in the post-diagnostic period, and exploring geographical variability
-Gathering information on the extent and nature of informal caring
-Gaining insight into the barriers and facilitators to providing and commissioning age-, needs- and condition-appropriate care and support for young onset dementia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire South Central Research Ethics Committee (Health Research Authority), 28/06/2017, ref:17/SC/0296

Study design
Observational; Design type: Qualitative

Primary study design
Observational

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Dementia

Interventions
The ANGELA Project uses a mix of qualitative and quantitative methods and consists of two work-streams:

Work-Stream 1 Improving the accuracy of young onset dementia diagnosis:
a) Developing 'quality indicators' to guide clinicians in assessing young onset dementia
b) Understanding the experience of younger people with dementia and their families/supporters during the diagnostic process
c) Examining the compliance of current UK practice with the 'quality indicators'

Phase 1: An E-Delphi approach is used with a group of 40 national and international experts and stakeholders (Delphi-PRO) to develop and design 'Quality indicators for accurate diagnosis'. These indicators act as a set of 'rules' to guide doctors through the correct steps in making a diagnosis of young onset dementia and include information about all the complicated features of the diseases that cause dementia in younger people, as well as advice on the best tests to use. A separate E-Delphi is also undertaken with 40 younger people with dementia and carers (Delphi-EXP) to develop guidelines regarding the lived experience of receiving a diagnosis and how this can be improved. This is achieved by reaching a consensus about the optimum diagnostic experience and how it should be delivered, considering for example how people are prepared for assessment and diagnosis. The two Delphi studies provide separate perspectives which complement one another to establish best practice guidelines for the diagnosis of young onset dementia.

Phase 2: The 'Quality indicators for accurate diagnosis' are then be compared to current UK clinical practice to identify potential gaps and develop guidance for improvement of diagnosis. The researchers select elements from the diagnostic decision-making tool to produce a scoring template of key ‘quality indicators’ which are tested by the research team in a small sample of case notes to determine inter-rater reliability. A randomised blinded retrospective case note audit is then be conducted to compare these ‘quality indicators’ to current clinical practice by rating the anonymised data from each selected record against the scoring template and calculating a percentage compliance score for each record.

WORK-STREAM 2. Improving post-diagnostic support for younger people with dementia and their family members/supporters:
a) Identifying and disseminating examples of good practice in post-diagnostic care provision across the care pathway
b) Investigating service use, costs and satisfaction with care, across the wider young onset dementia health and social care community
c) Examining the barriers and facilitators to providing and commissioning services that meet the needs of younger people with dementia and their supporters

Phase 1: A cross-sectional semi-structured national survey entitled ‘Improving Support and Service Use Survey’ and consisting of two sections is carried out during a 15-month period. The survey invites younger people with dementia and their supporters to provide free-text responses to questions addressing positive experiences of support (Section 1) and gather information on service use (via a set of questions based on the Client Service Receipt Inventory), quality of care and participants’ background (Section 2). The survey is made available in a number of different formats, including Internet-based, paper, by telephone or Skype, and face-to-face, so as to make it accessible to the widest possible range of individuals. To supplement the information gathered via the survey, the researchers go along to six to eight meetings that are attended by younger people with dementia to conduct focus groups with the attenders. At least one of these groups include people from Black and Minority Ethnic Communities and younger people with dementia who live alone, to ensure the inclusion of participants who may otherwise not be consulted or may not have access to others who can help them to complete the survey.

Phase 2: Semi-structured Skype, telephone or face-to-face interviews are carried out with 50 younger people with dementia and 50 family members/supporters, identified from those who completed the survey. The purpose of the interviews is to gain additional information and an in-depth understanding of the psycho-social, practical and physical needs that were met by services which were found to be positive. A diverse sample of younger people with dementia and family members/supporters are purposively recruited and interviewed, aiming to reach a point at which no new underlying needs met by the different sorts of services are discovered.

Phase 3: Semi-structured Skype, telephone or face-to-face interviews are conducted with an estimated sample of 35 commissioners and providers of services for younger people with dementia across the key study sites, to obtain their perspectives regarding barriers and facilitators to providing and commissioning age-, needs- and condition-appropriate services for younger people with dementia and their families/supporters, as identified in the ‘Improving Support and Service Use Survey’. In addition to interviewing at the study sites, approximately 10 purposively sampled interviews are undertaken across England in order to obtain an appropriate and diverse representation of the range of current care pathways. Commissioners selected include those working within Clinical Commissioning Groups, Local Authorities and joint commissioning, while service providers include those offering services funded by health, social care, third sector and independent sector.

Intervention Type

Other

Primary outcome measure

Work-stream 1, phase 1:
Consensus on quality indicators that screen for typical causes of cognitive and behavioural dysfunction and a rational approach to additional testing that is based on selected features of the history and examination, further taking into account the needs of younger people with dementia and their supporters during assessment and diagnosis.

Work-stream 1, phase 2:
Percentage compliance for each set of case notes with a 'quality indicators' scoring template (reviewing patient notes via a case note audit).

Work-stream 2, phase 1:
Service use section of the ‘Improving Support and Service Use Survey
1. The service use and satisfaction data (modified version of the Client Service Receipt Inventory) is assessed descriptively. Variability in access and comparisons between service types (Neurology-led services, Older People’s Mental Health Services, Young Onset Dementia-specific services) and geographically are explored to determine service use patterns.
2. The extent and cost of formal care for younger people with dementia will be calculated, if data allow, using validated national tariffs. Informal caring will be costed using a replacement cost approach. Using regression modelling, associations will be explored between service use and satisfaction (dependent variables) and service model, dementia diagnosis and severity (mild, moderate, severe), and informal caring, controlling for background differences between participants.

Improving Support section of the ‘Improving Support and Service Use Survey’
1. Positive examples of post-diagnostic support, advice, information, services or interactions are measured using open-text responses from the Internet and paper surveys, transcribed telephone interviews and focus groups. Each example will be separately tagged and coded according to types that will be decided through grouping similar items together. Data tables will collate all the positive examples, yielding descriptions of good practice in provision. Thematic analysis of descriptions of services will be undertaken, to illustrate positive features that are common across services received, for example considering the personal approach offered or the timeliness of service delivery. Data from this analysis contribute to the thematic framework that is used for analysis of data from the follow-up interviews.

Work-stream 2, phase 2:
Thematic analysis of the follow-up interview data will allow identifying super-ordinate themes concerning the underlying needs that services addressed for participants. Analysis is done to examine the to identify similarities and differences within and between groups of people participating in these follow up interviews. It is anticipated that this may include for example different family caregivers/ supporters, people with different diagnoses, people living in urban or rural areas and people with different ethnicities.

Work-stream 2, phase 3:
Data from interviews with service providers and commissioners are analysed using template analysis to produce a report with an account of service providers’ and commissioners’ perspectives on the barriers and facilitators to the provision of good services for younger people with dementia and their families/supporters. This is supported by illustrative examples.

Work-stream 2, overall:
The guidance developed as a result of the ‘Improving Support and Service Use Survey’ and

follow-up interviews are further refined to reflect the results of this analysis. A report is drawn up giving descriptions about types of positive services, their frequency, distribution and what sort of respondents reported them as positive. This report also provides a brief discussion of the positive features common across services.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
01/12/2016

Completion date
01/12/2019

Eligibility

Key inclusion criteria
1. People of any gender diagnosed with dementia before their 65th birthday
2. Diagnosed with dementia of recognised subtype as defined by the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (2013) and internationally accepted criteria for subtype diagnoses
3. People of any gender and age who are primary carers of younger people living with dementia or other family members / supporters who are affected by the diagnosis of young onset dementia

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 869; UK Sample Size: 869

Total final enrolment
233

Key exclusion criteria
1. Dementia caused by HIV
2. Traumatic brain injury
3. Down’s syndrome
4. Huntington’s chorea
5. Alcohol-related dementia

Date of first enrolment
15/08/2017

Date of final enrolment
05/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North East London NHS Foundation Trust (Lead Centre)
Tantallon House, Goodmayes Hospital Site
Barley Lane
Ilford
United Kingdom
IG3 8XJ

Study participating centre
Northern General Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
South Yorkshire
Sheffield
United Kingdom
S5 7AU

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Lancashire
Ashton-Under-Lyne
United Kingdom
OL6 7SR

Study participating centre
Worcestershire Health and Care NHS Trust
ISAAC Maddox House
Shrub Hill Industrial Estate
Worcester
Worcestershire
Worcester

United Kingdom
WR4 9RW

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Berkshire
Bracknell
United Kingdom
RG12 1BQ

Study participating centre
Imperial College Healthcare NHS Trust
St. Marys Hospital
Praed Street
Greater London
London
United Kingdom
W2 1NY

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
18 Mole Business Park
Randalls Road
Surrey
Leatherhead
United Kingdom
KT22 7AD

Study participating centre
Leeds and Yorkshire NHS Partnership Trust
South Wing
St Mary's House
St Martin's View
Leeds
United Kingdom
LS7 3JX

Study participating centre

Northumberland Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Sponsor information

Organisation
University College London

Sponsor details
Joint Research Office
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Alzheimer's Society

Alternative Name(s)
alzheimerssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

As the ANGELA project seeks to enhance knowledge and understanding, raise the profile, challenge attitudes, and influence key policy makers and service providers concerning the needs of younger people with dementia and their families/supporters, a series of actions have been designed for the publication and dissemination of the findings of the study. More precisely the findings of the study will be disseminated via:

1. A final written report - Estimated date: 12/2019
2. Journal publications - Estimated date: 12/2019 – 06/2020
3. Conference proceedings - Estimated date: 12/2019 – 12/2020
4. An executive summary which will be made available on the ANGELA project website and distributed to those who have supported the research - Estimated date: 12/2019
5. A ‘Knowledge Exchange Event’ where health and social care professionals, service providers and commissioners, younger people with dementia and carers will be invited - Estimated date: 12/2019 – 03/2020
6. A joint Royal College of Psychiatrists/Alzheimer’s Society/Faculty of the Psychology of Older People meeting where Delphi responders and the researchers will outline decisions that defined the best practice in diagnosis and post-diagnostic support - Estimated date: 12/2019 – 03/2020.
7. Distribution of the quality indicators for diagnosis to clinicians in leaflet form - Estimated date: 12/2019 – 03/2020
8. Leaflets containing examples of good practice sent to key service providers and commissioners - Estimated date: 12/2019 – 03/2020
9. The Alzheimer’s Society project monitors who will spread the results of the study to the wider community of young onset dementia via social media and to lay audiences with the support of the research team - Estimated date: 12/2019 – 06/2020
10. Highlighting the quality indicators and good practice examples on the YoungDementia UK and the ANGELA Project websites where they will be available to younger people with dementia, carers, commissioners and clinicians - Estimated date: 12/2019

Intention to publish date

31/12/2019

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 sensitive nature of the data and confidentiality reasons.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	17/07/2017	11/08/2017	No	Yes

Participant information sheet	version V2	17/07/2017	11/08/2017	No	Yes
Other publications	Patient and Public Involvement experiences	25/12/2019	03/02/2022	Yes	No
Other publications	a scoping review of lived experiences	24/10/2019	03/02/2022	Yes	No
Other publications	consensus on quality indicators for comprehensive assessment of dementia in young adults using a modified e-Delphi approach	13/07/2020	03/02/2022	Yes	No
Other publications	evidence-based statements to inform best practice for the care of people receiving a diagnosis of young onset dementia using a modified Delphi approach	30/10/2020	03/02/2022	Yes	No
Other publications	exploring the nature of post-diagnostic support services that were perceived positively by younger people with dementia and carers	18/02/2020	03/02/2022	Yes	No
Other publications	scoping review of key pointers to diagnostic accuracy	04/06/2019	03/02/2022	Yes	No
Results article	Project findings and recommendations	05/05/2021	03/02/2022	Yes	No
Results article	results of investigation into compliance with quality indicators in electronic health records	02/09/2021	03/02/2022	Yes	No
Results article	results of national UK survey of service use and satisfaction	07/10/2020	03/02/2022	Yes	No
HRA research summary			28/06/2023	No	No