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The Forget Me Not Approach: Improving the communication of a dementia diagnosis.

Submission date
04/08/2023

Recruitment status
No longer recruiting

Registration date
09/08/2023

Overall study status
Completed

Last Edited
23/10/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
One in three people are likely to develop dementia during their lifetime. Early diagnosis can help with accessing support and improve the quality of life for people living with dementia. Delivering a diagnosis of dementia can be stressful for medical professionals. However, this can result in unclear communication of a diagnosis and leave patients and people who care for them, uncertain of what is causing memory problems. There is very little communication training available for dementia diagnosis. The aim of this study is, therefore, to develop training videos in collaboration with people who are living with dementia to improve the experience of receiving or delivering a dementia diagnosis.

Who can participate?
People and their companions attending (or who have attended) memory clinics, and medical professionals who regularly deliver diagnoses of dementia.

What does the study involve?
Stage 1: People who have received a diagnosis of dementia in the past two years will be asked to take part in a workshop with other people who have dementia and their companions. They will be shown three videos of medical professionals giving a diagnosis of dementia. They will then be asked to take part in an open discussion about the videos to find out what could be improved in communicating a diagnosis of dementia. Workshops will last 2 hours. We will use the information identified in these workshops to make training videos.

Stage 2: The research team will develop training videos which will be free to access.

Stage 3: Researcher will show participants the accessible communication videos of dementia diagnosis after they have visited the memory clinic but before they have received their diagnosis feedback. The researcher will contact them again after their diagnosis feedback meeting to hear about their experiences and find out how the communication videos impacted this experience.

What are the possible benefits and risks of participating?
The benefits include the following:
1. Participants in stage 1 will get the opportunity to meet other people who have had similar

experiences of a diagnosis and are subsequently living with dementia.
2. Medical professionals will get the chance to reflect on their practice with others.
3. Participants in stage 3 will hopefully benefit through their use of the guidance videos, which is hoped will add clarity to the diagnosis process.

The risks include the following:
1. It is possible that groups will discuss aspects of a dementia diagnosis that are difficult or upsetting.
2. Participants may have communication difficulties and could find it hard to interact in workshops, especially those held virtually. This could lead to frustration and/or upset.
3. Participants could find interviews and workshops tiring, especially if they have a diagnosis of dementia.

Mitigation against risks:
Care will be taken to ensure that people have sufficient breaks and feel comfortable to raise concerns and leave the meeting if needed. Researchers will direct participants to resources collected on the Dementia Empowerment and Engagement Project (DEEP) website that may be useful for signposting to other national services that can offer support. Participants will also be supported to find advocacy and research groups in their areas.

To help with communication difficulties, all participants will be given a booklet in advance of the workshops, covering topic areas and space to write their notes regarding points they wish to make. Participants will also be sent a colourful sign that can be held up to indicate they would like to talk during the focus group, as recommended by DEEP and the Alzheimer's Society.

Where is the study run from?
The University of Bristol (UK) in collaboration with the University of Newcastle (UK)

When is the study starting and how long is it expected to run for?
January 2023 to October 2024

Who is funding the study?
National Institute of Health and Care Research (NIHR), Research for Patient Benefit Programme (RfPB) (UK)

Who is the main contact?
1. Dr Joseph Webb (Study Co-ordinator and joint Chief Investigator), Joseph.Webb@bristol.ac.uk
2. Dr Jillian Powell (Research Activity Co-ordinator), Jill.Powell@bristol.ac.uk

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Integrated Research Application System (IRAS)
326204

Central Portfolio Management System (CPMS)
57526

Study information

Scientific Title
The 'Forget Me Not' approach: Co-producing accessible guidance videos for communicating and receiving a dementia diagnosis.

Acronym
Forget Me Not

Study objectives
The study adopts a qualitative methodology and therefore does not aim to test a hypothesis. However, the objectives are:
1. To use adapted conversation analysis methodology with people living with dementia, companions, and clinicians to analyse an existing dataset of video-recorded dementia diagnosis feedback meetings and identify positive aspects of communication.
2. To create three free-to-access videos on dementia diagnosis delivery with people living with dementia that can be used to provide clear guidance to clinicians, people undergoing assessment for memory problems and companions.
3. To evaluate the usefulness of these videos with clinicians, people undergoing assessment for memory problems and companions.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/08/2023, Wales Research Ethics Committee 7 (Public Health Wales, Meeting Room Building 1, St. David's Park, Carmarthen , SA31 3HB, United Kingdom; +44 (0)2922 941107; Wales.REC7@wales.nhs.uk), ref: None provided

Primary study design
Interventional

Study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dementias and Neurodegeneration

Interventions
This proposal has been designed by co-applicants Roy James, Sandie Read and Harry Davis, a group of researchers living with dementia who call themselves the Forget Me Nots (FMNs). The FMNs have been working with CIs JW and JD on various research projects since 2016. Over the past pandemic year, the group have been meeting weekly on Zoom to plan future research ideas. Improving dementia diagnosis was first on the list.

The project will consist of three work packages.
Work Package 1 (WP1): Data workshops to develop video content. The aim of WP1 will be to hold data workshops to analyse previously collected video-recorded dementia diagnosis feedback meetings and identify positive aspects of the communication to use in the guidance videos. A dataset of 101 video-recorded dementia diagnosis feedback meetings from nine

memory clinics and 23 doctors across the UK was collected by members of the research team JD and RM for the NIHR RfPB ShareD study (Shared Decision Making in Dementia: NIHR RfPB PB-PG-1111-26063). This dataset has been transcribed with person-identifiable information removed and has ethical approval to be used again for research and training purposes (REC reference number 13/LO/1309).

The data workshops will begin with the study team at the University of Bristol. These will follow conversation analytic methodology where short videos are played repeatedly while group members have transcripts to scrutinise. JD, JW and the FMNs all have experience analysing video-recorded interactions with people with dementia.

JD will present various examples of different methods of delivering the diagnosis that were identified in the ShareD study. These include direct ("You have Alzheimer's disease") versus indirect deliveries ("this might be something called a dementia"), different ways that doctors present results from cognitive testing and different approaches to discussing prognosis. The team will have an open discussion about the communication. They will jointly decide video clips which to take forward to discuss with a wider group of stakeholders. This decision will be led by the Forget Me Nots according to what factors are most important to people with dementia and whether there are parts of the communication that are disagreed about or are unsure about and will warrant wider discussion.

There will be six to eight wider data workshops held with people who have received a diagnosis of dementia in the past two years, companions of people who have received a diagnosis in the past two years, and separate groups with clinicians who deliver dementia diagnoses. There will be five people in each group. The maximum total sample size will be 40 (20 people with dementia, 10 companions and 10 clinicians), providing a range of experiences and opinions. There will be a mixture of face-to-face and virtual groups, allowing national input while also including those who do not want to participate online. All participants will be paid for their time and travel where relevant.

Clinicians and support workers working in assessment services in Gateshead, Bristol and Devon will identify people who have received a diagnosis of dementia in the past two years. They will provide them with the Expression of Interest form which either the clinician or the participant will send to the study team. The study team will then call the potential participant to arrange a time to obtain informed consent. The study will also be advertised online using Twitter and dementia groups such as DEEP (the Dementia Empowerment and Engagement Project). Should Covid-19 precautions still be in place, the consent process and all meetings will occur over video call, if not, the participants will be offered a choice of face-to-face or online meetings.

The team will purposively recruit a diverse range of participants from different backgrounds and types of dementia. Clinician focus groups will include a variety of clinicians who deliver diagnoses in the Gateshead, Bristol, and Devon areas, including psychiatrists, geriatricians, dementia practitioners (nurses of different backgrounds and occupational therapists), and GPs.

The data workshops will be 2 hours long. Three videos will be shown to the participants, as chosen by the FMNs, and open discussion encouraged. The last 20 minutes of the session will be dedicated to forming a list of communication practices identified in the session that could be used in the guidance videos to be developed in work package 2 and adding additional aspects that participants feel should be included. The research team have experience in holding focus groups with clinicians and people with dementia, and JD and JW have experience including people with dementia in the analysis of qualitative data.

The data workshops will be audio recorded with participants' consent and the data transcribed. The transcripts will be analysed deductively by JW, JD and FMNs using framework analysis based on content. Framework analysis was chosen because it is a systematic and flexible approach to analysing qualitative data and is appropriate for use in research teams even where not all members have previous experience conducting qualitative research.

We will use the communication practices that the stakeholder group have identified as most important, and code the transcripts line by line. This will ensure we have systematic descriptions of the meaning of each communication practice that remain true to the words spoken by the stakeholders. These will then be included in the final guidance list, which will be used to form the content of the videos.

Work Package 2 (WP2): Co-design and co-production of guidance videos. In WP2 we will design and produce guidance videos with the Forget Me Nots, within the study team. There is no recruitment for this WP. While the content and focus of the videos will depend on what we learn from WP1, our preparatory work with the FMNs suggests the following themes and potential content:
1. How to tell someone they have dementia (for clinicians). Example content: Give information in a way that invites patient questions; make the interaction as 'non-clinical' as possible by establishing rapport; sitting in front of the person rather than behind a desk; making sure the person knows this is not the end of their life, but a start of a new one; think about the placement of chairs so patients can be near loved ones.
2. How to prepare for receiving a diagnosis of dementia (for people undergoing assessment). Example content: if you are told you have dementia, you might feel numb and stop taking information in; ask your companion to listen or take notes; don't feel afraid to ask the doctor to repeat things; ask clarifying questions if the doctor is unclear.
3. How to support someone receiving a diagnosis of dementia (for companions). Example content: be sure to sit near the person you are accompanying so the clinician can talk to you both at once; take notes and ask questions; remember you may need to take on the information your family member/friend might not remember; have a pre-diagnosis meeting conversation about what the person would like your role to be.

The first stage of the co-design will be to develop scripts and storyboards for the video content. The videos will follow the Conversation Analytic Role-play Method (CARM) format. Following CARM's general principle of walking participants through the interaction turn by turn, as the people in the interaction would experience it, we will show short re-enactments of the video recordings discussed in WP1 so that the viewer can experience in situ the challenges that are faced in real diagnosis meetings as they unfold. The viewer is then invited to pause the videos to reflect on what aspects of the communication work the best. The re-enactments and pause points will reflect the findings of WP1 and the issues that participants felt were most important, illustrating areas of importance for stakeholders. JW has received CARM training, but training will be sought for JD and MP and adapted training for the FMNs. The FMNs, JW and JD will feature in the videos, discussing the details of the communication and why they are important. Quotes from the data workshops in WP1 will be used where appropriate to convey information from the perspective of those receiving and delivering dementia diagnoses. The FMNs will also reflect on their experiences from the perspectives of people with dementia.

We will work with a professional film company that has expertise in collaborating with disabled people to produce training videos (www.redweather.co.uk), with the FMNs having the final say in video content and presentation. The re-enactments will involve actors for clinicians and

people with dementia and companions playing themselves. When we have the first full edit of the videos, we will hold four further workshops with the participants in WP1 when so they can advise as to changes prior to full evaluation.

Work Package 3 (WP3) – Testing and evaluating the videos. We will evaluate the videos in three national dementia diagnosis services: Gateshead, Bristol, and Devon. These provide variety in clinic set-up (primary versus secondary care) and setting (urban versus rural). Evaluation will employ qualitative methods to allow exploration of the videos' use in practice as "a yet-to-be-known" phenomenon, providing a detailed description of how participants respond to and act upon the video content.

We will meet with 20 clinicians from the three services to discuss their experiences delivering dementia diagnoses. These clinicians will be from a range of specialties (as described in WP1), to ensure a range of clinical perspectives. We will ask them to watch the videos and discuss how they might improve their confidence and skills. We will follow this up a week later, establishing if they used any of the guidance in their practice, and what they found useful. Clinicians will be paid for their time.

We will also ask clinicians to gain expressions of interest to take part in the research. They will provide eligible patients with the Expression of Interest form which either the clinician or the patient will send to the study team. The study team will then call the potential participant to arrange a time to obtain informed consent. We aim to recruit 30 people entering the memory assessment service and their companions (10 patient-companion dyads per service). Researchers will show the participants the videos before diagnosis feedback and ask for their views. They will then contact them again for a telephone call after their diagnosis feedback meeting to hear about their experiences and how the video impacted these. Dyads will be paid for their time.

The interviews will follow a pre-determined topic guide designed by the research team. They will be recorded and transcribed. Content analysis will draw out (1) aspects of the videos that were most/least useful, and (2) how the video impacted their clinical practice or experience of diagnosis. The transcripts will be coded line by line according to content, and these will be collated into sub-categories and categories that will provide an overarching description of participants' experiences with the videos. We will use this feedback in discussion with the FMNs, wider project team, and filmmakers to identify final changes to the videos before they are made available for public use.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Improving the experience of receiving and delivering a dementia diagnosis as follows:

1. Identify what aspects of a consultation in a memory assessment clinic work best in communicating a dementia diagnosis. Measured using feedback from viewing pre-recorded videos of dementia diagnosis in data workshops with the study team and wider data workshops with people who have received a dementia diagnosis in the past two years, companions of people who have received a diagnosis in the past two years, and in a separate workshop with clinicians who deliver dementia diagnoses in Work Package 1

2. Can co-produced communication training videos have a positive impact on the delivery or receipt of a dementia diagnosis? Measured through interviews with people in the process of a memory assessment and their companions, and separate interviews with clinicians who deliver dementia diagnoses in Work Package 2

Key secondary outcome(s)
Identify positive aspects of the communication of a dementia diagnosis as follows:

1. Identify what aspects of a consultation in a memory assessment clinic work best in communicating a dementia diagnosis. Measured using feedback from viewing pre-recorded videos of dementia diagnosis in data workshops with the study team and wider data workshops with people who have received a dementia diagnosis in the past two years, companions of people who have received a diagnosis in the past two years, and in a separate workshop with clinicians who deliver dementia diagnoses in Work Package 1

2. Can co-produced communication training videos have a positive impact on the delivery or receipt of a dementia diagnosis? Measured through interviews with people in the process of a memory assessment and their companions, and separate interviews with clinicians who deliver dementia diagnoses in Work Package 2

Completion date
04/10/2024

Eligibility

Key inclusion criteria
People attending (or who have attended) memory clinics:
1. Received a diagnosis in the last 2 years
2. OR be about to attend a memory clinic for a diagnostic appointment

Companions of those attending (or who have attended) memory clinics:
1. Have accompanied someone to a memory clinic to receive a diagnosis of dementia
2. OR be about to accompany someone to a memory clinic diagnostic appointment

Clinicians:
Regularly deliver diagnoses of dementia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
52

Key exclusion criteria
People with dementia who received a diagnosis of dementia over 2 years ago

Date of first enrolment
14/08/2023

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
Queen Elizabeth Hospital
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

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/will be available upon request.

At the end of the project, all study data will be prepared for long-term storage and safely retained for at least 10 years at the University of Bristol. After this time, they will be securely erased by Facility experts. Where consent is in place for indefinite reuse, at the end of the project, data will be deposited for controlled reuse in the Research Data Storage at the University of Bristol.

Anonymised qualitative project data (focus group and interview transcripts) will be deposited for reuse in the Research Data Storage Facility at the University of Bristol. The Co-CIs, Drs Joe Webb and Jemima Dooley (Joseph.Webb@bristol.ac.uk; Jemima.Dooley@bristol.ac.uk) will be Data Stewards. Controlled access can be given upon request to researchers wishing to reuse the data needing their own NHS Ethics approval. Requests will be considered by the University of Bristol's Data Access Committee. Check will be made by the University to ascertain whether data requestors are bonafide researchers' users needing institutional signatories to sign off a Data Access Agreement in which they must uphold certain conditions e.g. to store the data appropriately, not to share the data with anyone else, not to use the data for unapproved or commercial purposes and not to attempt to identify any research participants; and approved users' datasets watermarked with a unique user ID.

IPD sharing plan summary
Available on request