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Better Conversations with Primary Progressive Aphasia (BCPPA)

Submission date
26/02/2018

Recruitment status
Stopped

Registration date
28/02/2018

Overall study status
Stopped

Last Edited
24/05/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Current plain English summary as of 04/04/2019:
Background and study aims
Certain types of early-onset dementia, called primary progressive aphasia (PPA), initially present only as language difficulties. Speech and language therapists (SLTs) in the UK use a variety of communication training approaches to support people with PPA. The aim of this study is to find out whether the Better Conversations with Primary Progressive Aphasia (BCPPA) communication training improves communication strategies, self-efficacy, well-being and quality of life.

Who can participate?
Patients with PPA

What does the study involve?
Participants are randomly allocated to receive either BCPPA or no treatment. The BCPPA program consists of four 1.5 hour sessions over four weeks (total duration is a maximum of 6 hours). People with PPA and their conversation partners both attend and sessions are facilitated by a speech and language therapist (SLT). Video recordings are made by the participants at the start of the program, so that the SLT can assess the pair's difficulties before starting the program. First the SLT provides the person with PPA and their CP information and education on conversation. The SLT then supports the pair in analysing the video sample of their own conversation to identify points that facilitate or are a barrier to communication. Consequently participants are supported to set goals to identify target communication strategies which they practise using through role play and homework tasks. Participants are asked to provide written feedback after every session. Those participants allocated to the no treatment group receive the usual health care provision (anticipated to include neurology, GP reviews, allied health input such as physiotherapy). However, this excludes speech and language therapy for the duration of their participation in the study (i.e. they complete language, communication and quality of life measures with the SLT but they do not receive the BCPPA intervention). The period of no treatment is 5 weeks: 4 weeks when the treatment group receive BCPPA and 1 week when all participants complete the measures. After this brief period the participants allocated to the no treatment group resume all aspects of local speech and language therapy without further interruption.

What are the possible benefits and risks of participating?
It is possible that participants will not experience improvements in their communication, self-efficacy, well-being or quality of life as a result of the intervention. However, there is evidence to suggest that such interventions are effective for improving communication and well-being in adults with non-progressive aphasia and their carers. Importantly, there is no evidence to indicate that participants will experience any harmful side effects. Participants can withdraw from the study at any time. Participants may experience some upset or distress when completing the measures of language ability and when asked to reflect on their communication, mood and quality of life. However, most of the measures are frequently used. As a practising SLT the principal researcher will have the skills to ask the questions in a sensitive and supportive manner, which should minimise any risk of distress. In addition, the assessments have been deliberately designed to be brief (about 1.5 hours). Finally, if participants do not feel emotionally or physically well enough to continue then the assessment will be postponed. If deemed necessary, the SLT will then liaise with the participant to determine what further support may be required in order to complete the assessments. The presence of the video recording equipment might cause distress to the participants. It is also possible that the recording might influence communication between participants and SLTs. To minimise the risk of this happening, the participants are familiarised to the presence of recording devices, and understand why they are being recorded. Small recording devices will be used which do not have microphones or controls attached to them and which are outside the direct line of sight of the participants. One aspect of this study is the detailed analysis of video recordings where faces will be fully visible. It is not appropriate to blank out faces as people's expressions form a significant part of human communication, the focus of this study. Confidentiality can be guaranteed in the sharing of this footage at conferences and during teaching activities, but not anonymity. Allied health professionals viewing this footage are bound by professional codes of ethics requiring them to maintain client confidentiality. Participants (and their CPs) will be asked whether they are willing to accept the possibility of being recognised, and can opt out of this use of their data whilst remaining part of the study. Only the research team members will have access to the entire video recorded dataset. If any information that leads the principal researcher to believe that a participant is at risk of harm or harming others is disclosed by the participant, then confidentiality will be broken to ensure the safety of the person/people involved.

Where is the study run from?
1. South London and Maudsley NHS Foundation Trust (UK)
2. Avon and Wiltshire Mental Health Partnership NHS Trust (UK)
3. Berkshire Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2015 to December 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Anna Volkmer

Previous plain English summary:
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Who is the main contact?
Dr Anna Volkmer

Contact information

Type(s)
Scientific

Contact name
Dr Anna Volkmer

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34007

Study information

Scientific Title
Better Conversations with Primary Progressive Aphasia (BCPPA): communication training to keep families together

Acronym
BCPPA

Study objectives
Certain variants of early-onset dementia, called primary progressive aphasia (PPA), initially present only as language difficulties. Speech and language therapists (SLTs) in the UK report using a variety of communication training approaches to support people with PPA.

This project consists of three stages:
1. A survey of current speech and language therapy practices and review of the literature
2. Intervention refinement and manualisation
3. A controlled pilot study

The BCPPA program aims to improve communication strategies, self-efficacy, well-being and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Camden & Kings Cross Research Ethics Committee, 26/04/2017, ref: 17/LO/0357

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural, Complex Intervention, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied
Primary progressive aphasia

Interventions
A series of video-recorded focus groups will be conducted with people with PPA and their CPs to gather information on what they feel should be included in the Better Conversations with PPA (BCPPA) program. The information collected from the focus groups will contribute to the further refinement of the program for people with PPA.

The BCPPA program will be piloted with 42 dyads across the participating NHS sites. Having given consent to being video recorded participants will be randomly allocated to receive either BCPPA or no treatment. A UK wide survey of SLTs (Volkmer, 2016, unpublished) shows that there is no standard speech and language treatment for people with PPA thus it is not possible to have a usual care group.

BCPPA program:
The BCPPA program will consist of four 1.5 hour sessions over four weeks (total intervention duration will be a maximum of 6 hours). People with PPA and their CPs will both attend and sessions will be facilitated by a local collaborator (speech and language therapist, SLT) at the relevant NHS site. BCPPA is based on the techniques outlined in the Better Conversations with Aphasia program (BCA, Beeke et al, 2013). Video samples are made by the participants at the start of the program, so that the SLT can assess the pair's difficulties before commencing the program. First the SLT provides the person with PPA and their CP information and education on conversation. The SLT then supports the pair in analysing the video sample of their own conversation to identify points that facilitate or are a barrier to communication. Consequently participants are supported to set goals using the Goal Attainment Scales (Turner-Stokes, 2003) to identify target communication strategies which they practise using through role play and homework tasks. Participants will be asked to provide written feedback following every intervention session to provide acceptability and feasibility data. A proforma will be given to participants in a stamped, addressed envelope that can be returned anonymously to the principal researcher directly.

No treatment:
Those participants assigned to a no treatment condition will receive usual health care provision (anticipated to include neurology, GP reviews, allied health input such as physiotherapy). However, this will exclude speech and language therapy intervention for the duration of their participation in the study (i.e. they will be complete language, communication and quality of life measures with the local collaborator (SLT) but they will not receive the BCPPA intervention). The period of no treatment will be 5 weeks: 4 weeks when the treatment group will receive BCPPA and 1 week when all participants complete post-intervention measures. After this brief period the participants allocated to the no treatment group will resume all aspects of local speech and language therapy provision without further interruption.

Participants will be followed up by the local collaborator (SLT) following their involvement in the study. At this point participants will resume routine speech and language therapy. In line with the Medical Research Council Complex Interventions Guidance, the pilot study will define delivery and intervention (length and fidelity), gather information on recruitment and retention issues and the outcome measures for a main trial. Language, communication and quality of life measures will be completed with participants' pre- and post- intervention. Pre-intervention

these will be completed by the local collaborator (SLT) delivering the intervention. Post-intervention these will be completed by an assessor blind to the groups.

Intervention Type
Behavioural

Primary outcome measure
Quality of life is measured using the Dementia Quality of Life Measure (DEMQOL) (Mulhern et al, 2013) pre-treatment (week 1) and post-treatment (week 6)

Secondary outcome measures
1. Language is measured using the Comprehensive Aphasia Test (Swinburn et al, 2004) pre-treatment (week 1) and post-treatment (week 6)
2. Communication is measured using conversation samples; four video recordings of a 10-15 minute conversation, pre-treatment (week 1) and post-treatment (week 6)
3. Quality of life is also measured pre-treatment (week 1) and post-treatment (week 6) using the following:
3.1. The Aphasia Impact Questionnaire (Swinburn, Connect Press)
3.2. Communication Confidence Rating Scale for Aphasia (CCRSA) (Babbitt et al, 2011)
3.3. Perceived Stress Scale (Cohen et al, 1983) (completed by Conversation Partner only)
3.4. Zarit burden interview (Zarit, Orr, and Zarit 1985) (completed by Conversation Partner only)

Overall study start date
01/10/2015

Completion date
31/12/2021

Reason abandoned (if study stopped)
The trial was stopped as the recruitment sites no longer had capacity due to COVID-related staffing issues and priorities for seeing patients.

Eligibility

Key inclusion criteria
Pilot study:
1. Have a diagnosis or possible diagnosis of PPA
2. Have some ability to communicate and understand communication in order to participate in the BCPPA program
3. Are able to see and hear well enough to participate in the BCPPA program
4. Are functionally able to engage in the BCPPA program (i.e. able to maintain some concentration and remain in a 60-90 minute session, minimal challenging behaviour that would be unlikely to cause disruption)
5. English as their language of daily use
6. Have a conversation partner (CP) who is able to and consents to participating in the project

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
Planned Sample Size: 42; UK Sample Size: 42

Total final enrolment
21

Key exclusion criteria
Focus group:
1. History of brain lesions or major head trauma
2. Major physical illness or disability which could impact on participation

Pilot study:
1. History of brain lesions or major head trauma
2. Major physical illness or disability which could impact on participation
3. Major psychiatric diagnosis
4. Prominent behavioural disturbance
5. Prominent episodic memory, visual memory or visuoperceptual impairments

Date of first enrolment
01/11/2017

Date of final enrolment
01/10/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South London and Maudsley NHS Foundation Trust
Speech and language therapy department
Neuropsychiatry
Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ

Study participating centre

Avon and Wiltshire Mental Health Partnership NHS Trust
Speech and language therapy department
Jenner House
Avon Way, Langley Park
Chippenham
United Kingdom
SN15 1GG

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Speech and language therapy department
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1LD

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

NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: NIHR DRF 2015-08-182

Results and Publications

Publication and dissemination plan

The trialists are planning to submit a protocol for a peer reviewed journal article.

Results of the study will be disseminated via the following means:
1. Planned publication in a peer reviewed scientific journals 2020
2. Planned conference presentation
3. Publication on BCPPA UCLextend website

Other publications:
1. Results will also be disseminated via professional and user group publications including presentations at the PPA support group branch of the Rare Dementias Support Group based at UCL
2. It will be written up as part of a PhD thesis in the UCL Language and Cognition Research Department

Publications will abide by the NIHR regulations.

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. With the explicit consent of the participant or their consultee all video data collected at Stages 2 and 3 of the project will be archived in the UCL Human Communication Audio Visual Archive (CAVA) curated by UCL library either until one year after the study has been completed or for as long as the library exists depending on which option consent has been granted for. This has been discussed and agreed with the steering group for the project. Data that is stored on CAVA for longer than one year after study has been completed will be accessible by future researchers who will sign a CAVA Repository End User Licence Agreement to respect the confidentiality, rights and dignity, and use the data in a responsible way. The remaining datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			28/02/2018	No	Yes
Protocol article	protocol	13/10/2018		Yes	No
Thesis results		01/01/2020	18/07/2022	No	No
Results article	results	23/05/2023	24/05/2023	Yes	No
HRA research summary			28/06/2023	No	No