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Exploring supported conversation with familial caregivers of persons with dementia

Submission date
16/08/2018

Recruitment status
No longer recruiting

Registration date
05/09/2018

Overall study status
Completed

Last Edited
11/06/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Dementia can lead to difficulties in communication between caregivers and the individual with dementia. In this study, caregivers will be given a program to help them learn strategies to improve communication between them and the person under their care.

Who can participate?
Individuals with dementia and their familial caregivers who note communication difficulties

What does the study involve?
Caregivers are taught the program over a 4-week period and a week before and a week after the program the caregiver and the person under their care take part in assessments. The entire study takes 6 weeks.

What are the possible benefits and risks of participating?
Participants may get the benefit of improved communication. This study has no anticipated risks.

Where is the study run from?
University of Central Florida (USA)

When is the study starting and how long is it expected to run for?
January 2016 to September 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Joshua Troche
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Contact information

Type(s)

Public

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Additional identifiers

Protocol serial number
102756

Study information

Scientific Title
Exploring supported conversation with familial caregivers of persons with dementia

Study objectives
Supported Conversation for Adults with Aphasia can be adapted for individuals with dementia to help caregivers improve communication and participation between them and the person under their care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board at the University of Central Florida, 12/05/2016, ref: SBE-16-12158

Study design
Single-center interventional pre-post study design

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
A four-week course in an adapted Supported Conversations in Adults with Aphasia for individuals with dementia. Materials used in this study were taken and adapted from the

learning modules provided in Supported Conversation for Adults with Aphasia (SCA). Information from the FOCUSED program and TANDEM model were used to modify portions of the SCA for caregivers of individuals with dementia. Training sessions are broken up into two components similarly to the original materials used in SCA: (1) acknowledging competence and (2) revealing competence. Revealing competence is further broken down into three sub-components: Getting the message in, getting the message out, and verifying the message. All information is presented as a slide presentation to caregivers as a group.

A week before and a week after the program the caregiver and the person under their care will take part in pre and post-assessment. The entire study will take 6 weeks.

Intervention Type
Behavioural

Primary outcome(s)
Measured 1 week before the beginning of the 4-week course and 1 week after the 4-week course:
1. Ability to perform the strategies of Supported Conversation, measured using Measure of Skill in Supported Conversation (MSC)
2. Strength and participation in conversation, measured using Measure of Participation in Conversation (MPC)
3. Caregiver burden, measured using Zarit Burden Interview (ZBI)

Key secondary outcome(s))
Measured 1 week before the beginning of the 4-week course and 1 week after the 4-week course:
1. Unproductive behaviors in conversation, measured using trialists' own measure
2. Social validity (what caregivers thought of the program), measured using trialists' own measure

Completion date
19/09/2016

Eligibility

Key inclusion criteria
1. Individuals with mild to moderate dementia and their familial caregivers
2. Self-reported difficulties in communication

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
8

Key exclusion criteria
1. History of other neurological disease other than dementia
2. institutional dwelling

Date of first enrolment
15/05/2018

Date of final enrolment
22/05/2018

Locations

Countries of recruitment
United States of America

Study participating centre
University of Central Florida
4000 Central Florida Blvd
Orlando
United States of America
32816

Sponsor information

Organisation
University of Central Florida

ROR
https://ror.org/036nfer12

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. All the raw data will be included in the publication of the manuscript.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/01/2019	11/06/2019	Yes	No