

Exploring supported conversation with familial caregivers of persons with dementia

Submission date 16/08/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/09/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/06/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Pre-post design

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet**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 measure

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)

Secondary outcome measures

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

Overall study start date

11/01/2016

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

Age group

Adult

Sex

Both

Target number of participants

8

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

Sponsor details

4000 Central Florida Blvd
Orlando
United States of America
32816

Sponsor type

University/education

ROR

<https://ror.org/036nfer12>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Data will be disseminated and published after the conclusion of the trial. Primary and Secondary outcomes will be published.

Intention to publish date

15/12/2018

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