AWARD NUMBER: W81XWH-16-1-0527

TITLE: **Improving Family Quality of Life through Training to Reduce Care-Resistant Behaviors by People with Alzheimer Dementia and Traumatic Brain Injury**

PRINCIPAL INVESTIGATOR: David Geldmacher, MD

RECIPIENT: University of Alabama at Birmingham

REPORT DATE: **September 2020**

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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4. TITLE AND SUBTITLE

Improving Family Quality of Life through Training to Reduce Care-Resistant Behaviors by People with Alzheimer Dementia and Traumatic Brain Injury

5a. CONTRACT NUMBER W81XWH-16-1-0527

5b. GRANT NUMBER

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6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Alabama at Birmingham
1720 7th Avenue South, Suite 620
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
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13. SUPPLEMENTARY NOTES

14. **ABSTRACT: This project intends to determine whether distance-accessible real time caregiver coaching is associated with improved caregiver burden and quality of life among people providing care to individuals with behavioral and psychiatric symptoms of dementia or neuropsychiatric symptoms after traumatic brain injury. Development of caregiver training materials and intervention strategies occurred as planned and on schedule. Enrollment of participants began close to the original schedule and is ongoing. Potential barriers to recruitment, including the definition of "care resistant behavior" have been addressed and appear to have resolved a slow start to enrollment. Important qualitative observations about the intervention and participant responses have been derived by the intervention team and these are being considered for scholarly reporting and publication. An insufficient number of participants has completed the information for the research team to have collected quantitative data on caregiver burden and family quality of life for statistical analysis. This is consistent with our work plan and expectations for year 1. The project remains active and on schedule.**

15. **SUBJECT TERMS** NONE LISTED

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON** USAMRMC
a. REPORT Unclassified	**b. ABSTRACT** Unclassified	**c. THIS PAGE** Unclassified	Unclassified	69	**19b. TELEPHONE NUMBER** *(include area code)*

Standard Form 298 (Rev. 8-98)
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TABLE OF CONTENTS

1. INTRODUCTION

This research addresses whether theoretically-driven caregiver education and coaching in non-pharmacologic approaches to reduce care resistant behaviors as a trigger of behavioral and psychiatric symptoms of dementia (BPSD) and neuropsychiatric symptoms after Traumatic Brain Injury (NPTBI) will improve caregiver burden and improve quality of life (QOL) for patients and their families. This project will use the innovative approach of distance learning (DL) methods to **teach** caregivers of people with BPSD and NPTBI theoretically determined behavioral techniques and **coach** them on strategies to reduce those adverse behaviors. The combined qualitative, quantitative, and economic analyses will also provide pertinent information regarding the general acceptance, utility, reproducibility, and transferability of NeuroNS-Care to larger groups of family caregivers. These will help guide strategy for the near-certain implementation of synchronous and asynchronous caregiver training programs for both AD and TBI. The proposed study also has the potential to inform healthcare policy and practice for family caregivers of persons with dementia or recovering from TBI.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

Dementia – Traumatic Brain Injury – Caregiving – Caregiver Burden – Quality of Life

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Specific Aims:

1. Translate a theoretically-driven intervention, demonstrated to be effective to reduce care resistant behaviors among nursing home resident with dementia to a distance-learning education, training, and coaching program for family caregivers of people with dementia or TBI.
2. Assess the efficacy of the intervention for reducing frequency or severity of CRB-triggered symptoms of agitation, aggression, and irritability.
3. Assess the efficacy of the intervention for improving quality of life of patients, caregivers, and families
4. Determine how patient and caregiver characteristics influence the effectiveness of the intervention
5. Evaluate how the intervention affects the health care costs of people with dementia or TBI.

Major Task 1: Adapt MOUTh techniques to NeuroNS-Care protocol	Target Month	
Subtask 1: Prepare Regulatory Documents and Research Protocol for Study		
***Milestone Achieved**: Local IRB approval at UAB*	3	Completed 9/9/2016
*Milestone: HRPO approval (***HRPO Log Number A-19729**)	4	Completed 12/20/2016
Milestone : Educational materials completed and deployed to web site	4	Completed 1/13/2017
Milestone: Educational materials updated and maintained on web	4-36	N/A

Major Task 2: Hire/Train/Maintain Staff for Clinical Trials	**Timeline**	
Subtask1: Hiring and Training of Study Staff		100 complete
Milestone: Research staff trained	4	100% complete
Subtask 2: Facilitate hiring, training, supervision and fidelity checks as needed for attrition	4-36	100% Complete
Milestone Achieved: Maintained trained and available Independent Evaluators throughout duration of both clinical trials	4-36	100% Complete
Major Task 3: Randomized Controlled Trial		
Milestone: 1st participant consented, screened and enrolled	5	Completed 3/15/2017
Milestone: Report findings from overall studies	36/post funding	Preliminary findings reported – see appendix
Major Task 4: Data Analysis		N/A
Milestone: Report results from data analyses	36	Quantitative Analysis Complete Qualitative Analysis 75% complete

During year 2, we were unable to reach our enrollment goals; the study had low enthusiasm among potential participants because of unfamiliarity with videoconferencing, time commitments, uncertainty of the outcome, and the desire for rapid response to difficult behaviors (such as prescription medication).

Year three allowed us to complete the intervention on all enrolled subjects (59% of the target), and begin sharing results. Details follow. The analysis and dissemination was slowed by the COVID emergency. The remaining goals will be met during an approved no-cost extension

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

A 12-week cross-over design study, using a distance-learning , internet based, family caregiver coaching program was conducted. A total of 34 community-dwelling people with AD who had at least one recurring BPSD symptom associated with care resistant behavior and causing distress to a family caregiver were enrolled. Ten community dwelling survivors of traumatic brain injury with neuropsychiatric symptoms were also enrolled to assess the generalizability of the intervention to other disease states of interest to the CMDRP.

1) Major activities;
    a. Completion of the coaching intervention for the last of the 44 enrolled dyads (34 AD and 10 TBI) was achieved.
    b. Transcription and qualitative thematic analysis of the coaching sections was conducted
2) Specific objectives
    a. objectives for this time period were to complete the quantitative analysis of the data and begin reporting of results – these were achieved, but negatively impacted by COVID
3) Significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative) Full analytic details are in the appendix.
    a. Primary hypotheses 1: Although the effect of the intervention on caregiver burden was in a direction that indicated benefit, there was not statistically significant effect of the intervention on Zarit Burden Inventory (ZBI) scores
    b. Primary hypothesis 2: Three baseline variables were significantly associated with caregiver burden on the Zarit Burden Inventory; these were *caregiver neuroticism* ($P < 0.005$), *severity of BPSD* in the patient ($P < .001$) and *older caregiver age* ($P<.05$). No other baseline variables, including severity of cognitive deficits or caregiver personality traits of *mastery* and *resilience* achieved significance relative to the ZBI. In contrast, *caregiver resilience* was associated with higher Family-Quality of Life in Dementia scale scores ($P <.001$)
    c. Exploratory hypothesis 1: In the AD cohort, no effects of the intervention were detected on patient quality of life (DEMQOL or DEMQOL-proxy) or caregiver QOL (EQ-5D) – all P values >.05
    d. Exploratory hypothesis 2: In the TBI cohort, no benefit of the intervention was identified for Caregiver Burden, caregiver QOL, or patient QOL (all $P>.05$).
    e. Exploratory hypothesis 3: No sustained benefit of the intervention on ZBI or QOL measures was detected at late follow-up 12-18 weeks post intervention (all $P >.05$)
    f. Exploratory hypothesis 4: There was insufficient data available size to reliably analyze changes in health resource utilization. An exploratory, qualitative review of EQ-5D-5L responses will be conducted.
    g. Exploratory hypothesis 5: No statistically significant effects of the intervention were identified on FQOL instruments for dementia or TBI. (all $P >.05$)

4) Other achievements
    a. Qualitative analyses of the coaching sessions based on debriefing sessions with the coaches identified critical differences in caregiving challenges in the TBI and AD samples, suggesting that a single common intervention plan will be unlikely to meet the specific needs of these different populations.
    b. This analysis provided unexpected insights into the acceptance, mechanisms and content of teleconference based coaching, which will be important to our future work with caregivers for each illness state. We anticipate that these insights will be of increased utility for clinical practice and research following the rapid expansion and adoption of videoconference-based telemedicine in the post-COVID environment

The original proposal goals were "The combined qualitative, quantitative, and economic analyses will also provide pertinent information regarding the general acceptance, utility, reproducibility, and transferability of NeuroNS-Care to larger groups of family caregivers. These will help guide strategy for the near-certain implementation of synchronous and asynchronous caregiver training programs for both AD and TBI. The proposed study also has the potential to inform healthhcare policy and practice for family caregivers of persons with dementia or recovering from TBI."

The goal to "provide pertinent information regarding the general acceptance, utility, reproducibility, and transferability" of the intervention were well satisfied. We learned that 1) acceptance was lower than we expected; 2) utility was low, both because outcome measures did not identify clinically meaningful change, and implementation was very requiring extensive professional time; 3) reproducibility was good, with consistent thematic responses identified within AD and TBI caregiver groups; and 4) transferability of the one-on-one coaching to group sessions is unlikely to yield greater success. Dr. Jablonski's NIH grant proposal for group remote coaching sessions, (Efficacy of Tele-Coaching for Caregivers of Persons with Dementia Exhibiting Care-Resistant Behaviors; Proposal number R01AG061915) based on preliminary observations from this study was not funded.

Unmet goals: We were unable to identify sufficient use of healthcare resources in the small samples and short duration study to conduct a valid statistical analysis. Other contemporaneous caregiver intervention research that assessed utilization and reported since our study was proposed, have identified similar difficulties
(e.g. Manning CA, et al, (https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1002/alz.044033)

Overall status as reported under HRPO log# A-19729
    Number of subjects recruited/original planned target: 88 /150
    Number of subjects screened/original planned target: 80/150
    Number of patients enrolled/original planned target: 44/75
    Number of patients completed/original planned target: 32/75

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Drs. Geldmacher and Jablonski now consult with the Middle Alabama Area Agency on Aging, in support of that Agency's Administration for Community Living grant (ACL 90ADPI0042) in support of Home and Community Based services for persons with dementia. (see https://m4a.org/services/panda-project/). Dr. Jablonski has translated her qualitative observations from this study's tele-coaching approaches in education to the project team, in support of their "Dementia-Friendly Community" initiative.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

This project will likely impact community resources for informal caregivers by encouraging adoption of online coaching as an addition to existing community resources. The project will likely influence methods to expand effective means to providing caregiver support, knowledge, and reinforcement of strategies to address care-resistant behaviors that do not require the physical presence of the caregiver. these include expansion of telemedicine services for dementia care, and technology-rich approaches like smart phone apps. These are important expansions of service in a predominantly rural state like Alabama. Beginning in FY 2021, Dr. Geldmacher will participate in a program to develop a smart phone app aimed to better support dementia caregivers.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report." Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities; changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or improving social, economic, civic, or environmental conditions.*

As noted in the previous section, online coaching for informal caregivers has the potential to provide coaching resources to future caregivers who need support but lack access to resources that require a physical presence. It can add to the accessibility of already established community resources and create more coverage for areas that lack adequate resources for informal caregivers. It can be cost effective and has the potential to improve the lives of those caring for persons with dementia by reducing burden create by care-resistant behavior.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Extreme difficulty in recruitment was experienced in the first two years of the study; family caregivers were reticent to commit to the time required for coaching, the technology was daunting for some, and many caregivers who were approached wanted the more expedient and easier approach of drug treatment. – this required a reduction in sample size to 34 Alzheimer dyads and 10 TBI dyads (59% of the goal) Our reduced sample limited of meaningful analyses of resource utilization, but allowed us to increase focus on qualitative aspects of the intervention

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

We added recruitment sites and methods, but were unable to meet our projected enrollment. While disappointing, this has been identified as a recurring problem in studies focused on adverse behaviors in dementia. (see https://www.isctm.org/public_access/Feb2017/ISCTM-BPSD-Distribute-Working-Group-2017-final.pdf). *Our projection that the availability of care-delivery at home would overcome recruitment difficulty seen in traditional clinical trials was not supported.* This itself was a valuable learning

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Staff commitments continued unchanged in this reporting year.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS:

List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

- Jablonski RA, Winstead V, Geldmacher DS.. Description of Process and Content of Online Dementia Coaching for Family Caregivers of Persons with Dementia. *Healthcare* 2019;7:13. https://doi.org/10.3390/healthcare7010013

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Podium Presentations:

- Jablonski R, Winstead V, Geldmacher D. Perspectives of family caregivers confronted with care-resistant behavior from persons with dementia. Presented at 2020 Annual Scientific Meeting of the Gerontological Society of America (held virtually because of COVID pandemic) November 19, 2020

Poster Presentations:

- Jablonski R, Winstead V, Pilonieta G, Geldmacher D. Feasibility of online synchronous caregiver dementia coaching for rejection-of-care behaviors. Presented at 2019 Annual Scientific Meeting of the Gerontological Society of America, Austin TX, November 5, 2019
- Geldmacher DS, Jablonski RA, Winstead V, Pilonieta G. Family Quality of Life in Dementia and Caregiver Burden are Associated with Different Caregiver Personal Characteristics. Presented at 2020 Alzheimer's Association International Conference (held virtually because of COVID pandemic), July 30, 2020

Published Abstracts

- Jablonski R, Winstead V, Pilonieta G, Geldmacher D. Feasibility of online synchronous caregiver dementia coaching for rejection-of-care behaviors. *Innovation in Aging,* 2019;3 (S1):924
- Geldmacher DS, Jablonski RA, Winstead V, Pilonieta G. Family Quality of Life in Dementia and Caregiver Burden are Associated with Different Caregiver Personal Characteristics. *Alzheimer's & Dementia*, 16, e045333.
- Jablonski R, Winstead V, Geldmacher D. Perspectives of family caregivers confronted with care-resistant behavior from persons with dementia. *Innovation in Aging,* 2020;4 (S1):253

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other*

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source *of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".*

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Name	David Geldmacher, MD (no change)
Name	Rita Jablonski-Jaudon, PhD (no change)
Name	Vicki Winstead (no change)
Name	Felicia Underwood (no change)

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Dr. Geldmacher (PI) had the following changes in other research support during the reporting period:

Sponsor	Study	Role	End Date	Effort change (Calendar Months)
NIH/NIA	R01AG045154	Co-I	6/30/20	(0.96)
Biogen	251PP201	PI	4/4/20	(0.12)
Biogen	221AD302	PI	1/24/20	(0.12)
AbbVie	ABBE-8E12	PI	1/21/20	(0.84)
Effort change from ended studies:				-2.04
			Begin Date	
NIH/NIA	U54MD000502-17S2	Co-I	7/22/19	1.20
NIH/NIA	R01AG059009	Co-I	9/1/19	0.12
NIH/NIMH	R01MH121928	Co-I	1/1/20	0.60
NIH/NIA	1R01AG053798	PI	4/1/20	0.36
Effort Change from new studies				2.28
Net change in funded effort				+0.24 CM
Internal departmental support (from endowed funding) was reduced equivalent to the 0.24 month effort change. There was no effect on effort devoted to this study				

Drs. Jablonski and Winstead identify no significant changes in funding status during this reporting period.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
<u>Organization Name:</u>
<u>Location of Organization: (if foreign location list country)</u>
<u>Partner's contribution to the project</u> (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- Completion and submission of primary results manuscript
- Completion and submission of manuscript on caregiver characteristics' influence on Family Quality of Life
- Completion of qualitative analysis of coaching sessions and outcomes, with dissemination of results at national and international meetings, followed by submission of manuscripts to relevant peer-reviewed scientific research journals

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Important qualitative observations about the intervention of online coaching for informal caregivers of persons with dementia were obtained. These observations led to the development of a coaching training program that could be embedded into existing community resources for informal caregivers.

- An NIH grant (PI: Jablonski) was submitted but not funded.
- An ongoing collaboration with the federally funded Administration for Community Living funded dementia caregiver support program (ACL Grant 90ADPI0042) was initiated.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

The intervention could enhance the holistic approach to care in the clinical setting by adding an additional resource focused on the informal caregiver as a part of the persons with dementia care plan. This might include trained "lay navigators." We do not currently have outcome data on that potential impact.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

APPENDIX TO THE ANNUAL SUMMARY
AWARD NUMBER: W81XWH-16-1-0527

Period: 1 September 2019 to 31 August 2020
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TITLE: Improving Family Quality of Life through Training to Reduce Care-Resistant Behaviors by People with Alzheimer Dementia and Traumatic Brain Injury
PRINCIPAL INVESTIGATOR: David Geldmacher, MD

CONTENTS:

1. Work Product summary
2. Published abstracts
3. Peer-Reviewed research article for study data
4. Data analysis summary

WORK PRODUCT SUMMARY

Podium Presentations:

- Jablonski R, Winstead V, Geldmacher D. Perspectives of family caregivers confronted with care-resistant behavior from persons with dementia. Presented at 2020 Annual Scientific Meeting of the Gerontological Society of America (held virtually because of COVID pandemic) November 19, 2020

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- Jablonski R, Winstead V, Geldmacher D. Perspectives of family caregivers confronted with care-resistant behavior from persons with dementia. *Innovation in Aging,* 2020;4 (S1):253

Peer-reviewed published manuscripts

- Jablonski RA, Winstead V, Geldmacher DS.. Description of Process and Content of Online Dementia Coaching for Family Caregivers of Persons with Dementia. *Healthcare* 2019;7:13. https://doi.org/10.3390/healthcare7010013

Grant Proposals (based on data/observations from this project)

- Jablonski, R (PI). R01AG061915: Efficacy of Tele-Coaching for Caregivers of Persons with Dementia Exhibiting Care-Resistant Behaviors. National Institute of Aging, 9/1/2018-8/31/23. $1,450,259.
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- Jablonski, R. & Pickering, C. (MPI). R01AG074255: Testing Dementia Caregiver TeleCoaching to Recognize and Manage Care-Resistant Behaviors and Reduce Episodes of Abuse and Neglect. National Institute of Aging. 9/1/2021-8/31/2026. $3,590,969.
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PUBLISHED ABSTRACTS

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FEASIBILITY OF ONLINE SYNCHRONOUS CAREGIVER DEMENTIA COACHING FOR REJECTION-OF-CARE BEHAVIORS

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Problem: Two-thirds of family caregivers of persons living with dementia have encountered rejection-of-care behavior, usually during assistance with activities of daily living. Purpose: To describe the feasibility of an online videoconfer-encing platform to help caregivers prevent and reduce ROC behavior. Design: Quasi-experimental. Sample: Twenty-six family caregivers: 54% female, 77% white, 62% spouses (31% wives, 31% husbands), mean age 65 years, and college-educated (92%). Their care recipients were 61% fe-male, 77% white, mean age of 76 years, and college-educated

(88%). Procedure: Family caregivers who endorsed problematic ROC behaviors in their care recipients participated in six online, individual, synchronous, sequential, and weekly 1-hour coaching sessions. We measured general burden (Zarit Burden Inventory) and the frequency, severity, and associated distress of responsive behaviors (Neuropsychiatric Inventory Questionnaire). Data collection intervals were before coaching (baseline), immediately after the final session (Time 1), and six weeks (Time 2) and 12 weeks (Time 3) after the final session, respectively. Results: Caregivers reported less overall distress scores at Time 2 compared to baseline: 13.58 (SD 6.44) versus 17.42 (SD 6.90), t=2.56, p=0.017). Distress scores returned to baseline by Time 3. Caregivers reported less severe ROC behavior at Time 2 which was not statistically significant. Burden remained unchanged throughout the 24 weeks. Conclusion: Online caregiver coaching that targets ROC behavior is feasible. Qualitative review of the encounters suggests that a longer period of intervention and an outcome measure more sensitive to ROC effects on activities of daily living may be needed in future studies.

PERSPECTIVES OF FAMILY CAREGIVERS CONFRONTED WITH CARE-RESISTANT BEHAVIOR FROM PERSONS WITH DEMENTIA

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Problem: Care-resistant behavior is often bundled with other behavioral symptoms of dementia, but it is a unique behavior requiring targeted interventions. Purpose: To describe the experiences of caregivers receiving online coaching to manage care-resistant behaviors exhibited by persons with dementia. Design: Qualitative. Sample & Procedure: 20 caregivers (12 female, 8 male) were recruited from Memory Disorders and Geriatrics clinics to participate in 6 weeks of online coaching sessions delivered by a doctorally prepared nurse practitioner. Coaching sessions were recorded and transcribed. NVivo12 software was used to manage the thematic analyses. Results: Caregivers followed a general trajectory. They initially reported feelings of anger, frustration, and guilt. They believed that the person with dementia was purposefully "being stubborn and mean." As the coaching sessions progressed, these negative emotions and the attributions of intent altered. By the conclusion of the six weeks, caregivers expressed feelings of success and ingenuity in applying coaching strategies. Conclusion: Online coaching is an effective way to individualize strategies that enable the caregiver to manage and reduce care-resistant behavior. Implications: The use of a doctorally-prepared nurse practitioner to deliver coaching, while effective, is not sustainable. Next steps include developing a coaching training program that could be embedded into existing community resources for community-dwelling caregivers. Limitations: Participants were limited to referrals from two clinics in the same institution.

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DEMENTIA CARE AND PSYCHOSOCIAL FACTORS

POSTER PRESENTATIONS

Dementia care research (research projects; nonpharmacological)/Family/Lay caregiving

Family quality of life in dementia and caregiver burden are associated with different caregiver personal characteristics

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Abstract

Background: Most care for persons with dementia takes place in the context of family. Dementia is associated with diminished quality of life for both affected persons and their caregivers, as well as increased burden. There is a growing consensus in dementia care that service-delivery models for persons with dementia need to be family-centered, but few studies have explored the concept of "family quality of life" (FQOL) in dementia. As part of a planned coaching intervention to reduce burden in caregivers of people with behavioral and psychiatric symptoms of dementia (BPSD) associated with care resistance, we collected baseline data on factors that might influence burden, FQOL, and response to the intervention.

Method: The 42-item Family Quality of Life in Dementia (FQOL-D) questionnaire, Connor-Davidson Resilience scale (CD-RISC), Pearlin Mastery scale, and neuroticism items from Eysenck Personality Inventory(EPI) were collected from 26 family caregivers of people with AD who endorsed BPSD with care resistant behaviors. The Spearman correlation between caregiver personality traits and FQOL-D was calculated. In addition, relationships between caregiver burden, measured with the Zarit Burden Interview (ZBI), and caregivers' personality characteristics were ascertained.

Result: Of the 26 enrolled caregivers, 14 (53.85) were female, their mean age was 64.5 years and 24 (92%) were college-educated. Their care recipients were 61% female, 77% white, mean age of 76 years, and college-educated (88%). Mean scores were CDRISC 76.03 (+/-12.05), EPI 6.30 (+/-1.95), Pearlin 20.23 (+/-3.26) and FQOL 173.80 (+/-24.92). There were moderate correlations between FQOL and CDRISC ($r=0.5$). Secondary analysis showed moderate correlations between ZBI and Pearlin ($r=-0.42$) and EPI ($r=0.48$). All reported associations are $P<.05$

Conclusion: A relationship between Family Quality of Life and caregiver personal characteristics was identified. Higher baseline FQOL-D was associated with greater self-reported resilience. Similarly, higher mastery scores were associated with lower burden on the ZBI. Higher caregiver neuroticism was associated with higher reported burden. No relationships between mastery or neuroticism and FQOL-D were established in this small sample. We identified that the positive construct of FQOL-D may be associated with different caregiver characteristics than the negative emotional valance attributed to burden.

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Description of Process and Content of Online Dementia Coaching for Family Caregivers of Persons with Dementia

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Abstract: Family caregivers of persons with dementia encounter resistance to care behaviors (RCBs). The purpose of this methods paper was to describe the process and content of six weekly 60-min caregiver coaching sessions delivered synchronously through an online platform to 26 family caregivers of persons with dementia. All session notes were analyzed for process; two coaching sessions from five purposely-selected participants were transcribed and analyzed thematically for content. The six sessions followed an overall pattern. The first session included the most teaching and goal-setting; the coaches also queried the family caregiver about the premorbid personality, work history, and interpersonal attributes of the person with dementia. Sessions two through five were the most active coaching sessions; previously suggested strategies were evaluated and tailored; caregivers also role-played with the coaches and developed scripts designed to curtail RCB. The sixth session served as a review of successful caregiver strategies and concluded the coaching relationship. Four primary content themes emerged in the coaching process: (1) education; (2) caregiver communication; (3) affirmation of the caregiver; and (4) individualized strategies. These four content categories were used throughout the coaching process and were interwoven with each other so that the participant knew why the behavior was occurring, how to verbally address it, how to use a strategy effectively, and affirmation of the result. The coaching process and content demonstrated alignment with person-centered practices and relationship-centered care.

Keywords: dementia; caregiver; coaching; rejection/resistance to care behavior; internet-based

1. Introduction

In the United States, 16 million informal caregivers provide 18 billion hours of care to 5.5 million persons with Alzheimer's disease or related dementias annually; this care is valued at $230 billion US dollars [1]. Nearly 80% of persons with dementia living in the community require help with at least one activity of daily living (ADL) [2]. Persons with dementia requiring ADL assistance often exhibit resistance to care behaviors (RCBs) [3,4]. RCB refers to actions taken by a person with dementia to avoid receiving assistance or care activities [5–7]. RCB encompasses an entire spectrum of behaviors, from subtle verbal or nonverbal signals to full-on assaults [7,8]. Examples include pulling away or turning away from the caregiver, saying "no," crying, yelling, pushing the caregiver away, grabbing an object to evade care, clenching the mouth shut (to avoid medication, food, or mouth care), adducting limbs (to prevent the axillae or perineal areas from being cleansed), and striking the caregiver [6–8]. These behaviors vary in frequency and intensity. Terms variously used to describe RCB include agitation, refusals, resistiveness to care, rejection of care, and care-resistant behavior [7,9,10]. For clarity, this article will use “resistance to care” behavior. Investigators in the past ten years have made important distinctions between agitation and resistance to care. The major difference between the two involves contextual clues. That is, agitation usually occurs without a specific trigger, whereas RCB occurs in response to a precipitating event, such as bathing or mouth care [7,11,12]. Agitation is evident in persons with mild dementia, increases with moderate dementia, and wanes as the dementia progresses to severe. RCB, however, consistently increases with worsening dementia severity; one study found an eightfold increase in overall RCB when dementia progressed to the severe stage [12].

Fauth et al. discovered that 66% of their 234 informal caregivers encountered RCB, the majority of which occurred when caregivers attempted to assist with ADL [3]. These informal caregivers experienced feelings of distress, captivity, and depression when faced with RCB. Shirai and Koerner [13] reported similar prevalence of RCB with fluctuations over time. They collected RCB data over an 8-day period from 63 informal caregivers and concluded that informal caregivers who experienced both higher frequencies and higher fluctuations in RCB experienced significant increases in physical problems such as headaches and chest tightness [13]. Spigelmyer et al. [14] conducted a phenomenological study examining the experience of informal caregivers with RCB; the investigators reported that caregivers felt intensely guilty and incompetent when faced with RCB [14].

In long-term care settings, Mahoney et al. were among the first to distinguish RCB from other behavioral and psychological symptoms of dementia (BPSD). Jablonski and colleagues have been instrumental in testing theoretically driven strategies that enable long-term care staff to successfully provide mouth care to persons with dementia exhibiting RCB [8,9,15–17]. For this study Jablonski et al.’s non-drug, behavioral interventions were adapted to a distance-accessible education, training, and coaching program for family caregivers of people with Alzheimer’s disease. The coaching program contained both asynchronous content and six 60-min weekly real-time coaching sessions with family caregivers delivered via an internet-based platform. We distinguished teaching, which is content-focused and generalized, from coaching, which is process focused and specific to the individual caregiver/learner. This content represents one part of a larger research program measuring the impact of the coaching program on caregiver burden and quality of life for families caring for persons with dementia. By its nature, most qualitative research has reflective qualities, including this one. However, the primary aim of this paper is to describe the methods, including process and content, of the six weekly 60-min dementia coaching sessions that constitutes the primary intervention in the broader research program. This is done by using the interactions between coach and caregiver (using actual quotes) as exemplars of the process and the content of this process.

2. Operationalization of Coaching Sessions: Planned Process and Content

After receiving ethical approval from both the university (University of Alabama at Birmingham, UAB IRB-160819003) and the funder (United States Department of Defense, DOD HRPO A-19729) family members of persons with dementia were recruited from outpatient clinics within the same healthcare system. The family member participants were randomized to either immediate or delayed coaching sessions. All had immediate access to the asynchronous materials available on a password-protected website. The asynchronous content included six brief videos that provided and illustrated specific strategies for preventing and managing RCBs. The strategies have been published in-depth elsewhere [9,15–17].

Two members of the team served as coaches (RJ and VW). One coach was a nurse practitioner and researcher who had several years of clinical experience extending Jablonski and colleagues’ RCB mouth care work to other ADLs, such as bathing and medication administration. The other coach was a medical sociologist with experience implementing RCB research. The protocol allowed either coach to conduct coaching sessions.

The caregiver coaching sessions were operationalized a priori to follow a systematic process. Each coaching session was digitally recorded. During the sessions, the caregiver was queried about any problematic CRB and the strategies (if any) deployed to address it. Additional details, such as timing context, and success (or failure) were sought. The coaches adapted specific strategies to personalize the techniques to the needs of both the caregiver and the care recipient. The coaches assessed the ongoing efficacy of previously used interventions, and the resulting behavior, during each subsequent coaching session. The coaching goal for every session was to help the family caregiver become more independent with using and modifying the RCB techniques. Throughout the 6 coaching sessions, the efforts of family caregivers were acknowledged, praised, and reinforced.

The internet-based Go-To-Meeting™ platform was selected so that participants did not have to purchase any software; they downloaded the free version and responded to a link sent by the research team. Prior to the first scheduled coaching session, VW conducted a 20-minute practice session with the participants, using the link to assist with any technical problems. Every participant had a unique Go-to-Meeting™ link.

To date, 26 family caregivers have completed 6 coaching sessions. Each coaching session was approximately one hour in duration. Because of the length and depth of each one-hour coaching session, five participants that represented the diversity of the participant sample in terms of sequential entry into the study, gender, ethnicity, and family role of the caregiver (e.g., spouse versus adult child) were selected for the purpose of describing the content and process of the coaching sessions. Schatzman and Strauss [18] note that the use of purposeful sampling is feasible when choosing participants because of practical options such as constraints of time, the research framework, and burgeoning interests/concepts during the research process. These participants were also selected based on the richness of the data collected in their sessions and also represented the trajectory and content of the majority of the sessions The notes taken by the coaches during all coaching sessions were also analyzed. A description of the general pattern of all six coaching sessions emerged from the notes, which are described in the Results section, below. This pattern then informed our decision to select, and analyze, transcripts from the second and fifth sessions from the 5 purposively selected participants. The rationale for selecting these sessions was that sessions 2 and 5 best reflected caregiver struggles, problems, strategies, breakthroughs, and insights. During Session 2, participants provided richer descriptions of the RCBs as compared to the initial session. Participants also shared helpful information about underlying sources of strengths and challenges, for example, how existing family dynamics could be both supportive and frustrating. The Session 5 reflected the culmination of the previous 4 coaching sessions and consistently resulted in "a- ha" moments of exceptional clarity and understanding of the content. By Session 5, participants had tried the strategies and were becoming more confident with their abilities to reduce and manage RCB. The participants were selected to represent

The transcripts from Sessions 2 and 5 of the five purposively selected participants were transcribed, 10 transcripts total. Content analysis was employed on the 10 transcripts to better describe the behavioral strategies developed between the participants and the coaches. Content analysis is a research method that is useful in conceptualizing the meaning and relationship of language in a text in order to derive meaning [19]. All 10 transcripts were coded for concepts that described the coaching process. This provided a systematic method for thematic development based on the presence of these concepts. All 10 transcripts were compared against the original digital recordings for accuracy. Corrections were made if mistakes were noted.

3. Results

3.1. Sample and Demographics

The sample ($N = 5$) included 3 women and 2 men (see Table 1). The average age of the participants was 65.4 years. All of the caregivers were in their seventies except for one who was 29. Two of the caregivers were adult children of the care recipient.

Table 1. Demographics.

Participant/Caregiver ID	Age	Gender	Race	Relationship to Care Recipient
A	75	F	African-American	Daughter
B	74	M	White	Spouse
C	78	M	White	Spouse
D	71	F	White	Spouse
E	29	F	Asian	Daughter

3.2. Roles of Primary and Secondary Coaches

The analyses of the transcripts revealed that the coaching process evolved and individual roles of each coach emerged. Both coaches participated together in the coaching sessions. Initially, the plan was for VW to gain familiarity and experience by "listening in" to all 6 of RJ's coaching sessions with the first participant, and then for both coaches to conduct sessions independently. For the sessions reported here, RJ consistently served as the primary coach and VW as secondary coach. Participants were also aware that both coaches were present during each session.

After each session with any participant, both coaches engaged in debriefing activities and brainstormed ideas for the next session, which were incorporated into joint notes. This practice was found to be very helpful for both coaches; they continued to work together with all subsequent participants. The secondary coach would "listen in," and assist the primary coach with post-coaching debriefing. Feedback from the secondary coach served as an assessment tool for the session. The secondary coach was able to provide feedback for factors such as participant reaction, the trajectory of the sessions and provide affirmation for successful interactions. Debriefing was especially helpful to the primary coach since a majority of the interactions occurred between the participant and primary coach. The post-session debriefing also alerted both coaches to the maturation and evolution of the intervention that produced a growing collection of strategies.

During the shared sessions, the secondary coach (VW) would interject ideas if appropriate. Notes taken during the sessions were shared between coaches and informed the context of the next session. The notes served to remind coaches of previous sessions, provided insight into the sessions, and served as a "placeholder" for the next session. These notes were especially helpful when multiple coaching sessions with other participants were being conducted in the interval between sessions for any one participant. In the notes, coaches recorded problems described by the caregivers that were not easily addressed in the session and required further thought. Coaches would discuss the problem and work together, brainstorming, to provide unique/individualized strategies for the caregiver. After the first several sessions, it became apparent that directed homework was important for the participants. It served to encourage participants to implement the strategies thus providing the coaches an opportunity for feedback to the caregiver and to assess the efficacy of the strategies for the care recipient.

3.3. General Pattern of Six Week Caregiver Coaching Sessions

The following is a description of the pattern of content and coaching activities that emerged from coaching notes across all sessions:

Session 1 served as the introduction and goal-setting session. The primary coach first inquired about the premorbid personality, work history, and interpersonal attributes of the person with dementia. The coach also inquired about past and current living situations and premorbid relationship quality. This information helped the coaches to assess the strengths and challenges presented by the relationship between the caregiver and care-recipient. Goals were negotiated and determined by asking the caregiver, "Which refusal behavior is most important for us to help you with?" The coaches laid the foundation for the future sessions by emphasizing that the coaching sessions were to help caregivers "manage" and "reduce" negative impacts of RCB on their well-being; because of the progressive nature of dementia, eradication of BPSD was not a realistic goal, and any expectation of eradication would set the caregivers up for failure. Session 1 also included the most teaching of dementia content.

Initial RCB strategies were also introduced during the first session and tied to the "shrinking box" and "short-staffed" analogies; a description of these and other analogies can be found in Table 2. These strategies included communicating using "short, sweet, and concrete" sentences; using gestures and pantomimes as adjuncts to verbal communication; avoiding arguments; and "entering their reality" in lieu of therapeutic fibbing. Therapeutic fibbing was a term coined in 1999 by Beach and Kramer, and referred to the practice of lying to people with dementia [20]. "Entering their reality" [15,17] involved finding situations from their past that would provide a reason for engaging in a care activity or allowing the caregiver to provide assistance without triggering refusals.

Table 2. List of Analogies and Description.

Analogy	Purpose	Description
Shrinking box	Explanation of neurodegeneration and its impact on short-term memory	Coaches compared shrinking brains to shrinking boxes. As the boxes became smaller, recent memories fell out while new memories could not be placed in the shrinking box.
Short-staffedworking conditions	Explanation for periods of irritability and fatigue observed in the person living with dementia	The ongoing loss of neurons from neurodegeneration resulted in compensation from remaining neurons. These remaining neurons were likened to employees working with insufficient staff: the remaining employees would be expected to perform multiple and unfamiliar tasks, resulting in mistakes and fatigue. They would be irritable and cranky by the end of the shift.
Messy closet/Jewelry Box	Explanation for confabulation or erroneous long-term memories; also used to help explain altered sensation of time passing	The brain was compared to a compartmentalized closet or box, where memories were logically arranged in sequential patterns. If the clothes became haphazardly arranged in the closet, or if the compartments in the jewelry box disappeared, the contents would become disorganized and difficult to locate. This analogy was then applied to the brain, where the loss of neurons contributes to the jumbling of memories. The person with dementia was not lying or trying to be difficult.
Highways and back roads	Explanation for cognitive slowing and altered sensation of time passing	Neural networks were compared to highways. Loss of neurons resulted in "closed lanes" and "detours." Both created traffic slowing. Ongoing neuronal death resulted in some highways becoming completely severed. The memories may still be available, but unable to be accessed. In these situations, sensations (music, smells, touch, pictures) may access specific memories via "back roads."
Boat without an anchor	Additive explanation for confabulation or erroneous long-term memories; also used to help explain altered sensation of time passing	Short-term memory is necessary for people to "be anchored" in time and place. If short-term memory is impaired, the person with dementia becomes disoriented because they are like a boat without an anchor; they are bobbing around in a sea of memories without landmarks.

Table 2. *Cont.*

Analogy	Purpose	Description
Moving backwards in time	Explanation for apraxia around ADLs and other activities.	Persons with dementia generally experience apraxia in a sequential pattern, with loss of complex abilities occurring prior to loss of simpler abilities. The loss of abilities was couched as reverse chronological aging. People lose the ability to use objects or perform activities that were learned latest in life, while retaining abilities (such as feeding onself) learned early in life.
Brain as computer	Explanation to assist the caregiver to understand the person's inability to create new memories.	Loss of neurons compared to an older computer with no more memory.
Strategy Toolbox	Explanation of why strategies may require modifications over time and	Strategies compared to different tools in a toolbox. Just as every tool has a specific function, specific strategies are used in specific situations.

In Sessions 2–5, the coaches built on the initial RCB strategies *provided* during Session 1 while introducing new strategies as needed. Some content-focused and generalized teaching occurred throughout these sessions, but the amount of teaching progressively decreased while the amount of coaching increased (see Section 3.4 for specific coaching approaches). The caregiver was initially queried about the use and outcome of specific RCB strategies. The strategies were then tailored to fit unique situation of the caregiver and care-recipient. The coaches provided tailored "scripts" for the informal caregiver via role-playing, in which the coach assumed the role of the informal caregiver while the caregiver assumed the role of the person living with dementia. Throughout these five sessions, the coaches also validated and affirmed the informal caregiver's techniques and encouraged continued adaption and tailoring of general RCB strategies. Every session concluded with a "homework" assignment based on the management of the behaviors thus far. The subsequent session began with a report on the efficacy of the homework assignment.

Although the focus was on the RCBs, it became obvious during the first few sessions that participants often asked questions about medications and other behaviors that occurred in addition to the RCB. Even though the focus was on RCB, the family caregivers were frequently and inadvertently triggering RCB. Thus, it became important for the coaches to discuss caregiver and care-recipient interactions in order to avoid triggering RCB.

The final session, Session 6, served as a review of successful strategies for managing RCB and also as the conclusion of the coaching relationship.

3.4. *Four Themes of Coaching Content*

In the 10 transcripts, four primary themes emerged from qualitative analysis of the coaching process: (1) education; (2) caregiver communication; (3) affirmation of the caregiver; and (4) individualized strategies. These four content categories were used throughout the coaching process and were interwoven with each other so that the participant knew why the behavior was occurring, how to verbally address it, how to use a strategy effectively, and affirmation of the result. The next sections include descriptions of each component of the process, and it provides examples. Direct quotes (some lengthy) from transcripts are used to illustrate typical coaching approaches.

3.4.1. Education

Even though we differentiated teaching from coaching, the coaches provided each participant with a foundation for understanding the disease process that was systematic and continuous throughout the coaching sessions. This served to provide the caregivers with a "why and what" of care resistance.

They provided a basic and succinct explanation of the disease process beginning with the neurobiology of threat perception (for more information, see Jablonski et al. 2011). Information provided was tailored to the background of caregivers. For example, two of the caregivers had advanced degrees in the biological and social sciences respectively so greater detail was provided when discussing the neurobiology of threat perception. Analogies were especially useful in explaining specific concepts for all caregivers. These are listed in Table 2. Neurodegeneration, for example, was explained using the analogy of the shrinking box:

> *"The brain is like a box full of Christmas decorations. The decorations from 1964 are at the very bottom, while the decorations from last year at sitting at the top. As the box shrinks, the decorations from last year fall out. Meanwhile, you can more easily reach into the box and pull out the decorations from 1964 because you have fewer layers to move aside. The brain is like the box. As brain cells die, newer memories "fall out" while older memories are more accessible. That is why your family member cannot remember if she ate breakfast, but can tell you about some event 40 years ago. This is also why long, drawn out explanations and sentences do not work. The brain does not have enough space to 'hold onto' the entire conversation."*

Caregivers often reported that their family members had episodes of irritability and anger; they shared their frustration that the person with dementia did not respond to reason. An analogy of a business or factory with overworked employees was used to explain how a reduced number of neurons could cause frustration and agitation in someone with Alzheimer's disease.

> *"Imagine if you showed up to work and half of your coworkers had just quit. You and your remaining colleagues would have to scramble and do two- or three-times the amount of work you usually do. You would be expected to perform tasks for which you have had little, or even no training. You and your colleagues may be able to compensate for an hour or two. By lunchtime, all of you would be overwhelmed, tired, and cranky. Customers would notice mistakes; they would notice orders being incorrectly filled or not completed at all. If a customer tried to explain something to you or one of your overworked colleagues, you may not have the energy to follow the conversation and may become even more irritated. By the end of the shift, all of you would be exhausted. That is what is going on in your loved one's brain. Brain cells are trying to compensate and work harder. These hard-working cells become overwhelmed, especially in loud or crowded social situations. That is why your family member becomes irritable and may demonstrate anger, especially when you are trying to reason with them."*

Caregivers often conveyed that their family member would refuse care and make statements such as, "I've already bathed," when this event had not occurred. The coaches built on the analogies of "shrinking box" and "overworked staff" to help caregivers understand the confabulation that was often associated with care refusal behaviors. The coaches explained that the care recipient's sensation of time passage was impaired because of the combination of short-term memory loss and more readily accessed older memories, which might cause a long-ago memory of bathing to feel as if the experience had just occurred. The coaches couched this explanation within the context of comparing the brain to a compartmentalized box; as the "walls" of the box breaks down, the contents (memories) become mixed up and tangled. Furthermore, cognitive slowing was explained using a highway metaphor: as neurons die, the lanes of the highway decrease and the brain attempts to accesses alternative routes the way motorists may access detours. Just as detour routes can become crowded and the traffic moves slower, the brain's use of alternative (and less developed) networks can delay recall and slow down the ability to perform a desired action. Sometimes, these analogies were insufficient. In those cases, a new analogy of a boat without an anchor was introduced to help describe why persons with dementia may assert that an event had recently occurred when it had not.

Simple language to explain difficult concepts was useful in helping the caregiver understand a behavior with which they were struggling. The coaches also used the analogy of "moving backwards in time" to explain the person with dementia's problems with praxis. New analogies often incorporated previously used analogies:

> *Coach (to Caregiver A:) "As she's moving backwards in time, she may have forgotten about credit cards. 'Cause when you forget stuff, you forget stuff the reverse way you learned it. It's like the box that's shrinking. The newest stuff on top is the first to fall out. She probably started using credit cards in later adulthood."*

While educating the caregiver was a significant portion of session 1, education was interwoven into most ongoing interactions with the caregivers. A context for why the behavior might be occurring was combined with an immediate strategy, or what to do, to address it.

> *Coach to Caregiver B: "Ok, you're getting angry because you have to repeat yourself constantly."*
>
> *Caregiver B: "Yeah, that's right."*
>
> *Coach: "Right, she can't help it...her brain is shrinking so she has no place to put the memory she's making now."*

3.4.2. Caregiver Communication

In session 1, informal assessments were made about the quality and type of communication between the caregiver and the person living with dementia. In this assessment, patterns of communication that could trigger RCB were noted. This included tone and pitch level of voice, arguing, or cajoling. Throughout sessions 2 through 5, the coaches presented caregivers with new patterns of communication that included using scripts to communicate and a way of redefining interactions. Scripts were based on the relationship between caregiver and care recipient. In one interaction with caregiver C, the Coach stated,

> *Coach: "It's the truth, it's genuine, it's loving. Those are the three components of the communication that are so important. It takes practice to, what I call, (develop) the scripts."*

The coach then provided him with a script to encourage his wife to eat. The strategy was to get her to come to sit with him and ultimately, eat.

> *Caregiver C: "How do I say, 'it's time for lunch?' Her response is always, "I'm not hungry."*
>
> *Coach* (providing script to Caregiver C): *'I know you're not hungry, but I would love your company while I eat.'*

In another interaction in the same session with the same caregiver, the coach asserted the importance of redefining modes of interaction as a way of more effective and less provocative communication. The caregiver was struggling with the strategy of "entering their reality," where caregivers are coached to provide a dementia-centric rationale for accomplishing a task that is being resisted by the person with dementia. During this session, Caregiver C's wife (the person with dementia), joined him in front of the computer screen and began interacting with the coach about the numerous bathrooms in their house. This comment prompted Caregiver C to contradict his wife and the Coach to intervene:

> *Wife: There's so many bathrooms in that house.*
>
> *Caregiver C: Ain't but two bathrooms in that house.*
>
> *Coach* (responding to Caregiver C): *Okay, [*Name*]. Right there. Stop. Don't argue. Because of the changes in the brain, every time she saw the same bathroom it was like a new bathroom. In the future, if she says something like, "Oh, there was a whole bunch of bathrooms," you don't have to lie, or you can just say, "Boy, it sure felt like that." You're not arguing. You're acknowledging what she said. It's factual from her perspective. Just because a person sees something a certain way doesn't necessarily mean it's wrong...You can explain, but in your wife's situation, she doesn't have enough brain power to process the explanations, and every time your wife says something and you present reality, it feels to her like you're picking on her, you're arguing. That's going to increase her agitation. It'll start low*

> *in the morning and it's gonna build up. By suppertime, as the evening wears on, she may be very agitated, hard to settle down, and just into everything.*
>
> *Caregiver C: I feel like I'm on an edge or on a line that I don't want to cross and become combative or ugly or dictatorial. I want to be real and not manipulative although it is. I'm just really struggling.*
>
> *Coach: You're presenting things in a way that makes sense [to the person with dementia]. That's not manipulation. It's as if I go into the clinic and I have patients who speak Spanish. Okay, I can speak Spanish. Not well, but I can. I start talking to them in Spanish. That's not manipulation. That's communication. It's crossing the [communication] bridge. For me to expect that person to communicate in English when so much is going on is a little unfair. I communicate in Spanish, even if I screw it up.*

3.4.3. Affirmation of the Caregiver

It was important for the caregivers to believe that they were doing a good job. Caregivers often reported guilt or a sense of ineptitude in addressing RCB, as well as the negative emotions such as anger and resentment directed toward the care recipient. Affirmation was important and was used often. Caregivers were assured that they were being successful even when they had failed to use a discussed approach or strategy. The coaches also helped caregivers with setting realistic caregiving goals within the affirmations. Acknowledgement of their feelings in tandem with encouragement was also important. The following quotes illustrate this.

> *Coach to Caregiver B: A lot of care partners have this nagging concern. What if I don't know something?*
>
> *What if I can't do something? What if I make it worse? Honestly, I understand the little*
>
> *voice in your head saying those things, but it's BS. You have a lot of knowledge in you*
>
> *that you can adapt for this new journey, and you are successfully doing it.*
>
> *Caregiver D: "Some of it is with my mind frame too; knowing that I've got to change that too. It's*
>
> *just the way that it is going to be from here on out. That's part of it; knowing that I am*
>
> *going to have to change how we do things and when we do things and*
>
> *all of that. It's just accepting that and finding the best way to do it."*
>
> *Coach to Caregiver D: "Okay. A lot of people never get to that point. That's good that you are at that*
>
> *place where you are really taking stock of how this is all going to work and you're*
>
> *figuring it out."*

3.4.4. Individualized Strategies

The coaches incorporated previously published strategies developed for institutional paid caregivers to prevent and manage RCB within the context of mouthcare to the coaching of the current study's participants for assisting with other ADLs. These strategies included priming (using the environment to "trigger" procedural memories); distraction; chaining (caregiver begins the activity and allows the care recipient to finish the activity); bridging (caregiver has the person with dementia hold an object related to the caregiving activity, such as a wash cloth or soap during bathing); gentle touch; caregiver exhibiting happy/smiling facial expressions; caregiver speaking in short, respectful, 1-step sentences; caregiver avoiding excessive explanations; caregivers avoiding elderspeak (baby talk); and caregivers allowing as much self-care as safely possible [15–17]. The coaches consistently described the strategies as grounded in neurobiology. Placing behaviors in a physiologic context removed the personalization felt by caregivers; that is, caregivers often shared their perceptions that the person with dementia was rationally and purposefully engaging in a negative behavior. The coaches explained, using analogies, that many of the RCBs resulted from neurodegenerative changes:

> *Coach (to Caregiver B): Okay. The communication thing, does that make sense? Shorter sentences, at least try to look less scary, a little smile, and gestures and pantomime can also reinforce [the message]. If I were to say to your wife, "Take off your glasses," I would say, "Take off your glasses" [Coach pantomimed removing glasses] like that. Or if I was gonna say, "Brush your hair," I'd say "Brush your hair" Of course, I'd have a brush or I'd mimic a brush brushing my hair. The gestures and pantomime can reinforce what we're saying because there's pieces of the brain right here in the temporal lobes, and those pieces of the brain, they take sound and put meaning towards it. They take words and assign meaning. As those sides of the brain shrink, words pop in, and the brain looks at the word and says, "I don't know what to do with this." The word just gets dropped. By communicating in layers and putting the layers on top, you're more likely to get the message across.*
>
> *Caregiver B: I agree. I have found that gestures work a lot better, particularly in the—when there's a sequence of events that you've got to do.*

Strategies to address resistance to care behavior were personalized and adapted to the specific context and needs of both caregiver and care recipient. At each session, caregivers were asked if the suggested strategies had been effective in managing or reducing the RCB. The caregiver below had success in using distraction and bridging to keep her mother seated on the toilet:

> Caregiver E: *"last week you told me to put something in her hand to distract her from being angry... or to distract her from standing up. She's been sitting down to go to the bathroom."*

While the strategy of having her hold an empty prescription bottle worked initially worked, it was further adapted to be more successful for the care recipient. At times, the care recipient would throw the bottle on the floor and try to get up. The Coach suggested that Caregiver E put something in the bottle such as M&Ms or Tic Tacs. The Coach then explained that the sound of the candy rattling in the container might pique E's mother's interest and allow her to complete the task.

Caregivers were also coached to provide the person with dementia purposeful activities, which could then be interwoven into methods for preventing and managing future RCBs. Caregiver A was struggling with her mother's refusal to remove clothes and to bathe. Caregiver A shared that her mother had worked as a housekeeper throughout her life. The Coach suggested that Caregiver A "hire" her mother to do the laundry and start by taking off her clothes to make a full load. Caregiver A successfully used this strategy:

> Caregiver A: *I gave her some clothes to fold up.*
>
> Coach: *All right. How'd that work*?
>
> A: *She said give them—it worked out fine.*
>
> Coach: *Oh, really*?
>
> A: *I had to pay her but she folded 'em up real neat.*
>
> Coach: *She was pretty happy about that*?
>
> A: *Yes, she was happy with that.*

The Coach and Caregiver A also discussed how caregivers' emotions can impact the behavior of persons with dementia. This strategy became known as "the vibes," and was often used within the context of helping caregivers to assist the care recipient with finding appropriate and meaningful activities to minimize boredom, another RCB trigger:

> *Caregiver A: She used to make these little dolls and things like poodles out of the yarn. I tried to get her to remember that and she can't. I might try it again but she made beautiful things like that.*
>
> *Coach: Well ma'am, the goal is not for her to remember how to do it 'cause she may or may not. The goal is for her to sit and feel a sense of accomplishment. Because sometimes we get hung up on the end product because it's normal . . . What you can do is get the dementia out of the way so her personality*

> *can get through the cracks. She still has the same need to be loved, to be respected, to be taken seriously, to be treated with respect and so those things don't change. Us wanting our loved ones to go back to making the bread they made or the poodles or the doll baby clothes, we're just setting ourselves up to be frustrated. If you're frustrated, what happens to your mom?*
>
> *A: She gonna read them vibes and she'll get frustrated.*
>
> *Coach: Right and now you got a mess. I wanna keep you from—I want you to enjoy the ride, enjoy the journey and accept what your mom can do, what she can't. I'm not saying give up. I'm just saying switch up some of the expectations.*

The coaches explained to caregivers that their emotions, such as anger or frustration, could be felt by the person with dementia and trigger RCB. This was also described as "the vibes." Caregiver B realized that he was acting more like a parent than a spouse because of his caregiver role, causing his "vibe" to change:

> *Coach: Well, the other thing is, and this goes back to your wife, a kind word, a gesture, a compliment, that goes a long way too. Sometimes when we're caring for people with dementia we're so wrapped up in, we're constantly doing for them, that we forget that they would like a compliment or to be treated less like a care recipient and more like a partner.*
>
> *Caregiver B: True. I've seen that.*
>
> *Coach: When that dynamic changes, sometimes the spouse that is now—the spouse may not be able to articulate it, the care recipient spouse, but that spouse will often start to act up and will start to accuse the caregiver spouse of affairs, of not loving them, and what has happened is the vibe has changed. Some people don't care. They feel the shift, and they go, "it still feels good." Other people feel the shift, and they go, "Something's not right."*
>
> *B: That's a good way to explain that, and I can absolutely say that I have seen that. I didn't know what I was seeing. I wonder if that's what last night was.*

4. Discussion

This paper illustrates both the process and content of an online dementia coaching program for family caregivers of persons with dementia. The coaches successfully translated strategies developed to allow paid institutional caregivers to prevent and manage RCB within the context of mouth care to family caregivers to facilitate other ADLs in the home environment including bathing, dressing/undressing, medication administration, and eating. The coaching content was observed to fit in 4 categories: (1) education; (2) caregiver communication; (3) caregiver affirmation; and (4) individualized strategies. Even though the categories describe discrete themes, the coaching interactions usually addressed them concurrently rather than sequentially. These four content categories were used throughout the coaching process and were interwoven with each other so that the participant knew why the behavior was occurring, how to verbally address it, how to use a strategy effectively, and affirmation of the result. We were unable to find similar descriptions of caregiver coaching in the literature. However, Boots et al. [21], conducted a systematic review of 12 studies that used internet-based interventions to improve outcomes for informal caregivers of persons living with dementia; they concluded that the most successful interventions contained tailored information and used coaches to guide the use of the information.

Many of our caregivers were taught "therapeutic fibbing" from support groups and other dementia professionals. Therapeutic fibbing is lying to a person with dementia in order to obtain cooperation. We preferred the gentler strategy of "entering the care-recipient's reality." Caregiver A entered her mother's reality and "hired" her mother to assist with the laundry; Caregiver A's mother was a retired housekeeper. Caregiver A first told her mother to remove soiled clothing in order to have sufficient garments to make a full load of laundry. She asked her mother to fold clothes taken from the dryer. Caregiver A paid her mother once the clothes were folded. By entering her mother's reality, Caregiver A was able to accomplish the important task of removing her mother's soiled clothing in a respectful and dignified way, and she also provided her mother with a meaningful activity. When caregivers used entering their reality instead of therapeutic fibbing, the caregivers affirmed the care recipients' emotions instead of offering a glib response. Entering their reality was also another way to avoid provocative communication. Caregiver B, for example, was vexed by his wife's assertion that their house had more than two bathrooms and he corrected her during a coaching session. The Coach used entering their reality to illustrate to Caregiver B how he could validate his wife's perception with a statement such as, "it sure felt like that." The Coach explained how entering their reality can be used to acknowledge the care recipient's reality.

The coaching process and content as described here is aligned with person-centered practices. Person-centered care recognizes the individual person's self-determination, choices, worth, histories and interests [22]. The focus of care shifts from de-contextualized outcomes to those that are important to individuals. For people living with dementia, these outcomes often concern quality of life or the ability to function or care for themselves. Nolan and colleagues [23] took this idea one step further and proposed a relationship-centered model of care that includes not only the care recipient but also all who are involved in the care relationship. Their model's underlying assumption is that every individual in the caring relationship should experience a sense of worth, purpose, and achievement. This approach is particularly salient for informal caregivers of persons who exhibit RCB and present safety concerns for all involved. The coaching intervention described here clearly emerged to be aligned with Nolan and colleagues' relationship-centered model of care. The coaches inquired about the care-recipient's past history, behavioral patterns and preferences; they helped the informal caregivers facilitate personalized relationship-based care and prevent many RCBs [24,25].

Kales et al. suggested a framework for clinicians to determine the etiology and optimal management of neuropsychiatric behaviors exhibited by persons with dementia [26]. This framework employed the mnemonic DICE: a description of the behavior; investigation of possible underlying causes of the behavior; creation of a behavioral plan; and evaluation of the behavioral plan [26]. Even though there was no a priori decision to implement the DICE framework, the natural progression of the coaching sessions mirrored the 4 steps.

The coaching intervention exhibited a maturational process as the study progressed. The coaches built on previous metaphors and analogies, not only within the six coaching sessions, but also with each successive participant. Their repertoire of behavioral strategies also increased as the study progressed. Maturation of behavioral interventional strategies has been identified by one other group of researchers [15]. The evolution and maturation of behavioral interventions may affect internal validity as a study progresses; if not reported or described, such maturations may explain subsequent problems with reproducibility.

We limited our thematic analyses to 10 coaching sessions involving 5 family caregivers. Our understanding of the coaching content would be enhanced by analyzing additional coaching sessions with participants near the end of the study, in order to capture more strategies and educational analogies as they evolve. Another limitation of our design was restricting participation to one family caregiver. Nearly every participant was assisted by other informal family caregivers. We plan to evaluate the efficacy of an online coaching program delivered to multiple family members.

The informal feedback from our participants has been favorable. The information captured from this methods paper will inform the development of a coaching manual and training materials. Given the growing number of persons with dementia living in the community, there is a pressing need for ongoing coaching programs that can be delivered by community laypersons and delivered in cost-efficient modalities.

5. Conclusions

Caregiver education, caregiver communication, caregiver affirmation, and individualized strategies are the foundational components of a successful dementia coaching program. All four components occur concurrently during coaching sessions; the amounts of the components differ as coaching sessions progress. The participants understood the etiology of refusal behaviors and were equipped with strategies to effectively manage those behaviors.

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References

1. Alzheimer's Association. 2018 Alzheimer's Disease Facts and Figures. *Alzheimers Dementia* **2018**, *14*, 367–429. [CrossRef]
2. Alzheimer's Association. 2017 Alzheimer's Disease Facts and Figures. *Alzheimers Dementia* **2017**, *13*, 325–373. [CrossRef]
3. Fauth, E.B.; Femia, E.E.; Zarit, S.H. Resistiveness to care during assistance with activities of daily living in non-institutionalized persons with dementia: Associations with informal caregivers' stress and well-being. *Aging Ment. Health* **2016**, *20*, 888–898. [CrossRef] [PubMed]
4. Kales, H.C.; Gitlin, L.N.; Lyketsos, C.G. Assessment and management of behavioral and psychological symptoms of dementia. *BMJ* **2015**, *350*, h369. [CrossRef] [PubMed]
5. Ishii, S.; Streim, J.E.; Saliba, D. A conceptual framework for rejection of care behaviors: Review of literature and analysis of role of dementia severity. *J. Am. Med. Dir. Assoc.* **2012**, *13*, 11–23.e2. [CrossRef] [PubMed]
6. Mahoney, E.K. Rejection of Care in Dementia. In *Assessment Scales for Advanced Dementia*; Volicer, L., Hurley, A.C., Eds.; Health Professions Press: Baltimore, MD, USA, 2015; pp. 185–196.
7. Mahoney, E.K.; Hurley, A.C.; Volicer, L.; Bell, M.; Gianotis, P.; Hartshorn, M.; Lane, P.; Lesperance, R.; MacDonald, S.; Novakoff, L.; et al. Development and testing of the Resistiveness to Care Scale. *Res. Nurs. Health* **1999**, *22*, 27–38. [CrossRef]
8. Jablonski-Jaudon, R.A.; Winstead, V.; Jones-Townsend, C.; Azuero, A.; Mahoney, E.; Kolanowski, A.M. Revising the Resistiveness to Care Scale. *J. Nurs. Meas.* **2016**, *24*, 72–82. [CrossRef]
9. Jablonski, R.A.; Therrien, B.; Mahoney, E.K.; Kolanowski, A.; Gabello, M.; Brock, A. An intervention to reduce care-resistant behavior in persons with dementia during oral hygiene: A pilot study. *Spec. Care Dent. Off. Publ. Am. Assoc. Hosp. Dent. Acad. Dent. Handicap. Am. Soc. Geriatr. Dent.* **2011**, *31*, 77–87. [CrossRef]
10. Jablonski, R.A.; Kolanowski, A.; Therrien, B.; Mahoney, E.K.; Kassab, C.; Leslie, D.L. Reducing care-resistant behaviors during oral hygiene in persons with dementia. *BMC Oral Health* **2011**, *11*, 30. [CrossRef]
11. Hurley, A.C.; Volicer, L.; Camberg, L.; Ashley, J.; Woods, P.; Odenheimer, G.; Ooi, W.L.; McIntyre, K.; Mahoney, E. Measurement of observed agitation in patients with dementia of the Alzheimer type. *J. Ment. Health Aging* **1999**, *5*, 117–133.
12. Volicer, L.; Bass, E.A.; Luther, S.L. Agitation and resistiveness to care are two separate behavioral syndromes of dementia. *J. Am. Med. Dir. Assoc.* **2007**, *8*, 527–532. [CrossRef] [PubMed]
13. Shirai, Y.; Koerner, S.S. Examining the Influence of Care-Recipient Resistance on Family Caregiver Emotional and Physical Well-Being: Average Frequency Versus Daily Fluctuation. *J. Appl. Gerontol.* **2018**, *37*, 203–227. [CrossRef] [PubMed]
14. Spigelmyer, P.C.; Hupcey, J.E.; Smith, C.A.; Loeb, S.J.; Kitko, L. Resistiveness to Care as Experienced by Family Caregivers Providing Care for Someone With Dementia. *J. Nurs. Scholarsh.* **2018**, *50*, 36–46. [CrossRef] [PubMed]
15. Jablonski-Jaudon, R.A.; Kolanowski, A.M.; Winstead, V.; Jones-Townsend, C.; Azuero, A. Maturation of the MOUTh Intervention: From Reducing Threat to Relationship-Centered Care. *J. Gerontol. Nurs.* **2016**, *42*, 15–23. [CrossRef] [PubMed]

16. Jablonski, R.A.; Therrien, B.; Kolanowski, A. No more fighting and biting during mouth care: Applying the theoretical constructs of threat perception to clinical practice. *Res. Theory Nurs. Pract.* **2011**, *25*, 163–175. [CrossRef] [PubMed]
17. Jablonski, R.A.; Kolanowski, A.M.; Azuero, A.; Winstead, V.; Jones-Townsend, C.; Geisinger, M.L. Randomised clinical trial: Efficacy of strategies to provide oral hygiene activities to nursing home residents with dementia who resist mouth care. *Gerodontology* **2018**. [CrossRef] [PubMed]
18. Schatzman, L.; Strauss, A.L. *Field Research: Strategies for a Natural Sociology*; Prentice Hall, Inc.: Englewood Cliffs, NJ, USA, 1973.
19. Sandelowski, M. What's in a name? Qualitative description revisited. *Res. Nurs. Health* **2010**, *33*, 77–84. [CrossRef]
20. Beach, D.L.; Kramer, B.J. Communicating with the Alzheimer's resident: Perceptions of care providers in a residential facility. *J. Gerontol. Soc. Work* **1999**, *32*, 5–26. [CrossRef]
21. Boots, L.M.; de Vugt, M.E.; van Knippenberg, R.J.; Kempen, G.I.; Verhey, F.R. A systematic review of Internet-based supportive interventions for caregivers of patients with dementia. *Int. J. Geriatr. Psychiatry* **2014**, *29*, 331–344. [CrossRef]
22. Koren, M.J. Person-centered care for nursing home residents: The culture-change movement. *Health Aff. (Millwood)* **2010**, *29*, 312–317. [CrossRef]
23. Nolan, M.R.; Davies, S.; Brown, J.; Keady, J.; Nolan, J. Beyond person-centred care: A new vision for gerontological nursing. *J. Clin. Nurs.* **2004**, *13*, 45–53. [CrossRef] [PubMed]
24. Kolanowski, A.; Van Haitsma, K.; Penrod, J.; Hill, N.; Yevchak, A. "Wish we would have known that!" Communication Breakdown Impedes Person-Centered Care. *Gerontologist* **2015**, *55* (Suppl. 1), S50–S60. [CrossRef] [PubMed]
25. Caspar, S.; Cooke, H.A.; O'Rourke, N.; MacDonald, S.W. Influence of individual and contextual characteristics on the provision of individualized care in long-term care facilities. *Gerontologist* **2013**, *53*, 790–800. [CrossRef] [PubMed]
26. Kales, H.C.; Gitlin, L.N.; Lyketsos, C.G.; Detroit Expert Panel on Assessment; Management of Neuropsychiatric Symptoms of Dementia. Management of neuropsychiatric symptoms of dementia in clinical settings: Recommendations from a multidisciplinary expert panel. *J. Am. Geriatr. Soc.* **2014**, *62*, 762–769. [CrossRef] [PubMed]

PRIMARY QUANTITATIVE ANALYSIS RESULTS

Table Sample characteristics Baseline	**AD**	**TBI**
Diagnosis (N/ %)	34 (77.27)	10 (22.73)
Sex (N/%)		
Female	21 (61.76)	3 (30)
Male	13 (38.24)	7(70)
Race (N/%)		
White	25 (73.53)	9 (90)
AA	7 (20.59)	1 (10)
Asian	1 (2.94)	
AI	1 (2.94)	
Ethnicity (N/%)		
Non-Hispanic	32 (94.12)	10 (100)
Hispanic	2 (5.88)	
Education (N/ %)		
Less than HS		1 (10)
High School	7 (20.59)	6 (60)
13-15	16 (47.06)	2 (20)
More than 15 years	11 (32.35)	1 (10)
Age (Mean/SD)	74.88 (11.08)	39.9 (12.42)
Marital Status (N/%)		
Married	23 (67.65)	2 (20)
Widowed	7 (20.59)	
Divorced	3 (8.82)	3 (30)
Single	1 (2.94)	5 (50)
Cognitive testing		
Blessed	13.58 (4.23)	10.6 (3.94)
SLUMS	9 (5.70)	16.55 (6.63)
CAREGIVER		
Sex (N/%)		
Female	22 (64.71)	10 (100)
Male	12 (35.29)	
Education (N/ %)		
Less than HS		1 (10)
High School	4 (11.76)	4 (40)
13-15	11 (32.35)	4 (40)
More than 15 years	19 (55.88)	1 (10)
Age (Mean/SD)	61.44 (15.52)	56.3 (7.51)
Marital Status (N/%)		
Married	26 (76.47)	8 (80)

Single	5 (14.71)	1 (10)
Widowed	2 (5.88)	
Divorced	1 (2.94)	1 (10)
Relationship to the patient (N/%)		
Husband	8 (23.53)	
Wife	11 (32.35)	2 (20)
Daughter	10 (29.41)	
Mother		7 (70)
Son	3 (8.82)	
Daughter in Law	1 (2.94)	
Other relative	1 (2.94)	1 (10)
Employment (N/%)		
Retired	17 (50)	4 (40)
Full Time	11 (32.35)	1 (10)
Leave of absence	5 (14.71)	2 (20)
Part time	1 (2.94)	1 (10)
Disabled		1 (10)
Self-employee-FT		1 (10)
Personality traits (Mean/SD)		
CDR-Resilience	77.32 (11.70)	77.7 (10.63)
Eysenck- Neuroticism	6.44 (1.96)	8.3 (2.26)
Zarit -Caregiver Burden	37 (12.24)	45.4 (16.37)
Pearlin-Mastery	20.41 (3.19)	17.1 (2.64)
Quality of life (Mean/SD)		
DEMQL	91.44 (14.15)	87.8 (21.81)
FQOL TBI	NA	153.8 (8.6)
FQOL Q1-Q40	158.11 (22.45)	NA
FQOL2 Q1-42	172.88 (24.84)	NA
PSESDM	16.61 (2.65)	NA
NPI RAW (SEVERITY)	15.23 (6.38)	14.9 (6.83)
NPI DISTRESS	18.20 (7.88)	20.3 (10.42)
EQ VAS (Mean, SD)	84.11 (11.41)	79.8 (13.01)
Health state index score	0.82 (0.14)	0.76 (0.16)
Completed		
Yes	26 (76.47)	9 (90)
No	8 (23.53)	1 (10)

Table 1 Comparison between immediate and delayed group demographic characteristics at baseline AD Completed

Characteristic	All	Immediate Intervention	Delayed Intervention	χ2 / t-Test P-value	Fischer /KW
	N=26	n=14	n=12		
Sex (N/%)					
Female	16 (61.54)	8 (30.77)	8 (30.77)	0.6188	0.7015
Male	10 (38.46)	6 (23.08)	4 (15.38)		
Race (N/%)					
White	20 (76.92)	9 (34.62)	11 (42.31)	0.3818	0.4452
AA	4 (15.38)	3 (11.54)	1 (3.85)		
Asian	1 (3.85)	1 (3.85)	0		
AI	1 (3.85)	1 (3.85)	0		
Ethnicity (N/%)					
Non-Hispanic	24 (92.31)	14 (53.85)	10 (38.46)	0.1119	0.2031
Hispanic	2 (7.69)	0	2 (7.69)		
Education (N/ %)					
High School	3 (11.54)	2 (7.69)	1 (3.85)	0.149	0.1656
13-15	12 (46.15)	4 (15.38)	8 (30.77)		
More than 15 years	11 (42.31)	8 (30.77)	3 (11.54)		
Age (Mean/SD)	75.69 (11.58)	75.74 (11.64)	75.66 (12.01)	0.99	0.6607
Marital Status (N/%)					
Married	20 (76.92)	12 (46.15)	8 (30.77)	0.39	0.4609
Widowed	5 (19.23)	2 (7.69)	3 (11.54)		
Divorced	1 (3.85)	0	1 (3.85)		
Cognitive testing					
Blessed	13.07 (3.59)	13.14 (4.26)	13 (2.82)	0.91	0.897
Slums- n=23	9.69 (5.91)	9.636 (7.20)	9.75 (4.77)	0.96	0.7333
Caregiver					
Sex (N/%)					
Female	14 (53.85)	8 (30.77)	6 (23.08)	0.7157	1
M	12 (46.15)	6 (23.08)	6 (23.08)		
Education (N/ %)					
High School	2 (7.69)	0	2 (7.69)	0.2818	0.4009
13-15	7 (26.92)	4 (15.38)	3 (11.54)		
More than 15 years	17 (65.38)	10 (38.46)	7 (26.92)		
Age (Mean/SD)	64.5 (14.79)	65.07 (13.91)	63.83 (16.36)	0.57	0.918
Marital Status (N/%)					

Married	19 (73.08)	10 (38.46)	9 (34.62)	0.8244	1
Single	4 (15.38)	2 (7.69)	2 (7.69)		
Widowed	2 (7.69)	1 (3.85)	1 (3.85)		
Divorced	1 (3.85)	1 (3.85)	0		
Relationship to the patient (N/%)					
Husband	8 (30.77)	5 (19.23)	3 (11.54)	0.8429	0.9467
Wife	8 (30.77)	4 (15.38)	4 (15.38)		
Daughter	7 (26.92)	4 (15.38)	3 (11.54)		
Son	3 (11.54)	1 (3.85)	2 (7.69)		
Employment (N/%)					
Retired	15 (57.69)	10 (38.46)	5 (19.23)	0.1277	0.1456
Full Time	7 (26.92)	4 (15.38)	3 (11.54)		
Leave of absence	3 (11.54)	0	3 (11.54)		
Part time	1 (3.85)	0	1 (3.85)		
Personality traits (Mean/SD)					
CDR-Resilience	76.03 (12.05)	75.92 (12.39)	76.16 (12.18)	0.96	0.8168
Eysenck- Neuroticism	6.30 (1.95)	6.64 (1.78)	5.92 (2.15)	0.36	0.3204
Pearlin-Mastery	20.23 (3.26)	20.92 (3.38)	19.41 (3.05)	0.24	0.2893
PSESDM	16.38 (2.74)	15.57 (2.65)	17.33 (2.64)	0.1	0.0678
Zarit -Caregiver Burden	36 (13.007)	35.21 (14.40)	36.91 (11.73)	0.74	0.6613
DEMQL-Proxy	91.26 (14.16)	88.14 (15.90)	94.91 (11.41)	0.22	0.1894
FQOL Q1-Q40	158.53 (22.07)	160.71 (16.32)	156 (27.91)	0.61	0.8369
FQOL2 Q1-42	173.80 (24.92)	175.71 (19.06)	171.58 (31.18)	0.7	0.959
NPI RAW (Severity)	14.23 (6.048)	14.85 (6.89)	13.5 (5.09)	0.57	0.7966
NPI DISTRESS	17.42 (6.90)	18.92 (7.205)	15.66 (6.38)	0.233	0.3021
EQ VAS (Mean, SD)	84.42 (12.15)	86.57 (9.213)	81.91 (14.93)		0.361
Health state index score	0.83 (0.10)	0.830 (0.075)	0.8314 (0.1312)		0.971

Table Comparison between immediate and delayed group demographic characteristics at baseline TBI Completed

	All, N=9	Intervention		χ2 /t Test	Fischer /KW
		A n=4	B n=5		
Sex (N/%)					
Female	3 (33.3)	1 (11.11)	2 (22.22)	0.6353	1
Male	6 (66.67)	3 (33.33)	3 (33.33)		
Race (N/%)					
White	9 (100)	4 (44.44)	5 (55.56)		
AA					
Asian					
AI					
Ethnicity (N/%)					
Non-Hispanic	9 (100)	4(44.44)	5(55.55)		
Hispanic					
Education (N/ %)					
Less than HS	1 (11.11)	0	1(11.11)	0.2467	0.5238
High School	5 (55.56)	3 (33.33)	2 (22.22)		
13-15	2 (22.22)	0	2 (22.22)		
More than 15 years	1 (11.11)	1 (11.11)	0		
Age (Mean/SD)	39.88 (13.17)	47.5 (14.61)	33.8 (9.09)		0.1416
Marital Status (N/%)					
Married	2 (22.22)	1 (11.11)	1 (11.11)	0.5386	0.7143
Single	4 (44.44)	1 (11.11)	3 (33.33)		
Divorced	3 (33.33)	2 (22.22)	1 (11.11)		
Cognitive testing					
Blessed	11.22 (3.63)	12 (3.91)	10.6(3.74)		0.5386
Slums- n= 8	17.25 (6.73)	19.33 (5.85)	16 (7.54)		0.2967
Caregiver-TBI					
Sex (N/%)					
Female	9 (100)	4 (44.44)	5 (55.56)		
M					
Education (N/ %)					
Less than HS	1 (11.11)	0	1 (11.11)	0.3529	0.5714
High School	4 (44.44)	3 (33.33)	1 (11.11)		
13-15	3 (33.33)	1 (11.11)	2 (22.22)		
More than 15 years	1 (11.11)	0	1 (11.11)		

Age (Mean/SD)	55.66 (7.68)	60.5 (6.60)	51.8 (6.57)		0.1099
Marital Status (N/%)					
Married	8 (88.89)	4 (44.44)	4 (44.44)	0.3428	0.5556
Single					
Widowed					
Divorced	1 (11.11)	0	1 (11.11)		
Relationship to the patient (N/%)					
Mother	6 (66.67)	2 (22.22)	4 (44.44)	0.455	0.6825
Wife	2 (22.22)	1 (11.11)	1 (11.11)		
Niece	1 (11.11)	1 (11.11)	0		
Employment (N/%)					
Retired	4 (44.44)	2 (22.22)	2 (22.22)	0.2925	0.4603
Full Time	1 (11.11)	0	1 (11.11)		
Leave of absence	2 (22.22)	0	2 (22.22)		
Part time	1 (11.11)	1 (11.11)	0		
Self-employee FT	1 (11.11)	1 (11.11)	0		
Personality traits (Mean/SD)					
CDR-Resilience	77.44 (11.24)	85.75 (10.90)	70.8 (6.30)		0.0864
Eysenck- Neuroticism	8.11 (2.31)	7.75 (2.87)	8.4 (2.07)		0.9004
Pearlin-Mastery	17 (2.78)	18.25 (1.25)	16 (3.39)		0.1925
Zarit -Caregiver Burden	47.22 (16.25)	39.75 (16.91)	53.20(14.60)		0.2187
DEMQL	86.33 (22.60)	99.75 (23.96)	75.6 (16.34)		0.1099
FQOL TBI	153.33 (9)	152.25 (6.65)	154.2 (11.23)	0.75	
NPI RAW	15.77 (6.62)	12.75 (8.65)	18.2 (3.89)		0.2683
NPI DISTRESS	21 (10.80)	13.5 (8.10)	27 (9.11)		0.05
EQ VAS (Mean, SD)	83.11 (8.19)	85.75 (8.5)	81 (8.21)	0.42	
Health state index score	0.80 (0.10)	0.8160 (0.035)	0.8044 (0.139)	0.8656	

Bivariate analysis AD

CORRELATION BASELINE ZBI & CAREGIVER PERSONALITY TRAITS & COGNITION

Spearman Correlation Coefficients, N = 26	AD COMPLETED	
Prob > |r| under H0: Rho=0		
		ZBI
Eysenck	r	**0.48072**
	p-value	**0.0129**
CDR	r	-0.15838
	p-value	0.4397
Pearlin	r	**-0.42624**
	p-value	**0.0299**
PSESDM	r	-0.14475
	p-value	0.4805
NPI_Q_RAWSCORE (severity)	r	**0.44868**
	p-value	**0.0215**
NPI_CG_DISTRESS	r	0.30538
	p-value	0.1293
SLUMS	r	-0.10975
	p-value	0.6181
	n	23
Blessed	r	-0.06102
	p-value	0.7671
	n	26
EQVAS	r	-0.046
	pvalue	0.8237
	n	26
INDEX	r	0.37302
	p value	0.0605
	n	26

CORRELATION BASELINE FQOL-DEMOQL & CAREGIVER PERSONALITY TRAITS & COGNITION

Spearman Correlation Coefficients, N = 26				
Prob > |r| under H0: Rho=0			Include 42 qxs	
		DEMQOL_PROXY	FQOL_AD2	FQOL_SC
Eysenck	r	-0.01478	0.25325	0.20037
	p-value	0.9429	0.2119	0.3264
CDR	r	0.35981	**0.48853**	**0.45344**
	p-value	0.071	**0.0113**	**0.02**
Pearlin	r	0.16057	0.09902	0.11037
	p-value	0.4333	0.6303	0.5915
PSESDM	r	**0.54369**	-0.02729	-0.08328
	p-value	**0.0041**	0.8947	0.6859
NPI_Q_RAWSCORE (severity)	r	**-0.4191**	-0.23175	-0.16215
	p-value	**0.0331**	0.2546	0.4287
NPI_CG_DISTRESS	r	**-0.49923**	-0.18981	-0.1409
	p-value	**0.0094**	0.353	0.4924
SLUMS	r	-0.24247	-0.158	-0.136
	p-value	0.265	0.47	0.535
	n	23	23	23
Blessed	r	-0.06628	0.05	0.07
	p-value	0.7477	0.80	0.771
	n	26	26	26
EQVAS	r	0.034	0.36678	0.35681
	pvalue	0.8692	0.0653	0.0736
	n	26	26	26
INDEX	r	0.05341	-0.095	-0.073
	p value	0.7955	0.6428	0.7216
	n	26	26	26
FQOL_AD2	r	0.10407		
	p value	0.6129		

CORRELATION BASELINE ZBI & QUALITY OF LIFE MEASURES

Spearman Correlation Coefficients, N = 26
Prob > |r| under H0: Rho=0

	ZARIT	DEMQOL_PROXY_RAW	FQOL_AD2
ZARIT	1	-0.28402	-0.10936
p value		0.1597	0.5949
DEMQOL_PROXY_RAW	-0.284	1	0.10407
p value	0.1597		0.6129
FQOL_AD	-0.1094	0.10407	1
p value	0.5949	0.6129	

Table 2 Descriptive statistics for outcomes of interest by study group and week (N=26)

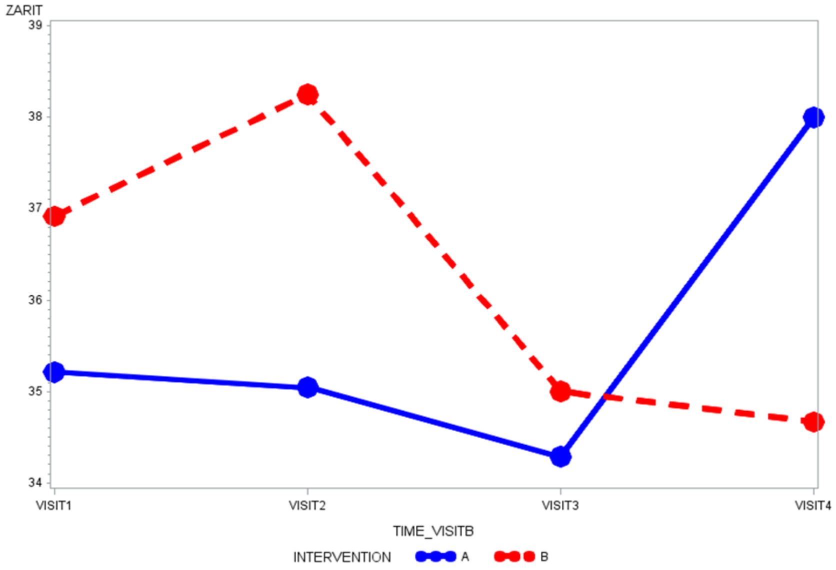
		Caregiver burden (ZBI)	**Patient Quality of Life (DEMOQL-Proxy)**	**Family Quality of Life**	**EQ5D5L**	**EQ5D5L INDEX**
Week	**Group**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
0	Immediate	35.21 (14.40)	**88.14 (15.90)**	**175.71 (19.06)**	86.57(9.21)	0.830 (0.081)
	Delayed	36.91 (11.73)	94.91 (11.40)	**171.58 (31.18)**	81.91 (14.930)	0.8314 (0.1312)
7	Immediate	35.04 (12.48)	95.92 (10.46)	176.57 (23.61)	NA	NA
	Delayed	**38.25 (12.14)**	93.83 (12.99)	169.66 (24.38)	NA	NA
13	Immediate	34.28 (11.03)	93.92 (12.71)	**182.35 (22.22)**	NA	NA
	Delayed	**35 (8.53)**	95.25 (11.72)	**175.41 (15.13)**	NA	NA
24	Immediate	38 (13.87)	**91.78 (20.20)**	176.07 (14.11)	81.16 (7.80)	0.8328 (0.0745)
	Delayed	34.66 (11.48)	94.33 (8.37)	173.50 (13.43)	74.833 (13.3949)	0.8393 (0.0972)

A decrease in burden scores from the baseline measurement to week 7 for the early treatment group, and between week 7 and week 13 for the late treatment group, will be interpreted as an immediate measure of efficacy regarding the intervention. Sustained effects will be measured by the burden scores measured at week 12 for the early treatment group and at week 24 for both groups

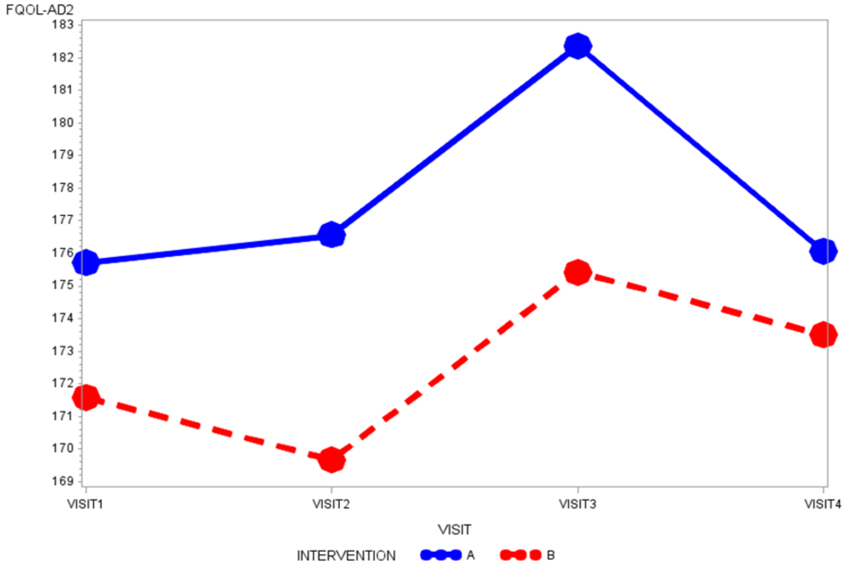
Graphical Representation of Mean Measurement over Time by intervention

AD

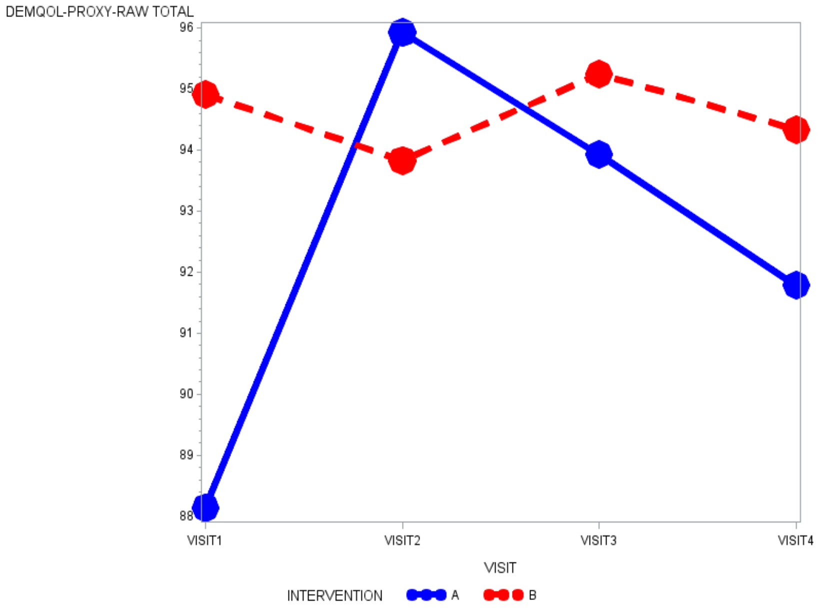
Zarit



FQOL2 Q1-42

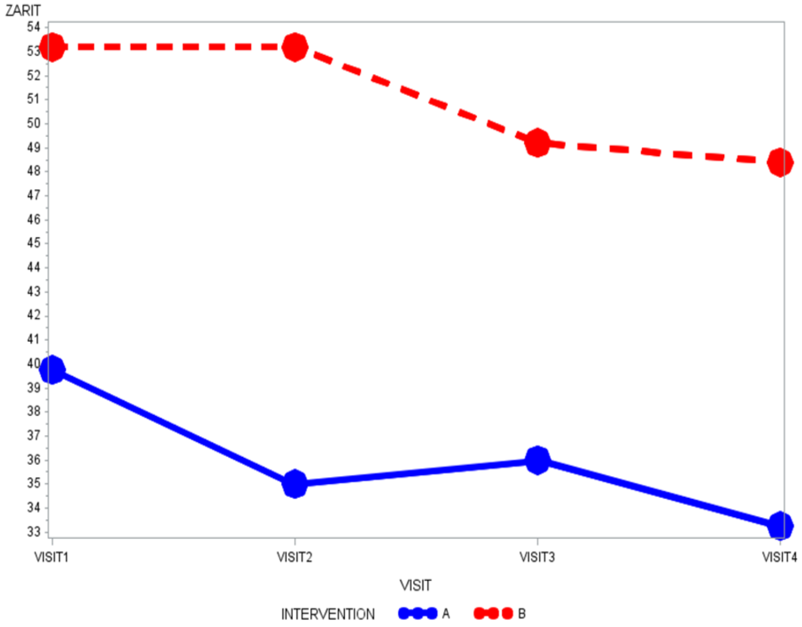


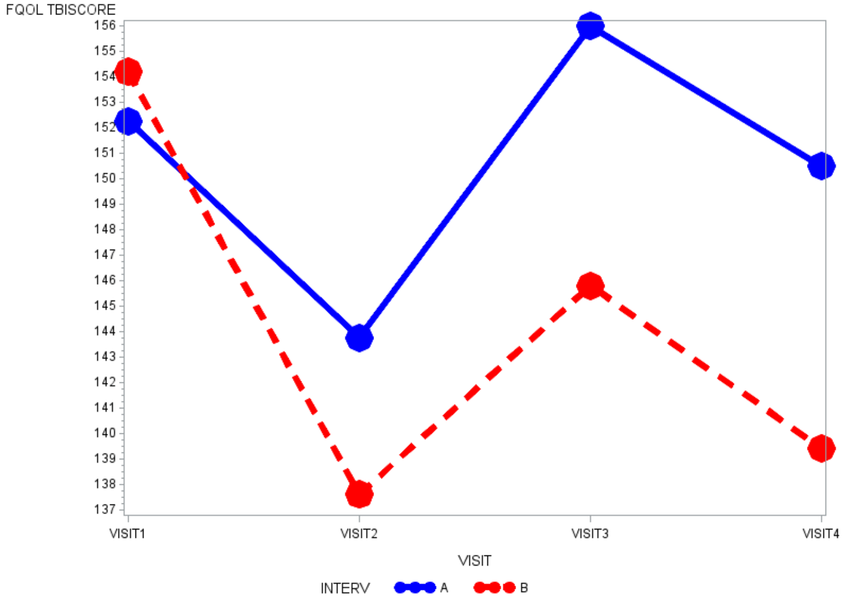
DEMOQL PROXY



TBI

Zarit





Primary Hypothesis 1

A 12-week cross-over design study, using a distance-learning , internet based, family caregiver coaching program ("the intervention") will reduce CAREGIVER BURDEN measured with the Zarit Burden Interview (ZBI) [59]in a sample of 50 community-dwelling people with AD who have at least one recurring BPSD symptom that is associated with care resistant behavior (CRB) and causes distress to a family caregiver. Repeated measures analysis of variance (ANOVA) will be examined to determine the impact of the intervention on ZBI scores of the caregivers. Terms in the model will include group membership (early versus late treatment) and time (baseline, weeks 7, 13, and 24). A decrease in burden scores from the baseline measurement to week 7 for the early treatment group, and between week 7 and week 13 for the late treatment group, will be interpreted as an immediate measure of efficacy regarding the intervention. Sustained effects will be measured by the burden scores measured at week 12 for the early treatment group and at week 24 for both groups

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no time Effect

H = Type III SSCP Matrix for tests

E = Error SSCP Matrix

S=1 M=0.5 N=10

Statistic	Value	F Value	Num DF	Den DF	Pr > F	
Wilks' Lambda	0.905728	0.76	3	22	0.5267	**NS**

There is no statistically significant difference at the four times

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no time*INTERVENTION Effect

H = Type III SSCP Matrix for tests*INTERVENTION
E = Error SSCP Matrix

S=1 M=0.5 N=10

Statistic	Value	F Value	Num DF	Den DF	Pr > F	
Wilks' Lambda	0.871834	1.08	3	22	0.3789	**NS**

Any difference between ZBI scores/means do not reliably depend on time in conjunction with the type of intervention. (in samples of this size)

Tests of Hypotheses for Between Subjects Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F	
INTERVENTION	1	8.43956	8.43956	0.02	0.8964	NS
Error	24	11692.06	487.1692			

Univariate Tests of Hypotheses for Within Subject Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F	Adj Pr > F		
						G - G	H-F-L	
time	3	60.84799	20.28266	0.58	0.6281	0.6068	0.6275	NS
time*INTERVENTION	3	151.6429	50.54762	1.45	0.2346	0.2386	0.2347	NS
Error(time)	72	2504.732	34.78795					

Although the effect of the intervention on caregiver burden was in a direction that indicated benefit, there was not statistically significant effect of the intervention.

Primary Hypothesis 2

Baseline variables including severity of cognitive deficits and caregiver personality traits of mastery, neuroticism, and resilience will be associated with the magnitude of ZBI response, as well as other QOL measures. Cognitive deficit scores and caregiver personality trait scores will be correlated with ZBI and QOL scores. Variables with significant correlations will then be used as inputs for multiple regression models to explain individual and cumulative contributions to variance. Coefficients from the regression analyses will also be used to examine relationships between these variables and ZBI scores, that is, if certain variables are exerting mediation or moderation effects on the ZBI. Give the large ZBI effect size reported in another study [60], we should be able to detect interaction effects with our sample size. Furthermore, analyses of covariances (ANCOVAs) will also be conducted determine changes in ZBI while controlling for cognitive deficit scores and caregiver personality trait scores."

***Spearman's correlations were conducted to examine the relationships between cognitive deficit scores and caregiver personality trait scores with ZBI scores. There were positive statistically**

significant correlations between ZBI with Neuroticism (r=0.48) and severity of behavioral symptoms (r=0.44) (p<0.05). There was a negative statistically significant correlations between ZBI with caregiver's mastery (r=-0.42) (p<0.05)

****Spearman's correlations were conducted to examine the relationships between cognitive deficit scores and caregiver personality trait scores with and QOL scores. There was a positive statistically significant correlation between patient quality of life with caregiver self-efficacy (PSESDM) (r=0.54) (p<0.05). There were negative statistically significant correlations between patient quality of life and severity of behavioral symptoms (r=-0.41) and caregiver distress (r=-0.49) (p<0.05)Family quality of life: There was a positive statistically significant correlation between family quality of life with resilience (r=0.48) (p<0.05)**

ZBI

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	43.27	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
VISIT	3	70	0.29	0.8301
INTERVENTION	1	23	0.5	0.4878
VISIT*INTERVENTION	3	70	1.55	0.2104
PEARLIN	1	70	2.5	0.1185
Eysenck_RAW_SCORE	1	23	10.31	**0.0039**
NPI_Q_RAWSCORE (Severity)	1	70	12.99	**0.0006**

Neuroticism (p=0.0039) and severity of the behavioral symptoms (0.0006) were significant associated with caregiver burden.

Caregiver age, sex education, relationship****;
Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	31.54	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
VISIT	3	70	0.31	0.8149
INTERVENTION	1	16	0.3	0.5904

VISIT*INTERVENTION	3	70	1.58	0.201
PEARLIN	1	70	1.5	0.2243
Eysenck_RAW_SCORE	1	16	11.61	**0.0036**
NPI_Q_RAWSCORE	1	70	10.9	**0.0015**
CAREG_AGE	1	16	5.21	**0.0365**
CAREG_GENDER	1	16	0.96	0.3419
Level_of_education__	2	16	0.97	0.4011
RELATIONSHIP_TO_PATI	3	16	1.97	0.1599

After controlling for other covariates, neuroticism (p=0.0036) and severity of the behavioral symptoms (0.0015) were significantly associated with caregiver burden. Also, caregiver age (p=0.0365) was significantly associated with caregiver burden

Demoql

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	27.64	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
VISIT	3	69	0.6	0.6161
INTERVENTION	1	24	0	0.9817
VISIT*INTERVENTION	3	69	1.25	0.2973
PSESDM	1	69	2.54	0.1158
NPI_Q_RAWSCORE	1	69	4.04	**0.0482**
NPI_CG_DISTRESS	1	69	2.22	0.1407

Caregiver age, sex education, relationship**.**

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	24.48	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
VISIT	3	69	0.59	0.6256
INTERVENTION	1	18	0.25	0.624
VISIT*INTERVENTION	3	69	1.29	0.2857

PSESDM	1	69	1.85	0.1781
NPI_Q_RAWSCORE (severity)	1	69	4.94	**0.0296**
NPI_CG_DISTRESS	1	69	1.4	0.2413
CAREG_GENDER	1	18	0.15	0.703
Level_of_education__Caregiver	2	18	1.36	0.2819
RELATIONSHIP_TO_PATIENT	3	18	0.37	0.777

FQOL

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	9.14	0.0025

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
VISIT	3	71	0.98	0.4052
INTERVENTION	1	24	1.45	0.2404
VISIT*INTERVENTION	3	71	0.24	0.868
CD_RISC	1	71	17.38	<.0001

Resilience (p=<.0001) was significantly associated with family quality of life
Caregiver age, sex education,
relationship**;**

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	8.12	0.0044

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
VISIT	3	71	0.96	0.417
INTERVENTION	1	18	1.82	0.194
VISIT*INTERVENTION	3	71	0.23	0.8776
CD_RISC	1	71	13.1	**0.0005**
CAREG_GENDER	1	18	1.11	0.3056
Level_of_education__	2	18	0.55	0.5855
RELATIONSHIP_TO_PATI	3	18	1.55	0.2364

After controlling for other covariates, resilience (p=<.0005) was significantly associated with family quality of life

"Exploratory Hypothesis 1

Because the intervention has been shown to successfully reduce CRB with BPSD in people with dementia, we will develop preliminary data to determine whether it will improve, either or both of the following:

a. patient QOL (measured with the DEMQOL and DEMQOL proxy)

b. caregiver health related QOL (measured with EQ-5D-5L)"

DEMQOL proxy TBI SUBJECTS

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no time Effect

H = Type III SSCP Matrix for time

E = Error SSCP Matrix

S=1 M=0.5 N=1.5

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.95246	0.08	3	5	0.9663

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no time*INTERVENTION Effect

H = Type III SSCP Matrix for time*INTERVENTION

E = Error SSCP Matrix

S=1 M=0.5 N=1.5

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.391354	2.59	3	5	0.1654

Repeated Measures Analysis of Variance

Tests of Hypotheses for Between Subjects Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F
INTERVENTION	1	2584.022	2584.022	4.12	**0.082**
Error	7	4392.2	627.4571		

Repeated Measures Analysis of Variance

Univariate Tests of Hypotheses for Within Subject Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F	Adj Pr > F	
						G - G	H-F-L
time	3	13.07778	4.359259	0.06	**0.9789**	0.9613	0.9789
time*INTERVENTION	3	776.1889	258.7296	3.72	**0.0273**	0.0391	0.0273
Error(time)	21	1460.7	69.55714				

		Visit 1		Visit 2		Visit 3		Visit 4	
Intervention	N	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
Immediate	4	99.75	23.96351	90	16.55295	95.5	12.47664	102.75	17.46186
Delayed	5	75.6	16.34931	86.2	6.379655	82.6	10.73778	75.4	7.635444

Caregiver health related QOL (measured with EQ-5D-5L) TBI SUBJECTS

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no tests Effect
H = Type III SSCP Matrix for tests
E = Error SSCP Matrix

S=1 M=-0.5 N=1.5

Statistic	**Value**	**F Value**	**Num DF**	**Den DF**	**Pr > F**
Wilks' Lambda	0.92216473	0.42	1	5	0.5446

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no tests*INTERVENTION Effect
H = Type III SSCP Matrix for tests*INTERVENTION
E = Error SSCP Matrix

S=1 M=-0.5 N=1.5

Statistic	**Value**	**F Value**	**Num DF**	**Den DF**	**Pr > F**
Wilks' Lambda	0.99976625	0.00	1	5	0.9740

Repeated Measures Analysis of Variance
Tests of Hypotheses for Between Subjects Effects

Source	**DF**	**Type III SS**	**Mean Square**	**F Value**	**Pr > F**
INTERVENTION	1	116.6666667	116.6666667	0.96	0.3724
Error	5	608.3333333	121.6666667		

Repeated Measures Analysis of Variance
Univariate Tests of Hypotheses for Within Subject Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F
tests	1	8.5952381	8.5952381	0.42	0.5446
tests*INTERVENTION	1	0.0238095	0.0238095	0.00	0.9740
Error(tests)	5	101.8333333	20.3666667		

Exploratory Hypothesis 2

The intervention, which has been shown to successfully reduce CRB in people with dementia (see preliminary data, above) can be applied in the TBI population to reduce frequency and severity of CRBassociated NPTBI with resulting improvement in one or more of the following (using the same measures as above): a. Caregiver Burden b. patient QOL (Exploratory H1)
c. caregiver QOL

Repeated measures ANOVA will be used to analyze changes in **caregiver burden, caregiver QOL, and patient QOL. T**erms in the model will include group membership (early versus late treatment) and time (baseline, weeks 7, 13, and 24). Positive changes in scores from the baseline measurement to week 7 for the early treatment group, and between week 7 and week 13 for the late treatment, will be interpreted as an immediate measure of efficacy regarding the intervention. Sustained effects will be measured by positive scores measured at week 13 for the early treatment group and at week 24 for both groups.

Caregiver burden TBI SUBJECTS

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no tests Effect
H = Type III SSCP Matrix for tests
E = Error SSCP Matrix

S=1 M=0.5 N=1.5

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.661071	0.85	3	5	0.5214

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no tests*INTERVENTION Effect
H = Type III SSCP Matrix for tests*INTERVENTION
E = Error SSCP Matrix
S=1 M=0.5 N=1.5

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.897477	0.19	3	5	0.8986

Repeated Measures Analysis of Variance

Tests of Hypotheses for Between Subjects Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F
INTERVENTION	1	2000	2000	3.01	0.1265
Error	7	4656.5	665.2143		

Repeated Measures Analysis of Variance

Univariate Tests of Hypotheses for Within Subject Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F	Adj Pr > F	
						G - G	H-F-L
tests	3	152.6778	50.89259	1.2	0.3331	0.3317	0.3331
tests*INTERVENTION	3	35.34444	11.78148	0.28	0.8403	0.7925	0.8403
Error(tests)	21	888.6	42.31429				

Level of INTERVENTION	N	ZARITVISIT1 Mean	Std Dev	ZARITVISIT2 Mean	Std Dev	ZARITVISIT3 Mean	Std Dev	ZARITVISIT4 Mean	Std Dev
A	4	39.75	16.91892	35	13.61372	36	18.05547	33.25	14.24488
B	5	53.2	14.60137	53.2	11.7771	49.2	13.08434	48.4	10.62073

Note: Scores at baseline were different

Exploratory Hypothesis 3

The intervention will result in retained benefits on caregiver burden and QOL ratings 3-6 months after the last intervention session is completed. Repeated measures ANOVA will be used to analyze ZBI and QOL scores for both sets of caregivers. Terms in the model will include group membership (early versus late treatment) and time (baseline, weeks 7, 13, and 24). Of particular note will be changes in ZBI, DEMQOL, and EQ-5D-5L scores for the early treatment group at both week 13 and week 24."

DEMOQL AD SUBJECTS

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no time Effect

H = Type III SSCP Matrix for tests

E = Error SSCP Matrix

S=1 M=0.5 N=10

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.89495152	0.86	3	22	0.4761

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no time*INTERVENTION Effect

H = Type III SSCP Matrix for tests*INTERVENTION
E = Error SSCP Matrix

S=1 M=0.5 N=10

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.83815313	1.42	3	22	0.2648

Repeated Measures Analysis of Variance
Tests of Hypotheses for Between Subjects Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F
INTERVENTION	1	118.02289	118.02289	0.23	0.636
Error	24	12322.25595	513.42733		

Repeated Measures Analysis of Variance
Univariate Tests of Hypotheses for Within Subject Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F	Adj Pr > F G - G
Time	3	185.279304	61.759768	0.83	0.4825	0.4671
Time*INTERVENTION	3	260.048535	86.682845	1.16	0.3299	0.3273
Error(tests)	72	5367.172619	74.544064			

INTERVENTION	N	Vsit 1 Mean	Std Dev	Visit2 Mean	Std Dev	Visit 3 Mean	Std Dev	Visit 4 Mean	Std Dev
Immediate	14	**88.1428571**	15.9028645	95.929	10.462	93.92857	12.71259	**91.78571**	20.2035
Delayed	12	**94.9166667**	11.4054081	93.833	12.995	95.25	11.72507	**94.33333**	8.370221

FQOL AD SUBJECTS

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no time Effect

H = Type III SSCP Matrix for tests
E = Error SSCP Matrix
S=1 M=0.5 N=10

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.8584922	1.21	3	22	0.3299

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no time*INTERVENTION Effect

H = Type III SSCP Matrix for time*INTERVENTION
E = Error SSCP Matrix
S=1 M=0.5 N=10

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.98239836	0.13	3	22	0.9404

Repeated Measures Analysis of Variance

Tests of Hypotheses for Between Subjects Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F
INTERVENTION	1	682.02289	682.02289	0.63	0.4352
Error	24	25988.13095	1082.83879		

Repeated Measures
Analysis of Variance
Univariate Tests of Hypotheses for Within Subject Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F	Adj Pr > F	
						G - G	H-F-L
Time	3	529.04853	176.34951	0.76	0.5212	0.5027	0.5169
Time*INTERVENTION	3	90.2793	30.0931	0.13	0.9423	0.9206	0.9377
Error(tests)	72	16743.79762	232.55274				

		VISIT1		VISIT2		VISIT3		VISIT4	
INTERVENTION	N	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
A	14	**175.714286**	19.0643791	176.57	23.61458	182.3571	22.22475	**176.0714**	14.11744
B	12	**171.583333**	31.184082	169.67	24.38827	175.4167	15.1385	**173.5**	13.43334

EQVAS AD SUBJECTS

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no tests Effect
H = Type III SSCP Matrix for tests
E = Error SSCP Matrix

S=1 M=-0.5 N=10

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.89189701	2.67	1	22	0.1167

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no tests*INTERVENTION Effect
H = Type III SSCP Matrix for tests*INTERVENTION
E = Error SSCP Matrix

S=1 M=-0.5 N=10

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.99070674	0.21	1	22	0.6541

Repeated Measures Analysis of Variance
Tests of Hypotheses for Between Subjects Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F
INTERVENTION	1	275.520833	275.520833	2.04	0.1675
Error	22	2975.458333	135.248106		

Repeated Measures Analysis of Variance
Univariate Tests of Hypotheses for Within Subject Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F
tests	1	368.520833	368.520833	2.67	0.1167
tests*INTERVENTION	1	28.520833	28.520833	0.21	0.6541
Error(tests)	22	3040.458333	138.202652		

Exploratory Hypothesis 5

The distance-accessible, internet based, caregiver training program will result in improvements in Family Quality of Life in Dementia (FQOL-D) and TBI (TBI-FQOL), new instruments designed to capture aspects of family function not assessed by individual AD or TBI patient QOL measures, or individual caregiver QOL assessments

FQOL AD SUBJECTS

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no time Effect

H = Type III SSCP Matrix for tests

E = Error SSCP Matrix

S=1 M=0.5 N=10

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.8584922	1.21	3	22	0.3299

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no time*INTERVENTION Effect

H = Type III SSCP Matrix for time*INTERVENTION

E = Error SSCP Matrix

S=1 M=0.5 N=10

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.98239836	0.13	3	22	0.9404

Repeated Measures Analysis of Variance
Tests of Hypotheses for Between Subjects Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F
INTERVENTION	1	682.02289	682.02289	0.63	0.4352
Error	24	25988.13095	1082.83879		

Repeated Measures Analysis of Variance
Univariate Tests of Hypotheses for Within Subject Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F	Adj Pr > F	
						G - G	H-F-L
Time	3	529.04853	176.34951	0.76	0.5212	0.5027	0.5169
Time*INTERVENTION	3	90.2793	30.0931	0.13	0.9423	0.9206	0.9377
Error(tests)	72	16743.79762	232.55274				

		VISIT1		VISIT2		VISIT3		VISIT4	
INTERVENTION	N	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
A	14	**175.714286**	19.0643791	176.57	23.61458	182.3571	22.22475	**176.0714**	14.11744
B	12	**171.583333**	31.184082	169.67	24.38827	175.4167	15.1385	**173.5**	13.43334

FQOL TBI SUBJECTS

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no TIME Effect

H = Type III SSCP Matrix for tests

E = Error SSCP Matrix

S=1 M=0.5 N=1.5

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.65412348	0.88	3	5	0.5104

MANOVA Test Criteria and Exact F Statistics for the Hypothesis of no TIME*INTERVENTION Effect

H = Type III SSCP Matrix for
tests*INTERVENTION

E = Error SSCP Matrix

S=1 M=0.5 N=1.5

Statistic	Value	F Value	Num DF	Den DF	Pr > F
Wilks' Lambda	0.85345285	0.29	3	5	0.834

Repeated Measures Analysis of Variance

Tests of Hypotheses for Between Subjects Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F
INTERVENTION	1	361.25	361.25	0.24	0.6373
Error	7	10417.25	1488.17857		

Repeated Measures Analysis of Variance

Univariate Tests of Hypotheses for Within Subject Effects

Source	DF	Type III SS	Mean Square	F Value	Pr > F	Adj Pr > F	
						G - G	H-F-L
time	3	865.805556	288.601852	1.09	0.3761	0.3665	0.3761
time*INTERVENTION	3	236.25	78.75	0.3	0.8273	0.7626	0.8273
Error(tests)	21	5573.25	265.392857				

Greenhouse-Geisser Epsilon	0.717
Huynh-Feldt-Lecoutre Epsilon	1.0454

Level of INTERVENTION	N	FQOLTBASELINE		FQOLTBI VISIT 2		FQOLTBI VISIT 3		FQOLTBI VISIT 4	
		Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
A	4	152.25	6.652067	143.75	45.74841	156	14.30618	150.5	10.66146
B	5	154.2	11.23388	137.6	22.91942	145.8	28.76978	139.4	26.01538

Table	**Distribution of EQ-5D-5L dimension responses at baseline and at visit 4 by intervention-AD**					
Dimension	**Baseline**		**p value**	**Visit 4**		**p value**
	n (%)		(Fisher's)	n (%)		
n=26	**Immediate**	**Delayed**		**Immediate**	**Delayed**	
	n=14	**n=12**		n=13	n=12	
MOBILITY			0.6174			0.107
(No problems)	11 (78.57)	8 (66.67)	Chisq=0.469	10 (76.92)	9 (75)	Chisq=0.1105
(Slight problems)	3 (21.43)	2 (16.67)		0	3 (25)	
(Moderate problems)	0	1 (8.33)		2 (15.38)	0	
(Severe problems)	0	1 (8.33)				
(Extreme problems/unable to do)						
Missing				1 (7.69)	0	
SELF-CARE						
(No problems)	14 (100)	12 (100)		12 (92.31)	12 (100)	1
(Slight problems)						Chisq=0.3268
(Moderate problems)						
(Severe problems)						
(Extreme problems/unable to do)						
Missing				1 (7.69)	0	
USUAL ACTIVITIES			0.0846			0.7868
(No problems)	14 (100)	9 (75)	Chisq=0.138	11 (84.62)	9 (75)	Chisq=0.5306
(Slight problems)		2 (16.67)		0	1 (8.33)	
(Moderate problems)		1 (8.33)		0	1 (8.33)	
(Severe problems)				1 (7.69)	1 (8.33)	
(Extreme problems/unable to do)						
Missing				1 (7.69)	0	
PAIN/DISCOOMFORT			0.2806			0.1793
(No problems)	5 (35.71)	6 (50)	Chisq=0.237	5 (38.46)	6 (50)	Chisq=0.171
(Slight problems)	8 (57.14)	3 (25)		5 (38.46)	1 (8.33)	
(Moderate problems)	0	2 (16.67)		2 (15.38)	5 (41.67)	
(Severe problems)	1 (7.14)	1 (8.33)				

(Extreme problems/unable to do)						
Missing				1	0	
ANXIETY/DEPRESSION			0.82			1
(No problems)	4 (28.57)	4 (33.33)	Chisq= 0.6564	2 (15.38)	2 (16.67)	Chisq=0.8106
(Slight problems)	6 (42.86)	5 (41.67)		8 (61.54)	8 (66.67)	
(Moderate problems)	4 (28.57)	2 (16.67)		2 (15.38)	2 (16.67)	
(Severe problems)	0	1 (8.33)				
(Extreme problems/unable to do)						
Missing				1 (7.69)	0	
Effect of intervention on EQ-5D-5l index score						
EQ VAS	86.57 (9.2130)	81.91 (14.930)	0.361	81.16 (7.80)	74.833 (13.395)	0.1743
Mean (SD)						
INDEX VALUE	0.830 (0.0757)	0.8314 (0.1312)	0.971	0.8328 (0.0745)	0.8393 (0.0972)	0.8559
Mean (SD)						

Table	**Distribution of EQ-5D-5L dimension responses at baseline and at visit 4 by intervention-TBI**					
Dimension	**Baseline**		**p value**	**Visit 4**		**p value**
	n (%)		(Fisher's)	n (%)		
	Immediate	**Delayed**		**Immediate**	**Delayed**	
MOBILITY			1			0.3651
(No problems)	3 (75)	4 (80)	Chisq=0.8577	2 (50)	3 (60)	0.1262
(Slight problems)	1 (25)	1 (20)		2 (50)		
(Moderate problems)						
(Severe problems)						
(Extreme problems/unable to do)						
Missing					2 (40)	
SELF-CARE						0.4444
(No problems)	4 (100)	5 (100)		4 (100)	3 (60)	0.1515
(Slight problems)						
(Moderate problems)						
(Severe problems)						
(Extreme problems/unable to do)						
Missing					2 (40)	
USUAL ACTIVITIES			0.44			0.444
(No problems)	4 (100)	3 (60)	chisq=0.1515	3 (75)	3 (60)	0.2317
(Slight problems)		2 (40)				
(Moderate problems)				1 (25)		
(Severe problems)						
(Extreme problems/unable to do)						
Missing					2 (40)	
PAIN/DISCOOMFORT			1			0.2381
(No problems)		1 (20)	chisq=0.637		2 (40)	0.1372
(Slight problems)	2 (50)	2 (40)		2 (50)		
(Moderate problems)	2 (50)	2 (40)		1 (25)	1 (20)	
(Severe problems)				1 (25)		
(Extreme problems/unable to do)						
Missing					2 (40)	
ANXIETY/DEPRESSION			1			0.1905
(No problems)	1 (25)	1 (20)	chisq=0.5489	3 (75)		0.0979
(Slight problems)	3 (75)	2 (40)		1 (25)	2 (40)	
(Moderate problems)		1 (20)			1 (20)	

(Severe problems)		1 (20)				
(Extreme problems/unable to do)						
Missing					2 (40)	
Effect of intervention on EQ-5D-5l index score						
EQ VAS						
Mean (SD)	85.75 (8.5)	81 (8.21)	0.42	84.25 (6.50)	78.33 (10.403)	0.4472
INDEX VALUE						
Mean (SD)	0.8160 (0.0349)	0.8044 (0.1396)	0.8656	0.77 (0.0667)	0.8420 (0.035)	0.1671