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TITLE: A Randomized Controlled Trial of the Group-Based Modified Story Memory Technique in TBI

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CONTRACTING ORGANIZATION: Kessler Foundation

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**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**

*Impairments in new learning and memory are among the most common deficits in individuals with Traumatic Brain Injury (TBI) and have been shown to exert significant negative impact on everyday life. There is thus a tremendous need for the development of effective interventions for learning and memory dysfunction in TBI, particularly group-based interventions for which 3rd party payment may be more forthcoming. The current study addresses this critical need through the conduct of a double blind, placebo-controlled, randomized clinical trial (RCT) of a group administration of the modified Story Memory Technique (mSMT). Over a decade of research and development conducted at our center has demonstrated the mSMT to be effective for improving new learning and memory in individuals with Multiple Sclerosis (MS) and TBI across three realms of functioning, objective behavior, brain functioning and everyday life. This convincing data provides Class I evidence supporting the efficacy of the mSMT for improving new learning and memory in these populations. Given the strong efficacy data on the mSMT, coupled with the current trends in insurance reimbursement, clinicians worldwide have highlighted the need to provide the mSMT via an effective group format. We have thus modified the treatment protocol for group administration. This pilot RCT tests the efficacy of a group administration of the mSMT for persons with moderate to severe TBI.*

**15. SUBJECT TERMS**

*Memory, TBI, cognition, cognitive rehabilitation, cognitive retraining, new learning, treatment*

| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
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**Table of Contents**

**Page**

1. **INTRODUCTION:**

*Impairments in new learning and memory are among the most common deficits in individuals with Traumatic Brain Injury (TBI) and have been shown to exert significant negative impact on everyday life. There is thus a tremendous need for the development of effective interventions for learning and memory dysfunction in TBI, particularly group-based interventions for which 3rd party payment may be more forthcoming. The current study addresses this critical need through the conduct of a double blind, placebo-controlled, randomized clinical trial (RCT) of a group administration of the modified Story Memory Technique (mSMT). Over a decade of research and development conducted at our center has demonstrated the mSMT to be effective for improving new learning and memory in individuals with Multiple Sclerosis (MS) and TBI across three realms of functioning, objective behavior, brain functioning and everyday life. This convincing data provides Class I evidence supporting the efficacy of the mSMT for improving new learning and memory in these populations. Given the strong efficacy data on the mSMT, coupled with the current trends in insurance reimbursement, clinicians worldwide have highlighted the need to provide the mSMT via an effective group format. We have thus modified the treatment protocol for group administration. This pilot RCT tests the efficacy of a group administration of the mSMT for persons with moderate to severe TBI.*

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

*Memory, TBI, cognition, cognitive rehabilitation, cognitive retraining, new learning, treatment*

3. **ACCOMPLISHMENTS:**

**What were the major goals of the project?**

***The current study addresses the following specific aims.***

*Aim 1. Objectively evaluate the efficacy of the group mSMT to improve new learning/memory in individuals with TBI with documented deficits in this area.*
*Aim 2. Increase the generalizability and real life application of the group mSMT by assessing outcome following group mSMT with global measures of everyday life, including one objective measure and multiple subjective measures.*
*Aim 3. Examine the neurofunctional changes resulting from the group-based mSMT in TBI subjects with impairments in new learning and memory. We will examine if neurofunctional changes in the brain are associated with behavioral improvements following the mSMT and if these changes are maintained over time.*
*Aim 4: Evaluate the long-term efficacy of the group mSMT through a 3-month follow-up.*

***To accomplish these aims, the following major tasks were identified:***

- *Major Task 1: Administratively Prepare for Clinical Trial*
  - *Target completion date: 1/1/17*
  - *Actual completion date: 1/1/17*
  - *Percent of completion: 100%*

- *Major Task 2: Coordinate Study Staff for Clinical Trial*
  - *Target completion date: 4/1/17*
  - *Actual completion date: 4/1/17*
  - *Percent of completion: 100%*
- *Major Task 3: Prepare Research Protocol*
  - *Target completion date: 2/1/17*
  - *Actual completion date: 2/1/17*
  - *Percent of completion: 100%*
- *Major Task 4: Participant Recruitment, Treatment, Participant Evaluation*
  - *Target completion date: 9/30/20*
  - *Actual completion date: n/a*
  - *Percent of completion: 38% (23 of 60 targeted)*
- *Major Task 5: Data Analysis*
  - *Target completion date: 9/30/2022*
  - *Actual completion date: ongoing*
  - *Percent of completion: 50%*

**What was accomplished under these goals?**

**1) Major Activities:**

| | Deadline | Status |
|---|---|---|
| **Major Task 1: Administratively Prepare for Clinical Trial** | 1/1/17 | complete |
| **Major Task 2: Coordinate Study Staff for Clinical Trials** | 4/1/17 | complete |
| **Major Task 3: Prepare Research Protocol** | 2/1/17 | complete |
| **Major Task 4: Participant Recruitment, Treatment, Participant Assessment** | 9/30/21 | complete |

**2) Specific Objectives:**

| | Deadline | Status |
|---|---|---|
| **Major Task 1: Administratively Prepare for Clinical Trial** | | |
| Subtask 1: Prepare Regulatory Documents and Research Protocol | | |
| Finalize consent form & human subjects protocol | 1/1/17 | complete |
| Submit protocol to IRB | 1/1/17 | complete |
| Submit protocol for Military IRB Review (ORP/HRPO) | 4/1/17 | complete |
| Submit amendments, adverse events and protocol deviations as needed | As needed | |
| Coordinate with Sites for annual IRB report for continuing review | Annually | |

| | | |
|---|---|---|
| *Milestone Achieved: Local IRB approval at KF* | 1/1/17 | complete |
| *Milestone Achieved: HRPO* | | |
| **Major Task 2: Coordinate Study Staff for Clinical Trials** | | |
| Subtask1: Hiring and Training of Study Staff | | |
| Prepare job description design | 11/1/16 | complete |
| Advertise and interview for project related staff | 1/1/17 | complete |
| Coordinate for space allocation for new staff | 1/1/17 | complete |
| *Train staff for treatment and assessment activities* | 3/1/17 | complete |
| *Milestone Achieved: Research staff trained* | 4/1/17 | complete |
| Subtask 2: Facilitate hiring, training, supervision and fidelity checks as needed for attrition and treatment fidelity | ongoing | complete |
| *Milestone Achieved: Maintained trained and available staff throughout duration of clinical trial* | ongoing | complete |
| **Major Task 3: Prepare Research Protocol** | | |
| Finalize administration procedures for group mSMT | 2/1/17 | complete |
| Finalize assessment procedures; assemble testing binders and testing files for NPE and AGF | 2/1/17 | complete |
| Ensure appropriate programming of ePrime stimulus delivery of neuroimaging stimuli | 2/1/17 | complete |
| Finalize timing and parameters for the collection of optimal imaging data | 2/1/17 | complete |
| Milestone Achieved: both outcome assessments and treatment protocol finalized and running smoothly | ongoing | complete |
| **Major Task 4: Participant Recruitment, Treatment, Participant Evaluation** | | |
| Subtask 1: Participant recruitment & enrollment | | |
| Begin recruitment and screening of appropriate potential participants for study participation | 4/1/17 | complete |
| *Milestone Achieved: 1st 3-5 participants consented, screened and enrolled* | 5/1/17 | complete |
| *Milestone Achieved: First group treatment period completed successfully* | 7/1/17 | complete |
| Recruitment and screening continues | | complete |
| Participants complete assigned condition group treatment to reach target n of 90 | | Complete; target n not achieved |
| Complete follow-up assessments 3 months after completion of treatment | | complete |
| *Milestone Achieved: Data collection complete; data analysis begins* | | Complete; data analysis ongoing |

***3) Significant results or key outcomes:***

*Data collection is complete, but data analysis is ongoing. We encountered difficulty with enrollment and tried several means of addressing this throughout the life of the grant. This was a very difficult study to recruit for because individuals have to come to Kessler for treatment and*

*because it is a group treatment, their schedules need to coincide. We thus initiated recruitment off-site at day treatment programs (clubhouse). This increased enrollment somewhat. We were exploring the possibility of expanding recruitment to a 3rd location when the COVID-19 pandemic hit. At that point, we shifted to a virtual format and ran 2 additional groups in that format. Our final n was 23. There are no other results to report as data analysis is ongoing.*

***4) other achievements.***

*n/a*

*Recruitment details:*

- ***420** people with moderate to severe TBI were contacted for potential participation in the study.*
    - ***75** were background screened*
        - *Thirty-three (33) didn't qualify based on background screen.*
        - *Forty-four (44) qualified based on the background screen*
        - *Thirty-two (32) were willing to complete the in-person screen*
            - *Three (3) failed in-person screen*
            - *Two (2) chose not to participate after passing the in-person screen*
            - *Twenty-seven (27) people passed the screenings and were enrolled*
        - *Twenty-three (23) participants completed the study*
            - *Four of the 23 also completed the imaging assessments at baseline and follow-up scans.*
        - *Four (4) additional participants dropped out after completing the baseline assessment*
    - ***78** were not interested due to time commitment or couldn't travel to us*
    - ***200** could not be reached after multiple attempts and did not return our calls*
    - ***22** moved out of state or could not travel to appointments*
    - ***5** asked to be called back in a few weeks or months*
    - ***40** did not qualify based on information garnered during a casual conversation (e.g. had a stroke rather than TBI)*

**What opportunities for training and professional development has the project provided?**

*This project was not intended to provide training and professional development. However, staff recruited for the study include bachelor's level research assistants that received substantial on-the-job training in neuropsychological assessment, working with persons with TBI and the cognitive rehabilitation protocol being studied. This was done through one-on-one work with a mentor and results in increased knowledge or skill in neuropsychological assessment and functioning. All study staff additionally participated in the semi-annual TBI Consumer Conference held (9/27/2019; and virtually through a speaker series throughout September and October 2020) and had many opportunities to attend lectures and workshops at Kessler or Rutgers University.*

**How were the results disseminated to communities of interest?**

*Results were not yet disseminated as we continue to analyze the data and determine best methods or dissemination. This is the case with most of our grants. Due to the fact that we often use every last minute of funding to collect data, data analysis and dissemination*

*occurs after the grant is complete. This work is all accomplished by PHD level staff – scientists and post-doctoral fellows - who maintain continuous Kessler Foundation core funding for at least part of their time. It is that time that we will use to complete dissemination activities.*

**What do you plan to do during the next reporting period to accomplish the goals?**

*n/a – final report*

4. **IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**
*The primary discipline impacted by the development of the group KF-mSMT is cognitive rehabilitation therapists and psychologists. This treatment protocol will be made available to that group via our website so that the results of the current study can and will impact clinical care, as the individual KF-mSMT has.*

**What was the impact on other disciplines?**
*Rehabilitation will be impacted as a whole as the KF-mSMT becomes more widely used. We hope that improved cognition will help people perform at higher levels in therapy and will facilitate improve outcomes for individuals with TBI.*

**What was the impact on technology transfer?**
The group-based version of the KF-mSMT is paper based and does not involve technology.

**What was the impact on society beyond science and technology?**
*The group KF-mSMT will be made available to clinicians that seek group-based programs to build learning and memory skills for individuals with TBI.*

5. **CHANGES/PROBLEMS:**

*While we are exploring different options for recruiting participants, this will not involve any changes to the study protocol. All methodology will remain as proposed.*

**Changes in approach and reasons for change**
*none*
**Actual or anticipated problems or delays and actions or plans to resolve them**
*The only anticipated delay was the delay in recruitment described above.*
**Changes that had a significant impact on expenditures**
*none*
**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
*none*
**Significant changes in use or care of human subjects**
*none*
**Significant changes in use or care of vertebrate animals.**
*none*
**Significant changes in use of biohazards and/or select agents**
*none*

6. **PRODUCTS:**

*The final sample included 23 individuals with moderate to severe TBI. Individuals were block randomized to treatment or placebo control conditions to facilitate the initiation of the treatment protocols for each group. Due to enrollment challenges secondary to scheduling as well as the COVID-19 pandemic, we moved to a 2-1, treatment – control randomization scheme to enable greater enrollment on the treatment group. The final groups included 16 participants assigned to the treatment group and 7 participants assigned to the control group. There were no significant differences between the groups in regard to age, education, pre-morbid IQ or pre-treatment learning and memory abilities (Table 1). There were additionally no significant differences between the groups in regard to gender, handedness, employment status, mechanism of injury, or severity of injury.*

***Table 1.***

| ***Variable*** | ***Treatment Group N=16 M(SD)*** | ***Control Group N=7 M(SD)*** | ***Test statistic*** |
|---|---|---|---|
| *Age* | *41 (12.32)* | *51.43 (11.55)* | -1.901 |
| *Education* | *15.56 (2.22)* | *16.0 (2.45)* | -.422 |
| *Months since injury* | *104.11 (111.96)* | *69 (74.13)* | .567 |
| *WASI-Vocabulary t score (pre-morbid verbal IQ)* | *50.75 (11.45)* | *48.86 (9.0)* | .387 |
| *WASI-Matrix Reasoning (pre-morbid non-verbal IQ)* | *51.56 (12.14)* | *45.14 (13.31)* | 1.135 |
| *Open Trial SRT Trials to Criterion (pre-morbid learning ability)* | *14.56 (2.68)* | *13.14 (3.62)* | 1.050 |

*Treatment effects were analyzed with Analysis of Covariance (ANCOVA). The primary outcome for the current study was the California Verbal Learning Test-II (CVLT-II). ANCOVA was performed on 2 performance variables from the CVLT-II: total learning across the 5 trials and total learning slope. There were no significant differences noted between the groups. Secondary outcomes included the BVMT-R and the Wechsler Memory Scale- IV*

*(WMS-IV) prose memory, which similarly did not show any significant differences from pre to post treatment.*

*Additional analyses that will be performed include non-parametric analyses on the neuropsychological outcomes (primary and secondary) as well as analyses on self-report variables, which have not yet been examined. These analyses will be conducted in the next several months.*

*Results will be disseminated in conference presentations for both consumers and professionals, as well as publications in professional journals.*

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**

***Nancy Chiaravalloti, PhD***; PI; no change

***Glenn Wylie, D.Phil.;*** co-I; no change

***John DeLuca, PhD***; co-I; no change

***Ekaterina Dobryakova, PhD***; co-I; no change

**Nancy Moore, MA;** Research Manager; no change

| | |
|---|---|
| Name: | *Brionna Robinson* |
| Project Role: | *Research Assistant* |
| Nearest person month worked: | *6* |
| Contribution to Project: | *Ms. Robinson had been involved with participant recruitment and conducting the treatment sessions.* |
| Funding Support: | *NIDILIRR Field Initiated grant* |
| Name: | *Alec DeGraaf* |
| Project Role: | *Research Assistant* |

| | |
|---|---|
| Nearest person month worked: | *4* |
| Contribution to Project: | *Mr. DeGraaf has been involved with participant recruitment and conducting the treatment sessions* |
| Funding Support: | *NIDILRR Field Initiated grant* |
| Name: | *Suzanne Zuckerman* |
| Project Role: | *Research Assistant* |
| Nearest person month worked: | *5* |
| Contribution to Project: | *Ms. Zuckerman has been involved with participant recruitment and conducting the Assessment sessions.* |
| Funding Support: | *NIDILIRR Field Initiated grant* |
| Name: | *Eric Stone* |
| Project Role: | *Research Assistant* |
| Nearest person month worked: | *1* |
| Contribution to Project: | *Mr. Stone had been involved with participant recruitment.* |
| Funding Support: | National MS Society and NJ Commission on TBI Research |
| Name: | *Tiffany Chang* |
| Project Role: | *Research Assistant* |
| Nearest person month worked: | *2* |
| Contribution to Project: | *Ms. Chang had been involved with participant recruitment and conducting the Assessment sessions. She has now left the organization.* |
| Funding Support: | *NIDILIRR Field Initiated grant* |
| Name: | *Michael Pellicane* |
| Project Role: | *Research Assistant* |
| Nearest person month worked: | *2* |
| Contribution to Project: | *Mr. Pellicane had been involved with participant recruitment and conducting the treatment sessions. He has now left the* |

| | |
|---|---|
| | *organization.* |
| Funding Support: | *NIDILIRR Field Initiated grant* |
| Name: | *Donya Green* |
| Project Role: | *Research Assistant* |
| Nearest person month worked: | 4 |
| Contribution to Project: | *Mr. Green had been involved with participant recruitment and conducting the assessments. He has now left the organization.* |
| Funding Support: | *NIDILIRR Field Initiated grant* |

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

*Nothing to Report.*

**What other organizations were involved as partners?**

*None. Nothing to Report.*

8. **SPECIAL REPORTING REQUIREMENTS**

*none*

9. **APPENDICES:**

*none*