AWARD NUMBER: W81XWH-15-1-0331

TITLE: Trauma-Informed Guilt Reduction (TrIGR) Intervention

PRINCIPAL INVESTIGATOR: Christy Capone, PhD

CONTRACTING ORGANIZATION: Brown University, Providence, RI

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Posttraumatic guilt and shame are common among Veterans and have been implicated in the development and maintenance of posttraumatic distress and a range of adverse outcomes, including posttraumatic stress disorder (PTSD), depression and suicidality, and alcohol/substance use disorders. There is a pressing need for effective treatments targeting transdiagnostic mechanisms such as guilt. We developed Trauma Informed Guilt Reduction (TrIGR) therapy as a therapeutic tool to help Veterans accurately appraise deployment-related guilt and to re-identify and re-engage with their values. Our previous pilot studies of TrIGR with OEF/OIF/OND Veterans and active duty Marines showed reductions in guilt distress and severity, PTSD symptoms, and depression with medium to large effect sizes. The overall objective of this study is to examine the efficacy of TrIGR in reducing deployment-related guilt. The overarching hypothesis is that TrIGR will reduce guilt, shame, and related distress, and these improvements will be significantly greater than in the comparison condition, Supportive Care Therapy (SCT). The study is a Stage 2 randomized, controlled trial of TrIGR compared to SCT. Recruitment of participants takes place at two VA Medical Centers (San Diego, CA and Providence, RI). 145 OEF/OIF/OND Veterans were randomized to TrIGR or SCT across two sites (53 in Providence). All eligible participants complete an in-person baseline assessment, receive 6 sessions of TrIGR or SCT in individual format, complete brief bi-weekly self-report measures during treatment, and complete follow-up assessments immediately post-treatment, and 3- and 6-months later. We completed data collection at the Providence site in December 2020.

15. SUBJECT TERMS
Guilt, shame, deployment, posttraumatic, distress, PTSD, depression, functioning, psychotherapy, intervention

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1. INTRODUCTION:

Posttraumatic guilt and shame are common among Veterans and have been implicated in the development and maintenance of posttraumatic distress and a range of adverse outcomes, including posttraumatic stress disorder (PTSD), depression and suicidality, and alcohol/substance use disorders. There is a pressing need for effective treatments targeting transdiagnostic mechanisms such as guilt. We developed Trauma Informed Guilt Reduction (TrIGR) therapy as a therapeutic tool to help Veterans accurately appraise deployment-related guilt and to re-identify and re-engage with their values. Our previous pilot studies of TrIGR with OEF/OIF/OND Veterans and active duty Marines showed reductions in guilt distress and severity, PTSD symptoms, and depression with medium to large effect sizes. The overall objective of this study is to examine the efficacy of TrIGR in reducing deployment-related guilt. The overarching hypothesis is that TrIGR will reduce guilt, shame, and related distress, and these improvements will be significantly greater than in the comparison condition, Supportive Care Therapy (SCT). The study is a Stage 2 randomized, controlled trial of TrIGR compared to SCT. Recruitment of participants takes place at two VA Medical Centers (San Diego, CA and Providence, RI). 145 OEF/OIF/OND Veterans were randomized to TrIGR or SCT across two sites (53 in Providence). All eligible participants complete an in-person baseline assessment, receive 6 sessions of TrIGR or SCT in individual format, complete brief bi-weekly self-report measures during treatment, and complete follow-up assessments immediately post-treatment, and 3- and 6-months later. We completed data collection at the Providence site in December 2020.

We also were approved to run a pilot study of the same intervention for guilt from events during the COVID-19 pandemic. For this extension, we are conducting a prospective, randomized, controlled pilot trial examining the efficacy of TrIGR compared to SCT for the treatment of guilt and distress related to a COVID-19 stressor. 72 male and female Veterans of OEF/OIF/OND will be randomized at the San Diego VA, Boston VA, and Brown University in Providence. Participants will complete a baseline assessment, receive 6 weekly sessions of TrIGR or SCT, complete a follow-up assessment post-treatment, and 1-month later. Study visits will be conducted over telehealth. Recruitment at the Providence site began in February 2021.

2. KEYWORDS

Guilt, shame, deployment, posttraumatic, distress, PTSD, depression, functioning, psychotherapy, intervention

3. ACCOMPLISHMENTS

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

Per our Statement of Work (SOW), effort was expended on the following milestones and subtasks during this year:

Conduct RCT (months 6-46)

Subtask 1: Enroll 75 at Providence site
Progress: We completed enrollment (67 participants) by March 2020 (enrollment ended 3 weeks early due to COVID-19 pandemic).
Subtask 2: Randomize to study condition (TrIGR or SCT)
Progress: We completed randomization (53 participants) in March 2020.
Subtask 3: Deliver study interventions
Progress: We completed study interventions in June 2020 (44/53 participants completed intervention).
Subtask 4: Conduct assessments

Progress: We completed study assessments in December 2020 (41/53 participants completed post-tx follow up; 43/53 completed 3-month follow up; and 42/53 completed 6-month follow up).
Subtask 5: Data collection
Progress: We completed data collection in December 2020.

131 participants were recruited/referred to the study. We screened 105 participants. Of those, 72 screened eligible, 11 screened ineligible, and 22 declined. 26 of the referred participants were unable to be screened. We consented 67 participants and randomized 53. The original planned target was 75. Of the 72 participants who screened eligible, 5 were not consented. 14 of the 67 consented participants were not randomized – 9 were not eligible after baseline assessment and 5 were no longer interested after baseline assessments. 51 of the 53 randomized participants completed the study.

Dissemination (months 46-48)
Subtask 1: Data cleaning and checking
Progress: We worked closely with the study statistician on the process of data cleaning and checking upon completion data collection.
Subtask 2: Conduct data analyses
Progress: Data analysis is in process.
Subtask 3: Prepare conference presentations and manuscripts.
Progress: We recently published a manuscript detailing the methods utilized in the main trial and the main outcomes paper is currently under review. Several conference presentations (e.g., symposia and poster presentations) are planned for November 2021.

Conduct Pilot RCT Related to COVID-19 (months 60-72)

Subtask 1: Enroll 24 at Providence site (Months 63-69).
Progress: We began recruitment in Y6Q2. We have screened 31 participants. We have consented 18 participants.
Subtask 2: Randomize to study condition (TrIGR or SCT) (Months 63-69).
Progress: We have randomized 9 participants.
Subtask 3: Deliver study interventions (Months 63-70).
Progress: We began study interventions Y6Q3. 6 participants have completed the intervention, 3 are still in treatment, and 0 discontinued the intervention.
Subtask 4: Conduct follow-up assessments (Months 64-71).
Progress: We will continue to assess all study participants per protocol. 5 participants have completed the post-treatment follow-up and 4 participants have completed the 1-month follow-up.
Subtask 5: Data collection (64-71).
Progress: Data collection was initiated Y6Q3.

45 participants have been recruited/referred to the study. We have screened 31 participants since we launched recruitment. Of those, 26 screened eligible, and 5 screened ineligible. 14 of the referred participants have been unable to be screened. We have consented 18 participants and randomized 9. The original planned target was 24. Of the 26 participants who screened eligible, 8 were not consented by 9/30/21. 7 of the 18 consented participants were not randomized – 5 were not eligible after baseline assessment, 2 were no longer interested after baseline

assessments, and 2 have completed baseline assessments and have MI sessions scheduled (and, if eligible, will be randomized after MI). 9 of 9 randomized participants have completed the study.

***Please see Figures 1 and 2 at the end of this document for a visual representation of these data.**

- **What was accomplished under these goals?**
  For the original RCT, the major activities of for the past FY were completing study data collection and data cleaning. Data analysis and the preparation of manuscripts are in process.

  For the Pilot RCT Related to COVID-19, the major activities for the past FY were beginning study recruitment and delivering the study interventions. Data collection is ongoing.

- **What opportunities for training and professional development has the project provided?**
  We have had several psychology trainees participating in study activities to learn about how to conduct randomized clinical trials and to be trained as study therapists and assessors.

- **How were the results disseminated to communities of interest?**
  Conference presentations and manuscripts for the original RCT are in preparation (see above).

- **What do you plan to do during the next reporting period to accomplish the goals?**
  During the next reporting period, we will focus on the milestones and subtasks as detailed in our SOW. Specifically, we will complete data analysis for the primary study and disseminate findings. For the COVID-19 supplement, we will continue to 1) enroll participants; 2) randomize participants; 3) deliver study interventions; and 4) conduct data collection.

4. IMPACT

- **What was the impact on the development of the principal discipline(s) of the project?**
  Nothing to Report

- **What was the impact on other disciplines?**
  Nothing to Report

- **What was the impact on technology transfer?**
  Nothing to Report

- **What was the impact on society beyond science and technology?**
  Nothing to Report

5. CHANGES/PROBLEMS

It took longer than anticipated to obtain regulatory approval for the pandemic extension, which resulted in a delay in starting recruitment. We

are currently actively recruiting participants and have been granted an extension that will allow us to meet our recruitment goals.

6. PRODUCTS

- **Publications, conference papers, and presentations**

1. Capone, C., Norman, S.B., Haller, M., Davis, B., Shea, M.T., Browne,K., et al. (2021). Trauma Informed Guilt Reduction (TrIGR) therapy for guilt, shame, and moral injury resulting from trauma: Rationale, design, and methodology of a two-site randomized controlled trial. *Contemporary Clinical Trials, 101, https://doi.org/10.1016/j.cct.2020.106251*
2. McLean, C. P., Back, S. E., **Capone, C.**, Morland, L., Norman, S. B.,Rauch, S. A. M., Schnurr, P. P., Teng, E., & Acierno, R. (2021). The impact of COVID-19 on psychotherapy participation among individuals with PTSD enrolled in treatment research. *Journal of Traumatic Stress. https://doi.org/10.1002/jts.22718*
3. Haller, M., Norman, S.B., Davis, B.C., Capone, C., Browne, K., &Allard, C.B. (2020). A model for treating Covid-19 related guilt, shame, and moral injury [Special Issue]. *Psychological Trauma: Theory, Research, Practice, and Policy, 12*(S1), S174-S176. http://doi.org/10.1037/tra0000742

- **Website(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

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

Name: Christy Capone, PhD
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-1720-171X
Nearest person month worked: 3CM
Contribution to Project: Dr. Capone continues to oversee project staff and all study protocols and procedures.

Name: M. Tracie Shea, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1CM
Contribution to Project: Dr. Shea conducts therapist trainings on the SCT condition and is providing regular supervision calls with therapists across sites.

Name: Lauren DeMoss, MS
Project Role: Project Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 10CM
Contribution to Project: Ms. DeMoss is responsible for coordinating all aspects of the study, recruiting and consenting patients, conducting baseline assessments, and managing day-to-day tasks for the study.

Name: Alex Brake, PhD
Project Role: Study Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2CM
Contribution to Project: Dr. Brake is a study therapist and has completed training in both interventions (SCT and TrIGR). He delivered both therapies to study participants and participates in regular supervision meetings. (February 2021 – August 2021)

Name: Timothy Carroll, PhD
Project Role: Study Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2CM
Contribution to Project: Dr. Carroll is a study therapist and has completed training in both interventions (SCT and TrIGR). He delivered both therapies to study participants and participates in regular supervision meetings. (February 2021 – August 2021)

Name: Maureen McDonnell, PhD
Project Role: Study Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2CM
Contribution to Project: Dr. McDonnell is a study therapist and has completed training in both interventions (SCT and TrIGR). She delivers both therapies to study participants and participates in regular supervision meetings. (August 2021 - present)

Name: Simone Arent, PhD
Project Role: Study Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2CM
Contribution to Project: Dr. Arent is a study therapist and has completed training in both interventions (SCT and TrIGR). She delivers both therapies to study participants and participates in regular supervision meetings. (August 2021 - present)

- **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?**

Organization Name: VA San Diego
Location of Organization: San Diego, CA
Partner's contribution to the project:
Financial Support: N/A
In-Kind Support: N/A
Facilities: N/A
Collaboration: Partnering PI
Personnel exchanges: N/A
Other: N/A

8. Special Reporting Requirements

A. Collaborative Awards

- VA San Diego will submit a separate report.

B. Quad Charts

- Attachment 1

9. Appendices

- Consort Diagram - Attachment 2
- Consort Diagram – COVID-19 Pilot RTC – Attachment 3

Trauma Informed Guilt Reduction (TrIGR) Intervention

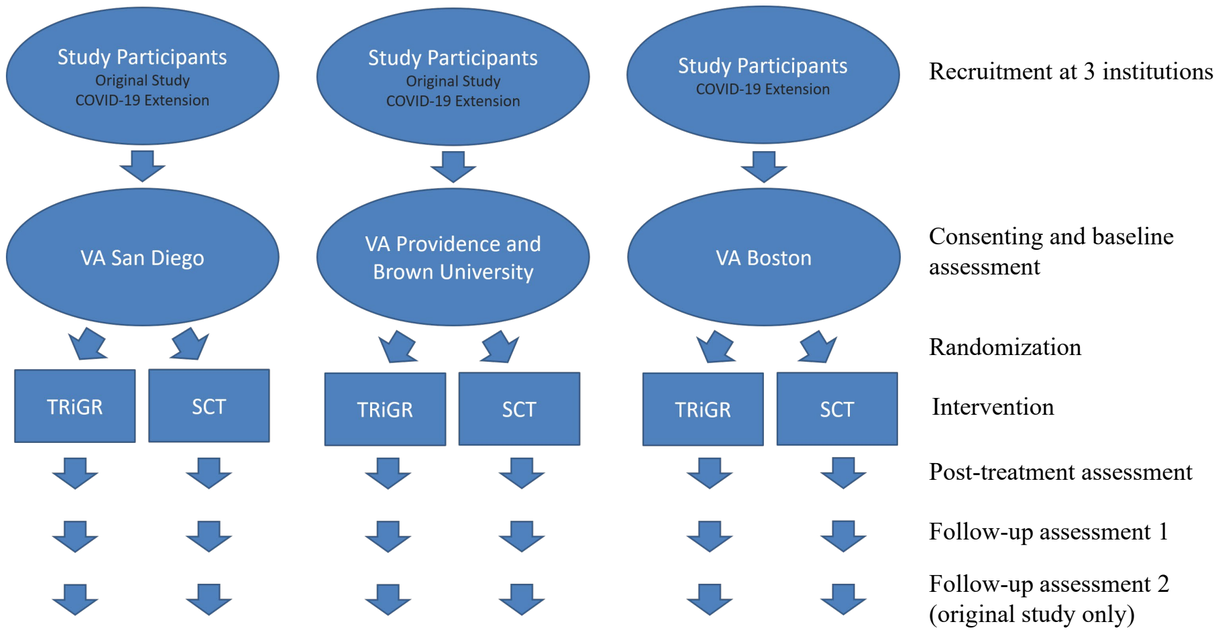
PI: Christy Capone, PhD **Org:** Brown University **Award Amount:** $1,292,682 direct

Study/Product Aim(s)

- Conduct a randomized clinical trial to determine if a six-session treatment, Trauma Informed Guilt Reduction (TrIGR), relative to supportive care therapy (SCT) at post-treatment, 3- and 6-month follow up reduces deployment-related guilt
- In COVID-19 extension, the primary aim is to examine the efficacy of TrIGR for reducing COVID-19 related guilt and shame in Veterans.

Approach

The primary study is a stage 2 randomized clinical trial across 2 VA Medical Centers (San Diego, Providence). 150 male and female Veterans of OEF/OIF reporting guilt related to a combat event will be randomized to TrIGR or SCT and followed through treatment, 3- and 6-month follow-up. The COVID-19 extension is a randomized clinical trial across 3 sites (San Diego VA, Brown University/Providence VA, and Boston VA). 72 Veterans will be enrolled. Hypotheses are that TrIGR, relative to SCT, will reduce guilt, distress, shame, disorder specific symptoms, and SI and alcohol/substance use and improve Quality of Life.



Study PI recently completed two open-label trials to evaluate the effectiveness of TrIGR. Participants showed significant reductions in guilt and distress over the course of treatment. Satisfaction with the intervention was extremely high. Study PI is currently awaiting IRB approval to begin recruitment for COVID-19 extension.

Timeline and Cost

Activities	FY 1	FY 2	FY 3	FY 4	FY 5	FY 6
Finalize procedures and approvals, hire and train staff						
Recruit, enroll, collect data						
Data analysis, report preparation						
Estimated Total Budget ($K)*	235 k	243 k	251 k	207 k		269 k

Updated: 10/01//2021

Original project COVID-19 extension

Goals/Milestones

Study Year 1 Goals –Prepare regulatory documents and research protocol
- ☑ Sign contracts, prepare protocol, and obtain approval from VA sites and USAMRMC
- ☑ Prepare, program, purchase and test all forms for study documentation
- ☑ Recruit and train research staff

Study Year 2 Goals – Participant recruitment, randomization, intervention
- ☑ Participant recruitment, randomization, pre-assessment and TrIGR/SCT
- ☑ Post-intervention, 3-mo and 6-mo post-tx follow-up assessments
- ☑ Validate audio recordings of TrIGR and SCT sessions

Study Year 3 Goals – Complete enrollment and validation of TrIGR/SCT sessions
- ☑ Complete recruitment, randomization, pre-assessment, and TrIGR/SCT
- ☑ Continue post-intervention and follow ups at 3- and 6- months

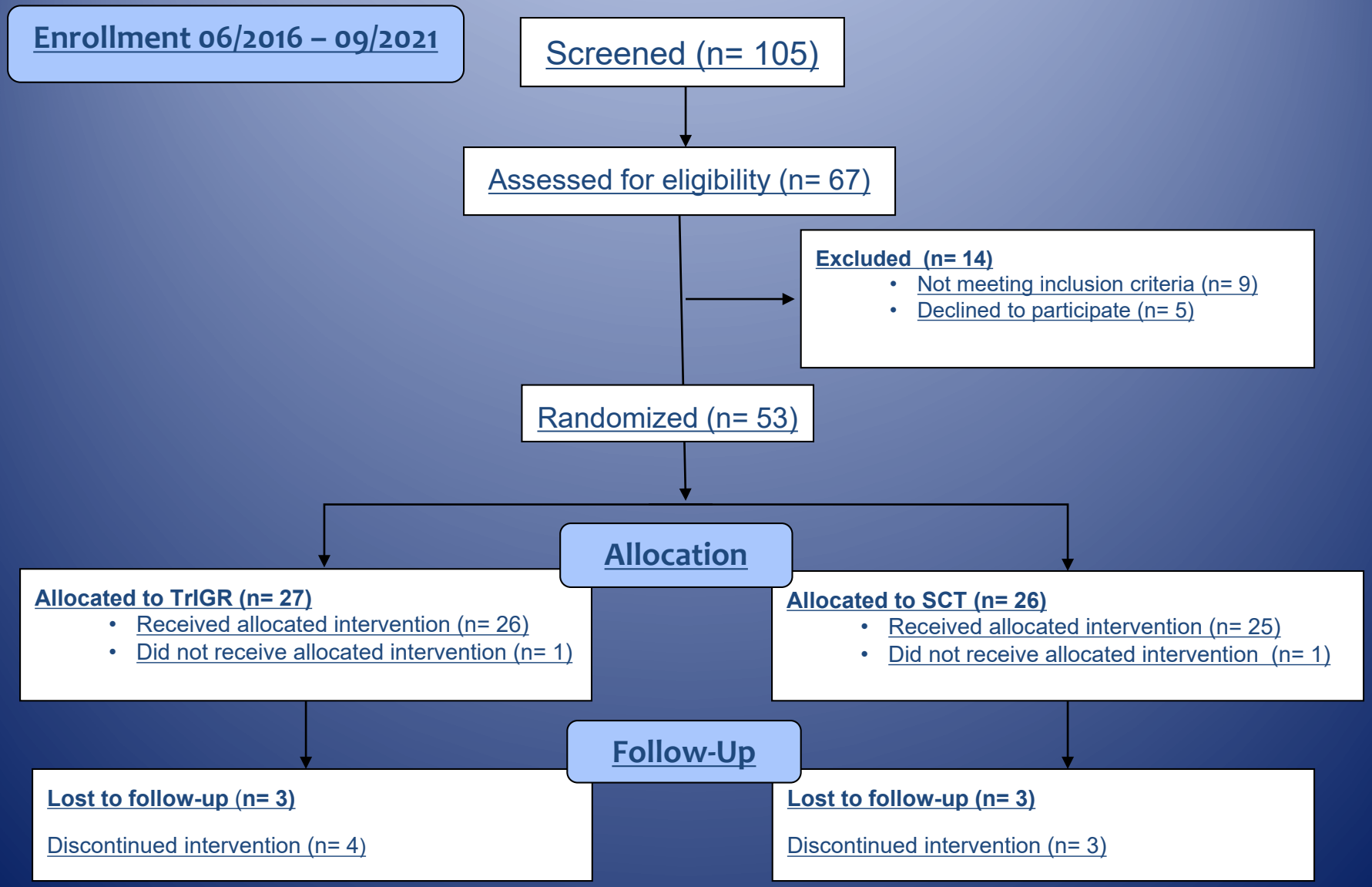
Study Year 4 Goals – Analyze data and prepare manuscripts
- ☑ Complete follow up assessments and data entry
- ☑ Ensure data integrity
- ☐ Data analysis and manuscript preparation – in process

Study Year 6 Goals –Conduct COVID-19 extension
- ☑ Prepare regulatory documents and research protocol
- ☐ Participant recruitment, randomization, intervention – in process
- ☐ Complete enrollment and validation of TrIGR/SCT sessions
- ☐ Analyze data and prepare manuscripts

Expenditures to date:
$1,120,404
Projected Expenditure:
$1,292,682

Attachment 2

CONSORT Diagram – Providence



Attachment 3

CONSORT Diagram – Providence – COVID-19 Pilot RTC