Expanding Access to Comprehensive Geriatrics Care via Telehealth (QUE 20-010)

NCT05166603

March 15, 2021

VA TeleGRACE
Geriatric Resources for Assessment and Care of Elders

TELE-GRACE IMPLEMENTATION PROJECT

STATISTICAL ANALYSIS PLAN: Aim 1 Effectiveness

Table of Contents

OVERALL TELEGRACE PROJECT RATIONALE

The Geriatric Resources for Assessment and Care of Elders (GRACE) program is a collaborative, multidisciplinary care model that includes geriatricians, social workers, nurse practitioners, and primary care providers and which provides home-based geriatric care management. GRACE has been demonstrated in a randomized controlled trial to improve quality of care and reduce healthcare utilization compared to usual care.[4] The VA-GRACE model of care was evaluated in a controlled study in a large VAMC among elderly Veterans who were recently admitted to the hospital, finding that GRACE was associated with 7.1% fewer ED

visits, 14.8% fewer 30-day readmissions, 37.9% fewer hospital admissions, and 28.5% fewer bed-days of care, saving the VAMC an estimated $200,000 per year after program costs.[3]

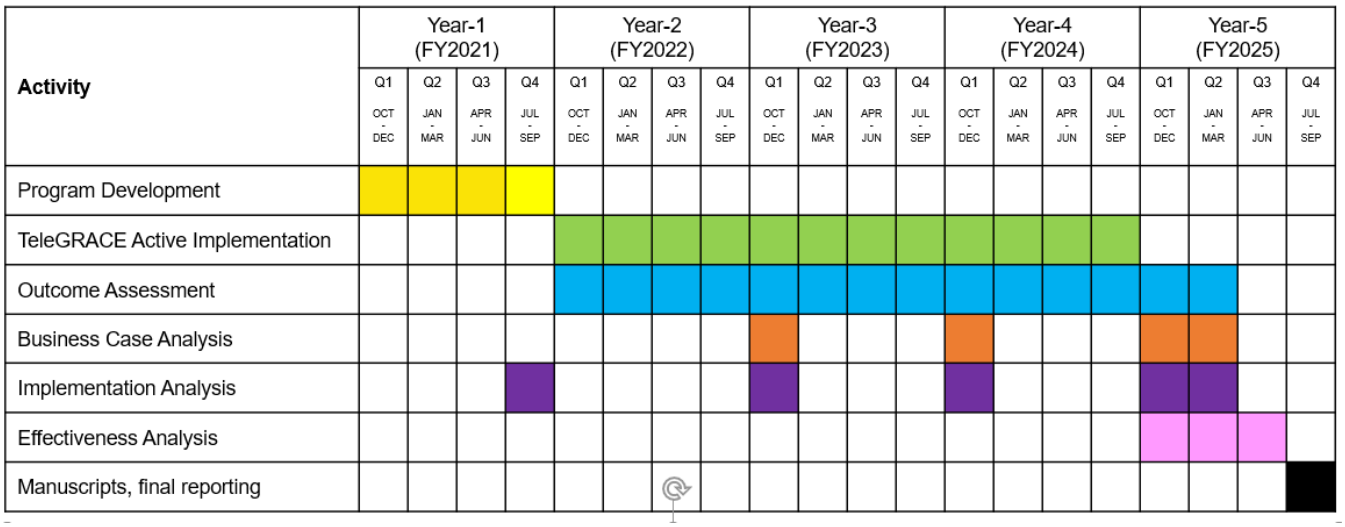
The Indianapolis VAMC GRACE program has been demonstrated to improve care and outcomes for older Veterans. In a propensity weighted data analysis with 634 GRACE patients and 5614 matched control patients, GRACE was significantly associated with lower all-cause mortality after discharge from an index hospitalization: all-cause mortality 90-day post discharge was 1.3% for GRACE patients and 8.5% for control patients. However, the reach of the program is limited due to logistical constraint of the 20-mile driving distance that the GRACE teams use for their home visits. **The overall objective of the TeleGRACE project is to improve the care and outcomes of older Veterans with a recent inpatient stay by expanding access to the GRACE program, by evaluating a telehealth implementation**. Specifically, the TeleGRACE project seeks to overcome the drive-time distance barrier that currently prevents the widespread application of GRACE to eligible older Veterans by implementing virtual home visits instead of in-person home visits.

The TeleGRACE evaluation will focus on three primary aims and a secondary aim:
Primary Aim 1: To examine the effectiveness of the TeleGRACE program, we designed a randomized controlled implementation trial (RCT) powered for the primary outcome of 90-day all-cause mortality. We will also examine its effectiveness for the secondary outcomes including 90-day readmissions, 1-year ED utilization (VA and non-VA), 1-year all-cause readmissions, 1-year mortality, as well as patient, caregiver, and staff satisfaction. We hypothesize that patients who receive TeleGRACE will have lower 90-day mortality than patients in usual care.

Primary Aim 2: to examine the implementation of the TeleGRACE program. The implementation strategy is reflecting & evaluating. Implementation outcomes are based on the REAIM framework and include reach, efficacy (Aim 1), and implementation (total number of Veterans served, fidelity).

Primary Aim 3: to conduct a business-case analysis (BCA). The business case analysis will calculate the net financial savings or loss for TeleGRACE as the difference in the overall intervention costs and savings due to downstream benefits for patients receiving TeleGRACE versus usual care controls.

TeleGRACE Program Evaluation



THIS ANALYSIS PLAN FOCUSES ONLY ON EFFECTIVENESS

To examine the effectiveness of the TeleGRACE program, we designed a randomized controlled implementation trial (RCT) powered for the primary outcome of 90-day all-cause mortality. We will also examine its effectiveness for the secondary outcomes including 90-day readmissions, 1-year ED utilization (VA and non-VA), 1-year all-cause readmissions, 1-year mortality, as well as patient, caregiver, and staff satisfaction. We hypothesize that patients who receive TeleGRACE will have lower 90-day mortality than patients in usual care.

METHODS

The TeleGRACE project will be a prospective, randomized controlled trial. The unit of randomization is the patient. **This project is an evaluation of a clinical program and is classified as quality improvement and not research.**

Intervention: In-Person versus Telehealth

The GRACE program involves geriatric-focused home visits by a nurse practitioner and a social worker followed by multidisciplinary meetings to discuss each Veteran's plan of care along with ongoing collaboration with VA primary care. This "in-person" model has been in effect at the Indianapolis VA medical center since 2010. In the telehealth approach, a staff member will be trained to conduct home visits using the GRACE protocol and will use video telehealth (i.e., VA video connect [VVC]) from the patient's home to connect with the GRACE multidisciplinary team members located at the coordinating center in Indianapolis. **The use of the virtual home visit instead of the in-person home visit is the only change that is made for the TeleGRACE program**. The multidisciplinary team meetings as well as the follow-up and coordination of care with the primary care PACT teams will be unchanged. The number of visits and the content of the assessments will be the same for TeleGRACE patients as for in-person GRACE patients.

Eligible Veteran Patients

Patients eligible to receive TeleGRACE services include:

- Veterans discharged from the Indianapolis VA medical center (VAMC) for an medical/surgical diagnosis (excludes substance use disorder-related admissions; excludes planned admissions)
- Age ≥70 years
- Not enrolled in home-based primary care (HBPC)
- Not enrolled in hospice
- Not in dialysis
- Primary care visit within VA in the prior 2 years
- Not residing in nursing home, skilled nursing facility, or CLC
- CAN score ≥95th percentile for mortality or missing CAN score
- Discharged from the hospital alive

Exclusion Criteria

- Patients who have been randomized to the control arm after their index hospitalization who become readmitted to the hospital may not be re-randomized.
- Enrolled in in-person GRACE
- Enrolled in home-based primary care (HBPC)
- Enrolled in hospice
- Enrolled in complex care program
- Dialysis (hemodialysis or peritoneal dialysis)
- Residing in nursing home, skilled nursing facility, or CLC
- Living >60 miles from the Indianapolis VAMC facility

Outcome Measures

The primary outcome for the TeleGRACE evaluation will be:

- 90-day all-cause mortality (measured as 90-days from discharge from the index hospital stay)

The secondary outcomes are:

- 90-day readmissions
- 1-year all-cause readmissions
- 1-year mortality
- 1-year ED utilization (VA and non-VA)
- 1-year falls

We will explore using time to nursing home placement as a secondary outcome. We have requested the data and will evaluate the data source for completeness; comparing it against chart review. If the team considers the data source to be accurate, then we will examine time to nursing home placement as a secondary analysis.

Randomization

Patients will be randomized in ratio of 1 (control):2 (intervention) stratified by site of primary care (Indianapolis VAMC versus non-Indianapolis [e.g., CBOCs]). We created a computer-generated randomization list (with random block sizes of 3 or 6) for each strata. With the current capacity

of VA GRACE program staff, our goal is to enroll 5 patients to TeleGRACE each month. The project will seek to enroll a total of 180 patients to TeleGRACE and 360 to usual care in a three-year recruitment period.

Data Sources

Corporate Data Warehouse (CDW) data

CDW data will be used to assess patient baseline characteristics (e.g., age, demographics, past medical history, prior healthcare utilization) as well as outcomes (i.e., ED utilization, readmission, mortality, and falls). In this way, the same data source is used to identify outcomes for both intervention and control patients.

Chart Review data

Chart review will be used to validate the TeleGRACE dose classification that is based on CDW data (see Per-Protocol analysis described below).

Follow-up Period

Patients will be followed for one year from the date of discharge from their index hospitalization. Unlike clinical trials that require in-person outcome assessments and hence implement "windows" for data collection, this evaluation will use electronic health record data for outcome assessment and hence no windows will be specified.

ANALYSIS PLAN

Intention-to-Treat Analysis

We will compare baseline characteristics between TeleGRACE patients and control patients using chi-square tests for categorical data and t-tests for continuous characteristics.

In the primary intention-to-treat (ITT) analysis, we will compare outcomes between patients randomized to usual care and those to TeleGRACE adjusting for the baseline characteristics that are significantly different by logistic regression for the binary outcome and Poisson regression for count data. If the sample size is sufficient, we will examine the effect of the TeleGRACE program by site of receipt of primary care services.

Per-Protocol Analyses

Not all patients who are randomized to receive TeleGRACE will receive services from the TeleGRACE staff. This situation is anticipated for patients who decline GRACE and others who become ineligible after discharge from the index hospitalization but before their first virtual home visit post-discharge (e.g., patients who die, get readmitted, or move to a skilled nursing facility after discharge). In the exceptionally rare case, patients may be discharged from TeleGRACE due to safety concerns for our staff (e.g., sexually or physically aggressive behavior, unwillingness to cage animals, unwillingness to store firearms). The per-protocol analyses will be similar to the planned intention-to-treat analysis but will compare the outcomes between patients who received GRACE service versus patients in usual care.

Given the expected heterogeneity in the number of TeleGRACE visits, patients will be classified into four categories as follows:

1. **Full TeleGRACE dose**: the patient received a virtual post-discharge transitional visit, followed by a virtual baseline visit with multidisciplinary team discussion, and then follow-up virtual discussion to ensure that the patient and caregiver agree with and understand the plan of care. These patients may receive additional follow-up contacts with the TeleGRACE/GRACE team members over the course of the one year follow-up period. Note: in the atypical situation where the patient did not receive a transitional visit but did receive a baseline assessment, the patient will still be classified as "full TeleGRACE dose).
2. **Transitional visit dose**: the patient received a virtual post-discharge transitional visit but did not receive a baseline visit. These patients may receive additional follow-up contacts (typically by telephone) with the TeleGRACE/GRACE team members over the course of the one-year follow-up period. In some cases, the patient may receive multiple transitional visits (e.g., after readmissions).
3. **Partial dose**: the patient received neither a post-discharge transitional visit nor a baseline visit but had other contact with the TeleGRACE/GRACE team (typically telephone visits).
4. **No TeleGRACE**: patients may have been contacted by the TeleGRACE/GRACE team in an attempt to schedule a visit, but these patients received no clinical visits or encounters. Patients who decline TeleGRACE services are included in this category. Please note: in a research randomized controlled trial, only patients who are potentially interested in participation are consented and then randomized. TeleGRACE is a quality improvement project, therefore enrollment follows procedures used in clinical care.

We will further examine the outcomes among patients across these 4 categories as well as the control patients.

Sensitivity Analyses

Considering the heterogeneity in the TeleGRACE patients, we plan to conduct the following sensitivity analyses

1. **Enrolled versus Randomized to TeleGRACE:** We will conduct the ITT analysis described above which compares patients *randomized* to TeleGRACE versus usual care controls. In addition, we will compare patients who *enrolled* in TeleGRACE versus control patients.
2. **Dose:** In addition to the description of TeleGRACE services as provided in the per-protocol analysis, the dose of the TeleGRACE program will be assessed in terms of:
    a. The total number of GRACE contacts (telephone, virtual or in-person) in the one-year post-discharge from the index event.
    b. Typically, home visits are conducted by a dyad of a nurse practitioner and social worker. Given staffing constraints, some patients may only receive a visit by a social worker or a nurse practitioner but not both. Therefore, each transitional, baseline, and follow-up visit will be assessed to describe whether it was conducted by social work, nursing, or other staff.
    c. A key element of the GRACE program is the development of a multidisciplinary plan via discussion at the weekly GRACE rounds. The number of times an individual patient is discussed by the entire team in the year post-discharge will

be recorded (the geriatrician's summary of the multidisciplinary discussion will be used to identify whether a patient was discussed during team rounds).

3. **Discontinuous Eligibility Periods:** Patients who become permanently ineligible for TeleGRACE (e.g., are readmitted and then subsequently discharged to a long-term care facility) will be censored on the date they became ineligible for the outcome measures because they became ineligible for services. However, this censoring plan will be implemented retrospectively because it is expected that the older persons who will be enrolled in this study may have intermittent periods of ineligibility (e.g., during a hospital stay and then followed by short-term rehabilitation stay). Such patients may still benefit from the intervention and hence will not be censored either from the intervention or control groups.
    a. For all intervention patients, we will calculate the proportion of eligible days a patient is cared for by the GRACE team as: the number of days that the patient was under the care of the GRACE team divided by the total number of days the patient was potentially eligible for GRACE.
    b. We will note whether the period of eligibility was either continuous or discontinuous.
    c. For patients with a discontinuous eligibility period, we will describe the patterns of discontinuity. For example, some patients may have a short hospital stay early post-discharge but then receive a relatively long period of GRACE services in the year post-discharge. In contrast, other patients may have recurrent hospitalizations some of which may be followed by short-term rehab stays resulting in fragmented eligibility periods of relatively short durations.
    d. If there are more than 10% patients censored for the outcomes, we will conduct Cox-regression analysis for the hazard of death and risk-exposure adjusted Poisson regression for the number of readmissions and number of falls.

POWER

For **Aim 1** (effectiveness of TeleGRACE versus usual care), we expect to observe 2% and 8% 90-day all-cause mortality for the TeleGRACE and usual care patients, respectively. This projected effect size is conservative based on our propensity-score weighting analysis comparing GRACE patients with usual care patients. With 180 TeleGRACE and 360 usual care patients, the study has 0.96 power at detect the efficacy of TeleGRACE program with a one-sided normal test at a significance level 0.05. Considering a 10% drop-out, the analysis has 0.94 power to establish the TeleGRACE efficacy with the same effect size.

DATA MONITORING

Enrollment

We will closely monitor the randomization of TeleGRACE with the expected rate of 5 per month. We will plot the number of actual randomized patients and its expected number against the study time and update the figure on a monthly basis. Prior to the DSMB meeting, we will estimate the current randomization rate and project the final number of randomized patients by end of the fourth year with the current rate along with its 95% confidence interval based on the Poisson distribution. If the upper bound of the 95% interval is below the target number of 180. We will modify the enrollment strategy to ensure that we achieve the enrollment goal.

Interim Analysis

Since the observed effect size of in-person GRACE versus usual care is quite substantial with respect to 90-day all-cause mortality, we plan an interim analysis when a half of the enrolled patients can be evaluated for the primary outcome. One-sided normal testing will be applied for the interim analysis using O'Brien-Fleming group sequential test with the overall type error controlled at 0.05. The hypotheses are:

$$H_0: p_1 = p_2 \; vs. \; H_1: p_1 < p_2,$$

where $p_1 \text{and } p_2$ stand for the 90-day all-cause mortality in TeleGRACE and usual care arms, respectively.

If the $Z - \text{test}$ statistic crosses the boundary of -2.54 at the interim analysis, the trial will be recommended for stopping for efficacy; otherwise, the trial will continue to the end with the crossing boundary for the test statistic at -1.66. The overall power with the interim analysis for this study is 0.82.

Safety

This is a quality improvement project; few safety issues are anticipated. The primary safety concern would be related to loss of data confidentiality for patients or staff interviewees. Any breaches of confidentiality will be reported.

REFERENCES

1. Statistics NCfVAa. Veteran Population: U.S. Department of Veterans Affairs, Fiscal Year 2016.
2. Statistics NCfVAa. Comparison of VA Users and Non-Users: FY2016: U.S. Department of Veterans Affairs, 2017.
3. Schubert CC, Myers LJ, Allen K, et al. Implementing Geriatric Resources for Assessment and Care of Elders Team Care in a Veterans Affairs Medical Center: Lessons Learned and Effects Observed. *Journal of the American Geriatrics Society* 2016;64(7):1503-9. doi: 10.1111/jgs.14179 [published Online First: 2016/06/16]
4. Counsell SR, Callahan CM, Clark DO, et al. Geriatric care management for low-income seniors: a randomized controlled trial. *Jama* 2007;298(22):2623-33. doi: 10.1001/jama.298.22.2623 [published Online First: 2007/12/13]
5. Luck J, Parkerton P, Hagigi F. What is the business case for improving care for patients with complex conditions? *J Gen Intern Med* 2007;22 Suppl 3:396-402. doi: 10.1007/s11606-007-0293-2 [published Online First: 2007/12/06]
6. Leatherman S, Berwick D, Iles D, et al. The business case for quality: case studies and an analysis. *Health Aff (Millwood)* 2003;22(2):17-30. doi: 10.1377/hlthaff.22.2.17 [published Online First: 2003/04/04]
7. Smith M, Barnett P, Phibbs C, et al. Microcost methods of determining VA healthcare costs. In: VA, ed. Menlo Park, CA: VA Health Economics Resource Center, 2010.

8. Rollins A, Kukla M, Salyers M, et al. Comparing the Costs and Acceptability of Three Fidelity Assessment Methods for Assertive Community Treatment. *Adm Policy Ment Health* 2017;44(5):810-16. doi: 10.1007/s10488-016-0785-7
9. Xu H, Daggy J, Yu D, et al. Joint modeling of medical cost and survival in complex sample surveys. *Stat Med* 2013;32(9):1509-23. doi: 10.1002/sim.5617 [published Online First: 2012/10/02]
10. VA Health Economic Resource Center (HERC). Budget Impact Analysis.
11. Mauskopf JA, Sullivan SD, Annemans L, et al. Principles of good practice for budget impact analysis: report of the ISPOR Task Force on good research practices--budget impact analysis. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 2007;10(5):336-47. doi: 10.1111/j.1524-4733.2007.00187.x [published Online First: 2007/09/25]
12. Druss BG, von Esenwein SA, Compton MT, et al. Budget impact and sustainability of medical care management for persons with serious mental illnesses. *The American journal of psychiatry* 2011;168(11):1171-8. doi: 10.1176/appi.ajp.2011.11010071 [published Online First: 2011/06/17]
13. Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 2014;17(1):5-14. doi: 10.1016/j.jval.2013.08.2291 [published Online First: 2014/01/21]