Protocol#: 18188

TITLE: AN EVALUATION OF VIRTUAL PSYCHIATRIC TRANSITION OF CARE OFFERED IN BEHAVIORAL HEALTH SETTINGS

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The study will be conducted in compliance with the protocol, ICH-GCP and any applicable regulatory requirements.

Protocol Approved By:

CLINICAL PRINCIPAL INVESTIGATOR:

Manuel Castro, MD

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Date

EXECUTIVE SPONSOR:

James Rachal, MD

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Date

CO-PRINCIPAL INVESTIGATOR:

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Jason Roberge, PhD, MPH

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Date

PROTOCOL SUMMARY	
Study Title	An Evaluation of Virtual Psychiatric Transition of Care (VPTC) Offered in Behavioral Health Settings
Study Design	A stepped-wedge trial assessing 30-day acute care utilization

Study Objectives	The primary objective is to evaluate the effectiveness of a post inpatient discharge virtual psychiatric care team compared to standard care, to reduce 30-day all cause non-elective acute care utilization (ED, observation, and inpatient encounters).
	
	Secondary objectives of the evaluation include:
	• Compare the effectiveness of the VPTC program compared to standard care, on 60-day all cause non-elective acute care utilization (ED visits, observation, and inpatient encounters).
	• Compare the effectiveness of the VPTC program compared to standard care, on 30-day behavioral health acute care utilization (ED visits, observation, and inpatient encounters).
	• Examine the percent of patients that had a behavioral health office visit within 7 days of discharge to standard of care
	• Examine the count of all cause avoidable ED visits within 30 days of discharge
	
	Exploratory analyses:
	• Count of patients: Identified, Refused, Enrolled, Graduated, Did not graduate and reason
	• Characterize: demographics and Charlson comorbidity score
	• Assess symptom improvement
	  o Suicidal ideation:
	  ▪ Percent of patients with a PHQ-9, Question 9=0 upon graduation among patients with an initial Q9>0
	  o Depression reduction:
	  ▪ Percent of patients with a 5 point reduction of their PHQ-9 score who had an initial PHQ-9 score ≥ 10
	  ▪ Show the distribution of PHQ-9 score reduction among participants
	  o Depression remission: Percent of patients with a PHQ-9 score <5 upon graduation who had an initial PHQ-9 score ≥ 5

Inclusion Criteria	Inclusion criteria: • Residency or shelter in North Carolina • 18 years of age or older on the day of discharge

	• Access virtual care (phone/video) • Discharged from a behavioral health hospital or a behavioral health unit Exclusion criteria: None
Study Procedures	The VPTC program has a focus on removing obstacles and social determinants that often impede patients from engaging in post hospitalization care. This program would support vulnerable patients, engaging them in virtual services to assist their transition to appropriate and patient centered outpatient care. This study is comprised of a pilot and a pragmatic trial. For the pilot, the Center for Outcomes Research and Evaluation (CORE) team will lead a qualitative evaluation of the psychiatric virtual transition of care (VPTC) program's implementation. The study team will gather first-hand accounts from patients and clinicians regarding their program experiences and program utilization. Changes to the program can be made as needed to optimize enrollment and implementation. The qualitative evaluation will assess the strengths and weaknesses of the VPTC program so modifications can be implemented. The pilot location will not be a part of the trial. For the trial, the VPTC program will be compared to standard care through a cluster randomized by site, stepped-wedge design. Behavioral Health facility or units that have discharged patients meeting inclusion criteria will be randomly assigned as either an intervention or standard care site. Intervention sites will be those using the VPTC program. This evaluation design will integrate into current workflows for the measurement of outcomes. Prior to discharge, patients may be referred to the VPTC program if they report residency or shelter in North Carolina, are 18 years of age or older on the day of discharge and can access virtual care (phone/video). The VPTC program is defined by several key components: • Introduction to the patient follow-up process • Psychiatric consultation • Medication management services with pharmacological consultation • following of Health Coaching participation (Movement, Nutrition, Sleep Hygiene, Stress Management, Pain Management, Perinatal/Postpartum Mood Disorders, Substance abuse) and provide treatment recommendations • Tracking of behavioral health symptoms (Depression, Anxiety, Suicidal ideation) and provide treatment recommendations • Health coaching; Psychoeducational support • Treatment and safety planning • Appointment reminders • Coordination for financial assistance • Assistance connecting with an outpatient care provider • Placement into an appropriate case management program, if needed

	• Navigation to additional psychiatric or substance use services, if needed • Motivational interviewing and brief therapeutic recommendations, if needed
Statistical Analysis	Analyses will include all patients identified as having been discharged and meeting the inclusion criteria. Baseline comparisons of the intervention and usual care groups will be made using univariate analyses. The primary analysis will be conducted using generalized linear mixed models with fixed effects for intervention, and intervention multiply by the time, accounting for the cluster randomized trial design with a random cluster (hospitals) or time (steps) effect. Results will be presented with odds ratios and 95% confidence intervals.

LIST OF ABBREVIATIONS

BHI	Behavioral Health Integration
CORE	Center for Outcomes Research and Evaluation
C-SSRS	Columbia – Suicide Severity Rating Scale
EDW	Enterprise Data Warehouse
VPTC	Virtual Psychiatric Transition of Care
NC	North Carolina
PHI	Private Health Information
PHQ-2	Patient Health Questionnaire - Screener for Depressive Disorders
PHQ-9	Patient Health Questionnaire – Screener for Severity of Depression
SOP	Standard Operating Procedures

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OBJECTIVES

1.1. Hypothesis

Patients discharged from behavioral health hospitals or units that offer a virtual psychiatric transition of care (VPTC) program will have a lower 30-day all cause acute care utilization rate (ED, observation, or inpatient) compared to patients discharged from behavioral health hospitals or units that do not offer the VPTC program.

1.2. Primary Objective

The primary objective is to evaluate the effectiveness of a virtual psychiatric care team compared to standard care, to reduce 30-day all cause non-elective acute care utilization (ED, observation, and inpatient encounters).

1.3. Secondary Objectives

- Compare the effectiveness of the VPTC program compared to standard care, on 60-day all cause non-elective acute care utilization (ED, observation, and inpatient encounters).
- Compare the effectiveness of the VPTC program compared to standard care, on 30-day behavioral health acute care utilization (ED, observation, and inpatient encounters).
    - Behavioral health: ED visit with a telepsychiatric consult; inpatient or observation discharge from a behavioral health hospital or unit)
- Examine the percent of patients that had a behavioral health office visit within 7 days of discharge
- Examine the count of avoidable ED visits within 30 days of discharge

1.4. Exploratory Analyses

- Qualitative review of the program
- Count of patients: Identified, Refused, Enrolled, Graduated, Did not graduate and reason
- Characterize: demographics and Charlson comorbidity score
- Assess symptom improvement
    - Suicidal ideation:
        - Percent of patients with a PHQ-9, Question 2=0 upon graduation among patients with an initial Q2>0
    - Depression reduction:
        - Percent of patients with a 5 point reduction of their PHQ-9 score who had an initial PHQ-9 score ≥ 10
        - Show the distribution of PHQ-9 score reduction among participants
    - Depression remission: Percent of patients with a PHQ-9 score <5 upon graduation who had an initial PHQ-9 score ≥ 5

2. BACKGROUND

The successful transition to outpatient care after behavioral health inpatient services or discharge from an emergency department (ED) is critical to reducing suicide risk and deterioration of mental health due to disease. Social determinants, limited network of outpatient care providers and disease progression often impede patients from accessing outpatient care after discharge. 2018 data from The National Committee for Quality Assurance demonstrated that 27.5% of Medicare patients Health Care attended their outpatient follow up appointment after discharge from inpatient psychiatric care. The percent for Medicaid patients was slightly higher at 35.8% and privately insured patients had a show rate of 46.6%. After interviewing patients who were readmitted to Atrium Health Behavioral Health (AH BH) inpatient hospitals, it was determined that additional support in that critical period after discharge is needed to assist patients in successfully transitioning to outpatient care.

The Virtual Psychiatric Transition of Care (VPTC) program offers support and services to patients in the immediate post discharge period to minimize suicide risk, decrease avoidable ED and inpatient care, while helping patients successfully connect with an outpatient care provider to maintain long term success in disease management. The VPTC program provides a robust virtual care delivery system for patients as they transition from inpatient to outpatient care by wrapping around services and support during high-risk transition periods.

3. RATIONALE

The foundational idea for the VPTC program came from the Atrium Health Hospital at Home care model which has garnered wide acclaim and financial support in the acute care world. A behavioral health care team comprised of licensed clinicians (Behavioral Health Professionals), health coaches, a consulting psychiatric pharmacist and psychiatric providers follow patients for 45 days or more depending on patient need after their acute care encounter. Patient enrolled in the VPTC program will receive the following core components: Introduction to the patient follow-up process, psychosocial assessment, tracking and treatment recommendations for (residential movement, nutrition, sleep hygiene, stress management, pain management, perinatal/postpartum mood disorders, substance abuse), tracking and treatment recommendations for behavioral health symptoms (depression, anxiety, suicidal ideation, etc.), placement into an appropriate case management program if needed, navigation to additional psychiatric or substance use services if needed, and motivational interviewing and brief therapeutic recommendations if needed.

For patients that have attempted suicide, they will begin the VPTC program following the zero suicide pathway. The Atrium Health Behavioral Health Service Line created the ‘Zero Suicide pathway’, in 2019 for those patients identified as “high risk” for suicide when leaving inpatient units. Zero Suicide is a national movement sponsored by the 2012 National Strategy for Suicide Prevention, National Alliance for Suicide Prevention, Suicide Prevention Resource Center and the Substance Abuse and Mental Health Services Administration (SAMHSA). It is a programmatic approach to keep patients from falling through the cracks in a fragmented and disconnected healthcare system and is based on the belief that suicide is preventable, and suicide deaths are not fated. Since access to mental health services is constrained in our community, patients often fall through the cracks when transitioning between points of care.

4. SUBJECT AND SITE SELECTION

4.1. Accrual

For this study, all patients discharged that meet the inclusion criteria are eligible for analyses. Patients meeting eligibility criteria will accrue in both the intervention and usual care arms of the study.

A weekly list will be generated indicating patients discharged the prior week at any of the participating locations. The list contains inpatient and observation encounters. The list will identify discharged patients at facilities throughout the project, not just once the facility has implemented the VPTC program. For the purposes of this project, we are not enrolling towards a targeted patient accrual. We will enroll patients during a pre-determined data collection period, See Section 5.

4.2. Accrual – Subjects

Patients 18 years of age or older at time of discharge, a resident of North Carolina, reported a telephone number in the electronic health record, and discharged from a behavioral health hospital or a behavioral health unit will be considered exposed to the intervention, whereas patients seen at locations not utilizing the VPTC program will be considered exposed to usual care. Patients who are in the intervention arm will be treated by the behavioral health care team (licensed clinicians, health coaches, a psychiatric pharmacist, and psychiatric providers). Virtual visits are conducted telephonically. Each week a list of discharged patients will be received by the behavioral health care team.

Patients included in the analysis of this study must meet the inclusion\exclusion criteria. Patients will begin accruing based on the time the location goes live according to the role out schedule. The VPTC program is available to any behavioral health patient, but the evaluation is centered on the cohort of patients meeting the inclusion criteria.

4.3. Participating sites

The program has been piloted at AH Stanly as part of usual care. AH Stanly will not be included in the quantitative assessment. As part of the research design and rollout of this project, randomization will occur at the site level. CORE will randomize the facility participation order in advance of project kickoff. Site enrollment will begin with 1 facility, adding on 1 additional facility on a rolling basis in 3-month intervals, until all 7 facilities are active in using the VPTC program. Once added, sites will begin utilizing the program in their daily practice among the target patient population.

The following Atrium Health sites will be randomized for participation in this project.

- AH Kings Mountain Psychiatry
- AH BH Davidson - Fraser Fir
- AH BH Davidson - River Birch
- AH BH Charlotte - ED OBS

- AH BH Charlotte - North and South
- CMC Main 6B
- AH BH Davidson - Mountain Laurel

4.4. Inclusion\Exclusion Criteria

4.4.1. Inclusion Criteria

Eligible patients in the analyses must meet each of the following criteria:

- Residency or shelter in North Carolina
- 18 years of age or older on the day of discharge
- Access virtual care (phone/video) - having a phone number in the electronic health record
- Discharged from a behavioral health hospital or a behavioral health unit

4.4.2. Exclusion Criteria

- None

4.5. Evaluable Population

Patients included in the evaluable population for this project, will have their data inform the final outcomes assessment. All patients who meet the inclusion and exclusion criteria in both groups of the study will be assessed for the primary outcome (intent to treat).

5. OVERALL DESIGN

5.1. Variables

5.1.1. Primary Outcome Variable

The primary outcome variable is 30-day all cause non-elective acute care post discharge utilization (ED, inpatient, and observation encounters).

5.1.2. Secondary Outcome Variables

a. Demographic characteristics (age, race, gender, insurance plan)
b. Charlson comorbidity index score
c. 60-day all cause non-elective acute care utilization (ED visits, observation, and inpatient encounters).
d. 30-day behavioral health acute care utilization (ED visits, observation, and inpatient encounters).
e. A behavioral health office visit within 7 days of discharge
f. An avoidable ED visit within 30 days of discharge

5.1.3. Exploratory Variables

g. Assess symptom improvement for depression
    i. Initial- PHQ-9 total score
    ii. Post- PHQ-9 total score
h. Assess suicidal ideation
    i. Initial- PHQ-9, Q9 score
    ii. Post- PHQ-9, Q9 score

5.2. Trial Design

5.2.1. Justification for stepped wedge cluster randomized control trial

The primary aim is to assess the effectiveness of a structured multidisciplinary care plan (intervention), compared with usual care (control) on 30-day all cause non-elective acute care utilization (ED visits, observation, and inpatient encounters). The VPTC program will be delivered at the level of location or cluster, thus minimizing contamination and the risk of selection bias, if subjects were randomized at the individual level. Therefore, the unit of randomization and analysis for this study will be the cluster. Considering logistical constraints and design rigor, the intervention will be rolled out sequentially instead of at the same time. Moreover, substantial and differential cluster-effects may exist because of distinct volume and characteristics of patients in each hospital. Thus, the stepped wedge design is advantageous compared with other alternative designs.

The stepped wedge design implies a baseline period, in which no clusters are exposed to the intervention. Then, at the chosen time interval of three months, one location will be randomized to cross from the control to intervention (Figure 1). This process continues until all seven locations have crossed over to the intervention. The order of this cross over process will be randomized. We will use randomization to assign location order so that if a high or low volume location is assigned cluster 1, a high or low volume location is assigned cluster 7. The single ED location will be assigned to cluster 4. SAS Enterprise Guide version 8.2 will be used for the randomization. Allocation will be communicated only to the behavioral health team initially to prevent contamination. Locations will learn of allocation in the month preceding roll-out. Patients in included locations will be blinded to the intervention or control period.

An example of the roll out schedule

Location	August 2021	November 2021	February 2022	May 2022	August 2022	November 2022	February 2023	May 2023
Location 1	0	1	1	1	1	1	1	1
Location 2	0	0	1	1	1	1	1	1
Location 3	0	0	0	1	1	1	1	1
Location 4	0	0	0	0	1	1	1	1
Location 5	0	0	0	0	0	1	1	1
Location 6	0	0	0	0	0	0	1	1
Location 7	0	0	0	0	0	0	0	1

1=Virtual Psychiatric Transition of Care Program; 0=Usual Care

5.2.2. Virtual Psychiatric Transition of Care Program

5.2.2.1. Zero Suicide Pathway

Depending on the patient's reason for admission, patients may start the VPTC program in the zero suicide pathway. Patients that meet criteria for this higher level of care will have attempted suicide. Patients are identified from the C-SSRS screening tool along with referrals from the treatment team and treating psychiatrist. Identified patients are enrolled a day or two prior to discharge and then contacted within 24 hours of discharge, to assess for suicidality and self-harm and to review safety plans and discharge instructions. Patients are contacted daily, to every few days until they no longer need the higher-level of outreach and will be transferred to the VPTC pathway. VPTC clinicians will continue to outreach with the patient for the remaining time in the VPTC program.

5.2.2.2. VPTC Pathway

If a patient has not attempted suicide as the reason for admission, VPTC clinicians will begin outreach with the patient within the first 24-72 hours after discharge. The first outreach with the patient will be completed by a licensed clinician who will complete a brief psychosocial assessment with the patient. After the initial outreach is completed a health coach will then reach out to the patient to set a weekly schedule. The weekly outreaches with the VPTC health coach will be patient centered and patient specific. These outreaches will help support patients through goal setting/treatment plans, medication support, linkage and support to community resources, and safety planning. These outreaches will also help patients identify any barriers they may have in attending their follow up care with their outpatient community providers. Throughout the outreaches at any point and time if a patient has a question or concern about their medication the VPTC licensed practicing nurse can contact the patient to help address those needs. At each outreach patient's safety is also assessed. At any point in the outreach if a patient endorses any safety concerns that patient will be assessed by a licensed qualified clinician to identify those safety concerns and create a safety plan with the patient.

If the patient is scheduled with a VPTC psychiatric provider for a hospital follow-up appointment, an LPN (Licensed Practical Nurse) will outreach to the patient before that visit to complete the nursing intake. The patient will then have their hospital follow up visit either with their community provider, or the VPTC psychiatric provider. The VPTC psychiatric provider will review medications that the patient started on the inpatient unit or emergency department and provide any further education, adjustments, and support. The provider is able to order the medications. The VPTC program will also have support from a psychiatric provider through weekly treatment team huddles to help support patients and identify any barriers they may be facing.

There may be cases where patients are eligible to enroll in full case management programs based on their insurance or other criteria. In these situations, the VPTC team will coordinate a care transition and the patient will be considered to have completed the program. For example, if a patient has Medicaid through a local management entity, a managed care organization providing local behavioral health care, and meets certain criteria, the patient will not require services from the VPTC team as they would be duplicative.

5.3. Patient Graduation from the VPTC Program

- Reached max benefit as deemed by the behavioral health care team
- Unable to connect: 4 calls attempted over 12 days
- Transition to lower level of care
    - Patients who transition to a primary care clinic
- Transition to higher level of care
    - Psychiatry/Treatment Program
    - Readmission to an Inpatient Facility
- Declined or no longer interested in services
- Death

5.4. Continuation of the Intervention

Patients may continue enrolling in the VPTC program after the study period has ended.

6. QUALITATIVE REVIEW

A qualitative evaluation will be conducted among the care team and patients at the pilot location. This evaluation aims to evaluate the implementation of the psychiatric virtual transition of care program and the nature of the targeted patient population. The qualitative data collection for this study will be guided by the Consolidated Framework for Implementation Research (CFIR). The CFIR incorporates several established implementation theories into a common framework. Composed of a menu of 39 constructs that fall into 5 domains (intervention characteristics, outer setting, inner setting, characteristics of individual, and process), the CFIR is used to design, guide, and evaluate health care delivery interventions by identifying potential or existing barriers and facilitators to implementation (Damschroder et al. 2009). Through the aggregation of corroborated constructs, the CFIR promotes a systematic and consistent use of implementation measures, which help render study findings intelligible and generalizable. The framework is well-suited to projects like the VPTC program as it allows for complex theory-building and cross-study comparisons using a common set of constructs while obviating the need to use multiple implementation frameworks.

Semi-structured CFIR-guided interviews will be conducted with 12 VPTC patients/care takers and 12 VPTC team members. This sample size was arrived at after considering the project's narrow study aim (Malterud et al., 2016). Clinician interviews will include a diversity of frontline staff, including, but not limited to, nurses, health coaches, psychiatrists, and discharge planners.

Patient-interviewees will have been enrolled in the VPTC program and be targeted using a convenience sample, a non-probability sampling strategy commonly used for studying reclusive and reluctant populations (Bernard, 2017; Guest et al., 2006). A VPTC team member will reach out to the patient and ask if contact can be made to discuss their thoughts on the VPTC program. A researcher will call to follow-up with and schedule an interview with the patient. During recruitment calls, potential patient-interviewees will be assured that their receiving of care is not in any way contingent on consenting to an interview. This assertion will be reaffirmed by the interviewer before the beginning of interviews. Patients that complete an interview will be compensated for their time with a $25 Clincard.

Clinician-interviewees will be recruited through snowball sampling: The VPTC coordinator will identify and refer clinicians and other relevant staff for interviews, these interviewees will in turn be asked to identify other potential respondents. A researcher will send up to two weekly emails to introduce clinicians to the qualitative review and encourage them to contact us to schedule an interview. A researchers will schedule an appointment with those who reply to the email and are interested. All interviews will be conducted via telephone and will be audio recorded.

The recorded interviews will be de-identified and then parsed and analyzed using ATLAS.ti 9. The analytical approach will be inductive—building theory on patterns found in the data—as such analyses are typically well-suited for exploratory examinations of novel or under-studied social phenomena. Coding will begin at the question-level, allowing the qualitative team to compare all interviewee answers to a specific question. Next. a vertical analysis across interviews will be conducted using the constant comparative method, a "scrutiny-based technique" (Ryan and Bernard, 2003: 101) foundational to grounded theory, an approach in which theory building is based in empirical analysis rather than deductive inference. Using this comparative method, codes will be produced inductively and iteratively, as early codes often have a contingent and provisional quality and must be delineated and refined through a continual comparison with preceding and subsequent data (Boeije, 2002). During these vertical readings, codes will be used to paraphrase and summarize passages.
Themes will be developed using the constant comparative method, which provides a framework to understand the commonalities and differences within and among interviews, as the method is also a method of identifying contrasts. (Bradley, Curry & Devers 2007). Themes will be inferred from particular, reoccurring instances—through the repeated parsing and partitioned of interview data according to CFIR constructs and the relevance to our research questions. Once barriers and facilitators of implementation have been identified using the CFIR framework, recommendation will be drafted to optimize implementation of the VPTC program.

The most immediate risk of the aforementioned data collection procedures to interviewees is the potential for embarrassment, should their unredacted interview data be shared. Several measures will be put in place to protect the identity and confidentiality of interviewees: recordings of the interviews will be stored on a password-protected computer accessible only to pertinent project staff; transcriptions of the interviews will be de-identified, i.e. the names of interviewees, employers, and care providers will be redacted; and interview quotes used in subsequent presentations, reports, and publications will be anonymized.

7. DATA COLLECTION AND REPORTING

Patient demographics, Charlson comorbidity score, and utilization will be obtained from the electronic medical record and billing systems. Data from the initial assessment and follow-up contacts will be stored in HealtheCare, a care management platform in Cerner. Data will be retrieved by an application specialist on the research team. Data may be retrieved retrospective to a patient's completion of the intervention or

usual care arm of the study. A participation rate can be generated from the count of patients enrolled in the VBHI program over the count of patients meeting the inclusion criteria.

A bi-monthly report will be produced for the intervention arm. The report will be by primary care practice and overall showing the prior 2 weeks of activity.

- Count of patients meeting the inclusion criteria
- Count of patients with a HealtheCare account
- Count of patients enrolled in the VBHI program
- Patient list with their enrollment status in HealtheCare

A monthly report will be produced for the intervention arm. The report will be by primary care practice and overall. Report to be generated 2 weeks after the end of the month showing the prior month of activity.

- Count of patients meeting the inclusion criteria
- Count of patients with a HealtheCare account
- Count of patients enrolled in the VBHI program
- Patient list with their enrollment status in HealtheCare

7.1. Sample Size Analysis

Calculations of sample size were based on primary analysis of 30-day non-elective acute care utilization on a binary group. Our preliminary data shows that average unique patients in each hospital (cluster size) per three months ranged from 159 to 300, we expected an enrollment rate of 40%. Thus, the average effective cluster size is 96 with a standard deviation of 15. Conservatively, we would at least expect an average cluster size of 81. With the assumption of detecting a change from 20% in the control period to 14% in the intervention period for 30-day non-elective acute care utilization, a mean cluster size of 81 with seven clusters and seven steps (8 time periods inclusive of a control period) would achieve a power of 0.89 if intra-class correlation coefficients (ICC)=0.20 and two-side α=0.05. Holding other parameters constant, the larger ICC is, the higher the power we will obtain. The coefficient of variation (CV) of sample size is approximately 0.15. To account for this varying cluster size, we inflated the number of patients by 10% resulting in an average cluster size of 89 patients per three months, resulting in a sample size of 2,495 patients among the intervention group and 4,990 patients overall inclusive of our control population. In this pragmatic trial, those assigned to the intervention but did not enroll in VPTC during the intervention period (around 60%) would also be counted in the intervention arm. It is within our expectation that intervention arm eventually has smaller reduction in 30-day non-elective acute care utilization (i.e. 0.4*0.14 +0.6*0.20=17.6%, difference=2.4%). However, we still ensure a power above 0.80 as long as over 2,495 patients actually received VPTC. The power was calculated by using the PASS 15.

7.2. Statistical analysis

Distributions of baseline characteristics for locations and patients will be compared between the intervention or control periods to assess effectiveness of the randomization, and statistical or clinical differences will be adjusted in sensitivity analyses. All analyses for treatment and control periods comparisons will use an intention-to-treat approach and results will be reported used the CONSORT extension to cluster randomized trials.

The primary outcome for this study is 30-day all cause non-elective acute care utilization. Characteristics of the locations and individuals will be summarized by levels of randomization steps, locations, and individuals. The count, rates and 95% confidence intervals of 30-day non-elective acute

care utilization in the control period will be presented and compared with that in the treatment period. The primary analysis will be conducted using generalized linear mixed models with fixed effects for intervention, and intervention multiply by the time, accounting for the cluster randomized trial design with a random cluster (hospitals) or time (steps) effect. We will estimate and report the intra class correlation coefficients for all outcome measures to assess assumptions for sample size analyses and for future investigations using similar designs and outcomes. The primary analyses will follow the intention to treat principle with an additional per protocol analysis including those who actually used VPTC. The secondary analyses will include within cluster comparisons of intervention and control periods (not adjusting for any confounding effect of time), as well as comparisons of a series of (unbalanced) quasi-parallel cluster trials between those enrolled and unenrolled clusters at each intervention enrollment period. The same analyses plan will also be applied to secondary outcomes.

7.3. Missing Data

All the related available electronic data will be pulled without missing any subjects. Thus, the missing of outcome variables are less likely to occur. However, the missing information on covariables is unavoidable. Sensitivity analyses are recommended for trials with missing data. We will compare baseline characteristics such as age and gender between patients with complete follow-up data to those with missing data by intervention period to assess potential biases that may exist in the complete case analysis. We will conduct sensitivity analyses for the primary and secondary outcomes using several methods which have different missing data assumptions: (1) complete case analyses which assumes missing completely at random; (2) multiple imputation using M=10 imputations, which assumes missing at random; and (3) assigning poor scores and good scores for missing values differentially by treatment group, which aligns with non-ignorable missingness (the data missingness is related to the actual value).

7.4. Training

Beginning two to three weeks prior to first patient enrolment at the respective location, the VPTC program coordinator and those responsible for discharge will begin training on the materials supporting the program. This will include communication touchpoints between the coordinator and discharge facilitator.

7.5. Data Collection Dates

The implementation of the VPTC program is expected to begin in November 2021 with last enrollment in July 2023.

8. INTERVENTION PLAN

8.1. Behavioral Health Professional Assessments

The initial patient assessment by the behavioral health care team captures components such as:

- Insurance
- Primary care provider
- Outpatient Psychiatry provider
- Collateral resource
- Recent visit summary
- Substance abuse
- Medication barriers
- Appointment Barriers
- Transportation needs
- Access to medications
- Community Resources
- Columbia-Suicide Rating Scale to assess for suicide ideation
- Review Hospital Discharge plan
- Crisis plan and follow up

8.2. Follow-up Assessments

The follow-up contact assessments are comprised of components such as:

- Columbia-Suicide Rating Scale to assess for suicide ideation
- Appointment reminder\follow-up
- Medication reconciliation
- Medication access barriers
- Substance use disorder follow-up
- Supportive listening
- Psychoeducation
- Utilization of community resources
- Crisis planning and adherence to the plan by the patient
- Abnormal Involuntary Movement Scale (AIMS)
- PHQ-9 screening tool
- GAD-7 screening tool

8.3. Psychiatric Virtual Appointments

- Medication reconciliation
- Review of history of treatment
- Review of current treatment
- Review Discharge plan

9. STUDY GOVERNANCE

This quality improvement trial will be conducted at Atrium Health. It will be run jointly by the Center for Outcomes Research and Evaluation (CORE) and the Behavioral Health Service Line. Manuel Castro, MD, (Psychiatry) will serve as the clinical principal investigator with oversight from the Executive Committee (EC). Jason Roberge, PhD, MPH will serve as co-principal investigator on behalf of CORE. The EC will consist of leaders across the System involved in the trial, quality improvement, and implementation (Table 2). The EC will have the overall responsibility of trial oversight and direction. The EC will support dissemination of project findings and next steps. The EC will receive progress reports from the team. When appropriate, ad hoc committee meetings will be scheduled to discuss pressing concerns.

Table 2. Executive Committee	
James Rachal	Atrium Health Executive Leadership – Psychiatry
Eva McNeill	Atrium Health Executive Leadership – Behavioral Health
Wayne Sparks	Atrium Health Executive Leadership – Psychiatry
Christine Zazzaro	Atrium Health Executive Leadership – Behavioral Health
Martha Whitecotton	Atrium Health Executive Leadership – Behavioral Health
Andrew McWilliams	Atrium Health Executive Leadership – CORE Medical Director

10. SAFETY RISKS AND REPORTING

The data collection and intervention for this project presents no more than minimal risk to patients. This study is evaluating the VPTC program among discharged patients. The program itself is similar to existing virtual programs managed by the behavioral health service line for patients discharged from the emergency room. The implementation of the VPTC program and its components complement ongoing patient care through virtual patient navigation within Atrium Health. The addition of an evaluation design that aligns with existing patient care expansion thus confers minimal additional risk to patients.

Other potential risks of participation in this project include the risk of health information disclosure. There is always the risk of disclosure of a patient's private health information (PHI) or medical information. However, the processes identified in this protocol to enable the execution of this project, do not increase inherent risk of disclosure. Atrium Health utilizes several hard and soft safety controls in the protection of patient information and medical records. Security controls include, but are not limited to, multiple system firewalls, access restrictions to patient records and information, locked offices and buildings housing research and patient data, and multiple layers of username and password protected computer and system access. Statistical tools and programs that are developed are stored on secure restricted access file shares. Programs have versioning controls turned on and access to the file shares are restricted. Access is granted through a request process that requires multiple authorizations and is controlled centrally by our Information and Analytics Service Department.

The CORE project team will ensure that appropriate handling of patient PHI follows standard Atrium Health procedure. Confidentiality will be maintained according to ICH E6; 4.8.10, part 0: "Records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or

regulations, will not be made publicly available. If the results of the study trial are published, the patient's identity will remain confidential.' In the event of PHI disclosure, the appropriate internal departments will be informed and processed per legislation and privacy regulations.

10.1. Data Quality Assurance

This study will be organized, performed, and reported in compliance with the study protocol, standard operating procedures (SOPs) of the CORE and Atrium Health, and other applicable regulations and guidelines (e.g. GCP).

10.2. Safety Reporting to the IRB

All events occurring during the conduct of a protocol and meeting the definition of a reportable safety event per the IRB guidelines, will be reported to the IRB within 10 working days of the Investigator learning of the event, per their requirements.

Major protocol deviations that result in a threat to subject safety or the integrity of the study will be reported to the IRB per their requirements.

10.3. Data Monitoring by the Sponsor

The conduct of this project will abide by standard operating procedures set forth by both Atrium Health and CORE. The Principal Investigators, statistician, and other team members will meet as needed to review enrollment and retention, study progress, and validity/integrity of the data. Documentation of these meetings will be kept with study records.

11. RESEARCH COMPLETION

The Principal Investigators have the right to close the project at any site at any time.

For any closure, the following applies:

- Closure should occur only after consultation between involved parties.
- In case of a partial study or location closure, patients still participating in the VPTC program, or those who are considered in follow-up, must be taken care of in an ethical manner.

The study will be considered complete when one or more of the following conditions is met:

- The enrollment period has ended, and the data collection period is complete.
- All subjects have dropped out or discontinued from the study after the enrollment period is completed, but prior to data collection cutoff.
- The IRB or Principal Investigator discontinues the study.
- The Principal Investigator defines an administrative or clinical cut-off date.

Upon study completion, a final report will be presented to the Executive Committee and all key stakeholders. The final report will detail all findings including primary, secondary and post-hoc outcomes. The team will also prepare a manuscript for publication focused on outcomes and feasibility of implementation of the VPTC program.

12. ETHICAL AND LEGAL ISSUES

12.1. Ethical and Legal Conduct of the Study

The procedures set out in this protocol, pertaining to the conduct, evaluation, and documentation of this study, are designed to ensure that the Investigators abide by Good Clinical Practice (GCP) guidelines and under the guiding principles detailed in the Declaration of Helsinki. The study will also be carried out in keeping with the applicable local laws and regulation(s).

Documented approval from appropriate agencies (e.g. IRB) will be obtained before the start of the study, per GCP, local laws, regulations, and organizations.

Strict adherence to all specifications laid down in this protocol is required for all aspects of study conduct; the Investigators may not modify or alter the procedures described in this protocol.

Modifications to the study protocol will not be implemented without consulting the Principal Investigator and the IRB, as applicable. The Principal Investigator must assure that all study personnel, including co-investigators and other study staff members, adhere to the study protocol and all applicable regulations and guidelines regarding research both during and after study completion.

The Principal Investigator will be responsible for assuring that all the required data will be collected and properly documented.

12.2. Confidentiality

All records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

12.3. Disclosure of Data

The Principal Investigator, his associates and co-workers, and the appropriate regulatory agencies may use the information and data included in this protocol as necessary for the conduct of the study. Information contained in this study, and data and results from the study are confidential and may not be disclosed without the written permission of the Principal Investigator.

13. RETENTION OF RECORDS

Essential documentation including all IRB correspondence, will be retained for at least 2 years after the investigation is completed. Documentation will be readily available upon request.

14. PUBLICATION POLICY

The Principal Investigator or designee must send any draft manuscript, abstract, or conference presentation to members of the project Executive Committee for feedback and transparency, prior to submission of the final version. The Principal Investigator will be responsible for all relevant aspects regarding data reporting and publication.

The Principal Investigator or designee will ensure that the information and results regarding the study will be made publicly available on the internet at www.clinicaltrials.gov.

15. REFERENCES

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