Protocol#: 13957

TITLE: AN EVALUATION OF VIRTUAL BEHAVIORAL HEALTH INTEGRATON INTO PRIMARY CARE

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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:

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Manuel Castro, MD

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Date

EXECUTIVE SPONSOR:

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Ruth Krystopolski, MBA

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Date

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Date

PROTOCOL SUMMARY	
Study Title	An evaluation of Virtual Behavioral Health Integration (VBHI) into Primary Care
Study Design	A pragmatic randomized trial evaluating total cost of care
Study Objectives	The primary objective is to evaluate the effectiveness of the virtual behavioral health integration (VBHI) program compared to usual care, on reducing the total cost of care reimbursed from Medicare and value-based contracts within 90 days of a patient's primary care visit. Secondary objectives of the evaluation include: • Compare demographics, Charlson comorbidity index, and social determinants of health among patients (hunger vital signs, home, education, employment, social and emotional health) between the two arms of the study • Compare the 90-day acute care utilization rate after the index primary care visits • Compare the 90-day primary care utilization rate after the index primary care visit • Compare the pharmacy related 90-day total cost of care after the index primary care visit • Stratify and report objectives by index primary care visit diagnoses (substance use disorder, depression/dysthymia, anxiety) Exploratory analyses among patients who enrolled in the VBHI program. A subgroup of patients whose index primary care visit is within 9 months of the study start. Assessment at 3, 6, 9, and 12-months • Symptom improvement o Depression: 50% reduction of PHQ-9 score from initial assessment o Depression Remission: Percent of PHQ-9 scores <5 (for 2 consecutive months upon graduation) o Suicidal ideation: Percent of PHQ-9, Question #9=0 or C-SSRS negative upon graduation o Anxiety: GAD-7, 50% reduction from initial assessment • Health Outcomes o Reduction in BMI among patients with an initial BMI ≥ 25.0 o Reduction in HbA1c among diabetic patients with an initial A1c ≥ 9 o Reduction in LDL cholesterol level among patients with an initial LDL ≥ 160
Inclusion Criteria	Inclusion criteria: • 18 years of age or older • Primary care office visit at a selected site based on preventative and outpatient CPT codes • Have a PHQ-9 and an overall score >10 or Question 9 >0

	• Medicare or value-based contract associated with a patient in the past year at the time of the primary care visit Exclusion criteria: • A patient will contribute to the analysis once using their initial enrollment to either arm of the study • No insurance claim for the index primary care visit in the data warehouse upon evaluation
Study Procedures	Patients who present to participating primary care practices with an elevated patient health questionnaire (PHQ-9) score or report suicide ideation (Question 9) will be treated and followed per the proposed virtual behavioral health integration (VBHI) program or usual care. As part of the current care process, all patients with a primary care visit are given the PHQ-2 survey. A score ≥2 triggers the PHQ-9 survey. Of the primary care practices eligible for the VBHI program, half will be randomly assigned to either the control or intervention arm. Each day a list of patients with an elevated PHQ-9 score from the prior day is generated along with the associated insurance plan for the patient. All patients who meet eligibility criteria at sites where the VBHI program is offered will be considered exposed to the intervention; whereas, patients seen at sites not utilizing the VBHI 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 either by video assessment or telephonically. For the primary and secondary objectives, patients will be followed for up to 90 days after their primary care visit. For the exploratory analysis, patient with a primary care visit within 9 months of the study start date will be followed for up to 12 months after their primary care visit. The VBHI program is defined by several key components: • Introduction to the patient follow-up process • Psychosocial assessment • Track (Residential 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, and Suicidal ideation) and provide treatment recommendations • 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 meeting the inclusion and exclusion criteria. Comparisons of the intervention and usual care groups will be made using univariate analyses such as the t-test and chi-square test. The primary outcome, the 90-day total cost of care, will be compared between the two groups of patients using a generalized linear mixed model. 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
GAD-7	Generalized Anxiety Disorder Screener
HbA1c	Hemoglobin A1c
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
VBHI	Virtual Behavioral Health Integration

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OBJECTIVES

1.1. Hypothesis

Depressed patients who visit a primary care practice that offers a virtual behavioral health integration (VBHI) program will have lower 90-day total costs of care compared to patients receiving primary care at practices without VBHI.

1.2. Primary Objective

Compare the effectiveness of the VBHI program compared to usual care, on modifying the total cost of care reimbursed by Medicare and value-based contracts within 90 days of a patient's index office visit.

1.3. Secondary Objectives

For the primary and secondary objectives, patients will be followed up to 90 days.

- Compare demographics, Charlson comorbidity index, and social determinants of health among patients (hunger vital signs, home, education, employment, social and emotional health) between the two arms of the study
- Compare the patient-centric 90-day utilization rate after the index primary care visit
- Compare the 90-day primary care utilization rate after the index primary care visit
- Compare the pharmacy related 90-day total cost of care after the index primary care visit
- Stratify and report outcomes by index primary care visit diagnoses (substance use disorder, depression/dysthymia, anxiety)

1.4. Exploratory Analyses

For the exploratory analysis, patients who enrolled in the VBHI program in the first 9 months from study start will have their symptoms (depression score reduction, depression remission, suicidal ideation score reduction, anxiety score reduction) and health outcomes (BMI, LDL, and HbA1c) assessed at 3, 6, 9, and 12-months.

- Symptom improvement
    - Depression: Percent of patients with a 50% reduction of PHQ-9 score from initial assessment
    - Depression Remission: Percent of patients with a PHQ-9 score <5 (for 2 consecutive months upon graduation)
    - Suicidal ideation: Percent of patients with a PHQ-9, Question #9=0 or C-SSRS negative upon graduation
    - Anxiety: Percent of patients with a 50% reduction of GAD-7 score among patients with an initial score of > 10
- Health Outcomes
    - Reduction in BMI among patients with an initial BMI ≥ 25.0
    - Reduction in HbA1c among diabetic patients with an initial A1c ≥ 9
    - Reduction in LDL cholesterol level among patients with an initial LDL ≥ 160

2. BACKGROUND

Mental illness is highly prevalent among adults with reports as high as 20% and a common reason for visits to primary care.[1] Affective disorders like depression and anxiety generate significant healthcare costs and result in social and vocational disability. Almost half of patients who are treated for major and minor depression are seen exclusively in primary care, with another 20% to 30% treated in both specialty and primary care settings.[2-4]

Mental health treatment among primary care practices is typically delivered through short episodes of care.[5] Primary care providers tend to offer less intensive mental health treatment than that provided by psychiatrists.[6] The level of involvement of primary care providers to deliver outpatient mental health care often depends on: (1) lack of mental health providers in the region;[7] (2) willingness to prescribe psychotropic medications;[5] and (3) knowledge of mental health disorders.[8] Clinical implications of a mental illness comorbidity include increased risk of suicide, psychiatric hospitalization, increased disability, decreased compliance with treatment of medical illness, and markedly increased utilization of medical services.[1] If untreated, depression and anxiety disorders can contribute to high medical utilization. It has been reported that 24% percent of the top 10% (high) healthcare utilizers have a diagnosis of current major depression and 22%, from an anxiety disorder.[1]

Mental health providers have increasingly targeted their efforts on delivering virtual psychiatric consultation in the primary care setting.[1] Use of virtual care programs providing mental health services is on the rise, often in rural and underserved areas where access to mental health services is not present or limited.[9] Telepsychiatry efforts are often also implemented to improve rural providers' capacity for managing patients with mental health illnesses.[10] Outpatient psychiatric consultation programs have utilized clinicians to conduct telephone consultations as an efficient means to provide consultative, supplemental, and follow-up care.[11] Evidence has shown that telepsychiatric evaluation services can be economical and with levels of quality and patient satisfaction similar to those found with face-to-face evaluations.[12] Few programs, however, have reported on efforts to integrate these multiple services into a comprehensive "virtual mental health clinic" that can both provide a wide range of clinical services and support providers by means of educational offerings. No studies to date have shown through a rigorous evaluation the effect of virtual behavioral health integration on total cost of care that include value-based contracts. The proposed virtual behavioral health integration (VBHI) program into the primary care setting is a structured mental illness treatment program that includes both behavioral treatment and counseling components aimed at reducing cost of care, developing and sustaining adaptive coping strategies, and improving short term acute care utilization.

3. RATIONALE

To enhance the care of patients seen in the primary care setting, Atrium Health has designed a virtual behavioral health integration program. A behavioral health care team comprised of licensed clinicians (Behavioral Health Professionals), health coaches, a consulting psychiatric pharmacist and psychiatric providers follow patients for up to 3 months or more depending on patient need after their primary care office visit. This virtual behavioral health integration (VBHI) program is currently available in 36 Atrium Health primary care practices providing support to over 200 providers and medical residents. The Behavioral health Service line is expanding the program to additional primary care practices. Atrium

Health and the Carolinas Physician Alliance is interested in evaluating the effectiveness of the program on reducing the total cost of care.

Patients may be referred to the VBHI program if they are identified as depressed after administration of the depression screening tool (PHQ-9) or for other concerns by their primary care provider. The primary care provider can request assistance by a real-time in office video assessment or by a telephonic out of office assessment. Patients referred by a provider for 'other concern' instead of depression are not included in the evaluation.

For this study, patients who have an elevated PHQ-9 score or report suicidal/homicidal ideation are eligible for analyses and be identified from a behavioral health patient report. Patients meeting eligibility criteria will accrue in both the intervention and usual care arms of the study. At intervention sites, the VBHI program team will reach out to patients utilizing video assessment or telephonic outreach. Patient enrolled in the VBHI 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.

There may be cases where patients are eligible to enroll in full case management programs based on their insurance and other criteria –in these situations the VHBI team will coordinate a seamless care transition. For example, if a patient has Medicaid through Cardinal Innovations, a managed care organization providing local behavioral health care, and meets certain criteria, the patient would no longer require services from VHBI team as they would be duplicative.

For the primary and secondary objectives, a patient's contact with the VBHI program ends after 90 days following the primary care office visit, or if there is a failure to contact, or becomes enrolled with a case-management program which provides behavioral health services, or declines services, or dies. The behavioral health care team will ensure the patient is enrolled in a case management program through contact with staff before ending contact with the patient.

This research project is a parallel group, cluster randomized quality improvement evaluation which seeks to evaluate the total cost of care among patients in the VBHI program for up to 90 days after their primary care visit. The outcomes evaluation of this quality improvement intervention has been designed to integrate into the routine care and minimize frontline staff burden by deploying an evaluation in a real-world setting.

4. SUBJECT AND SITE SELECTION

4.1. Accrual – Primary Care Practices

Randomization will occur at the practice level with the primary care practices being identified as an intervention or usual care site for the duration of the study. Out of 20 primary care clinics that have shown interest in the VBHI program, 10 will be randomized into the intervention arm and 10 into the usual care arm. Not all sites in the intervention arm are starting the program immediately. There will be a scheduled rollout of 2-3 clinics per month. As intervention sites come on board, a corresponding control site will begin contributing to the evaluable population. Twelve practices indicated their readiness to incorporate the VBHI program into patient care in 2019 with the remaining indicating 2020. A practice labeled as low volume had historically averaged 15 or less eligible patients per month. A practice labeled as high volume had historical averaged 16 or more eligible patients per month.

Twelve practices were identified by the behavioral health team for a 2019 rollout based on the readiness to engage with the VBHI program in 2019. Practices were clustered by patient volume per month (low n=8, high n=4). The 8 practices with lower volumes were randomly ordered and assigned as either a case or control (1:1). The 4 practices with higher volumes were randomly ordered and assigned as either a case or control (1:1). The six primary care practices and corresponding matched control practice were then randomly ordered for a 2019 rollout. Each month that a practice starts using the VBHI program, patients start accruing from the randomly matched control practice.

Eight practices were identified by the behavioral health team for a 2020 rollout based on the readiness to engage with the VBHI program in 2020. These practices were not ready to engage in 2019. Practices were clustered by patient volume per month (low n=4, high n=4). The 4 practices with lower volumes were randomly ordered and assigned as either a case or control (1:1). The 4 practices with higher volumes were randomly ordered and assigned as either a case or control (1:1). The four primary care practices and corresponding matched control practice were then randomly ordered for a 2020 rollout. Each month that a practice starts using the VBHI program, patients start accruing from the randomly matched control practice.

4.2. Accrual – Subjects

Patients 18 years of age or older at primary care practices with a PHQ-9 overall score >10 or Question 9 >0, and with Medicare or other value-based contract where the VBHI program is offered will be considered exposed to the intervention; whereas, patients seen at sites not utilizing the VBHI 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 either by video assessment or telephonically. As part of the current care process, all patients with a primary care visit are given the PHQ-2 survey. A score ≥2 triggers the PHQ-9 survey. Patients who present to participating primary care practices with an elevated patient health questionnaire (PHQ-9) score or report suicide ideation (Question 9) will be

treated and followed per the proposed virtual behavioral health integration (VBHI) program or usual care. Each weekday a list of patients is received by the behavioral health care team. The list includes patients with an elevated PHQ-9 score from the prior day and the associated insurance plan for the patient. The insurance plan is included so that the behavioral health team can target patients with Medicare
or other value-based contracts that report total costs back to Atrium Health. On Mondays, the team receives a list of patients seen between Friday and Sunday.

Patients included in the analysis of this study must meet the inclusion\exclusion criteria and have an insurance claim for the index primary care visit when they became eligible in the enterprise data warehouse (EDW). Patients will begin accruing based on the time the practice goes live according to the role out schedule and will continue for 17 months. The VBHI program is available to any patients in the practice but the evaluation is centered on the cohort of patients meeting the inclusion criteria.

4.3. Inclusion\Exclusion Criteria

4.3.1. Inclusion Criteria

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

- 18 years of age or older
- Primary care office visit at a selected site based on preventative and outpatient CPT codes
- Have a PHQ-9 and an overall score >10 or Question 9 >0
- Medicare or value-based contract associated with a patient in the past year

4.3.2. Exclusion Criteria

- A patient will contribute to the analysis once using their initial enrollment to either arm of the study
- No insurance claim for the index primary care visit in the data warehouse upon evaluation

4.4. 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 arms will be assessed for the primary outcome (intent to treat and by per protocol).

5. OVERALL DESIGN

5.1. Variables

5.1.1. Primary Outcome Variable

The primary outcome variable is total cost of care. A claim for the primary care visit is first identified in the EDW for a patient that meets the inclusion criteria. The total cost of care is defined as the summation of all paid claims <= 90 days after the primary care visit.

5.1.2. Rates and Variable Descriptions

a. Demographic characteristics (age, race, gender, insurance plan)
b. Charlson comorbidity index score

If we determine that we can identify hospital and primary care visits through claims data, we will use that as a source over using just Atrium Health encounters for the utilization rates as specified below.

c. Patient-centric defined 90-day utilization rate. This is a utilization rate among patients with an ED, inpatient, or observation encounter to any Atrium Health facility (<= 90 days after the primary care visit).
d. The 90-day primary care utilization rate. This is a utilization rate among patients with a primary care encounter (<= 90 days after the primary care visit).

e. Primary care visit
    i. At least one CPT code for preventative or outpatient visit
f. Pharmacy related 90-day total cost of care. The pharmacy total cost of care is defined as the summation of all pharmacy paid claims within 90 days of the primary care visit among patients with pharmacy claim data (<= 90 days after the primary care visit).

Symptom and health outcomes are assessed at 3, 6, 9, and 12-months among patients who enrolled in the VBHI program.

g. Asses symptom improvement for depression
    i. Pre- PHQ-9 score from primary care visit
    ii. Post- PHQ-9 score
h. Primary care visit diagnoses (primary or secondary billed diagnoses)
    i. substance use disorder
    ii. depression/dysthymia
    iii. anxiety
i. Anxiety
    i. Pre- GAD-7 score from initial enrollment
    ii. Post- GAD-7 score

j. Suicidal ideation
    i. Pre- PHQ-9, Q9 score from primary care visit
    ii. Post- PHQ-9, Q9 score
k. Remission of depressive symptoms
    i. PHQ-9 less than 5 in 2 consecutive months
l. BMI
    i. Pre- BMI level from primary care visit
    ii. Post- BMI level
m. HbA1c among diabetic patients
    i. Pre- A1c level from primary care visit
    ii. Post- A1c level
n. LDL cholesterol level
    i. Pre- LDL level from primary care visit
    ii. Post- LDL level

o. Hunger vital signs – reported upon enrollment
    i. Within the past 12 months, we worried whether our food would run out before we got the money to buy more?
    ii. Within the past 12 months the food we bought just didn't last and we didn't have the money to get more?
p. Home – reported upon enrollment
    i. What is your housing situation today?
    ii. Are you worries about losing your house?
q. Education – reported upon enrollment
    i. What is the highest level of school you have finished?
r. Employment – reported upon enrollment
    i. What is your current work situation?
s. Social and emotional health – reported upon enrollment
    i. How often do you see or talk to people that you care about and feel close to?
    ii. Stress is when someone feels tense, nervous, anxious, or can't sleep at night because their mind is troubled. How stressed are you?
    iii. Do you feel physically and emotionally safe where you currently live?
    iv. In the past year, have you been afraid of your partner or ex-partner?
    v. In the past year, have you spent more than 2 nights in a row in jail, prison, detention center, or juvenile correctional facility?

5.2. Virtual Behavioral Health Integration

The flow of patients from initial contact to their follow-up calls is outlined in Appendix 1. In the existing VBHI primary care workflow, all patients are given the PHQ-2 survey. A score ≥2 triggers the PHQ-9 survey. The following day the behavioral health team receives a patient report. The report

includes patients seen the prior day at intervention sites that had an elevated PHQ-9 score >10 or reported suicide ideation (Question 9 >0). The Monday report includes patients seen Friday-Sunday. Patients associated with Medicare or other value-based insurance plan are identified in the report. The behavioral health care team will reach out to these patients for enrollment utilizing video assessment or telephonic outreach. The patient always has the option not to be followed by the behavioral health care team.

The behavioral health care team will complete the initial behavioral health assessment. The initial health assessment contains information such as preferred communication method, GAD-7, psychiatry provider, collateral resources, recent ED and hospital utilization, substance use disorder, medication barriers, appointment barriers, community resources, and crisis planning.

The frequency of follow-up assessments depends on the clinical presentation and medication recommendation and/or adherence. The assessment includes information such as a suicide ideation safety screening, an appointment reminder, appointment barrier evaluations, medication reconciliation, medication obtainment follow-up, substance use disorder follow-up, supportive listening, psychoeducation, community resource follow-up, and additional crisis planning.

The Columbia-Suicide Severity Rating Scale (C-SSRS) helps identify whether someone is at risk for suicide, and the severity and immediacy of the risk. It also identifies level of support the person needs. The screening tool is administered during each phone contact to measure suicide ideation. Follow-up patients enrolled in the VBHI program will receive follow-up phone calls. The frequency of calls is dependent on the clinical presentation and medication recommendation and/or adherence. A follow-up assessment is completed upon each phone call.

5.3. Usual Care

All patients are given the PHQ-2 survey during the primary care visit. A score ≥ 2 triggers the PHQ-9 survey. The PHQ-9 offers providers a concise, self-administrated screening and diagnostic tool for Major Depressive Disorder (Table 1). Treatment can be based on the patients total PHQ-9 score. The patient's provider in the primary care practice has the option to refer the patient to community based behavioral health services, begin medication management within the primary care setting, or encourage the patient to obtain a psychiatric evaluation at the nearest emergency department to assess safety concerns including both suicidal and homicidal ideation. For patients that have a diagnosis of depression or dysthymia, the PHQ-9 is administered every 4 months. There are no follow-up behavioral health services based on the PHQ-9 score once the patient leaves the primary care practice.

PHQ-9 Score	Provisional Diagnosis	Treatment Recommendation
0-4	No Depression	None

5-9	Major Depression, mild	Reassurance and/or supportive counseling Education to call if deteriorates
10-14	Major Depression, moderate	Antidepressant and/or Psychotherapy
15-19	Major Depression, moderately severe	Antidepressant and/or Psychotherapy
≥20	Major Depression, severe	Antidepressant and Psychotherapy

Table 1. PHQ-9 scores and standard treatment recommendations

5.4. Patient Graduation from the VBHI Program

- Reached max benefit as deemed by the behavioral health care team
- Depression remission – PHQ-9 <5 for 2 consecutive months
- Unable to connect: 4 calls attempted over 12 days
- Transition to lower level of care
    - Patients who transition to a primary care clinic not utilizing VBHI services
    - Moved out-of-state
    - Discharged from primary care clinic utilizing VBHI services
- Transition to higher level of care
    - Psychiatry/Treatment Program
- Patient states that they are no longer interested in services but their last PHQ-9 >5
- Declined or no longer interested in services
- Death

5.5. Continuation of the Intervention

Patients from participating primary care sites may continue enrolling in the VBHI program after the study period has ended.

6. 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

6.1. Power Analysis

We are working with our data management group to develop the 90-day total cost of care measure. With this version of the protocol we can only estimate cost savings. In the literature, studies on behavioral health integration tend to evaluate symptom improvement or utilization. Blue Cross Blue Shield of Kansas City data were used to conduct a case control program evaluation in 2018. This study assessed the cost effectiveness of embedding a Behavioral Health Clinician into an Existing Primary Care Practice. Though not virtual, we would assume a similar direction in cost saving reduction in our program. The results demonstrated that integrating behavioral health services into the practice was associated with $860.16 per member per year savings or 10.8% savings in costs.[13]

6.2. Statistical analysis

Prior to analysis, descriptive statistics will be calculated to screen all variables for accuracy and to examine distributions.

All analyses will follow the intention-to-treat ("ITT") principle, such that patients will be analyzed based on the assignment of their primary care site to the VBHI program or usual care. Balance in baseline characteristics between the groups will be assessed using Student's t-test for normally distributed data, the Wilcoxon rank sum test for ordinal data or interval data that are not normally distributed, and the chi-square test for categorical data. Normality will be assessed using the Shapiro Wilk test and Q-Q plots.

The primary outcome, total cost of care, will be compared between the VBHI and usual care groups using a linear mixed-effects model with a random effect to account for within-practice correlation. The primary predictor in the model is an indicator for assignment to the VBHI program versus usual care. Additional baseline covariates will be included in the model if they are either strongly correlated with the dependent variable or show baseline imbalance between the two groups.

The secondary outcome of pharmacy-related total cost of care will be compared between treatment groups using the same approach as for the primary outcome. A similar approach will be used to compare 90-day patient-centric, primary care, and avoidable care utilization rates, except the models will be generalized linear mixed models with a logit link, where utilization (yes/no) is the binary dependent variable.

Sub-analyses of the primary and secondary outcomes using the above methods will be performed on the data stratified by index primary care visit diagnosis.

In addition, per-protocol analyses of the primary and secondary outcomes will be performed to evaluate the effect of VBHI program participation, in contrast to the ITT analysis evaluating the effectiveness of referral to the program. The per-protocol analyses will include only subjects who received and adhered to the treatment (VBHI program or usual care) assigned to their clinic. The analyses will be similar to those described above for ITT, except the primary predictor is an indicator for treatment (VBHI program or usual care) received rather than treatment assigned. To help address confounding due to incomplete adherence, the per-protocol analyses will adjust for pre-randomization and post-randomization factors that predict adherence. To identify such factors, a separate, multivariable logistic regression analysis will be performed on the full dataset with adherence (yes/no) as the dependent variable.

Exploratory analyses will evaluate baseline to 3-, 6-, 9-, and 12-month changes in symptom improvement and health outcomes using generalized linear mixed models with a logit link, where the dependent variable is binary (e.g., 50% reduction of PHQ-9 score from initial assessment (yes/no)). Random effect terms in the model will account for within-practice clustering and within-patient correlation. Fixed effects will be the treatment group indicator, time indicator, and interaction between treatment group and time.

All tests will be two-sided and the data will be analyzed using SAS Enterprise Guide 7.1 (SAS Institute Inc., Cary, NC, USA).

6.3. Data Collection Dates

The implementation of the VBHI program will begin in August 2019.

7. PROJECT TIMELINE

	2019								2020			2021					
	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Dec	Jan	Feb	Mar	Apr-June	July	Aug
Identify Key personnel																	
Draft Charter																	
Draft Protocol																	
Initial IRB Submission																	
Registration with Clinical Trials.gov																	
First Patient on Study																	
Enrollment Duration																	
Last Patient on Study																	
Last Patient Follow-up																	
Waiting on claims/ work on manuscript																	
Analysis/ Report																	

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

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

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
Ruth Krystopolski	Atrium Health Executive Leadership – Population Health
Wayne Sparks	Atrium Health Executive Leadership – Psychiatry
Erica Todd	Atrium Health Executive Leadership – Behavioral Health
Martha Whitecotton	Atrium Health Executive Leadership – Behavioral Health
John Franko	Atrium Health Executive Leadership – Primary Care
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. The VBHI program is currently offered at 36 primary care clinics within Atrium Health. This study is evaluating the VBHI program among additional clinics that will offer the program to their patients. However, patients who present to the primary care setting with a behavioral health crisis are considered a high-risk population. The implementation of the VBHI 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 site closure, patients still participating in the VBHI 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 as described in section 8.3.
- 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 VBHI 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

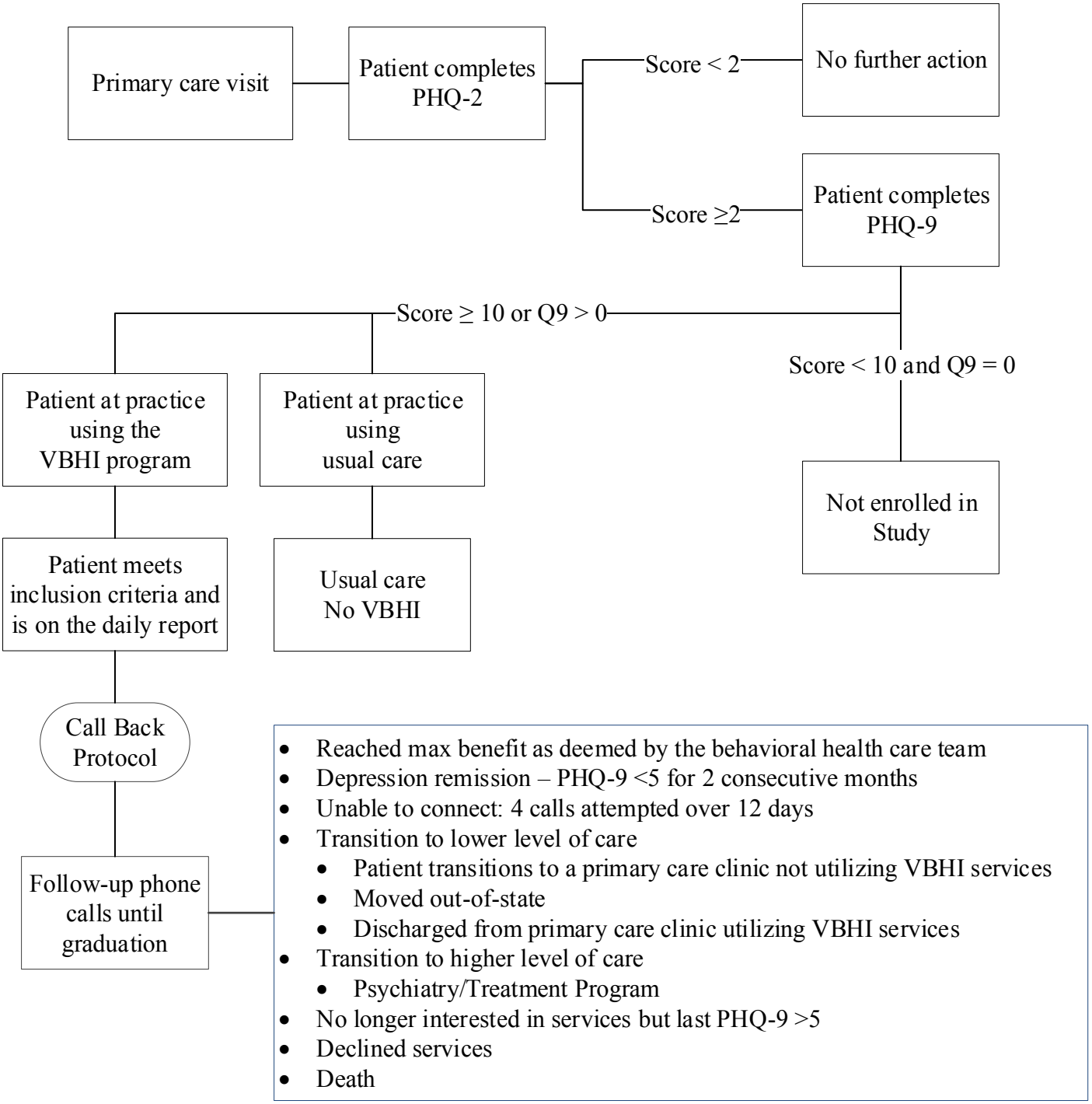
The Principal Investigator or designee must send any draft manuscript, abstract, or conference presentation to members of the project Executive Committee for feedback and transparency, prior to submission of the final version. The Principal Investigator will be responsible for all relevant aspects regarding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

APPENDICES

APPENDIX 1: Patient Navigation

This diagram shows the patient contact points among the population.



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