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Evaluation of the Intensive Outpatient Clinic: Study protocol for a prospective study of high-cost, high-need patients in the University of Utah Health system

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Abstract

Introduction: The University of Utah (UofU) Health Intensive Outpatient Clinic (IOC) is a primary care clinic for medically-complex (high-cost, high-need) patients with Medicaid. The clinic consists of a multi-disciplinary care team aimed at providing coordinated, comprehensive, and patient-centered care. The protocol outlines the quantitative design of an evaluation study to determine the IOC's effects on reducing healthcare utilization and costs, as well as improving patient-reported health outcomes and quality of care.

Methods and analysis: High-risk patients, with high utilization and multiple chronic illnesses, were identified in the Medicaid ACO population managed by the University of Utah Health Plans for IOC eligibility. A prospective, case-control study design is being used to match 100 IOC patients to 200 control patients (receiving usual care within the University of Utah) based on demographics, health utilization, and medical complexity for evaluating the primary outcome of change in healthcare utilization and costs. For the secondary outcomes of patient health and care quality, a pre-post design will be used to examine within-person change across the 18 months of follow-up (i.e., before and after IOC intervention). Logistic regression and hierarchical, longitudinal growth modeling are the two primary modeling approaches.

Ethics and dissemination: This work has received ethics approval by the University of Utah Institutional Review Board. Results from the evaluation of primary and secondary outcomes will be disseminated in scientific research journals and presented at national conferences.

Trial Registration Number: Not applicable

Article Summary

Article focus

- A prospective evaluation of the effectiveness of an intensive outpatient clinic (IOC) in comparison to previous care or usual care among high-cost, high-need patients in University of Utah Health, with an 18-month follow-up period.
- Primary outcomes include healthcare costs and utilization.
- Secondary outcomes include patient-reported physical and mental health, quality of life, and care quality.
- Correlates and predictors of the clinic's effectiveness and different trajectories of primary and secondary outcomes will also be examined.

Key messages

- The first prospective evaluation of a new, intensive outpatient care clinic, developed for the highest-need, costliest patients within the University of Utah Health system, will provide information about outcomes and future implementation of this care model throughout the state of Utah and nationwide.
- Findings will improve the implementation of the IOC to provide better care for patients, leading to long-term improvements in population health and cost-effectiveness.
- The joint evaluation of healthcare costs and utilization with patient-reported outcomes of health and perceived healthcare quality will allow investigation of explanatory mechanisms, and will strengthen findings with respect to improvements in the patient experience

Strengths and limitations of this study

- A longitudinal, pre-post intervention design with a wide range of robust, validated outcome measures are strengths of this study.
- The study utilizes a quasi-experimental design, which limits causal inferences.
- The study design does not allow identification of which specific components of the IOC care model are the most effective; rather, it focuses on the efficacy of the IOC in its entirety.
- Difficulty with patient recruitment, commonly noted in similar evaluation studies, might limit the sample size and statistical power for testing study hypotheses.

Background

In 2002, the top five percent of healthcare spenders within the US population accounted for 49% of the nation's total healthcare costs. In contrast, 50% of the US population with the lowest health spending represented only three percent of the nation's total healthcare costs.[1] Today, the top one percent of patients still account for more than 20% of U.S. health expenditures.[2] Importantly, these expenditures are relatively stable from year-to-year; of the top 5 percent of health spenders in 2002, nearly 34% of these individuals maintained their ranking through the following year.[3] Furthermore, the proportion of the highest utilizers who maintain their high spending has continued to increase.[3] Individuals with this pattern of healthcare spending have been referred to as "super-utilizers", due to their high-frequency (and often preventable) use of hospital and emergency department services, as well as the high costs associated with these visits. Borrowing from the literature and our experience, a more accurate term to describe this population is "high-risk/high-need" – a term that focuses on the patient's medical and social needs rather than their medical spending ("super-utilizer").

High-risk, high-need patients tend to be medically complex, with comorbid chronic conditions that are poorly controlled due to mental health issues, substance abuse, or other psychosocial stressors (e.g., food insecurity, homelessness, social disruption, or lack of social support).[4] These patients are more likely to be older, female, have higher out-of-pocket healthcare expenses relative to their income, have multiple chronic conditions, and report poorer self-rated health and physical functioning as compared to the rest of the population.[1-5] Many are either uninsured or publicly insured through Medicare or Medicaid.[5,6] These patients frequently receive their medical care in emergency departments and hospitals, which adopt traditional approaches to care that emphasize the acute, specialized treatment and diagnosis of clinical problems, rather than treating the whole patient. However, because these high-need patients face a variety of ongoing medical, behavioral, and social complications, the fragmented and specialized care they receive results in both unmet needs for individual care and higher costs to the health system.

In response to this need for innovative care models to serve the highest-risk, highest-cost patients, the University of Utah Health began the Intensive Outpatient Clinic (IOC) in February of 2017. The IOC enrolls patients who not only have the highest rates of healthcare utilization in the University's health system, but who have multiple, chronic health conditions for which they might be receiving highly fragmented care. The IOC, with an interdisciplinary care team dedicated to providing patient-centered care, will deliver *comprehensive*, *coordinated*, and *customized* primary care to these patients. Such care will be designed to address the full continuum of health needs and care preferences within our patient population. Previous clinical models that are similar to the IOC have had success with outcomes such as reduced hospitalizations, emergency department visits, and total healthcare costs, as well as improvements in patients' activation and engagement in their care—a key factor known to impact clinical outcomes in the care process.[10, 11] However, little is known about patient-reported outcomes from these care delivery models beyond activation and engagement. Therefore, this study will prospectively evaluate the IOC's effects on healthcare utilization, costs, and patient health and healthcare quality to assess the extent to which the IOC will reduce overall healthcare utilization/costs and improve patients' disease management and overall experiences with their healthcare.

Objectives

The objectives of the proposed study are to evaluate the IOC's effect on 1) healthcare costs and utilization, and 2) patient-reported health and quality of care, to determine whether this type of clinic will improve the quality and delivery of care and reduce healthcare spending for high-utilizing patients.

The proposed study aims to answer the following research questions:

1) Compared to standard care among medically-complex and high-utilizing University of Utah (UofU) Health patients who are not enrolled in the IOC, will the IOC reduce healthcare spending and utilization—including reductions in emergency department (ED) visits, hospital admissions and length of stay, and total healthcare costs (i.e., sum of medical reimbursed amount and prescription reimbursed amount)?
2) Compared to their first clinic visit (before receiving any care at the IOC), will the IOC patients report improvements in their health (including physical function, quality of life) and quality of care (trust in one's provider, self-efficacy, perceived access to community resources, care coordination) across 18 months of follow-up?

Study Design

To answer the first research question, a prospective matched case-control study will be conducted for the IOC for patients in the University of Utah Health system in Salt Lake City, Utah, the United States. The allocation ratio of cases to controls will be 1:2. Following the recommendation from Austin (2010),[12] we assume that the 1:2 matching will improve precision and minimize bias. For the evaluation of healthcare cost and utilization, propensity score- matched control groups will be identified from the University of Utah Health Plans (UUHP) claims database. Healthcare costs and utilization along with demographic information (such as age, gender) and medical history (e.g., comorbidities, disease severity, and index appointment/visit date) of the case and control groups will be from the UUHP claims database.

To answer the second research question, a pre-post study design will be used to evaluate improvements in IOC patients' health and quality of care. The intervention group will be recruited from their first visit at the IOC and invited to complete four surveys prospectively for a period of 18 months.

Methods

Study Setting

The Intensive Outpatient Clinic (IOC) is part of the University of Utah Health and began its operations in February of 2017. The clinic is located in West Valley City (a suburb of Salt Lake City that provides a convenient location for IOC patients). The IOC provides patients with 24/7 phone access to providers, same-day appointment scheduling, integrative care across specialties, care coordination across physical and behavior health providers, case management and self-management education provided by licensed clinical social workers/nurse practitioners/registered nurse care coordinators (RNCCs), and medication interventions and collaborative practice care for chronic diseases performed by a clinical pharmacist (PharmD).

Participants/Inclusion & Exclusion Criteria

IOC Patient Characteristics

There are a number of criteria potential patients need to meet in order to be eligible for care at the IOC. Patients are candidates for the IOC if they fall into the category of high-risk and high-cost, defined by a high number of comorbidities, hospitalizations, and emergency department visits, as well as seeing multiple providers and accounting for a high proportion of costs to the healthcare system. Other indicators include social or behavioral health concerns (e.g., homelessness or food insecurity, substance abuse, or mental health disorder). This pool of potential patients has their medical records reviewed by the IOC staff who refine the selection of patients to those who struggle to engage with the health

system (poor compliance, high no-show rate, poorly controlled disease states). Thus, the identification of eligible IOC patients is an iterative process using both predictive modeling and provider chart review and nominations. Exclusion criteria include: 1) patients whose sole medical problem is a new onset cancer diagnosis or an organ transplant; 2) patients with behavioral health issues that exceed the clinic's ability to assist; and 3) patients > 65 years of age (i.e. Medicare).

Control Patient Characteristics for Healthcare Cost and Utilization Analysis

For the primary outcome analysis, patients in the control group will receive standard care at University of Utah Health, whether it is primary or specialty care. As part of the standard care, they might have a primary healthcare provider in addition to specialty providers who treat or help in managing their chronic health conditions.

To identify patients in the control group who have similar characteristics of the patients in the case group (i.e., IOC patients) propensity score matching will be used to minimize observable confounders that could potentially affect the outcomes. We will match each IOC patient to two control subjects with propensity score matching (i.e., nearest-neighbor matching) using logistic regression models. Matching will be based on variables such as: year of birth, sex, race, baseline Elixhauser Comorbidity Index (or Charlson Comorbidity Index), baseline numbers of inpatient, emergency room, and outpatients visits, healthcare costs one year prior to index date, and mental disorder status. Matching using calipers of a specified width will be used to match untreated subjects with a similar propensity score. Calipers of width 0.2 of the standard deviation of the logit of the propensity score will be used because this width had estimates of intervention effect with lower mean squared error compared to other methods. If multiple control subjects have propensity score values that are equally close to that of the case subject, then one of these control subjects is selected at random. As we employ one-to-two matching without replacement, the final matched sample will consist of unique subjects in both groups. To assess the balance in the baseline covariates between the groups, the standardized difference methods for both continuous and categorical variables will be used. If standardized differences are less than 10% (or 0.10), we assume that the imbalance between the groups is negligible. Entry into the study (i.e., start of follow-up) of the IOC patients will be based on the first IOC visit date. Follow-up of the controls will begin the same dates as the matched IOC patients, providing equal follow-up time for both groups. The reason for 1 vs. 2 matching is that it could improve small variance (i.e., precision) without increase in bias.[12, 13]

Interventions (Care at the IOC)

When patients come to the IOC, they receive care from a multidisciplinary team consisting of physicians (including one physician consultant who specializes in Addiction Medicine), a nurse practitioner, a clinical pharmacist, registered nurse care manager, a licensed clinical social worker, and medical assistants.

The physicians lead the care team, and are responsible for initial patient contact and recruitment, longitudinal acute and chronic disease management, preventive care services, interventions, and referrals to specialty care, supported by the nurse practitioner. The clinical pharmacist (PharmD) regularly performs medication reconciliations, monitors potential adverse drug interactions, prescribes and manages selected chronic diseases (e.g., diabetes, asthma, hypertension) using collaborative practice agreement, and promotes medication adherence. The pharmacist also performs ad-hoc tasks as needed by the physician (e.g., determining appropriate new medication therapies for patients, helping patients switch pharmacies, or trouble-shooting problems with patients' diabetic equipment, if

applicable). Further coaching is provided by medical assistants who will educate patients on disease management techniques to help them keep on track with their care plans. Because it has been recognized that the integration of physical and mental health care improves patient outcomes, a licensed clinical social worker (LCSW) integrates patients' mental health needs with their physical care plans. The care manager builds rapport through phone calls and home visits, and also connects patients to available community resources (e.g., transportation). For patients who choose this option, they are able to receive short- or long-term therapy services in the clinic. The Nurse Care Manager builds initial patient rapport through telephonic, electronic, and home visits, and also connects patients to available community resources (e.g., transportation). To help coordinate care between team members and patients, the Nurse Care Manager integrates and coordinates the interactions between IOC staff and patients, provides frequent "touches" with the office through multiple channels, and coordinates internal and external appointment scheduling to facilitate timely and comprehensive care.

Outcome Measures

Primary Outcomes: Healthcare Costs & Utilization

Costs. Healthcare costs of patients will be extracted from claims data and evaluated prospectively, from 24 months prior to IOC enrollment and up to 18 months after. Cost outcomes will include: total healthcare cost (sum of medical reimbursed amount and prescription reimbursed amount), inpatient cost, ED cost and prescription cost. Healthcare costs will be adjusted to 2018 dollars using Personal Health Care Expenditure component of the National Health Expenditure Accounts[14] for the cost calculations to reflect inflation over time. Both outcomes will be aggregated in each month for trends analysis and will be aggregated before and after the IOC intervention or index date (for the controls).

Utilization. Patients' healthcare utilization records will be collected from claims data and evaluated prospectively, from 24 months prior to IOC enrollment and up to 18 months after. Specific outcomes of interest include the number of hospital admissions, length of hospital stay, number of emergency department (ED) visits, and office visits. This healthcare utilization information will be identified from the place of services where patients receive healthcare services.

Secondary Outcomes: Patient Health and Care Experience/Care Quality

Patient-reported outcomes of mental and physical health, and patients' experiences with their healthcare will be collected, as described below. Covariates will include patient background characteristics that may provide useful targets for intervention, or that may predict intervention efficacy.

Patient Health

Health outcomes include general and specific measures of physical health, behavioral health, and quality of life.

Mental & Behavioral Health. Includes the PROMIS® Depression, Anxiety, Sleep Disturbance, and Applied Cognitive General Concerns scales.[15] All surveys use a 5-point Likert-type scale with higher scores indicating higher severity. Other patient-reported outcomes include surveys of Mania, [16] Psychosis, Dissociation, Repetitive Thoughts, [17] Personality Disorder, and Substance Abuse.[18]

Physical Health. Two self-rated health items will ask participants to indicate their general health status on a Likert-type scale (*poor, fair, good, excellent*) and visual analog scale (from 0 to 100). The presence of physical symptoms will be assessed with the Somatic Severity scale.[19]

Quality of Life. Quality of life indicators will be the PROMIS® scales of Pain Interference, Physical Function, and Satisfaction with Social Roles and Activities. [15] Higher scores for the Pain Interference items reflected higher impact of pain on daily functioning; whereas higher scores for Satisfaction with Social Roles or Activities and Physical Function indicate increased role satisfaction and better physical functioning.

Patient Care Experience/Care Quality

Items on patients' experience with their healthcare, including self-efficacy for disease management, trust in health providers, and perceptions of provider communication, care coordination, access to care/community resources, and self-efficacy for disease management.

Access/Referrals to Community Resources. To determine patient access to community resources and referral by providers and clinic staff to community resources, participants will be asked three questions from the PACIC survey.[20] Patients will be asked, "Over the past 6 months, when receiving medical care, I was:" 1) Encouraged to attend programs in the community that could help me; 2) Asked how my work, family, or social situation related to taking care of my illness; and 3) Helped to make plans for how to get support from my friends, family or community. The PACIC uses a 5-point Likert scale of *almost never, generally not, sometimes, most of the time*, and *almost always*.

Trust. The Patient Trust Scale, [21] developed by Audiey Kao and colleagues adapted from the Trust-in-Physicians scale, [22] is a 10 question 5-point Likert scale which asks questions concerning trust in one's physician on issues such as referrals, hospital admission, medical testing, and medications.

Communication. The Modified Picker Survey,[22] also modified by Audiey Kao and colleagues from the Picker survey,[23-25] is a 7 question survey using a 4 point scale (never, sometimes, usually, always) concerning patient and physician communication. Questions cover issues such as having enough time to explain reasons for the visit, if there was enough time for the physician to answer questions, and if patients were involved in decisions as much as they wanted to.

Care Coordination. Three questions were selected from the Continuity of Care: When Patients Encounter Several Clinicians Survey[26] which cover indicators of discontinuity, or where patients feel like their care is disjointed or feel abandoned by the health care system.

Self-Efficacy. The Self-Efficacy to Manage Disease in General section from the Self-Efficacy Scale[27] will be used to measure patient motivation to manage their illness or disease. Questions cover topics such as knowing when to visit a doctor, managing emotional distress, and patient confidence in managing their condition.

Covariates: Individual Differences

Covariates will include patient background characteristics that may provide useful targets for intervention, or that may predict intervention efficacy. Covariates will include items on patient demographics and other baseline characteristics, including health literacy, numeracy, acculturation, and trait-like preferences for medical intervention (i.e., Medical Maximizing-Minimizing). Some covariates (i.e., employment status and Medical Maximizing-Minimizing preferences) may also be treating as time-varying or included as intervention outcomes in exploratory analyses.

Demographics. Participants will be asked five demographic questions which include age, gender, highest level of education completed, race, and ethnicity.

Health Literacy. To ascertain participant literacy, the Chew, Bradley, and Boyko three-question health literacy screener will be used.[28]

Numeracy. The Subjective Numeracy Scale is a 6-point Likert scale 4 question survey developed by Fagerlin and colleagues[29, 30] which asks patients their math skills without asking math questions.

Employment Status. Participants will be asked four questions on their work situation. These questions are: 1) Do you work?; 2) About how many hours do you work per week?; 3) Does your health prevent you from working as many hours as you would like?; and 4) If your health improved, how many hours per week would you like to work?

Acculturation. To understand patients' language (and social) preferences, the Short Acculturation Scale for Hispanics[31] was adapted to incorporate multiple languages. This survey uses a 5 point Likert scale. Question responses originally were "only Spanish, Spanish better than English, both equally, English better than Spanish, and only English"; or "only Spanish, more Spanish than English, both equally, more English than Spanish, and only English." Instead of using "Spanish," patients will be asked about their "native language." Only 4 questions out of the 12 question scale will be used. These questions are: 1) In general, what language(s) do you read and speak?; 2) What language(s) do you usually speak at home?; 3) In which language(s) do you usually think?; and 4) What languages do you usually speak with your friends?

Medical Maximizing-Minimizing Preferences. At all four assessments, participants are also asked to complete the Medical Maximizer-Minimizer Scale,[32] a 10-question survey that measures where patients fall along the spectrum of wanting to do as much as possible when it comes to their health (e.g., aggressive treatments, or tests of little diagnostic value) to as little as possible (e.g., watchful waiting). Response options were "Yes," "No," or "I don't know." Examples of items included, "It is important to treat disease even when it doesn't not make a difference in survival," and "If I feel unhealthy, the first thing I do is to go to the doctor and get a prescription."

Adverse Childhood Experiences. At the baseline assessment, participants were asked to complete the Adverse Childhood Experiences (ACE) Study Questionnaire, [33] a 17-item survey that asks participants to indicate whether they have ever experienced a series of traumatic childhood experiences (e.g., physical or sexual abuse, neglect) prior to 18 years of age (0 = *No*, 1 = *Yes*).

Timeline of Survey Administration

An overview of all survey outcome measurements and time-points are included in Table 1. Participants in the study will be given surveys at four time-points over 18 months. Surveys will be administered at baseline and again at 6-, 12-, and 18- month follow-ups. Shorter follow-up surveys will be administered every 6 months up to 18 months after baseline. The 6- , 12-, and 18-month surveys will only include items on physical and mental/behavioral health, quality of life, employment status, self-efficacy, Medical Maximizing-Minimizing, and quality of care (e.g., trust, communication, care coordination, access/referral to community resources, and self-efficacy).

Table 1: Survey Timeline

	Baseline	6 months	12 months	18 months
Patient Health				

PROMIS Applied Cognition-General Concerns	x	x	x	x
PROMIS Anxiety	x	x	x	x
PROMIS Depression	x	x	x	x
PROMIS Pain Interference	x	x	x	x
PROMIS Physical Function	x	x	x	x
PROMIS Satisfaction with Social Roles and Activities	x	x	x	x
PROMIS Sleep Disturbance	x	x	x	x
Mania	x	x	x	x
Somatic Severity	x	x	x	x
Psychosis	x	x	x	x
Sleep Disturbance	x	x	x	x
Repetitive Thoughts	x	x	x	x
Dissociation	x	x	x	x
Personality Disorder	x	x	x	x
Substance Use	x	x	x	x
Care Experience/Quality				
Access/Referral to Community Resources	x	x	x	x
Trust	x	x	x	x
Communication	x	x	x	x
Care Coordination	x	x	x	x
Self-Efficacy	x	x	x	x
Covariates				
Demographics	x			
Literacy	x			
Numeracy	x			
Employment Status	x	x	x	x
Acculturation	x			
Maximizer-Minimizer	x	x	x	x
Adverse Childhood Experiences (ACE)	x			

Sample Size

Based on a sample size of *n* = 100, we hypothesize that the mean difference in patients' reported health and care quality before and after IOC intervention will be up to 20%. We assume the standard deviation of the differences equals 0.10 and mean score at baseline 0.31.[34] Using these assumptions, we will obtain over 80% power to detect an effect size=0.5.

Statistical power for the healthcare cost was estimated based on an assumed standard deviation (i.e., $15,000) for change in the healthcare cost over 12 months of $6,139.[35] The difference in healthcare costs between the case and the control groups is assumed to be 21%. [36] Considering these numbers and a 1:2 matching (100 cases to 200 controls), the minimum detectable treatment effect with 80% power, 2-sided α=0.05 is $1,222 in the healthcare cost outcome.

Recruitment, Enrollment and Consent

There are multiple recruitment processes for the study. All new IOC patients will be recruited at the time of their first visit to the IOC. Those who want to participate will enroll at that time. For all participants, informed consent will be completed through an electronic data capture when potential participants access the study survey link. Because surveys will be completed online, all participants will be informed that if they wish to participate, completion of the surveys will imply their consent.

Data Collection Methods

Healthcare Costs/Utilization

The data for this study will be collected from claims databases for both the case and the control groups.

Patient Health/Care Quality

Some data for this study will be collected by electronic data capture, and some data will be collected as part of routine care at the clinic for the intervention group. The survey is available to intervention participants through REDCap.

As this is a minimal risk study, data monitoring will be conducted by either the PI, a study coordinator or research nurse, and/or a research assistant. Data will be monitored at least every 6 months to review and confirm participant eligibility and review missing data from survey responses. For participants who discontinue the study, data that was collected previously from completed surveys will still be included in the final analysis, using robust statistical methods to account for missing data and attrition. For participants who substantially deviate from the intervention protocol, the study staff will note this in a separate administrative form in the electronic data capture and their outcome data may be dropped from the final analysis (pending that they are a substantial outlier). Data regarding reasons for drop-out will be collected (e.g., death of a participant, relocation).

Data Management

As all data is collected through electronic data capture, there will be no manual entry of survey data. Data will be stored on the secure electronic data capture server located at the University of Utah, as well as on password-protected computers and locked storage cabinets only accessible to the research team. All data which could link participants to their responses will be stored in a password-protected electronic folder separate from the survey responses and only accessible to the research team. Data will be monitored periodically (every 6 months) by the postdoctoral fellow to confirm patient eligibility, and to document missing data and participant drop-out.

Statistical Methods

Descriptive Statistics

Descriptive statistics such as mean, standard deviation, frequency, proportion, kernel density will be used to compare baseline characteristics (e.g., comorbid conditions, mental disorder status, health utilization) between IOC and control group patients for the primary analysis of healthcare costs/utilization, and to identify potential outliers for both primary and secondary analyses. They will also be used to evaluate bivariate associations between predictors, covariates (e.g., health literacy, numeracy, and acculturation), and primary or secondary outcomes.

Primary Outcome Measures: Healthcare Costs and Utilization

Healthcare costs/utilization 24 months before and 18 months after intervention will be considered. We will use parametric and non-parametric methods to compare costs between the two groups (i.e., case and control groups). As the mean is the most useful statistic to evaluate costs related to the IOC intervention, we will calculate means and standard deviations for total costs (i.e., the sum of medical costs and medication costs) by group. We will explore cost data distributions graphically and statistically. With univariate and multivariate techniques, we will examine the relationship between intervention and total cost. As cost data are typically skewed, we will use nonparametric bootstrapping methods with 2000 pair-wise replications to compare mean costs and avoid distributional assumptions. Confidence intervals around the mean cost difference will be calculated with bias-corrected and accelerated methods. To examine healthcare costs, an estimated generalized linear regression (GLM) with log link and gamma distribution will be applied. In order to examine health care utilization, Negative Binomial Regression (NBR) will be used to handle over dispersion (i.e. mean ≠ variance) of the number of inpatient or ER visits.

Secondary Outcome Measures: Patient Health and Care Experience/Quality

The patient-reported health and quality of care outcomes include several domains with multiple questions. For ordinal or binary measures, conditional logistic regression will be used to predict the odds ratio of a positive healthcare experience as a function of time in the IOC intervention (with first visit as the reference), after controlling for baseline characteristics such as patient demographics (e.g., age, gender, employment status), comorbid conditions, and healthcare utilization. For these measures, a positive patient healthcare experience is defined as answering “Yes, somewhat” or “Yes, definitely” when there are three response categories (e.g., “No”, “Yes, somewhat” and “Yes, definitely”), or answering “Yes” when there are two response categories (“Yes” and “No”).

Longitudinal, multi-level regression analyses or growth models within an MLM framework will be used to assess patterns of change in continuous patient-reported outcomes (i.e., self-efficacy, trust, care coordination) as a function of time in the intervention (again, with the first IOC visit as the reference time-point) across the four assessments at baseline, 6, 12, and 18 months. Analyses will be adjusted for baseline characteristics including age, gender, employment status, comorbid conditions, and mental disorder status. Time-varying predictors will also be incorporated, such as employment status and chronic health conditions. In some cases, multivariate techniques may be used to combine patient-reported domains into a single outcome for subsequent modeling. For example, Confirmatory Factor Analysis (CFA) can be applied to load the indicators of trust in provider, communication, care coordination, and access to community resources onto a single, underlying factor that reflects a patient’s positive healthcare experience.

Handling Missing Data

Missing data are assumed to be in part at random (MAR) and in part not at random (MNAR).[37] Full information maximum likelihood (FIML) estimation methods will be applied that make use of all available data; this approach has been shown to reduce bias and increase efficiency in the estimation of

model parameters and their standard errors, relative to traditional missing data approaches.[38] Longitudinal attrition analyses will help to identify missing data patterns and mechanisms of missingness (e.g., the extent to which patient demographics and health variables predict missingness across the 18 months of follow-up).

Ethics and Dissemination

This study of health and healthcare improvements among the highest-cost, highest-need patients in the University of Utah Health system, most of whom are publicly insured and have both medical and behavioral health issues, requires special consideration of barriers related to culture, language, health literacy, and social determinants (e.g., homelessness, unemployment, lack of social support). Before recruitment and conduct of the study, ethics approval was obtained from the University of Utah IRB board (approved protocol number IRB_00100959). Any modifications to the study will be submitted to the University of Utah IRB for approval.

Dissemination of results from this study will occur locally and nationally. Specifically, primary outcomes from the healthcare utilization and cost analysis will be shared in meetings with the health plan/medical group and with other University clinics. Manuscripts based on the intervention care model, as well as primary and secondary outcomes at 6, 12, and 18 months of follow-up will be submitted to scientific, peer-reviewed journals in the field. Results will also be presented nationally at scientific meetings.

Declaration of Interests

The investigators have no conflicts of interest to declare.

Access to Data

Only members of the study team will have access to participant surveys and identifying information (PHI). All PHI collected in the study will be stored in a password-protected environment at the University of Utah. This information will not be shared outside of the study team and the University of Utah IRB, unless IRB approval has been obtained. There will be no limits to access of the data for members of the research team. Once project data collection is complete, investigators will be able to access the dataset to conduct additional analyses after appropriate Institutional Review Board approvals have been obtained.

Discussion

A small percentage of individuals account for a disproportionately large amount of U.S. health spending, placing an appreciable burden on the healthcare system and the economy. A subset of these patients are not only medically-complex, but they typically also have challenging social circumstances and unmet behavioral health concerns, which exacerbate their health problems and drive their acute and costly utilization. Although intensive outpatient programs (also referred to as “super-utilizer programs” or “ambulatory ICUs”) are being developed across the country to respond to the need for innovative care models for these high-need, high-risk patients, these programs must be tailored to the communities they serve. The Intensive Outpatient Clinic (IOC) was developed at the University of Utah Health, which aims to deliver comprehensive, coordinated, and tailored care to the highest-need and costliest patients. This prospective, comparative case-control study aims to evaluate the effectiveness of the IOC in regard to reductions in cost and utilization, as well as the IOC’s efficacy at improving patient-reported outcomes (PROs) that reflect patients’ health, care experience, and engagement in self-care and disease management.

Some possible limitations of the study include its pre-post and quasi-experimental design, which may limit inferences of causality relative to randomized controlled trials (RCTs). Also, difficulty with patient recruitment, commonly noted in similar evaluation studies, might limit the sample size and statistical power for testing the study hypotheses. Lastly, our study design will not allow us to specify which specific components of the IOC are the most effective at improving patient outcomes or at reducing costs and utilization. Examining the efficacy of the IOC in its entirety will be a crucial first step in evaluation, which can be used to guide future research efforts that aim to identify the elements that help to explain the intervention's impact on outcomes of interest. Despite these common challenges, however, the results from this study will be used to inform ways to improve the implementation of the IOC to provide better care for patients, leading to long-term improvements in population health and cost-effectiveness. The IOC's care model will also provide insight and guide the development of high-risk/high-need programs nationwide that aim to reduce the fragmentation of care and improve clinical outcomes among their communities' highest-utilizing patients.

Author contributions

EO, AF, PW conceptualized the study and its design. JK provided statistical expertise. BK provides the medical care. All authors contributed to the write-up of the study protocol by providing comments on drafts written by BB and ML and approved the final manuscript.

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Competing Interests

None

Ethics Approval

Ethics approval has been granted for this study by the University of Utah Health Sciences Institutional Review Board (Approval number IRB_00100959).

Provenance and peer review

Not commissioned; internally peer reviewed.

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Evaluation of the Intensive Outpatient Clinic: Study protocol for a prospective study of high-cost, high-need patients in the University of Utah Health system

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Evaluation of the Intensive Outpatient Clinic: Study protocol for a prospective study of high-cost, high-need patients in the University of Utah Health system

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Abstract

Introduction: The University of Utah (UofU) Health Intensive Outpatient Clinic (IOC) is a primary care clinic for medically-complex (high-cost, high-need) patients with Medicaid. The clinic consists of a multi-disciplinary care team aimed at providing coordinated, comprehensive, and patient-centered care. The protocol outlines the quantitative design of an evaluation study to determine the IOC's effects on reducing healthcare utilization and costs, as well as improving patient-reported health outcomes and quality of care.

Methods and analysis: High-risk patients, with high utilization and multiple chronic illnesses, were identified in the Medicaid ACO population managed by the University of Utah Health Plans for IOC eligibility. A prospective, case-control study design is being used to match 100 IOC patients to 200 control patients (receiving usual care within the University of Utah) based on demographics, health utilization, and medical complexity for evaluating the primary outcome of change in healthcare utilization and costs. For the secondary outcomes of patient health and care quality, a pre-post design will be used to examine within-person change across the 18 months of follow-up (i.e., before and after IOC intervention). Logistic regression and hierarchical, longitudinal growth modeling are the two primary modeling approaches.

Ethics and dissemination: This work has received ethics approval by the University of Utah Institutional Review Board. Results from the evaluation of primary and secondary outcomes will be disseminated in scientific research journals and presented at national conferences.

Trial Registration Number: Not applicable

Article Summary

Strengths and limitations of this study

- A longitudinal, pre-post intervention design with a wide range of robust, validated outcome measures are strengths of this study.
- The study utilizes a quasi-experimental design, which limits causal inferences.
- The study design does not allow identification of which specific components of the IOC care model are the most effective; rather, it focuses on the efficacy of the IOC in its entirety.
- Difficulty with patient recruitment, commonly noted in similar evaluation studies, might limit the sample size and statistical power for testing study hypotheses.

Background

In 2002, the top five percent of healthcare spenders within the US population accounted for 49% of the nation's total healthcare costs. In contrast, 50% of the US population with the lowest health spending represented only three percent of the nation's total healthcare costs.[1] Today, the top one percent of patients still account for more than 20% of U.S. health expenditures.[2] Importantly, these expenditures are relatively stable from year-to-year; of the top 5 percent of health spenders in 2002, nearly 34% of these individuals maintained their ranking through the following year.[3] Furthermore, the proportion of the highest utilizers who maintain their high spending has continued to increase.[3] Individuals with this pattern of healthcare spending have been referred to as "super-utilizers", due to their high-frequency (and often preventable) use of hospital and emergency department services, as well as the high costs associated with these visits. Borrowing from the literature and our experience, a more accurate term to describe this population is "high-risk/high-need" – a term that focuses on the patient's medical and social needs rather than their medical spending ("super-utilizer").

High-risk, high-need patients tend to be medically complex, with comorbid chronic conditions that are poorly controlled due to mental health issues, substance abuse, or other psychosocial stressors (e.g., food insecurity, homelessness, social disruption, or lack of social support).[4] These patients are more likely to be older, female, have higher out-of-pocket healthcare expenses relative to their income, have multiple chronic conditions, and report poorer self-rated health and physical functioning as compared to the rest of the population.[1–5] Many are either uninsured or publicly insured through Medicare or Medicaid.[5,6] These patients frequently receive their medical care in emergency departments and hospitals, which adopt traditional approaches to care that emphasize the acute, specialized treatment and diagnosis of clinical problems, rather than treating the whole patient. However, because these high-need patients face a variety of ongoing medical, behavioral, and social complications, the fragmented and specialized care they receive results in both unmet needs for individual care and higher costs to the health system.

In response to this need for innovative care models to serve the highest-risk, highest-cost patients, the University of Utah Health began the Intensive Outpatient Clinic (IOC) in February of 2017. The IOC enrolls patients who not only have the highest rates of healthcare utilization in the University's health system, but who have multiple, chronic health conditions for which they might be receiving highly fragmented care. The IOC, with an interdisciplinary care team dedicated to providing patient-centered care, will deliver *comprehensive*, *coordinated*, and *customized* primary care to these patients. Such care will be designed to address the full continuum of health needs and care preferences within our patient population. Previous clinical models that are similar to the IOC have had success with outcomes such as reduced hospitalizations, emergency department visits, and total healthcare costs, as well as improvements in patients' activation and engagement in their care—a key factor known to impact clinical outcomes in the care process.[7,8] However, little is known about patient-reported outcomes from these care delivery models beyond activation and engagement. Therefore, this study will prospectively evaluate the IOC's effects on healthcare utilization, costs, and patient health and healthcare quality to assess the extent to which the IOC will reduce overall healthcare utilization/costs and improve patients' disease management and overall experiences with their healthcare.

Objectives

The objectives of the proposed study are to evaluate the IOC's effect on 1) healthcare costs and utilization, and 2) patient-reported health and quality of care, to determine whether this type of clinic will improve the quality and delivery of care and reduce healthcare spending for high-utilizing patients.

The proposed study aims to answer the following research questions:

1) Compared to standard care among medically-complex and high-utilizing University of Utah (UofU) Health patients who are not enrolled in the IOC, will the IOC reduce healthcare spending and utilization—including reductions in emergency department (ED) visits, hospital admissions and length of stay, and total healthcare costs (i.e., sum of medical reimbursed amount and prescription reimbursed amount)?
2) Compared to their first clinic visit (before receiving any care at the IOC), will the IOC patients report improvements in their health (including physical function, quality of life) and quality of care (trust in one's provider, self-efficacy, perceived access to community resources, care coordination) across 18 months of follow-up?

Study Design

To answer the first research question, a prospective matched case-control study will be conducted for the IOC for patients in the University of Utah Health system in Salt Lake City, Utah, the United States. The allocation ratio of cases to controls will be 1:2. Following the recommendation from Austin (2010),[9] we assume that the 1:2 matching will improve precision and minimize bias. For the evaluation of healthcare cost and utilization, propensity score- matched control groups will be identified from the University of Utah Health Plans (UUHP) claims database. Healthcare costs and utilization along with demographic information (such as age, gender) and medical history (e.g., comorbidities, disease severity, and index appointment/visit date) of the case and control groups will be from the UUHP claims database.

To answer the second research question, a pre-post study design will be used to evaluate improvements in IOC patients' health and quality of care. The intervention group will be recruited from their first visit at the IOC and invited to complete four surveys prospectively for a period of 18 months.

Methods

Patient and Public Involvement

The development of research questions, outcome measures, and design of the study was informed by: 1) the study team's interactions with patients during clinical visits and 2) an ongoing, qualitative study of patients and providers at the clinic. These interviews have aided the study team's understanding of patients' past experiences with healthcare, priorities for their health, and preferences for the receipt and delivery of care. The results of this study will be disseminated to study participants after the completion of the study, through summary results and stories provided in newsletters.

Study Setting

The Intensive Outpatient Clinic (IOC) is part of the University of Utah Health and began its operations in February of 2017. The clinic is located in West Valley City (a suburb of Salt Lake City that provides a convenient location for IOC patients). The IOC provides patients with 24/7 phone access to providers, same-day appointment scheduling, integrative care across specialties, care coordination across physical and behavior health providers, case management and self-management education provided by licensed clinical social workers/nurse practitioners/registered nurse care coordinators (RNCCs), and medication interventions and collaborative practice care for chronic diseases performed by a clinical pharmacist (PharmD). Enrollment in the study began in July of 2017, and enrollment is ongoing.

Participants/Inclusion & Exclusion Criteria

IOC Patient Characteristics

There are a number of criteria potential patients need to meet in order to be eligible for care at the IOC. Patients are candidates for the IOC if they fall into the category of high-risk and high-cost, defined by a high number of comorbidities, hospitalizations, and emergency department visits, as well as seeing multiple providers and accounting for a high proportion of costs to the healthcare system. Other indicators include insurance status (publically insured through Medicaid), social or behavioral health concerns (e.g., homelessness or food insecurity, substance abuse, or mental health disorder). This pool of potential patients has their medical records reviewed by the IOC staff who refine the selection of patients to those who struggle to engage with the health system (poor compliance, high no-show rate, poorly controlled disease states). Thus, the identification of eligible IOC patients is an iterative process using both predictive modeling and provider chart review and nominations. Exclusion criteria include: 1) patients whose sole medical problem is a new onset cancer diagnosis or an organ transplant; 2) patients with behavioral health issues that exceed the clinic's ability to assist; 3) patients receiving exclusive palliative care or those at high-risk for mortality in the coming weeks; and 4) patients > 65 years of age (i.e. Medicare). All patients who receive care at the IOC are invited to enroll in the study; however, for the secondary analysis, all new patients are eligible to participate in the survey at their first clinic visit (i.e. prior to receiving care). Patients with language barriers, cognitive difficulties, or atypical enrollment processes (e.g., acute medical needs requiring emergency department referral) that preclude them from completing the survey are not eligible.

Control Patient Characteristics for Healthcare Cost and Utilization Analysis

For the primary outcome analysis, patients in the control group will receive standard care at University of Utah Health, whether it is primary or specialty care. As part of the standard care, they might have a primary healthcare provider in addition to specialty providers who treat or help in managing their chronic health conditions.

To identify patients in the control group who have similar characteristics of the patients in the case group (i.e., IOC patients) propensity score matching will be used to minimize observable confounders that could potentially affect the outcomes. We will match each IOC patient to two control subjects with propensity score matching (i.e., nearest-neighbor matching) using logistic regression models. Matching will be based on variables such as: year of birth, sex, race, baseline Elixhauser Comorbidity Index (or Charlson Comorbidity Index), insurance status (Medicaid), baseline numbers of inpatient, emergency room, and outpatients visits, healthcare costs one year prior to index date, and mental disorder status. Matching using calipers of a specified width will be used to match untreated subjects with a similar propensity score. Calipers of width 0.2 of the standard deviation of the logit of the propensity score will be used because this width had estimates of intervention effect with lower mean squared error compared to other methods. If multiple control subjects have propensity score values that are equally close to that of the case subject, then one of these control subjects is selected at random. As we employ one-to-two matching without replacement, the final matched sample will consist of unique subjects in both groups. To assess the balance in the baseline covariates between the groups, the standardized difference methods for both continuous and categorical variables will be used. If standardized differences are less than 10% (or 0.10), we assume that the imbalance between the groups is negligible. Entry into the study (i.e., start of follow-up) of the IOC patients will be based on the first IOC visit date. Follow-up of the controls will begin the same dates as the matched IOC patients, providing equal follow-up time for both groups. The reason for 1 vs. 2 matching is that it could improve small variance (i.e., precision) without increase in bias.[9,10]

Interventions (Care at the IOC)

When patients come to the IOC, they receive care from a multidisciplinary team consisting of physicians (including one physician consultant who specializes in Addiction Medicine), a nurse practitioner, a clinical pharmacist, registered nurse care manager, a licensed clinical social worker, and medical assistants.

The physicians lead the care team, and are responsible for initial patient contact and recruitment, longitudinal acute and chronic disease management, preventive care services, interventions, and referrals to specialty care, supported by the nurse practitioner. The clinical pharmacist (PharmD) regularly performs medication reconciliations, monitors potential adverse drug interactions, prescribes and manages selected chronic diseases (e.g., diabetes, asthma, hypertension) using collaborative practice agreement, and promotes medication adherence. The pharmacist also performs ad-hoc tasks as needed by the physician (e.g., determining appropriate new medication therapies for patients, helping patients switch pharmacies, or trouble-shooting problems with patients' diabetic equipment, if applicable). Further coaching is provided by medical assistants who will educate patients on disease management techniques to help them keep on track with their care plans. Because it has been recognized that the integration of physical and mental health care improves patient outcomes, a licensed clinical social worker (LCSW) integrates patients' mental health needs with their physical care plans. The care manager builds rapport through phone calls and home visits, and also connects patients to available community resources (e.g., transportation). For patients who choose this option, they are able to receive short- or long-term therapy services in the clinic. The Nurse Care Manager builds initial patient rapport through telephonic, electronic, and home visits, and also connects patients to available community resources (e.g., transportation). To help coordinate care between team members and patients, the Nurse Care Manager integrates and coordinates the interactions between IOC staff and patients, provides frequent "touches" with the office through multiple channels, and coordinates internal and external appointment scheduling to facilitate timely and comprehensive care.

Outcome Measures

Primary Outcomes: Healthcare Costs & Utilization

Costs. Healthcare costs of patients will be extracted from claims data and evaluated prospectively, from 24 months prior to IOC enrollment and up to 18 months after. Cost outcomes will include: total healthcare cost (sum of medical reimbursed amount and prescription reimbursed amount), inpatient cost, ED cost and prescription cost. Healthcare costs will be adjusted to 2018 dollars using Personal Health Care Expenditure component of the National Health Expenditure Accounts[11] for the cost calculations to reflect inflation over time. Both outcomes will be aggregated in each month for trends analysis and will be aggregated before and after the IOC intervention or index date (for the controls).

Utilization. Patients' healthcare utilization records will be collected from claims data and evaluated prospectively, from 24 months prior to IOC enrollment and up to 18 months after. Specific outcomes of interest include the number of hospital admissions, length of hospital stay, number of emergency department (ED) visits, and office visits. This healthcare utilization information will be identified from the place of services where patients receive healthcare services.

Secondary Outcomes: Patient Health and Care Experience/Care Quality

Patient-reported outcomes of mental and physical health, and patients' experiences with their healthcare will be collected, as described below. Covariates will include patient background

characteristics that may provide useful targets for intervention, or that may predict intervention efficacy.

Patient Health

Health outcomes include general and specific measures of physical health, behavioral health, and quality of life.

Mental & Behavioral Health. Includes the PROMIS® Depression, Anxiety, Sleep Disturbance, and Applied Cognitive General Concerns scales.[12] All surveys use a 5-point Likert-type scale with higher scores indicating higher severity. Other patient-reported outcomes include surveys of Mania,[13] Psychosis,[14] Dissociation,[14] Personality Disorder,[14] Repetitive Thoughts, [15] and Substance Abuse.[16]

Physical Health. Two self-rated health items will ask participants to indicate their general health status on a Likert-type scale (*poor, fair, good, excellent*) and visual analog scale (from 0 to 100). The presence of physical symptoms will be assessed with the Somatic Severity scale.[17]

Quality of Life. Quality of life indicators will be the PROMIS® scales of Pain Interference, Physical Function, and Satisfaction with Social Roles and Activities.[12] Higher scores for the Pain Interference items reflected higher impact of pain on daily functioning; whereas higher scores for Satisfaction with Social Roles or Activities and Physical Function indicate increased role satisfaction and better physical functioning.

Patient Care Experience/Care Quality

Items on patients' experience with their healthcare, including self-efficacy for disease management, trust in health providers, and perceptions of provider communication, care coordination, access to care/community resources, and self-efficacy for disease management.

Access/Referrals to Community Resources. To determine patient access to community resources and referral by providers and clinic staff to community resources, participants will be asked three questions from the PACIC survey.[18] Patients will be asked, "Over the past 6 months, when receiving medical care, I was:" 1) Encouraged to attend programs in the community that could help me; 2) Asked how my work, family, or social situation related to taking care of my illness; and 3) Helped to make plans for how to get support from my friends, family or community. The PACIC uses a 5-point Likert scale of *almost never, generally not, sometimes, most of the time*, and *almost always*.

Trust. The Patient Trust Scale,[19] developed by Audiey Kao and colleagues adapted from the Trust-in-Physicians scale,[20] is a 10 question 5-point Likert scale which asks questions concerning trust in one's physician on issues such as referrals, hospital admission, medical testing, and medications.

Communication. The Modified Picker Survey,[20] also modified by Audiey Kao and colleagues from the Picker survey,[21–23] is a 7 question survey using a 4 point scale (never, sometimes, usually, always) concerning patient and physician communication. Questions cover issues such as having enough time to explain reasons for the visit, if there was enough time for the physician to answer questions, and if patients were involved in decisions as much as they wanted to.

Care Coordination. Three questions were selected from the Continuity of Care: When Patients Encounter Several Clinicians Survey[24] which cover indicators of discontinuity, or where patients feel like their care is disjointed or feel abandoned by the health care system.

Self-Efficacy. The Self-Efficacy to Manage Disease in General section from the Self-Efficacy Scale[25] will be used to measure patient motivation to manage their illness or disease. Questions cover topics such as knowing when to visit a doctor, managing emotional distress, and patient confidence in managing their condition.

Covariates: Individual Differences

Covariates will include patient background characteristics that may provide useful targets for intervention, or that may predict intervention efficacy. Covariates will include items on patient demographics and other baseline characteristics, including health literacy, numeracy, acculturation, and trait-like preferences for medical intervention (i.e., Medical Maximizing-Minimizing). Some covariates (i.e., employment status and Medical Maximizing-Minimizing preferences) may also be treating as time-varying or included as intervention outcomes in exploratory analyses.

Demographics. Participants will be asked five demographic questions which include age, gender, highest level of education completed, race, and ethnicity.

Health Literacy. To ascertain participant literacy, the Chew, Bradley, and Boyko three-question health literacy screener will be used.[26]

Numeracy. The Subjective Numeracy Scale is a 6-point Likert scale 4 question survey developed by Fagerlin and colleagues[27,28] which asks patients their math skills without asking math questions.

Employment Status. Participants will be asked four questions on their work situation. These questions are: 1) Do you work?; 2) About how many hours do you work per week?; 3) Does your health prevent you from working as many hours as you would like?; and 4) If your health improved, how many hours per week would you like to work?

Acculturation. To understand patients' language (and social) preferences, the Short Acculturation Scale for Hispanics[29] was adapted to incorporate multiple languages. This survey uses a 5 point Likert scale. Question responses originally were "only Spanish, Spanish better than English, both equally, English better than Spanish, and only English"; or "only Spanish, more Spanish than English, both equally, more English than Spanish, and only English." Instead of using "Spanish," patients will be asked about their "native language." Only 4 questions out of the 12 question scale will be used. These questions are: 1) In general, what language(s) do you read and speak?; 2) What language(s) do you usually speak at home?; 3) In which language(s) do you usually think?; and 4) What languages do you usually speak with your friends?

Medical Maximizing-Minimizing Preferences. At all four assessments, participants are also asked to complete the Medical Maximizer-Minimizer Scale,[30] a 10-question survey that measures where patients fall along the spectrum of wanting to do as much as possible when it comes to their health (e.g., aggressive treatments, or tests of little diagnostic value) to as little as possible (e.g., watchful waiting). Response options were "Yes," "No," or "I don't know." Examples of items included, "It is important to treat disease even when it doesn't not make a difference in survival," and "If I feel unhealthy, the first thing I do is to go to the doctor and get a prescription."

Adverse Childhood Experiences. At the baseline assessment, participants were asked to complete the Adverse Childhood Experiences (ACE) Study Questionnaire,[31] a 17-item survey that asks

participants to indicate whether they have ever experienced a series of traumatic childhood experiences (e.g., physical or sexual abuse, neglect) prior to 18 years of age (0 = *No*, 1 = *Yes*).

Timeline of Survey Administration

An overview of all survey outcome measurements and time-points are included in Table 1. Participants in the study will be given surveys at four time-points over 18 months. Surveys will be administered at baseline and again at 6-, 12-, and 18- month follow-ups. Shorter follow-up surveys will be administered every 6 months up to 18 months after baseline. The 6- , 12-, and 18-month surveys will only include items on physical and mental/behavioral health, quality of life, employment status, self-efficacy, Medical Maximizing-Minimizing, and quality of care (e.g., trust, communication, care coordination, access/referral to community resources, and self-efficacy).

Table 1: Survey Timeline

	Baseline	6 months	12 months	18 months
Patient Health				
PROMIS Applied Cognition-General Concerns	x	x	x	x
PROMIS Anxiety	x	x	x	x
PROMIS Depression	x	x	x	x
PROMIS Pain Interference	x	x	x	x
PROMIS Physical Function	x	x	x	x
PROMIS Satisfaction with Social Roles and Activities	x	x	x	x
PROMIS Sleep Disturbance	x	x	x	x
Mania	x	x	x	x
Somatic Severity	x	x	x	x
Psychosis	x	x	x	x
Sleep Disturbance	x	x	x	x
Repetitive Thoughts	x	x	x	x
Dissociation	x	x	x	x
Personality Disorder	x	x	x	x
Substance Use	x	x	x	x
Care Experience/Quality				
Access/Referral to Community Resources	x	x	x	x
Trust	x	x	x	x
Communication	x	x	x	x
Care Coordination	x	x	x	x

Self-Efficacy	x	x	x	x
Covariates				
Demographics	x			
Literacy	x			
Numeracy	x			
Employment Status	x	x	x	x
Acculturation	x			
Maximizer-Minimizer	x	x	x	x
Adverse Childhood Experiences (ACE)	x			

Sample Size

Based on a sample size of *n* = 100, we hypothesize that the mean difference in patients' reported health and care quality before and after IOC intervention will be up to 20%. We assume the standard deviation of the differences equals 0.10 and mean score at baseline 0.31.[32] Using these assumptions, we will obtain over 80% power to detect an effect size=0.5.

Statistical power for the healthcare cost was estimated based on an assumed standard deviation (i.e., $15,000) for change in the healthcare cost over 12 months of $6,139.[33] The difference in healthcare costs between the case and the control groups is assumed to be 21%.[34] Considering these numbers and a 1:2 matching (100 cases to 200 controls), the minimum detectable treatment effect with 80% power, 2-sided α=0.05 is $1,222 in the healthcare cost outcome.

Recruitment, Enrollment and Consent

There are multiple recruitment processes for the study. All new IOC patients will be recruited at the time of their first visit to the IOC. To minimize bias, all patients at the IOC will be invited to enroll. Those who want to participate will enroll at that time. For all participants, informed consent will be completed through an electronic data capture when potential participants access the study survey link. Because surveys will be completed online, all participants will be informed that if they wish to participate, completion of the surveys will imply their consent.

Data Collection Methods

Healthcare Costs/Utilization

The data for this study will be collected from claims databases for both the case and the control groups.

Patient Health/Care Quality

Some data for this study will be collected by electronic data capture, and some data will be collected as part of routine care at the clinic for the intervention group. The survey is available to intervention participants through REDCap.

As this is a minimal risk study, data monitoring will be conducted by either the PI, a study coordinator or research nurse, and/or a research assistant. Data will be monitored at least every 6 months to review and confirm participant eligibility and review missing data from survey responses. For participants who discontinue the study, data that was collected previously from completed surveys will still be included in

the final analysis, using robust statistical methods to account for missing data and attrition. For participants who substantially deviate from the intervention protocol, the study staff will note this in a separate administrative form in the electronic data capture and their outcome data may be dropped from the final analysis (pending that they are a substantial outlier). Data regarding reasons for drop-out will be collected (e.g., death of a participant, relocation).

Data Management

As all data is collected through electronic data capture, there will be no manual entry of survey data. Data will be stored on the secure electronic data capture server located at the University of Utah, as well as on password-protected computers and locked storage cabinets only accessible to the research team. All data which could link participants to their responses will be stored in a password-protected electronic folder separate from the survey responses and only accessible to the research team. Data will be monitored periodically (every 6 months) by the postdoctoral fellow to confirm patient eligibility, and to document missing data and participant drop-out.

Statistical Methods

Descriptive Statistics

Descriptive statistics such as mean, standard deviation, frequency, proportion, kernel density will be used to compare baseline characteristics (e.g., comorbid conditions, mental disorder status, health utilization) between IOC and control group patients for the primary analysis of healthcare costs/utilization, and to identify potential outliers for both primary and secondary analyses. They will also be used to evaluate bivariate associations between predictors, covariates (e.g., health literacy, numeracy, and acculturation), and primary or secondary outcomes.

Primary Outcome Measures: Healthcare Costs and Utilization

Healthcare costs/utilization 24 months before and 18 months after intervention will be considered. We will use parametric and non-parametric methods to compare costs between the two groups (i.e., case and control groups). As the mean is the most useful statistic to evaluate costs related to the IOC intervention, we will calculate means and standard deviations for total costs (i.e., the sum of medical costs and medication costs) by group. We will explore cost data distributions graphically and statistically. With univariate and multivariate techniques, we will examine the relationship between intervention and total cost. As cost data are typically skewed, we will use nonparametric bootstrapping methods with 2000 pair-wise replications to compare mean costs and avoid distributional assumptions. Confidence intervals around the mean cost difference will be calculated with bias-corrected and accelerated methods. To examine healthcare costs, an estimated generalized linear regression (GLM) with log link and gamma distribution will be applied. In order to examine health care utilization, Negative Binomial Regression (NBR) will be used to handle over dispersion (i.e. mean ≠ variance) of the number of inpatient or ER visits.

Secondary Outcome Measures: Patient Health and Care Experience/Quality

The patient-reported health and quality of care outcomes include several domains with multiple questions. For ordinal or binary measures, conditional logistic regression will be used to predict the odds ratio of a positive healthcare experience as a function of time in the IOC intervention (with first visit as the reference), after controlling for baseline characteristics such as patient demographics (e.g., age, gender, employment status), comorbid conditions, and healthcare utilization. For these measures, a positive patient healthcare experience is defined as answering “Yes, somewhat” or “Yes, definitely” when there are three response categories (e.g., “No”, “Yes, somewhat” and “Yes, definitely”), or answering “Yes” when there are two response categories (“Yes” and “No”).

Longitudinal, multi-level regression analyses or growth models within an MLM framework will be used to assess patterns of change in continuous patient-reported outcomes (i.e., self-efficacy, trust, care coordination) as a function of time in the intervention (again, with the first IOC visit as the reference time-point) across the four assessments at baseline, 6, 12, and 18 months. Analyses will be adjusted for baseline characteristics including age, gender, employment status, comorbid conditions, and mental disorder status. Time-varying predictors will also be incorporated, such as employment status and chronic health conditions. In some cases, multivariate techniques may be used to combine patient-reported domains into a single outcome for subsequent modeling. For example, Confirmatory Factor Analysis (CFA) can be applied to load the indicators of trust in provider, communication, care coordination, and access to community resources onto a single, underlying factor that reflects a patient's positive healthcare experience.

Handling Missing Data

Missing data are assumed to be in part at random (MAR) and in part not at random (MNAR).[35] Full information maximum likelihood (FIML) estimation methods will be applied that make use of all available data; this approach has been shown to reduce bias and increase efficiency in the estimation of model parameters and their standard errors, relative to traditional missing data approaches.[36] Longitudinal attrition analyses will help to identify missing data patterns and mechanisms of missingness (e.g., the extent to which patient demographics and health variables predict missingness across the 18 months of follow-up).

Ethics and Dissemination

This study of health and healthcare improvements among the highest-cost, highest-need patients in the University of Utah Health system, most of whom are publicly insured and have both medical and behavioral health issues, requires special consideration of barriers related to culture, language, health literacy, and social determinants (e.g., homelessness, unemployment, lack of social support). Before recruitment and conduct of the study, ethics approval was obtained from the University of Utah IRB board (approved protocol number IRB_00100959). Any modifications to the study will be submitted to the University of Utah IRB for approval.

Dissemination of results from this study will occur locally and nationally. Specifically, primary outcomes from the healthcare utilization and cost analysis will be shared in meetings with the health plan/medical group and with other University clinics. Manuscripts based on the intervention care model, as well as primary and secondary outcomes at 6, 12, and 18 months of follow-up will be submitted to scientific, peer-reviewed journals in the field. Results will also be presented nationally at scientific meetings.

Declaration of Interests

The investigators have no conflicts of interest to declare.

Access to Data

Only members of the study team will have access to participant surveys and identifying information (PHI). All PHI collected in the study will be stored in a password-protected environment at the University of Utah. This information will not be shared outside of the study team and the University of Utah IRB, unless IRB approval has been obtained. There will be no limits to access of the data for members of the research team. Once project data collection is complete, investigators will be able to access the dataset to conduct additional analyses after appropriate Institutional Review Board approvals have been obtained.

Discussion

A small percentage of individuals account for a disproportionately large amount of U.S. health spending, placing an appreciable burden on the healthcare system and the economy. A subset of these patients are not only medically-complex, but they typically also have challenging social circumstances and unmet behavioral health concerns, which exacerbate their health problems and drive their acute and costly utilization. Although intensive outpatient programs (also referred to as "super-utilizer programs" or "ambulatory ICUs") are being developed across the country to respond to the need for innovative care models for these high-need, high-risk patients, these programs must be tailored to the communities they serve. The Intensive Outpatient Clinic (IOC) was developed at the University of Utah Health, which aims to deliver comprehensive, coordinated, and tailored care to the highest-need and costliest patients. This prospective, comparative case-control study aims to evaluate the effectiveness of the IOC in regard to reductions in cost and utilization, as well as the IOC's efficacy at improving patient-reported outcomes (PROs) that reflect patients' health, care experience, and engagement in self-care and disease management.

Some possible limitations of the study include its pre-post and quasi-experimental design, which may limit inferences of causality relative to randomized controlled trials (RCTs). Also, difficulty with patient recruitment, commonly noted in similar evaluation studies, might limit the sample size and statistical power for testing the study hypotheses. Lastly, our study design will not allow us to specify which specific components of the IOC are the most effective at improving patient outcomes or at reducing costs and utilization. Examining the efficacy of the IOC in its entirety will be a crucial first step in evaluation, which can be used to guide future research efforts that aim to identify the elements that help to explain the intervention's impact on outcomes of interest. Despite these common challenges, however, the results from this study will be used to inform ways to improve the implementation of the IOC to provide better care for patients, leading to long-term improvements in population health and cost-effectiveness. The IOC's care model will also provide insight and guide the development of high-risk/high-need programs nationwide that aim to reduce the fragmentation of care and improve clinical outcomes among their communities' highest-utilizing patients.

Author contributions

EO, AF, PW conceptualized the study and its design. JK provided statistical expertise. BK provides the medical care. All authors contributed to the write-up of the study protocol by providing comments on drafts written by BB and ML and approved the final manuscript.

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Competing Interests

None

Ethics Approval

Ethics approval has been granted for this study by the University of Utah Health Sciences Institutional Review Board (Approval number IRB_00100959).

Provenance and peer review

Not commissioned; internally peer reviewed.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **(abstract, page 2)**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **(abstract, page 2 & article summary, page 3)**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **(page 4)**
Objectives	3	State specific objectives, including any prespecified hypotheses **(pages 4 & 5)**
Methods		
Study design	4	Present key elements of study design early in the paper **(page 5)**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **(pages 5, 7-8, & 10)**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls **(pages 5-10)** *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case **(page 6)**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **(pages 7-10)**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **(pages 10-11 & 11-12)**
Bias	9	Describe any efforts to address potential sources of bias **(pages 11 & 13)**
Study size	10	Explain how the study size was arrived at **(page 11)**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **(pages 11-12)**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **(pages 12-13)**
		(*b*) Describe any methods used to examine subgroups and interactions **(page 12)**
		(*c*) Explain how missing data were addressed **(page 13)**
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed **(page 6)** *Cross-sectional study*—If applicable, describe analytical methods taking account of

sampling strategy

(*e*) Describe any sensitivity analyses **(not applicable)**

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed **(not applicable)**
		(b) Give reasons for non-participation at each stage **(not applicable)**
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders **(not applicable)**
		(b) Indicate number of participants with missing data for each variable of interest **(not applicable)**
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) **(not applicable)**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time **(not applicable)**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure **(not applicable)**
		Cross-sectional study—Report numbers of outcome events or summary measures **(not applicable)**
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included **(not applicable)**
		(*b*) Report category boundaries when continuous variables were categorized **(not applicable)**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **(not applicable)**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **(not applicable)**
Discussion		
Key results	18	Summarise key results with reference to study objectives **(not applicable)**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **(page 14)**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **(not applicable)**
Generalisability	21	Discuss the generalisability (external validity) of the study results **(not applicable)**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **(page 15)**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at

http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.