Methadone patient access to collaborative treatment (MPACT): Protocol to establish feasibility of adoption and impact on methadone treatment delivery and patient outcomes

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Abstract

Background: Access to methadone treatment can reduce opioid overdose death by up to 60%, but U.S. patient outcomes are suboptimal. Federally-allowed methadone treatment accommodations during the COVID public health emergency were not widely adopted. It is likely that staff-level characteristics such as trauma symptoms influence adoption of treatment innovation.

Objective: Methadone Patient Access to Collaborative Treatment (MPACT) is a two-phased project (pilot and field trial) to develop and test a staff-level, multimodal intervention to increase staff adoption of methadone treatment innovation and ultimately improve patient outcomes of treatment retention.

Methods: A pilot and national trial will measure implementation feasibility, acceptability and effects of the MPACT intervention on treatment practice change, clinic culture, patient retention, and patient Posttraumatic stress symptoms (PTSS). The pilot will be a single-arm 5.5-month pilot study of MPACT conducted in two Arizona methadone treatment clinics (rural and urban) among 100 patients and 22 staff. The national trial will be a 20-month cluster randomized trial conducted among 40 clinics, 800 patients (20 per clinic) and 520 staff (13 per clinic). Data will be gathered by staff and patient survey and patient chart review. The primary study outcome is increased patient methadone treatment retention measured as: 1) time to first treatment interruption from study enrollment, 2) active in treatment at enrollment, day 30, 60, 90, and 120, 3) continuous days in treatment during the study period. Secondary study outcomes include reductions in vicarious trauma (VT) and PTSS among enrolled opioid treatment program staff and PTSS among enrolled patients.

Results: This is a protocol (no results to report)

Conclusions: The MPACT study will provide a foundation for an evidence-based, staff-level intervention aimed at improving patient retention in methadone treatment. Future studies should examine the individual components of MPACT to determine

their differential contributions to the primary outcome of patient methadone treatment retention, and to secondary outcomes of staff and patient reduction in stress symptoms. Clinical Trial: NCT06513728 (for pilot)
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Title: Methadone patient access to collaborative treatment (MPACT): Protocol to establish feasibility of adoption and impact on methadone treatment delivery and patient outcomes

Short Title: Methadone patient access to collaborative treatment (MPACT): Study protocol

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Abstract

Background:
Access to methadone treatment can reduce opioid overdose death by up to 60%, but U.S. patient outcomes are suboptimal. Federally-allowed methadone treatment accommodations during the COVID public health emergency were not widely adopted. It is likely that staff-level characteristics such as trauma symptoms influence adoption of treatment innovation. Methadone Patient Access to Collaborative Treatment (MPACT) is a two-phased project (pilot and field trial) to develop and test a staff-level, multimodal intervention to increase staff adoption of methadone treatment innovation and ultimately improve patient outcomes of treatment retention.

Methods and Analysis:
A pilot and national trial will measure implementation feasibility, acceptability and effects of the MPACT intervention on treatment practice change, clinic culture, patient retention, and patient Posttraumatic stress symptoms (PTSS). The pilot will be a single-arm 5.5-month pilot study of MPACT conducted in two Arizona methadone treatment clinics (rural and urban) among 100 patients and 22 staff. The national trial will be a 20-month cluster randomized trial conducted among 40 clinics, 800 patients (20 per clinic) and 520 staff (13 per clinic). Data will be gathered by staff and patient survey and patient chart review. The primary study outcome is increased patient methadone treatment retention measured as: 1) time to first treatment interruption from study enrollment, 2) active in treatment at enrollment, day 30, 60, 90, and 120, 3) continuous days in treatment during the study period. Secondary study outcomes include reductions in vicarious trauma (VT) and PTSS among enrolled opioid treatment program staff and PTSS among enrolled patients.

Conclusion
The MPACT study will provide a foundation for an evidence-based, staff-level intervention aimed at improving patient retention in methadone treatment. Future studies should examine the individual components of MPACT to determine their differential contributions to the primary outcome of patient methadone treatment retention, and to secondary outcomes of staff and patient reduction in stress symptoms.

Introduction

Methadone is one of the most essential tools available to reduce opioid overdose deaths because it is safe, effective and patient-preferred for the treatment of opioid use disorder (OUD).[1,2,3] Access to methadone, one of two safe and effective OUD treatments, can reduce overdose mortality by up to 60%.[4,5] But the promise of methadone is significantly diminished by geographic maldistribution of clinics and wide variations in the delivery of methadone maintenance treatment (MMT) across the country.[6,7,8] Treatment variations likely produce the observed wide-ranging MMT retention rates (30-84%).[9,10]

MMT in the United States (U.S.) is delivered only by opioid treatment programs (OTP, 'methadone clinics') certified and accredited by the federal government.[11] Treatment quality and access maldistribution mean that the impact of poor MMT outcomes is felt most acutely in rural communities as well as among by populations who are Black, Hispanic, or Indigenous.[12] Unlike other healthcare environments, OTPs serve a daily average of more than 100 people in a narrow time window[13] and have been described as feeling "like bus stations"[14] rather than medical clinics. OTPs have been criticized as being unresponsive to patient need for treatment flexibility,[15] and are not equipped to address what we know to be higher rates of patient trauma exposure and posttraumatic stress symptoms (PTSS) compared to the general population.[16,17] While MMT outcomes can be impeded by patient trauma,[18] it is also possible that poor MMT outcomes and patient trauma are exacerbated by OTP practice and culture.[19,20] Patients report disenfranchisement from treatment decision-making through language referring to dosing as "privileges." Staff can be experienced as "carceral,"[21] and patients feel tied to the OTP by "liquid handcuffs" due to daily required in-clinic supervised dosing.[22]

Policy and systems evolution is occurring to improve the way MMT is delivered in the U.S. Unprecedented U.S. regulatory change during the COVID public health emergency (PHE)[23] and again in February 2024[24] permitted and then further clarified methadone dosing and delivery flexibility so that treatment was more individualized and patient-centered. But as has been observed, policy changes during the PHE were insufficient to ensure sustained changes.[25,26,27] This is likely the result of multiple factors hindering implementation of MMT innovation. Implementation science suggests that in addition to the outer setting

factor of federal policy, there are inner setting factors which likely influence the adoption of MMT treatment innovation.[28] These include clinic organizational characteristics and culture, as well as staff characteristics and staff beliefs. Figure 1 displays our current thinking about hypothesized relationships between and among inner setting factors, adoption of innovation and patient outcomes.

Figure 1 about here
Caption: Potential Inner Setting Factors Impacting Methadone Treatment Outcomes

Staff trauma is one particular inner setting factor that is linked to the adoption of innovation and quality of treatment delivery. A preliminary study by several authors here suggests that OTP staff trauma may play a central role in shaping clinic culture and methadone treatment practice changes.[29] Evidence from studies among other types of health professionals demonstrate that vicarious trauma (VT), or work related trauma (i.e., co-experiencing patient suffering; change in worldviews because of ongoing co-suffering), is associated with reduced staff empathy and increased posttraumatic stress symptoms (PTSS).[30] VT outcomes include burnout, reduced patient empathy and compassion satisfaction, low morale, impaired clinical decision making, and compromised patient care.[31,32,33] The only extant study of OTP staff trauma histories and symptoms found that 63% of staff exhibited PTSS at clinical levels, indicating a need for treatment.[34] Therefore, a potential strategy to facilitate adoption of MMT innovation is to implement staff-level interventions aimed at reducing PTSS and VT.

To this end, we developed Methadone Patient Access to Collaborative Treatment (MPACT): a multimodal intervention to increase staff awareness of and readiness to adopt MMT treatment innovation. MPACT promotes treatment flexibilities allowed by federal regulators and patient-centered, trauma-informed MMT, and seeks to empower OTP staff and clinic groups to adopt these treatment flexibilities by addressing staff VT and PTSS, which will improve treatment quality and ultimately MMT retention. The objective of this study is to test the adoption feasibility and impact of MPACT on methadone treatment delivery and patient outcomes. There are six specific aims for the MPACT study over the 6-year project period. The specific aims are listed here and will be described in following subsections.

Phase 1, Years 1-2: MPACT Intervention Development and Pilot Testing

1. Develop MPACT through multilevel, iterative planning with methadone clinic staff and people with

recent methadone treatment experience.

2. Determine MPACT implementation feasibility, acceptability and preliminary effect on methadone treatment practice change and clinic culture.
3. Determine the preliminary effect of MPACT on methadone treatment retention, and patient posttraumatic stress symptoms.

Phase 2, Years 3-6: Hybrid, cluster randomized controlled trial

4. Quantify the effects of MPACT on methadone treatment practice change and clinic culture.
5. Determine the efficacy of MPACT on methadone treatment retention and patient and staff posttraumatic stress symptoms outcomes.
6. Evaluate the effect of patient and staff trauma on primary outcomes and staff MPACT implementation.

Ethics Approval

The MPACT study protocol and related documents were reviewed and approved by the University of Arizona Human Subjects Protection Program (#STUDY00003631 (pilot), #STUDY00005677 (trial)), the single IRB overseeing all sites participating in the study: Indiana University, Western Michigan University, and Columbia University. All participants will engage in an online informed consent process with online agreement provided by the participant prior to study enrollment. The consent will be downloaded and retained by the study as documentation. Patient participants will consent to both survey participation and the release of specified elements of their clinic medical record for the purpose of the study.

Confidentiality of staff and patient participants in the enrolled-MPACT clinics will be preserved by making every effort to prevent the clinic leadership and staff from knowing which patients are enrolled as study participants and keeping clinic leadership and patients from knowing which staff are enrolled as study participants. Unique identifiers will be created at the time of enrollment and used throughout the study period. All study personnel (staff and investigators) have been trained in human subjects protection through the completion of Social Behavioral Research and Biomedical Research modules with the CITI program, have completed the conflict of interest training, and have declared conflict(s) of interest for review by the University of Arizona Human Subjects Protection Program. All data discussed and reported will be aggregated and de-identified. All information will be stored in a secure and encrypted drive and accessible only by the Principal Investigator and the Study Coordinator. The study was registered under Clinicaltrials.gov

(NCT06513728 for the phase 1 pilot and NCT06556602 for the phase 2 trial).

Methods

Phase 1, Years 1-2: MPACT Intervention Development and Pilot Testing

AIM 1: Develop MPACT through multilevel, iterative planning with methadone clinic staff and people with recent methadone treatment experience.

MPACT is an experimental intervention comprised of four, evidence-based components adapted by a group of people who have been in methadone treatment within the past five years in Arizona, a group of OTP staff in all clinic roles (front desk, peer support staff, case management, counseling, clinical supervision, medical and administrative) from three Arizona OTPs (2 urban and 1 rural), and a group of subject matter experts focused on clinical supervision, human resources, and employee education.

The adaptation of MPACT components was accomplished through an iterative co-development process involving OTP staff and methadone community (patient) groups. The creation of a trauma-informed co-development space was crucial to facilitate safer and more open discussions. To accomplish this, we established a parallel, intervention refinement process using a helical structure developed by this team and based on our prior research with structural indicators for community based participatory action research.[35] As shown in Figure 2, the 'hand off' of work drives an iterative (helical) thinking process. This structure provides distinct spaces for thoughtful dialogue within and between each group.

Fig 2 about here
Caption: Trauma-Informed, Collaborative Development Structure to Refine MPACT Components

The outcome of the co-development process was a robust multimodal intervention (MPACT) comprised of the following four elements:

1. Accredited Psychoeducational Training. A jointly accredited, self-paced, 3-module psychoeducational training focused on 1) the definition and application of patient-centered, trauma-informed methadone treatment, 2) public and clinic policy (federal and state), and 3) clinic staff role in helping or hindering patient-centered, trauma-informed methadone treatment. The training seeks to empower staff to initiate any positive change at the individual and staff group level. Joint accreditation offers continuing medical

education (CMEs) for physicians and nurses, as well as continuing education credits (CEs) for social workers, psychologists, peer support specialists, case managers and administrators. Training completion is incentivized by the award of three, free CEs according to professional discipline. While training is voluntary, to receive the continuing education credits, staff of MPACT-enrolled clinics must complete the training within two weeks of MPACT launch within the clinic. New staff can complete the training as they are hired during the MPACT intervention period. This modular training approach was adapted from a prior successful project focused on increasing pharmacy syringe sales to people who use drugs.[36]

2. Staff Wellness Education and Assessment. All staff in MPACT-enrolled clinics will receive training about trauma exposure and reactions, trauma informed methadone treatment, availability and modalities of trauma treatment and VT through curated presentation materials. These materials will be accessible to all staff through an MPACT web portal and through training or communications as determined by the enrolled clinics. The training materials are designed for easy integration into clinic employee trainings, onboarding, or as refresher training. As part of the training, staff will be introduced to an anonymous online "wellness" screener which includes an 8-item PTSD symptoms screener (PCL-5)[37,38] and an 8-item Vicarious Trauma Scale (VTS).[39] Individual screening outcomes (results) trigger a curated and immediately presented message regarding self-care, referral to the VA PTSD Coach[40,41] (a downloadable, free app) and/or referral to the employee assistance program offered as a behavioral health benefit to employees. Employees will have access to wellness training throughout the MPACT intervention period and can us the self-screener as often as needed. The screener will also be "advertised" in staff-only areas with a curated poster on stress, including a link or QR for easy access.

3. Trauma-Informed Clinic Self-Assessment. A trauma-informed clinic self-assessment (TICA) will be conducted quarterly during the study period. The TICA is based on anonymous, individual staff responses to a 16-item survey measuring staff development, resources, support, safe physical environments, policies, and patient-centered practices specific to methadone clinics using research team-derived measures. The items were selected and modified by the study team using the organizational trauma-informed practices (O-TIPS)

tool as a reference instrument.[42] Summarized results will be shared with clinic leadership who will decide how and when to present to and discuss findings with staff.

4. Reflective Supervision. Reflective supervision is an evidence-based professional development intervention focusing on the relationship and process of collaborative case consultation and reflection for clinicians providing psychosocial support.[43,44] Reflective supervision provides strategic guidance to increase self-reflectiveness, self-awareness, and encourages participants to independently process clinical encounters and solve challenges. These skills have been shown to improve patient care.[45,46] To our knowledge, there are no existing Reflective Supervision models tailored to OTP staff. Therefore, we adapted the standard reflective supervision practices to apply and be accessible to all OTP staff who have intensive and consultative interactions with patients. These staff roles such as case managers, counselors, and peer support staff. Reflective supervision will begin in Month 1 of the intervention period and will continue on a biweekly basis throughout the intervention period at each of the MPACT enrolled clinics. Sessions will be facilitated by a reflective supervisor, a clinically licensed staff member, trained by the MPACT study clinician.

AIM 2: Determine MPACT implementation feasibility, acceptability and preliminary effect on methadone treatment practice change and clinic culture

AIM 3: Determine the preliminary effect of MPACT on methadone treatment retention, and patient posttraumatic stress symptoms.

A single arm 5.5-month pilot study of MPACT will address AIMS 2 and 3 and involves two Arizona-based OTPs (1 rural and 1 urban), 100 patients and 22 staff (25 patients and 6 staff of the rural clinic, and 75 patients and 16 staff of the urban clinic). Data collection through online survey of staff participants, and online or phone survey of patient participants will occur monthly during the study period which began in October of 2024 and ending in March of 2025. The four elements of MPACT the intervention will be delivered over a 4-month period following study recruitment. Eligibility criteria for study inclusion include being 18 years of age or older, being a staff member or a patient at one of the two pilot clinics and being willing to participate in monthly surveys during the study period, and (for patients), agreeing to study review of selected components of their medical charts.

Measures

The primary study outcome is increased patient methadone treatment retention. This outcome is measured in three ways: 1) time to first treatment interruption, calculated as the number of days to first missed dose from day zero (MPACT enrollment), 2) active in treatment, a binary (yes/no) if receiving dose at points in time on day 0, day 30, day 60, day 90, day 120, 3) continuous days in treatment during the study period, calculated as time (days) to discharge. Data measuring this outcome will be gathered by patient survey and chart review.

Secondary study outcomes include reductions in vicarious trauma and posttraumatic stress symptoms among enrolled clinic staff and posttraumatic stress symptoms among enrolled patients. Data measuring secondary outcomes will be gathered by survey of staff and patients enrolled in the study. For staff and patients, posttraumatic stress symptoms will be measured using the 8-item Post Traumatic Stress Disorder symptoms screener (PCL-5).[47,48] Staff vicarious trauma will be measured by the Vicarious Trauma Scale (VTS),[49] burnout will be measured by a 9-item scale,[50] and compassion satisfaction and compassion fatigue will be measured by the shortened, 9-item SProQOL.[51]

The degree to which methadone treatment is patient centered is also a secondary outcome measured through staff surveys (assessing whether they believe they are providing it) and patients surveys (assessing whether they feel they are experiencing it). Patient centered care competency will be measured by a 19-item scale[52] including the following subscales: respecting patient perspectives, promoting patient involvement in the care process, providing patient support, advocating for patients. Patient-centered care, as defined by the study team, will be measured using a 5-item instrument that reflects the concepts of patient-centered care introduced during the accredited training modules. This scale will be administered to staff, with an adapted version used for patients.

Other individual-level variables of interest for the staff participants include: 1) personal characteristics – demographics, personal substance use disorder and treatment experience, trauma exposure history (measured

by the LEC-5),[53] 2) work characteristics - training, education and licensure related to their clinic role, 3) empowerment using a 5-item empowerment scale,[54] 4) stigma- toward people with opioid use disorder with a 9-item scale,[55] self-stigma with a 9-item scale,[56] and fear of enacted stigma through a 9-item scale,[57] 5) beliefs - about trauma informed care measured by the ARTIC (Attitudes toward trauma informed care)[58] and about abstinence measured by the Abstinence Orientation Scale;[59] 6) comfort with targeted practices related to the most recent federal changes to methadone treatment delivery measured by items adapted from prior studies measuring comfort with practices,[60,61,62] and 7) fidelity to MPACT – the degree to which the clinic implements the MPACT intervention.

Other individual-level variables of interest for the patient participants include: 1) personal characteristics – demographics, housing, trauma history (LEC-5), trauma symptoms (PCL-5), 2) methadone treatment -time in treatment, dose sufficiency, 3) empowerment – as measured by a 15-item scale[63] and through an adapted 16-item KIM Alliance scale, [64] and 4) fidelity to MPACT – the degree to which the clinic implements the MPACT intervention.

As this is a hybrid (implementation/effectiveness) pilot and trial, we are specifically focused on reach, implementation, adoption and (in the trial) maintenance using the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) framework.[65] Measures collected for the pilot will also be collected for the trial.

Data Collection

Primary and secondary study outcomes will be measured by surveys and patient chart reviews. Surveys will be administered monthly for the pilot study: A1 (baseline at enrollment), A2-A5 in 30-day sequences through the study period, with contact reminder at day 27 and completion forgiveness period of 5 days (day 35). Figure 3 displays the sequencing of measures across the 5 pilot surveys.

Figure 3 about here
Caption: Sequencing of MPACT Primary and Secondary Measures (A1-A5)

For the 20-month trial, there will be 8 surveys from baseline at enrollment (A1) and the remaining seven conducted every 77 days. Survey responses will be collected using the Qualtrics platform (Provo, Utah), accessible directly by participants or by the study staff for patient participants who choose to complete the survey over the phone. In such cases, the survey will be read verbatim to the patient, and their responses will be entered into the survey database in real time. Participants will be offered financial remuneration totaling $100 for the completion of all 5 surveys on time and during the study period.

For all enrolled patients, a review of their methadone clinic medical chart will include the duration of their treatment at the clinic, from treatment initiation to discharge or study end, whichever occurs first. This review will take place at the conclusion of the study period in accordance with the data sharing agreement (DSA) between the clinic organization and the University of Arizona. A feasibility test with a sample of 50 charts with de-identified data was conducted in June 2024 and confirmed timely data transfer, data completeness and utility for outcome measurement. The following medical chart segments will be reviewed as part of the study: 1) the digest of patient history of starting and leaving treatment at that clinic (dates), 2) case notes, 3) discharge summary, 4) treatment plans, 5) milligram dosing, and 6) take home medication status over time. Case notes include qualitative data on patient stability, challenges reported by the patient (e.g housing, transportation, safety, dosing sufficiency et cetera), and instances of missed doses. For the trial, the data will be transferred using unique identifiers that will correspond with the study unique identifiers. No personally identifying information (name, street address) will be transferred.

Study Recruitment

Recruitment will be stepwise for both the pilot and the trial. As noted, the pilot is already under way. For the national trial, clinics will first be recruited through email from a national list of methadone clinics responding to a prior survey by this team during 2024.[66] A second strategy will involve an email to the state opioid treatment authorities (SOTA) with a request to forward study information and the recruitment flyer to methadone clinic directors in their state. SOTAs are the single opioid regulator in each state. Clinics that allow study recruitment among staff and patients, establish a data sharing agreement for the transfer of

patient study participants at the conclusion of the 20 month trial, and identify a clinic 'champion' to assist with study enrollment and study contact will be eligible for randomization as described below.

Following clinic enrollment, each clinic champion will post recruitment flyers in staff-only areas (for staff participants) and in patient-only areas (for patient participants). Recruitment flyers for staff lead to an online study portal presenting information about the study and requesting agreement to participate. If agreement is made, staff participants will immediately complete the enrollment survey (baseline A1). The same process will occur for patients with the addition of a study phone number that can be called for those seeking to learn about the study and potentially enroll over the phone.

Patient and staff confidentiality will be maintained by centralizing the enrollment process. Recruitment flyers will be displayed in staff-only and patient-only areas with a QR code/URL, and (for patients) a phone number to learn more about the study and to enroll. This process ensures the anonymity of study participants within the clinic, meaning that patients and staff participants will not be known to the study clinic. Further, at the time of enrollment, a unique identifier will be established by the participant and will be used henceforth. At no time with the clinic leadership or clinic champion know the identity of study participants. The only exception to this is at the conclusion of the study when patient chart data transfer will occur, and at that time only one person handling data transfer will have the name and birth dates for the participants whose chart will be transferred for study purposes.

Fidelity Tracking

MPACT fidelity tracking will assess the degree to which clinics assigned to the intervention arm implement MPACT components. This will be evaluated during biweekly telephone conversations with the Clinic Champion during the pilot study and monthly contact during the trial. A Fidelity Tracker will first be populated with data from study databases, including accredited training completion, TICA survey participation (percentage of staff completing surveys), the number of anonymous wellness self-screenings, and reflective supervision participation (number of staff by role per biweekly session). During fidelity

conversations, the clinic champion will indicate the number of wellness trainings offered staff (current or new staff) in the past two weeks, whether posters for the screener were shared in the staff-only areas, and whether there were other issues raised by staff about MPACT participation that may require troubleshooting.

Phase 2, Years 3-6: Hybrid, cluster randomized controlled trial

AIM 4: Quantify the effects of MPACT on methadone treatment practice change and clinic culture.

AIM 5: Determine the efficacy of MPACT on methadone treatment retention and patient and staff posttraumatic stress symptoms outcomes.

AIM 6: Evaluate the effect of patient and staff trauma on primary outcomes and staff MPACT implementation.

Findings from the pilot will determine preliminary effect size to confirm power analyses and final sampling for a Hybrid Type 1, 20-month cluster randomized controlled trial among 40 clinics, 800 patients (20 per clinic) and 520 staff (13 per clinic). This Hybrid Type 1 trial will focus primarily on MPACT's effect outcomes while examining the association of MPACT implementation fidelity and acceptability and identifying the multilevel factors influencing implementation.

For the trial, the clinic is the unit of randomization. The intervention condition will be the MPACT intervention and the control condition will involve an accredited training about methadone that does not overlap aspects of the MPACT intervention. As shown in Figure 4, we will allow a 20-month study period to accommodate staggered trial initiation through month 12 of year 4. Given the 15-month trial period, we will allow for new staff members to enroll through the end of the 7th month of their site's trial period.

Figure 4

Caption: Cluster Randomized Controlled Trial of MPACT

Clinic stratification factors. By the time of trial planning finalization, we anticipate that the state regulatory environment in each trial location will be a likely outer setting impact. Given the importance of state policy for regulating OTPs and methadone treatment, we will measure state regulatory favorability toward OTPs using a two-level coding structure used in prior studies by this team.[67,68] We will code state laws based on the Pew state regulatory review[69] as 'expanding methadone access" or "not expanding/limiting access." Randomization to trial condition will be stratified based on outcomes of this state regulatory coding.

Statistical Analysis

Our primary outcome is patient time to first treatment interruption (confirmed in pilot). Secondary outcomes include retention (yes/no) at selected time points (1, 3, 6, and 12 months) and time to treatment discontinuation. To accommodate the clustering induced by nesting patients within clinics, we will use a mixed effects Cox proportional hazards model (shared frailty model)[70,71] to accommodate differential survival probability among clusters. The mixed model will include a random intercept for clinic and fixed treatment effect for MPACT/control assignment. We will also include patient level covariates for age, sex, and time under methadone maintenance treatment.

Our initial sample size calculation uses asymptotic normal results for log hazard ratio (HR) as well as sample size inflation factors (e.g., Donner)[72] for cluster-randomized trials. In designing the future R33 trial we will make use of specific sample size methods for cluster randomized trials with time-to-event outcomes.[73,74] The relative frequency of first treatment interruption[75] is estimated as 66% at 12 months of MMT until we have confirmation from the pilot. We evaluate the number of clinics and number of patients assuming that MPACT intervention reduces this frequency to 45%, 50% and 55%. The power curves based on independent observations (no cluster effect) are shown in Figure 5. The graph shows that recruitment of 40 clinics, with 20 patients per clinic, provides greater than 80% power to detect a difference in treatment interruption rates of 66% (control) and 55% (MPACT) with α=0.05. Consistent with the cluster randomization trial design, we also consider the average number of patients per clinic as 10, 20, 40, and different degrees of intra-clinic clustering using intra-class correlation coefficients (ICC) of 0.05 and 0.10.

Figure 5 about here

Caption: Number of clinics and patients for 80% power (vs.66% treatment interruption rate), MPACT trial

Conclusion

The MPACT study will provide a foundation for an evidence-based, staff-level intervention aimed at improving patient retention in MMT. Future studies should examine the individual components of MPACT to determine their differential contributions to the primary outcome of patient MMT retention, and to secondary outcomes of staff and patient reduction in stress symptoms.

Acknowledgments
We are grateful to the MPACT Community and Staff Groups for their contributions to this study. We also thank the Drug Policy Research and Advocacy Board (DPRAB) for their support and direction to improve the health of people who use drugs. Research reported in this publication was supported by the National Institute On Drug Abuse of the National Institutes of Health under Award Number R61DA059889. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Abbreviations

CE: Continuing Education
CME: Continuing Medical Education
DPRAB: Drug Policy Research and Advocacy Board
IRB: Institutional Review Board (human subjects protection)
MMT: Methadone treatment
MOUD: Medication for Opioid Use Disorder
MPACT: Methadone Patient Access to Collaborative Treatment
OTP: Opioid Treatment Program (“methadone clinic”)
OUD: Opioid Use Disorder
PHE: COVID Public Health Emergency
PTSS: Posttraumatic Stress Symptoms
SOTA: State Opioid Treatment Authority
TICA: Trauma Informed Clinic Assessment (part of the MPACT intervention)
VT: Vicarious Trauma

Data Availability

Data from the pilot and trial will be coded for sufficient de-identification and shared to the HEAL data ecosystem within one year of pilot and of trial conclusion, or at the time of first publication from the pilot (or trial), whichever occurs first.

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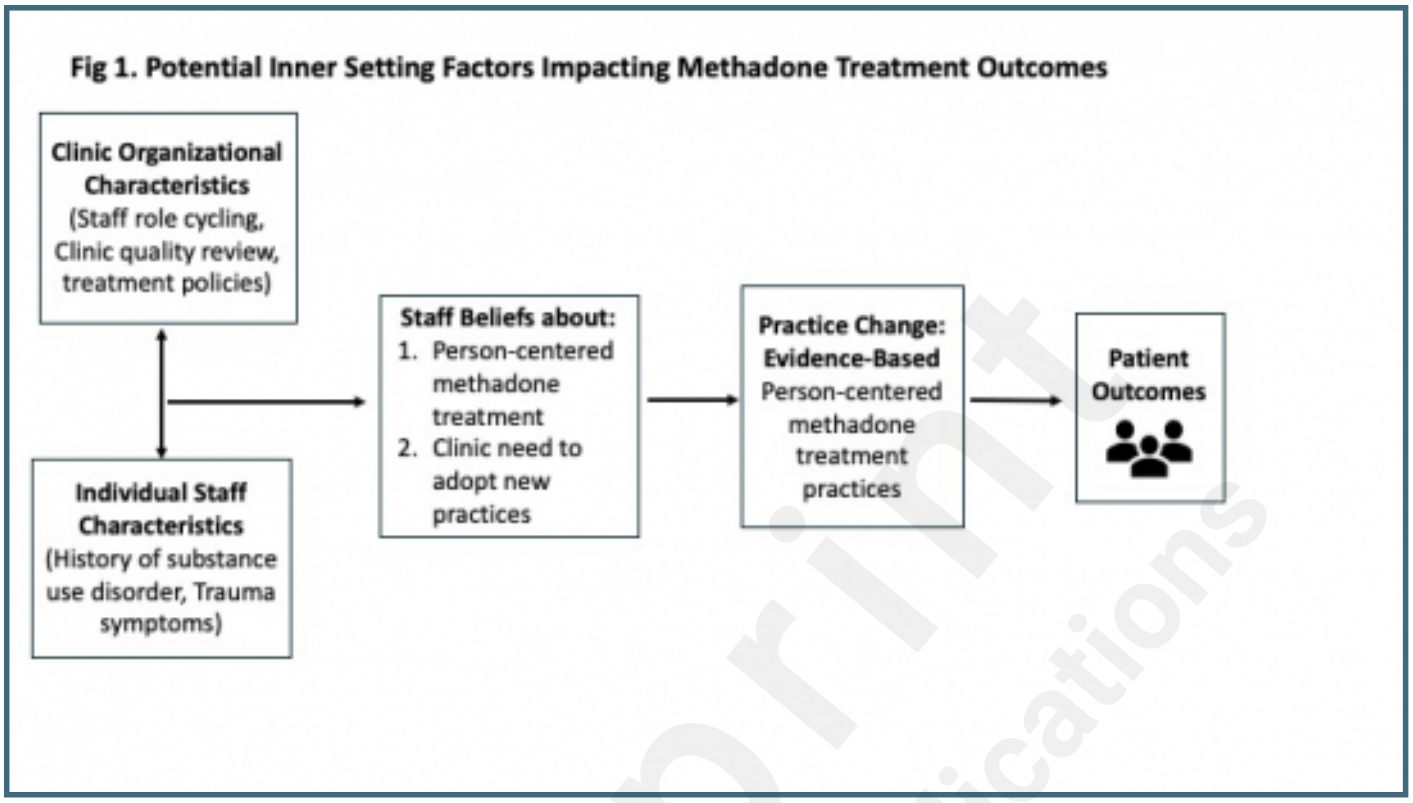
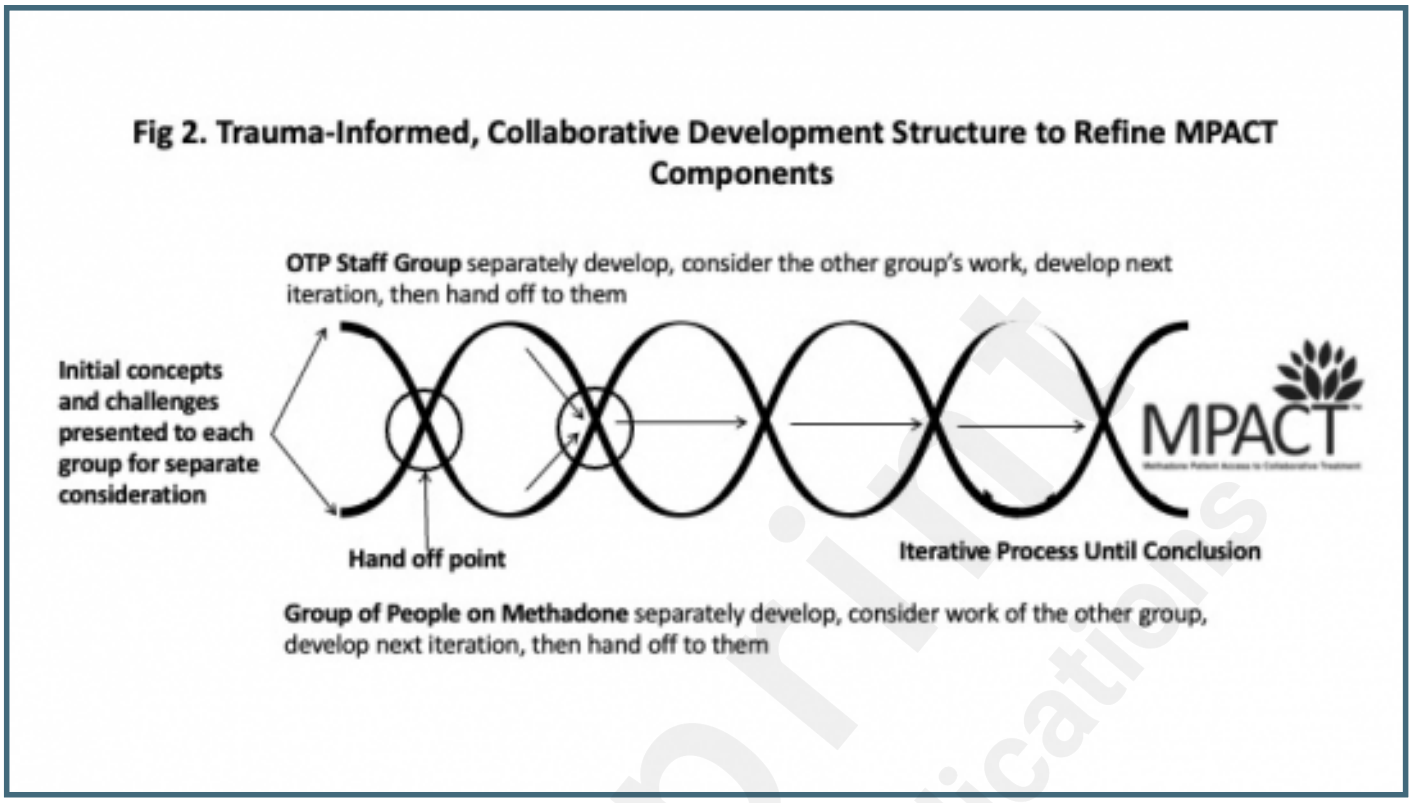
Supplementary Files

Figures

Potential Inner Setting Factors Impacting Methadone Treatment Outcomes.



Trauma-Informed, Collaborative Development Structure to Refine MPACT Components.



Sequencing of MPACT Primary and Secondary Measures (A1-A5).

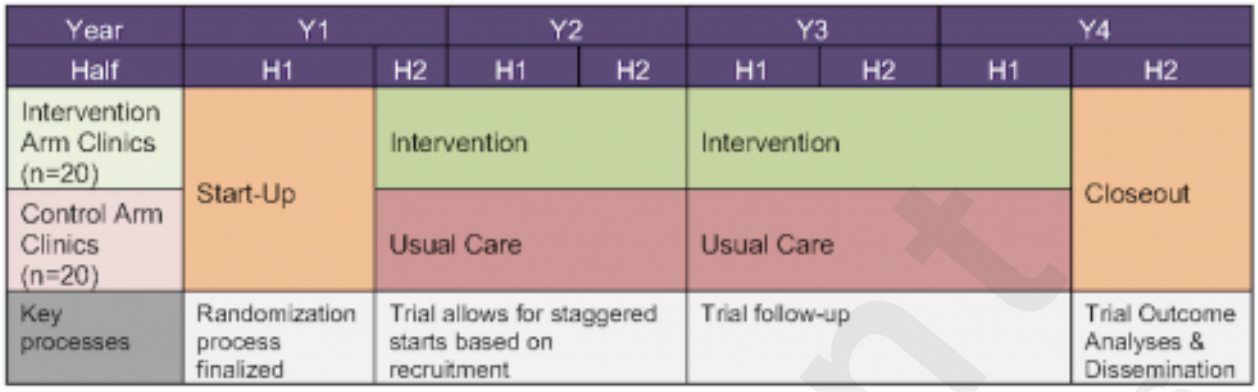
Figure 3. Sequencing of MPACT Primary and Secondary Measures (A1-A5)

	A1 (Enrollment)		A2	A3	A4	A5
Construct	Staff Items (#)	Patient Items (#)				(Study Conclusion)
Personal Characteristics						
Demographics	5	6				
Personal SUD experience	10					
Methadone Treatment						
Time in MMT and clinic, reasons for methadone		13				
Methadone interruption		2	X	X	X	X
Dose, sufficiency, OD		13	X	X	X	X
Trauma History & Symptoms						
Trauma History (LEC)	17	17				
Vicarious Trauma Scale	8			X		X
PCL-5 (Trauma Symptoms)	8	8		X		X
Burnout, Compassion Fatigue						
Burnout Scale	9		X	X	X	X
ProQoL (Compassion fatigue, Compass Sat, Burnout)	9		X	X	X	X
Work Characteristics						
Years working (SUD and this clinic) and role	5		X	X	X	X
Training and education for role	2					
Baseline exposure to MPACT related practices						
Reflect Sup (some staff)	1		X	X	X	X
Self-Care	9			X		X
MPACT specific practices	9		X	X	X	X
Empowerment						
Staff Empowerment Scale	5			X		X
Patient Empowerment (Bann Scale)		15	X	X	X	X
Beliefs						
Abstinence Orientation Scale	11			X		X
Comfort with MMT innovations	10			X		X
ARTIC (Attitudes toward trauma informed care)	10					X
Person Centered Climate (PCQ-S)	5			X		X
Stigma						
Stigma toward people with OUD	8					X
Self-Stigma	9					X
Fear of enacted stigma	9					X
Patient Centered Care Practices						
PCC (person centered competence)	19			X		X
Team-derived PCC Scale	6	6	X	X	X	X
KIM Alliance Scale		16	X	X	X	X
Implementation						
MPACT feasibility, accept and fit; likelihood of continuing practices						9

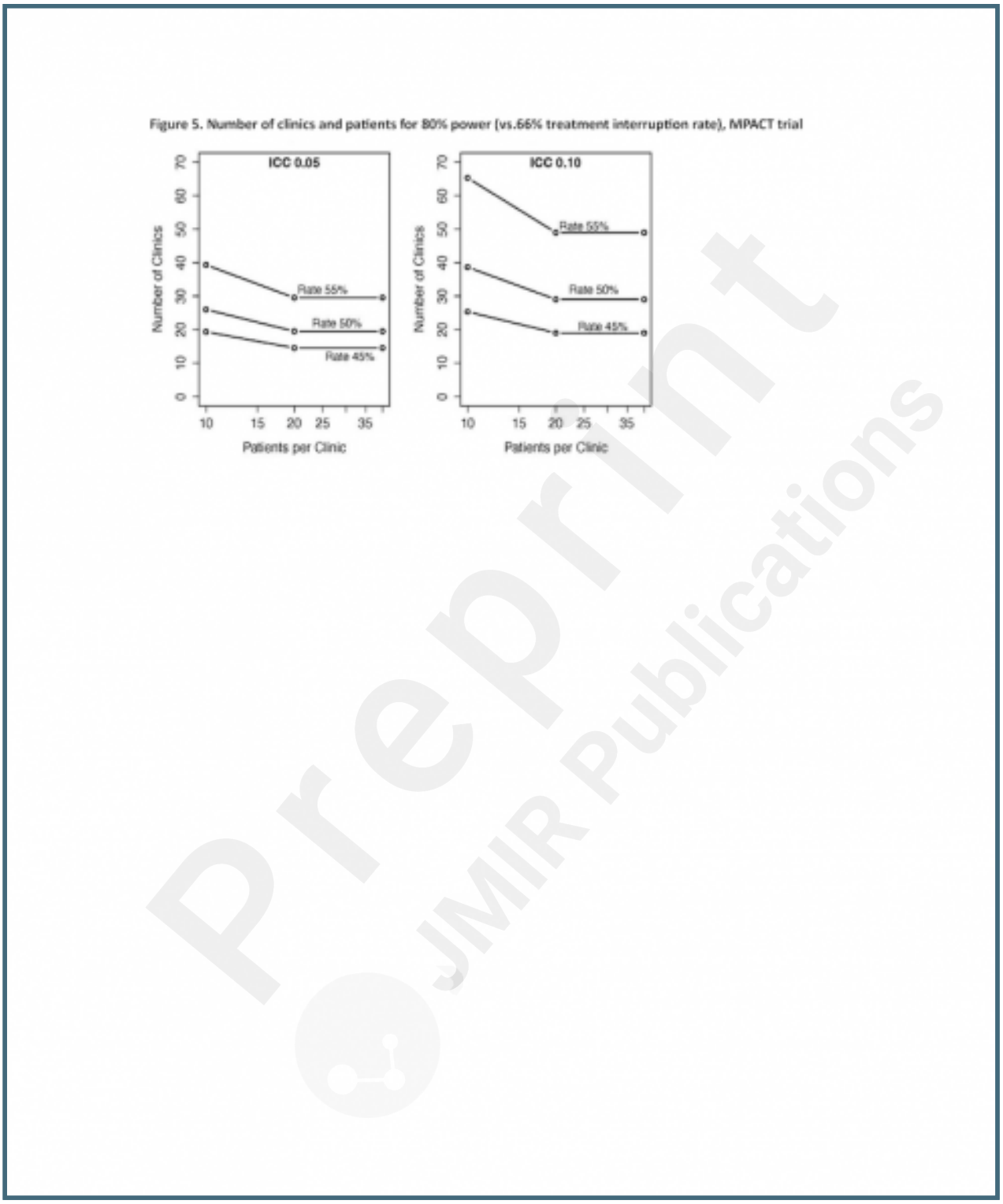
Abbreviations: SUD (substance use disorder), MMT (methadone treatment), OD (overdose), OUD (opioid use disorder)

Cluster Randomized Controlled Trial of MPACT.

Figure 4: Cluster Randomized Controlled Trial of MPACT



Number of clinics and patients for 80% power (vs.66% treatment interruption rate), MPACT trial.



Multimedia Appendixes

Summary Statement with Peer Reviews for the MPACT Grant.
URL: http://asset.jmir.pub/assets/21fed1895ac7c7bd672655ef85a6603e.pdf

CONSORT (or other) checklists

CrEDIT.
URL: http://asset.jmir.pub/assets/8aeac3a8ca975a0f2b7a80e1b474b257.pdf