FY 2020 Houston EMA Ryan White Part A/MAI Service Definition **Clinical Case Management**	
HRSA Service Category Title: **RWGA Only**	**Medical Case Management**
Local Service Category Title:	**Clinical Case Management (CCM)**
Budget Type: **RWGA Only**	**Unit Cost**
Budget Requirements or Restrictions: **RWGA Only**	Not applicable.
HRSA Service Category Definition: **RWGA Only**	***Medical Case Management services (including treatment adherence)*** are a range of client-centered services that link clients with health care, psychosocial, and other services. The coordination and follow-up of medical treatments is a component of medical case management. These services ensure timely and coordinated access to medically appropriate levels of health and support services and continuity of care, through ongoing assessment of the client's and other key family members' needs and personal support systems. Medical case management includes the provision of treatment adherence counseling to ensure readiness for, and adherence to, complex HIV/AIDS treatments. Key activities include (1) initial assessment of service needs; (2) development of a comprehensive, individualized service plan; (3) coordination of services required to implement the plan; (4) client monitoring to assess the efficacy of the plan; and (5) periodic re-evaluation and adaptation of the plan as necessary over the life of the client. It includes client-specific advocacy and/or review of utilization of services. This includes all types of case management including face-to-face, phone contact, and any other forms of communication.
Local Service Category Definition:	**Clinical Case Management**: Identifying and screening clients who are accessing HIV-related services from a clinical delivery system that provides Mental Health treatment/counseling and/or Substance Abuse treatment services; assessing each client's medical and psychosocial history and current service needs; developing and regularly updating a clinical service plan based upon the client's needs and choices; implementing the plan in a timely manner; providing information, referrals and assistance with linkage to medical and psychosocial services as needed; monitoring the efficacy and quality of services through periodic reevaluation; advocating on behalf of clients to decrease service gaps and remove barriers to services helping clients develop and utilize independent living skills and strategies. Assist clients in obtaining needed resources, including bus pass vouchers and gas cards per published HCPHS/RWGA policies.
Target Population (age,	Services will be available to eligible HIV-infected clients residing in

gender, geographic, race, ethnicity, etc.):	the Houston EMA with priority given to clients most in need. All clients who receive services will be served without regard to age, gender, race, color, religion, national origin, sexual orientation, or handicap. Services will target low income individuals with HIV/AIDS who demonstrate multiple medical, mental health, substance use/abuse and psychosocial needs including, but not limited to: mental health counseling (i.e. professional counseling), substance abuse treatment, primary medical care, specialized care, alternative treatment, medications, placement in a medical facility, emotional support, basic needs for food, clothing, and shelter, transportation, legal services and vocational services. Services will also target clients who cannot function in the community due to barriers which include, but are not limited to, mental illness and psychiatric disorders, drug addiction and substance abuse, extreme lack of knowledge regarding available services, inability to maintain financial independence, inability to complete necessary forms, inability to arrange and complete entitlement and medical appointments, homelessness, deteriorating medical condition, illiteracy, language/cultural barriers and/or the absence of speech, sight, hearing, or mobility. *Clinical Case Management* is intended to serve eligible clients, especially those underserved or unserved population groups which include: African American, Hispanic/Latino, Women and Children, Veteran, Deaf/Hard of Hearing, Substance Abusers, Homeless and Gay/Lesbian/Transsexual.
Services to be Provided:	Provision of Clinical Case Management activities performed by the Clinical Case Manager. *Clinical Case Management* is a working agreement between a client and a Clinical Case Manager for a defined period of time based on the client's assessed needs. *Clinical Case Management* services include performing a comprehensive assessment and developing a clinical service plan for each client; monitoring plan to ensure its implementation; and educating client regarding wellness, medication and health care compliance in order to maximize benefit of mental health and/or substance abuse treatment services. The *Clinical Case Manager* serves as an advocate for the client and as a liaison with mental health, substance abuse and medical treatment providers on behalf of the client. The Clinical Case Manager ensures linkage to mental health, substance abuse, primary medical care and other client services as indicated by the clinical service plan. The Clinical Case Manager will perform *Mental Health* and *Substance Abuse/Use Assessments* in accordance with RWGA Quality Management guidelines. Service plan must reflect an ongoing discussion of mental health treatment and/or substance abuse treatment, primary medical care and medication adherence, per client need. *Clinical Case Management is* both office and community-based. Clinical

	Case Managers will interface with the primary medical care delivery system as necessary to ensure services are integrated with, and complimentary to, a client's medical treatment plan.
Service Unit Definition(s): **RWGA Only**	One unit of service is defined as 15 minutes of direct client services and allowable charges.
Financial Eligibility:	Refer to the RWPC's approved *Financial Eligibility for Houston EMA Services*.
Client Eligibility:	HIV-infected individuals residing in the Houston EMA.
Agency Requirements:	*Clinical Case Management* services will comply with the HCPHS/RWGA published Clinical Case Management Standards of Care and policies and procedures as published and/or revised, including linkage to the CPCDMS data system *Clinical Case Management Services* must be provided by an agency with a documented history of, and current capacity for, providing mental health counseling services (categories b., c. and d. as listed under *Amount Available* above) or substance abuse treatment services to PLWH/A (category a. under *Amount Available* above) in the Houston EMA. Specifically, an applicant for this service category must clearly demonstrate it has provided mental health treatment services (e.g. professional counseling) or substance abuse treatment services (as applicable to the specific CCM category being applied for) in the previous calendar or grant year to individuals with an HIV diagnosis. Acceptable documentation for such treatment activities includes standardized reporting documentation from the County's *CPCDMS* or Texas Department of State Health Services' *ARIES* data systems, Ryan White Services Report (RSR), SAMSHA or TDSHS/SAS program reports or other verifiable published data. Data submitted to meet this requirement is subject to audit by HCPHS/RWGA prior to an award being recommended. **Agency-generated non-verifiable data is not acceptable.** In addition, applicant agency must demonstrate it has the capability to continue providing mental health treatment and/or substance abuse treatment services for the duration of the contract term and any subsequent one-year contract renewals. Acceptable documentation of such continuing capability includes current funding from Ryan White (all Parts), TDSHS HIV-related funding (Ryan White, State Services, State-funded Substance Abuse Services), SAMSHA and other ongoing federal, state and/or public or private foundation HIV-related funding for mental health treatment and/or substance abuse treatment services. Proof of such funding must be documented in the application and is subject to independent verification by HCPHS/RWGA prior to an award being recommended. Loss of funding and corresponding loss of capacity to provide mental health counseling or substance abuse treatment services as applicable may result in the termination of Clinical Case Management Services

	awarded under this service category. Continuing eligibility for Clinical Case Management Services funding is explicitly contingent on applicant agency maintaining verifiable capacity to provide mental health counseling or substance abuse treatment services as applicable to PLWH/A during the contract term. **Applicant agency must be Medicaid and Medicare Certified**.
Staff Requirements:	Clinical Case Managers must spend at least 42% (867 hours per FTE) of their time providing direct case management services. Direct case management services include any activities with a client (face-to-face or by telephone), communication with other service providers or significant others to access client services, monitoring client care, and accompanying clients to services. Indirect activities include travel to and from a client's residence or agency, staff meetings, supervision, community education, documentation, and computer input. Direct case management activities must be documented in the Centralized Patient Care Data Management System (CPCDMS) according to CPCDMS business rules. *Must comply with applicable HCPHS/RWGA Houston EMA/HSDA Part A/B Ryan White Standards of Care:* <u>Minimum Qualifications:</u> **Clinical Case Managers** must have at a minimum a Bachelor's degree from an accredited college or university with a major in social or behavioral sciences and have a current and in good standing State of Texas license (LBSW, LSW, LMSW, LCSW, LPC, LPC-I, LMFT, LMFT-A or higher level of licensure). The Clinical Case Manager may supervise the Service Linkage Worker. CCM targeting Hispanic PLWHA must demonstrate both written and verbal fluency in Spanish. <u>Supervision:</u> The **Clinical Case Manager** (CCM) must function with the clinical infrastructure of the applicant agency and receive supervision in accordance with the CCM's licensure requirements. At a minimum, the CCM must receive ongoing supervision that meets or exceeds HCPHS/RWGA published Ryan White Part A/B Standards of Care for Clinical Case Management. If applicant agency also has Service Linkage Workers funded under Ryan White Part A the CCM may supervise the Service Linkage Worker(s). Supervision provided by a CCM that is <u>not</u> client specific is considered **indirect time** and is not billable.
Special Requirements: **RWGA Only**	Contractor must employ full-time Clinical Case Managers. Prior approval must be obtained from RWGA to split full-time equivalent (FTE) CCM positions among other contracts or to employ part-time staff. **Contractor must provide to RWGA the names of each Clinical Case Manager and the program supervisor no later than 3/30/17. Contractor must inform RWGA in writing of any**

	changes in personnel assigned to contract within seven (7) business days of change. Contractor must comply with CPCDMS data system business rules and procedures. Contractor must perform CPCDMS new client registrations and registration updates for clients needing ongoing case management services as well as those clients who may only need to establish system of care eligibility. Contractor must issue bus pass vouchers in accordance with HCPHS/RWGA policies and procedures.

FY 2022 RWPC "How to Best Meet the Need" Decision Process

Step in Process: **Council**		Date: **06/10/2021**
Recommendations:	Approved: Y:_____ No: ______ Approved With Changes:______	If approved with changes list changes below:
1.		
2.		
3.		
Step in Process: **Steering Committee**		Date: **06/03/2021**
Recommendations:	Approved: Y:_____ No: ______ Approved With Changes:______	If approved with changes list changes below:
1.		
2.		
3.		
Step in Process: **Quality Improvement Committee**		Date: **05/18/2021**
Recommendations:	Approved: Y:_ ___ No: ______ Approved With Changes: _______	If approved with changes list changes below:
1.		
2.		
3.		
Step in Process: **HTBMTN Workgroup #1**		Date: **04/20/2021**
Recommendations:	Financial Eligibility:	
1.		
2.		
3.		

FY 2019 PERFORMANCE MEASURES HIGHLIGHTS
RYAN WHITE GRANT ADMINISTRATION
HARRIS COUNTY PUBLIC HEALTH (HCPH)

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Summary Reports for all Services

Highlights from FY 2019 Performance Measures

Measures in this report are based on the 2019/2020 Houston Ryan White Quality Management Plan, Appendix B. HIV Performance Measures.

Clinical Case Management

- During FY 2019, from 3/1/2019 through 2/29/2020, 1,299 clients utilized Part A clinical case management. According to CPCDMS, 732 (56%) of these clients accessed primary care two or more times at least three months apart during this time period after utilizing clinical case management.
- Among these clients, 32% accessed mental health services at least once during this time period after utilizing clinical case management.
- For clients who have lab data in CPCDMS, 80% were virally suppressed.

Ryan White Part A
HIV Performance Measures
FY 2019 Report

Clinical Case Management

All Providers

For FY 2019 (3/1/2019 to 2/29/2020), 1,299 clients utilized Part A clinical case management.

HIV Performance Measures	FY 2018	FY 2019	Change
A minimum of 75% of clients will utilize Part A/B/C/D primary care two or more times at least three months apart after accessing clinical case management	542 (49.5%)	732 (56.4%)	**6.9%**
35% of clinical case management clients will utilize mental health services	328 (30.0%)	413 (31.8%)	**1.8%**
75% of clients for whom there is lab data in the CPCDMS will be virally suppressed (<200)	453 (78.6%)	548 (80.2%)	**1.6%**
Less than 15% of clients will be homeless or unstably housed	164 (15.0%)	142 (10.9%)	**-4.1%**

According to CPCDMS, 24 (1.9%) clients utilized primary care for the first time and 97 (7.5%) clients utilized mental health services for the first time after accessing clinical case management.

Clinical Chart Review Measures	FY 2018
85% of clinical case management clients will have a case management care plan developed and/or updated two or more times in the measurement year	3%
Percentage of clients identified with an active substance abuse condition referred to substance abuse treatment	*100%

Of the 14 clinical case management clients with active substance use disorder, all 14 (100%) received a referral for further treatment.

Harris County
Public Health
Building a Healthy Community

Ryan White Part A
Quality Management Program- Houston EMA
Case Management Chart Review FY 19-20
Ryan White Grant Administration

CUMMULATIVE SUMMARY, DE-IDENTIFIED

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Overview

Each year, the Ryan White Grant Administration Quality Management team conducts chart review in order to continuously monitor case management services and understand how each agency implements workflows to meet quality standards for their funded service models. This process is a supplemental complement to the programmatic and fiscal audit of each program, as it helps to provide an overall picture of quality of care and monitor quality performance measures.

A total of 661 medical case management client records were reviewed across seven of the ten Ryan White-Part A funded agencies, including a non-primary care site that provides Clinical Case Management services. The dates of service under review were March 1, 2019- February 28, 2020. The sample selection process and data collection tool are described in subsequent sections.

Case Management is defined by the Ryan White legislation as a, “range of client-centered services that link clients with health care, psychosocial, and other services,” including coordination and follow-up of medical treatment and “adherence counseling to ensure readiness for and adherence to HIV complex treatments.” Case Managers assist clients in navigating the complex health care system to ensure coordination of care for the unique needs of People Living With HIV. Continuous assessment of need and the development of individualized service plans are key components of case management. Due to their training and skill sets in social services, human development, psychology, social justice, and communication, Case Managers are uniquely positioned to serve clients who face environmental and life issues that can jeopardize their success in HIV treatment, namely, mental health and substance abuse, poverty and access to stable housing and transportation, and poor social support networks.

Ryan White Part-A funds three distinct models of case management: Medical Case Management, Non-Medical Case Management (or Service Linkage Work), and Clinical Case Management, which must be co-located in an agency that offers Mental Health treatment/counseling and/or Substance Abuse treatment. Some agencies are also funded for Outreach Services, which complement Case Management Services and are designed to locate and assist clients who are on the cusp of falling out of care in order to re-engage and retain them back into care.

The Tool

A copy of the Case Management Chart Review tool is available in the Appendix of this report.

The Case Management Chart Review tool is a pen and paper form designed to standardize data collection and analysis across agencies. The purpose of the tool is to capture information and quantify services that can present an overall picture of the quality of case management services provided within the Ryan White Part-A system of care. This way, strengths and areas of improvement can be identified and continuously monitored.

The coversheet of the chart abstraction tool captures basic information about the client, including their demographics, most recent appointments and lab results, and any documented psychological, medical, or social issues or conditions that would be documented in their medical record.

The content of the second sheet focuses on coordination of case management services. There is space for the chart abstractor to record what type of worker assisted the client (Medical Case Manager, Service Linkage Worker, Outreach Worker or Clinical Case Manager) and what types of services were provided. Any notes about case management closure are recorded, as well as any assessments or service plans or documented reasons for the absence of assessments or service plans.

The Sample

In order to conduct a thorough and comprehensive review, a total of 661 client records were reviewed across seven agencies for the 2019-2020 grant year. This included eighty-four (84) Clinical Case Management charts at a non-primary care site. In this Case Management Chart Review Report, any section that evaluated a primary care related measure excludes the sample of the non-primary care site. Minimum sample size was determined in accordance with *Center for Quality Improvement & Innovation* sample size calculator[2] based on the total eligible population that received case management services at each site.

Agency	A	B	C	D	E	F	G
# of Charts Reviewed	105	105	105	97	79	86	84

TOTAL 661 (577 excluding non-PCare site)

For each agency, a randomized sample of clients who received a billable Ryan White- A service under at least one (1) of eleven (11) case management subcategory codes during the March 1, 2019- February 28, 2020 grant year was queried from the Centralized Patient Care Data Management System data base. Each sample was determined to be comparable to the racial, ethnic, age, and gender demographics of each site's overall case management patient population.

Cumulative Data Summaries

APPOINTMENTS & ENCOUNTERS

The number of HIV-related primary care appointments and case management encounters in the given year were counted for each client.

HIV-RELATED PRIMARY CARE APPOINTMENTS

For this measure, the number of face-to-face encounters for an HIV-related primary care appointment with a medical provider was counted. Any number of appointments above three per year was simply coded as 3 appointments. Any Viral Load/CD4 count lab test that accompanied the appointment was also recorded.

HIV MEDICAL # appt	A	B	C	D	E	F	TOTAL	PERCENT
0	10	10	16	16	4	14	70	**12%**
1	22	13	18	4	21	18	96	**17%**
2	39	20	16	8	20	15	118	**20%**
3	34	62	55	69	34	39	293	**51%**
Total	*105*	*105*	*105*	*97*	*79*	*86*	*577*	

The overall sample trends towards a higher number of primary care appointment in the year, with the majority of the case management review clients having at least 3 appointments in the year (51%), followed by 20% of the clients having 2 appointments in the year.

CASE MANAGEMENT ENCOUNTERS

Frequency of case management encounters were also reviewed. The number and types of the encounters (face-to-face vs. phone), as well as who provided the service (Clinical, Medical, Non-Medical Case Manager or Outreach Worker) were also recorded.

The distribution of frequency of case management encounters could be described as an inverted bell curve, with most of the clients clustering either at the low end of one encounter (33%) within the year or more than 5 encounters (26%).

> *“Overall, the average number of case management encounters for the entire sample was* ***three (3)****.”*

CASE MGMNT # appointments	A	B	C	D	E	F	G	TOTAL	PERCENT
1	39	32	36	31	30	27	25	220	**33%**
2	24	26	19	16	15	12	11	123	**19%**
3	18	13	14	13	10	13	6	87	**13%**
4	11	8	10	12	7	6	3	57	**9%**
5	13	26	26	25	17	28	39	174	**26%**
Total	*105*	*105*	*105*	*97*	*79*	*86*	*84*	*661*	

VIRAL SUPPRESSION

Any results of HIV Viral Load + CD4 count laboratory tests that accompanied HIV-related primary care appointments were recorded as part of the case management chart abstraction. Up to three laboratory tests could be recorded. Lab results with an HIV viral load result of less than 200 copies per milliliter were considered to be virally suppressed.

Upon coding, clients who were suppressed for all of their recorded labs (whether they had one, two, or three tests done within the year), were coded as "Suppressed." Clients who were unsuppressed (>200 copies/mL) for all of their labs were coded as "Unsuppressed." Clients who had more than one laboratory test done and were suppressed for at least one and unsuppressed for at least one were coded as "Mixed Status," and clients who had no laboratory tests done within the entire year were coded as "Unknown."

SUPPRESSION STATUS	A	B	C	D	E	F	TOTAL	PERCENT
Suppressed for all labs	69	64	68	54	51	64	370	**64%**
Mixed status	10	12	9	13	14	6	64	**11%**
Unknown (no recent labs on file)	13	10	18	18	7	13	79	**14%**
Unsuppressed for all labs	13	19	10	12	7	3	64	**11%**
Total	*105*	*105*	*105*	*97*	*79*	*86*	*577*	

Across all primary care sites, the case management clients reviewed for these samples had a viral load suppression rate of 64%. In contrast, this result is much lower than what is typical for the Ryan White Part A Houston Primary Care Chart review, which has hovered around 85% for the past several years. This difference may be due to a number of factors, most likely of which is the difference in characteristics of the two reviews' samples. The Primary Care chart review sample is collected from a pool of clients who are considered *in care*, or have at least two medical appointments with a provider with prescribing privileges in the review year. Additionally, "fluctuating viral load" is one of the eligibility criteria for medical case management, so clients who have challenges maintaining a suppressed viral load are more likely to be seen by case management and be included in this sample.

CARE STATUS

The chart abstractor also documented any circumstances in the record for which a client was new, lost, returning to care, or some combination of those care statuses. A client was considered "New to Care," if they were receiving services for the first time at that particular agency (so not necessarily new to HIV treatment or the Houston Ryan White system of care). "Lost to Care" was defined as not being seen for an HIV-related primary care appointment within the last six months and not having a future appointment scheduled, even beyond the review year. "Re-engaged in Care" was defined as any client who was previously lost to care, either during or before the review year, and later attended an HIV-related primary care appointment.

CARE STATUS	A	B	C	D	E	F	TOTAL	PERCENT
New to Care	4	2	7	4	6	5	28	**5%**
Lost to Care	7	12	13	3	3	8	46	**8%**
Re-engaged in Care	7	14	8	6	10	0	45	**8%**
Both New and later Lost to Care in the same review year	1	0	1	0	0	0	2	**<1%**
Re-engaged and later lost again	1	3	0	3	0	2	9	**2%**
N/A	85	77	76	80	60	71	449	**78%**
Total	*105*	*105*	*105*	*97*	*79*	*86*	*577*	

Overall, 5% of the sample was considered New to Care, 8% was Lost to Care, and 8% was Re-engaged in Care.

When a client's attendance met one of the above care statuses, their medical record was reviewed to understand if case management or other staff was involved in coordinating their care. Activities that counted as "Coordination of Care" were any actions that welcomed the client into or back into care or attempted to retain them in care, such as: reminder phone calls, follow-up calls, attendance or introduction at the first appointment, or home visits. For agencies funded for Outreach Services, several progress notes appeared for clients who were lost or re-engaged in care.

COMORBIDITIES

In an effort to understand and document common comorbidities within the Houston Ryan White system of care, co-occurring conditions were recorded, including mental health and substance abuse issues, other medical conditions, and social conditions. This inventorying of co-morbidities may prove particularly helpful for selecting future training topics for case management staff.

MENTAL HEALTH & SUBSTANCE USE DISORDER (history or active)

Any diagnosis of a mental health disorder (MH) or substance use disorder issue (SUD) was recorded in the chart review tool, including a history of mental illness or substance use. All Electronic Medical Records include some variation of a "Problem List" template. This list was often a good source of information for MH and SUD diagnoses, but providers sometimes also documented diagnoses or known histories of illness within progress notes without updating the Problem List. Clients sometimes also self-reported that they had been diagnosed with one of the below conditions by a previous medical provider. Any indication of the presence of mental illness or SUD, regardless of where the information was housed within the medical record, was recorded on the chart abstraction tool. Clients could also have or have had more than one of the MH or SUD issues. Any conditions other than alcohol misuse, other SUD, depression, bipolar disorder, anxiety, or schizophrenia were recorded as "Other." The most common types of conditions that became coded as "Other" were Post-Traumatic Stress Disorder and Adjustment Disorder.

Diagnosis or Issue	A	B	C	D	E	F	G	TOTAL	PERCENT
Alcohol abuse/dependence	5	6	3	4	3	3	11	35	**5%**
Other Substance dependence	17	18	19	16	11	4	19	104	**16%**
Depression	25	41	32	26	13	15	39	191	**29%**
Bipolar disorder	10	6	4	5	4	3	12	44	**7%**
Anxiety	4	21	11	16	8	12	29	101	**15%**
Schizophrenia	4	1	2	0	0	2	6	15	**2%**
Other	11	16	16	29	4	4	15	95	**14%**

Overall, 41% of the sample had either an active diagnosis or history of a mental health or substance abuse issue documented somewhere within their medical record. This is inclusive of the Clinical Case Management site, for which diagnosis with or clinical indication of a MH or SUD issue is an eligibility criteria.

MENTAL HEALTH & SUBSTANCE USE DISORDER REFERRALS

For clients with an *active* diagnosis of a mental health or SUD issue, the chart abstractor recorded if they were referred or already engaged in MH/SUD services. This measure was *not* inclusive of clients who had a previous history of symptoms or whose recovery treatment was considered long complete. Because of this, the percentage in the top row of the previous chart and the percentage of clients considered "N/A" for a MH/SA referral do not equal 100%.

MH referral	A	B	C	D	E	F	TOTAL	PERCENT
N/A	70	54	65	56	57	63	365	63%
Yes	28	42	34	34	20	19	177	31%
No	7	9	6	7	2	4	35	6%
Total	105	105	105	97	79	86	577	

Overall, 63% of the sample would not have been appropriate for a MH or SUD referral based on the information available in their medical record. An additional 31% either did receive a referral or were already engaged in treatment and 6% did not receive a referral.

MEDICAL CONDITIONS

Medical conditions other than HIV were also recorded in an effort to understand what co-occurring conditions may be considered commonly managed alongside HIV within the case management population. Sexually Transmitted Infections and Hypertension were common, at 24% and 23% prevalence within the sample, respectively. Obesity was the most common co-occurring condition that was coded in the "Other" category.

Medical Condition	A	B	C	D	E	F	TOTAL	PERCENT
Smoking (hx or current)	54	31	18	12	10	5	130	23%
Opportunistic Infection	3	2	1	1	1	2	10	2%
STIs	20	37	28	19	23	9	136	24%
Diabetes	16	18	9	11	3	9	66	11%
Cancer	1	1	0	0	0	0	2	0%
Hepatitis	18	8	3	3	2	3	37	6%
Hypertension	43	24	20	22	9	17	135	23%
Other	8	33	21	24	11	30	127	22%

SOCIAL CONDITIONS

Any indication within the medical record that a client had experienced homelessness/housing-related issues, pregnancy/pregnancy-related issues, a release from jail or prison, or intimate partner violence at any point within the review year was recorded in the chart abstraction tool. Homelessness and housing issues were the most commonly identified "Social Condition" within the sample.

Social Issue	A	B	C	D	E	F	G	TOTAL	PERCENT
Homelessness or housing-related issues	6	14	5	4	10	1	6	46	**7%**
Pregnancy or pregnancy-related issues	0	0	1	0	4	2	0	7	**1%**
Recently released	4	3	4	2	3	0	2	18	**3%**
Intimate Partner Violence	1	2	2	1	2	2	12	22	**3%**

COMPREHENSIVE ASSESSMENTS

A cornerstone of service provision within case management is the opportunity for the client to be formally assessed at touchpoints throughout the year for their needs, treatment goals, and action steps for how they will work with the case manager or care team to achieve their treatment goals. Agencies need to use an approved assessment tool and service plan, which may either be the sample tools available through Ryan White Grant Administration or a pre-approved tool of the agency's choosing.

The Ryan White Part-A Standards for medical case management state that a comprehensive assessment should be completed with the client at intake and that they should be re-assessed at least every six months for as long as they are receiving medical case management services. A more formal, comprehensive assessment should be used at intake and annually, and a brief reassessment tool is sufficient at the 6-month mark. In other words, the ideal standard is that every client who receives case management services for an entire year should have at least two comprehensive assessments on file. A service plan should accompany each comprehensive assessment to outline the detailed plan of how the identified needs will be addressed with the client.

# of Comp assessments	A	B	C	D	E	F	G	TOTAL	PERCENT
0	4	13	16	31	5	21	26	116	**18%**
1	1	24	21	12	10	36	23	127	**19%**
2	1	0	3	1	0	4	6	15	**2%**
N/A	99	68	65	53	64	25	31	405	**61%**
Total	105	105	105	97	79	86	84	661	

The client was considered "N/A" for a comprehensive assessment if they did not work with a medical case manager throughout the year. As outlined above, 61% of the sample did not work with a Medical Case Manager within the year. 18% of the sample received zero comprehensive assessments, 19% received one, and 2% received two.

SERVICE PLANS

As mentioned, each comprehensive assessment should be accompanied by a service plan, otherwise known as a care plan, to outline what action will be taken to address the needs that are identified on the comprehensive assessment. A service plan can be thought of as an informal, working contract between client and social worker of who will be accountable for which actions in order for the client to meet their determined treatment goals. As with the comprehensive assessment, each completed service plan was recorded in the chart abstraction tool, along with any documented justification for why a service plan was missing if it should have been completed.

# of service plans	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**TOTAL**	**PERCENT**
0	4	22	26	33	6	29	29	149	**23%**
1	2	15	11	10	9	29	20	96	**15%**
2	0	0	3	1	0	3	6	13	**2%**
N/A	99	68	65	53	64	25	31	405	**61%**
Total	105	105	105	97	79	86	84	661	

It is notable that less service plans are completed than comprehensive assessments, even though the two processes are intended to occur together, one right after the other.

BRIEF ASSESSMENTS

Like Medical Case Management, Non-Medical Case Management is guided by a continuous process of ongoing assessment, service provision, and evaluation. Clients should be assessed at intake using a Ryan White Grant Administration approved brief assessment form and should be reassessed at six-month intervals if they are still being serviced by a Non-Medical Case Manager.

# of Brief assessments	**A**	**B**	**C**	**D**	**E**	**F**	**TOTAL**	**PERCENT**
0	20	33	53	63	5	52	226	**39%**
1	50	43	31	12	47	13	196	**34%**
2	8	1	4	0	4	1	18	**3%**
N/A	27	28	17	22	23	20	137	**24%**
Total	105	105	105	97	79	86	577	

Completion of brief assessments were recorded, along with any justification of why an assessment was not completed if one would have been expected. 24% of the sample would not been applicable for a brief assessment, as they did not receive services from a Non-Medical Case Manager. 39% of the sample received zero brief assessments, 34% received one, and 3% received two.

ASSESSED NEEDS

All data from assessment tools was captured in the chart review tool. A total of 173 Comprehensive Assessments and 211 Brief Assessments were reviewed and recorded in order to quantify the frequency of needs. The count recorded is a raw count of how many times a need was recorded, encompassing both comprehensive and brief assessments and including clients who may have had the same need identified more than once at different points in time.

The most frequently assessed needs were: 1) Medical/Clinical, 2) Dental Care, 3) Vision Care, 4) Medication Adherence Counseling, 5) Mental Health, and (6) Insurance. It should be noted, however, that there are no universal standards or instructions across case management systems on how to use these tools or how these needs are defined. Anecdotally, some case managers reported that they automatically checked “Medical/Clinical” and “Medication Adherence Counseling” as a need, regardless of whether or not the client needed assistance accessing medical care, because it was their understanding that this section *always* needed to be checked in order to justify billing for medical case management services. Therefore, this compilation of comprehensive and brief assessments should not be considered representative of *true need* within the HIV community in Houston, but rather, as representative of issues that case managers are discussing with clients.

Need identified on assessment	A	B	C	D	E	F	G	TOTAL	PERCENT
Medical/Medication	30	17	25	10	38	18	9	147	**22%**
Vaccinations	5	1	2	0	2	1	0	11	**2%**
Nutrition/Food Pantry	0	13	4	1	21	4	5	48	**7%**
Dental	13	22	11	2	30	10	8	96	**15%**
Vision	13	18	10	3	28	13	3	88	**13%**
Hearing Care	0	1	0	0	5	1	3	10	**2%**
Home Health Care	0	1	0	1	4	0	2	8	**1%**
Basic Necessities/Life Skills	2	11	1	1	8	2	1	26	**4%**
Mental Health	5	19	9	8	23	13	12	89	**13%**
Substance Use Disorder	1	8	2	3	8	2	1	25	**4%**
Abuse	0	0	3	1	4	1	1	10	**2%**
Housing/Living Situation	3	12	6	5	18	6	18	68	**10%**
Support Systems	1	5	2	3	14	1	6	32	**5%**
Child Care	0	0	0	0	0	1	1	2	**0%**
Insurance	8	6	14	4	33	10	9	84	**13%**
Transportation	25	12	6	7	17	7	2	76	**11%**
HIV-Related Legal Assistance	0	2	2	2	2	0	3	11	**2%**
Cultural/Linguistic	0	0	0	2	1	4	0	7	**1%**
Self-Efficacy	0	0	0	2	4	2	2	10	**2%**
HIV Education/Prevention	3	4	3	4	11	1	1	27	**4%**
Family Planning/ Safer Sex	2	6	4	1	10	1	1	25	**4%**
Employment	0	3	4	4	9	4	3	27	**4%**
Education/Vocation	0	0	0	2	7	0	5	14	**2%**
Financial Assistance	1	5	3	0	16	6	6	37	**6%**
Medication Adherence Counseling	7	18	18	8	37	19	6	113	**17%**
Client Strengths	0	1	0	0	3	0	3	7	**1%**

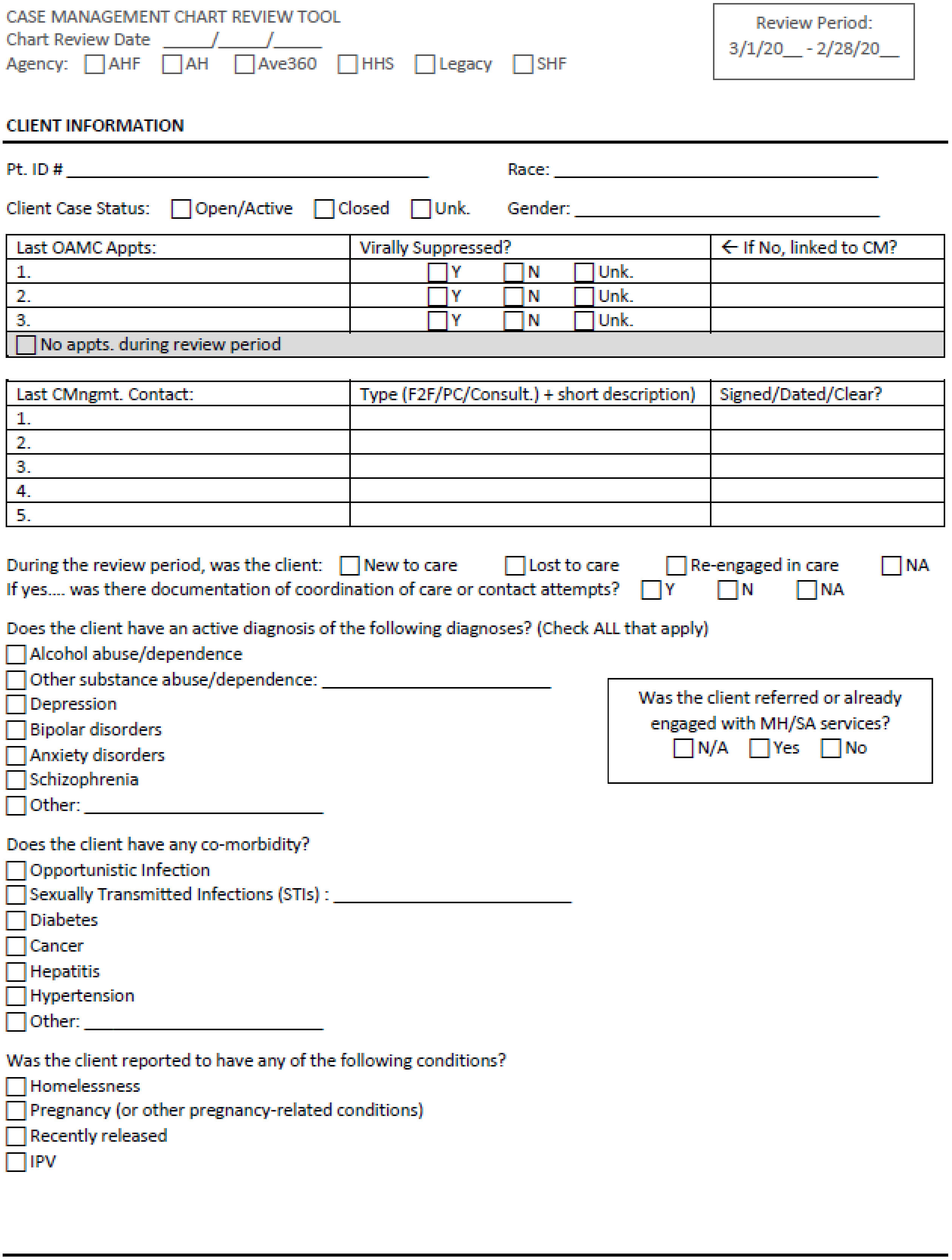
Conclusion

The 2019-2020 Case Management chart review highlighted many trends about the case management client population, strengths in case management performance, and areas identified for future attention and improvement.

Overall, we continue to learn more about the needs of this patient population by expanding the sample size of the review and adding new elements to the chart abstraction tool. The most common co-occurring conditions were: Sexually Transmitted Infections (24%), Depression (29%), and Hypertension (23%). Diabetes and Obesity were also relatively common and providing overview information on nutrition counseling may be a useful topic for future frontline case management trainings. The prevalence of complex co-morbidities emphasizes the unique benefit that case managers contribute to the HIV treatment setting.

There were also many areas of high performance displayed in this chart review. Most (51%) of the clients in the sample had at least three HIV-related primary care appointments within the review year. Case Management staff demonstrated a high level of coordination of care in many areas. For example, 88% of those with active mental health or substance abuse symptoms either received a referral for further treatment or counseling or were already engaged in services. 87% of the clients who were New, Lost, or Returning to Care (or some combination) received coordination of care activities from case management in an effort to retain them in care.

Appendix (Case Management Chart Review Tool)



CASE MANAGEMENT CHART REVIEW TOOL
Chart Review Date _____/_____/_____
Agency: ☐ AHF ☐ AH ☐ Ave360 ☐ HHS ☐ Legacy ☐ SHF

Review Period:
3/1/20__ - 2/28/20__

CLIENT INFORMATION

Pt. ID # ______________________________ Race: ____________________________

Client Case Status: ☐ Open/Active ☐ Closed ☐ Unk. Gender: ____________________________

Last OAMC Appts:	Virally Suppressed?	← If No, linked to CM?
1.	☐ Y ☐ N ☐ Unk.	
2.	☐ Y ☐ N ☐ Unk.	
3.	☐ Y ☐ N ☐ Unk.	
☐ No appts. during review period		

Last CMngmt. Contact:	Type (F2F/PC/Consult.) + short description)	Signed/Dated/Clear?
1.		
2.		
3.		
4.		
5.		

During the review period, was the client: ☐ New to care ☐ Lost to care ☐ Re-engaged in care ☐ NA
If yes.... was there documentation of coordination of care or contact attempts? ☐ Y ☐ N ☐ NA

Does the client have an active diagnosis of the following diagnoses? (Check ALL that apply)
☐ Alcohol abuse/dependence
☐ Other substance abuse/dependence: ________________________
☐ Depression
☐ Bipolar disorders
☐ Anxiety disorders
☐ Schizophrenia
☐ Other: _________________________

Was the client referred or already engaged with MH/SA services?
☐ N/A ☐ Yes ☐ No

Does the client have any co-morbidity?
☐ Opportunistic Infection
☐ Sexually Transmitted Infections (STIs) : _________________________
☐ Diabetes
☐ Cancer
☐ Hepatitis
☐ Hypertension
☐ Other: _________________________

Was the client reported to have any of the following conditions?
☐ Homelessness
☐ Pregnancy (or other pregnancy-related conditions)
☐ Recently released
☐ IPV

INSURANCE, BENEFITS, AND INCOME INFORMATION

Health Insurance: ☐ Uninsured ☐ Medicaid ______ ☐ Medicare_______ ☐ Commercial __________
☐ VA ☐ Other? _________

Spouse/partner:	Children:	Other Dependents:	TOTAL HOUSEHOLD SIZE 1 2 3 4 5 6 7 8 9 10 Unk
Client Income $:	Spouse Income $:	Other Income $:	TOTAL HOUSEHOLD INCOME $:

Did the client lose insurance or coverage during the review period? ☐ Y N ☐ Unk. ☐
If so, were they provided with information/education or assistance? ☐ Y N ☐ NA ☐

CASE MANAGEMENT SERVICES

What types of services were provided by a **Medical Case Manager** (MCM?)	What types of services were provided by a **Service Linkage Worker** (SLW?)	Was the client referred for **Clinical Case Management** services in the review period?
☐ **NA (Client not assisted by MCM)** ☐ Comprehensive assessment ☐ Service Plan ☐ Medication adherence counseling ☐ Coordination of medical care ☐ Transportation ☐ ADAP/medication assistance ☐ Eligibility ☐ Community resource/benefits brokerage ☐ Other ____________________ Did client meet criteria for MCM? Y ☐ N ☐ Unk. ☐	☐ **NA (Client not assisted by SLW)** ☐ Brief assessment ☐ SLW referred client to OAMC ☐ OAMC visit scheduled by SLW ☐ SLW accompanied client to OAMC ☐ SLW called client to remind about OAMC visit ☐ Client did not keep OAMC appt. and SLW contacted them ☐ ADAP/medication assistance ☐ Transportation voucher ☐ Eligibility Were any of the above services provided by an Outreach Worker? Y ☐ N ☐ Unk. ☐	☐ **No- not applicable** ☐ No- applicable, but no referral documented ☐ Yes- and there is evidence of coordination of services ☐ Yes- and there is no evidence of coordination of services ☐ Yes- but client refused services or is already engaged in treatment

Was the case discharged/closed for CM during the review period?		Y ☐	N ☐	NA ☐	Unk. ☐
If yes…….	Client met agency criteria for closure?	Y ☐	N ☐	NA ☐	Unk. ☐
	Client completed treatment program (CCM)	Y ☐	N ☐	NA ☐	Unk. ☐
	Date and reason noted?	Y ☐	N ☐	NA ☐	Unk. ☐
	Summary of services received?	Y ☐	N ☐	NA ☐	Unk. ☐
	Referrals noted?	Y ☐	N ☐	NA ☐	Unk. ☐
	Instructions given to client at discharge?	Y ☐	N ☐	NA ☐	Unk. ☐

ASSESSMENTS & SERVICE PLANS

		If no assessment or plan:		
Brief Assess. Date 1:	Brief Assess. Date 2:	☐ evidence of one just outside of review period	☐ reason documented	☐ enough info to complete
Comp. Assess. Date 1:	Comp. Assess. Date 2:	☐ evidence of one just outside of review period	☐ reason documented	☐ enough info to complete
Service Plan Date 1:	Service Plan Date 2:	☐ evidence of one just outside of review period	☐ reason documented	☐ enough info to complete

COMPLETED ASSESSMENTS

	MOST RECENT ASSESSMENT TYPE (circle one) Comprehensive Brief					NEXT MOST RECENT ASSESSMENT TYPE (circle one) Comprehensive Brief				
Domain	Assessed?	Need Identified?	Accounted for in Service Plan?	Accounted for in progress notes?	Follow-up (referral, action, etc.)	Assessed?	Need Identified?	Accounted for in Service Plan?	Accounted for in progress notes?	Follow-up (referral, action, etc.)
Medical/Clinical										
Vaccination										
Nutrition/Food Pantry										
Dental Care										
Vision Care										
Hearing Care										
Home Care Needs										
Basic Necessities/Life Skills										
Mental Health										
Substance/Alcohol Use										
Abuse History										
Housing/Living Situation										
Support System										
Child Care/Guardianship										
Insurance Benefits										
Transportation										
HIV-Related Legal										
Cultural/Linguistic										
Self-Efficacy										
HIV Education/Prevention										
Family Planning/Safer Sex										
Employment/Income										
General Education/Vocation										
Financial Assistance										
Medication Adherence										
Client Strengths										
Other										

Case Management in Primary Care for Frequent Users of Health Care Services: A Realist Synthesis

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ABSTRACT

PURPOSE Case management (CM) is a promising intervention for frequent users of health care services. Our research question was how and under what circumstances does CM in primary care work to improve outcomes among frequent users with chronic conditions?

METHODS We conducted a realist synthesis, searching MEDLINE, CINAHL, Embase, and PsycINFO (1996 to September 2017) for articles meeting the following criteria: (1) population: adult frequent users with chronic disease, (2) intervention: CM in a primary care setting with a postintervention evaluation, and (3) primary outcomes: integration of services, health care system use, cost, and patient outcome measures. Academic and gray literature were evaluated for relevance and robustness. Independent reviewers extracted data to identify context, mechanism, and outcome (CMO) configurations. Analysis of CMO configurations allowed for the modification of an initial program theory toward a refined program theory.

RESULTS Of the 9,295 records retrieved, 21 peer-reviewed articles and an additional 89 documents were retained. We evaluated 19 CM interventions and identified 11 CMO configurations. The development of a trusting relationship fostering patient and clinician engagement in the CM intervention was recurrent in many CMO configurations.

CONCLUSION Our refined program theory proposes that in the context of easy access to an experienced and trusted case manager who provides comprehensive care while maintaining positive interactions with patients, the development of this relationship fosters the engagement of both individuals and yields positive outcomes when the following mechanisms are triggered: patients and clinicians feel supported, respected, accepted, engaged, and committed; and patients feel less anxious, more secure, and empowered to self-manage.

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INTRODUCTION

Frequent users of health care services are a small proportion of the population who account for a disproportionate number of visits to emergency departments, thereby placing a heavy strain on limited resources.[1-3] Frequent users generally have complex health care needs, owing to a combination of chronic health conditions,[4,5] mental health issues,[6,7] and social vulnerability.[8,9] These individuals are hospitalized at greater rates than infrequent users, have lower perceived quality of life,[10] and have a greater mortality rate.[8,11,12] These complex health care needs make it difficult for the health care system to provide integrated care, highlighting the need for improved management of care for this population.

Case management (CM) is a promising intervention to improve health care integration for frequent users and to reduce health care costs.[13-15] Case management is defined as "a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health care needs through communication and available resources to promote quality, cost-effective outcomes."[16] Case management offers support for patients and their families to manage their medical and social issues more effectively and improve their health status and health care use[17]; it is designed to enhance care coordination, avoid duplication of services, and reduce health care costs.[18]

The effectiveness of the CM approach for frequent users has been evaluated in many systematic reviews, the majority of which reported positives outcomes such as reduction of health care use and cost and improvement in patient quality of life and satisfaction.[13-15,19] Case management is a complex social intervention rooted in intricate social systems, all of which influence the outcomes of the intervention.[20] Whereas quantitative systematic reviews provide evidence for the effectiveness of CM, the causal mechanisms underpinning this intervention, and how contextual factors influence the links between the causal mechanisms and the intervention outcomes, remain unclear. A deeper understanding of how, when, and why CM is successful is needed for its effective implementation in different contexts.

Table 1. Definition of Terms

Term	Definition
Context (C)	Aspects of the background of the intervention (eg, characteristics of the people involved in the intervention, the environment in which the intervention occurs, the social and political context, etc)
Mechanism (M)	The generative, causal force influencing the effect of program resources on participants' reasoning, attitudes, and behaviors (sensitive to variation in context)
Outcome (O)	Effect of the intervention, dependent on the interactions between the context and mechanism
CMO configuration	Relation between context, mechanisms, and outcomes that is a form of realist causal explanation
Initial program theory	A preliminary exploration of the theory on how the intervention works
Demiregularity	Semipredictable patterns that could emerge from CMO configurations that appear repeatedly, or the interpretation of which is strongly supported by theory
Program theory	An empirically testable proposition that lies in an intermediate position relative to generalizable grand theories of social systems on one end and detailed descriptions of situational microphenomena on the other
Case manager	Health care professional who provides the intervention. Can also refer to the CM team
Frequent user	Individuals/patients who frequently use health care services. Can also include their family and caregivers
Health care clinician	Health care professionals involved in the case management intervention (eg, emergency department staff, family physician, etc)
Self-management support	Activities the purpose of which is to help patients and their families play a greater role in the management of their health

CM = case management; CMO = context + mechanism = outcome.

The research question of the present study was how and under what circumstances does CM in primary care work to improve outcomes among frequent users with chronic conditions?

METHODS

Design

Realist synthesis (RS) methodology is a theory-driven approach to synthesizing evidence regarding complex social interventions involving a chain of processes, to identify invisible causal mechanisms, examine how they operate under different conditions, and determine how contextual factors influence links between these mechanisms and outcomes. These relations in RS provide a causal explanation for outcomes and are expressed in the form of context + mechanism = outcome (CMO) configurations, a mechanism being the combination of resources offered by the intervention and the way these resources change stakeholders' reasoning.[21,22] An initial program theory is developed based on assumptions regarding the mechanisms by which the intervention might work. Via the CMO configuration and the formulation of patterns (demiregularities), the initial program theory is iteratively refined.[20,21] The outcome is a program theory that is connected to the empirical data yet sufficiently abstracted from it to allow for generalizations regarding what works, for whom, and under what circumstances. Table 1 provides definitions of RS terms and other terms used in this article.

The present RS followed the 5 nonlinear and interrelated stages recommended by Pawson, as listed below.[23] This article is presented according to the RAMESES reporting guidelines.[24] Full details are available in our published protocol.[25]

Stage 1. Focusing the Scope of the Realist Synthesis and Promoting Stakeholder Engagement

The review team included academic researchers, decision makers, clinicians, frequent users of primary health care services, and research assistants from across Canada. To promote their engagement, all team members were invited to 2 working sessions, during which we focused the scope of the RS. Specifically, the review team identified the research question, clarified the purpose of the review, and articulated an initial program theory based on the findings of the parent systematic review[26] and other CM literature. The initial program theory consisted of the following 5 main resources: case finding, care planning, coordination/integration of services, self-management support, and intensity of the intervention (Supplemental Figure 1, http://www.AnnFamMed.org/content/18/3/218/suppl/DC1).[13-15,19] The working sessions also included a 3-hour training on the RS approach.

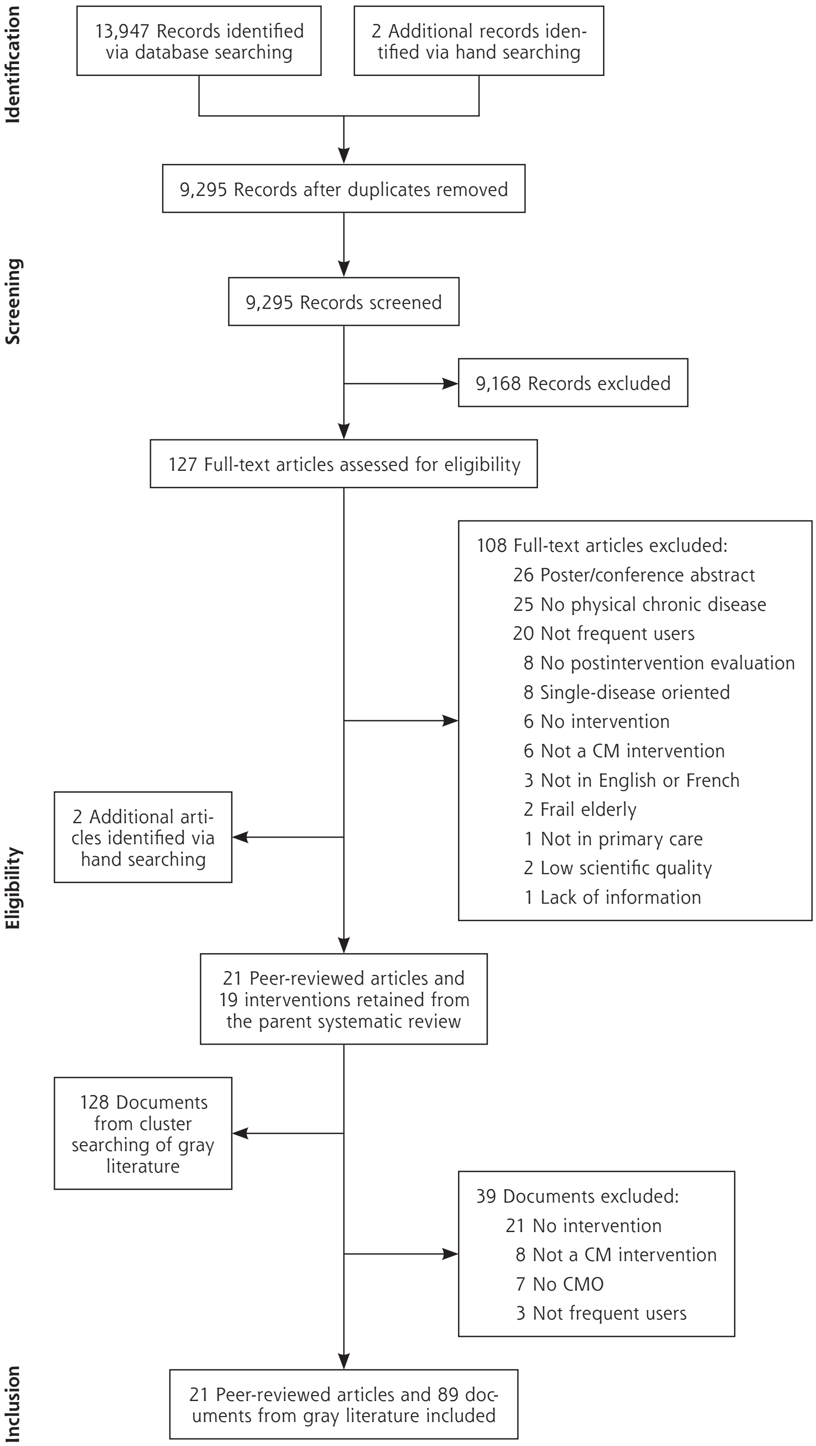
Stage 2. Searching for Evidence

As planned in our protocol,[25] we searched for evidence from all of the studies included in our parent systematic review detailing the methods and characteristics of the included studies.[26] The comprehensive search strategy used in our parent systematic review yielded 21 peer-reviewed articles published during the period 1996 to September 2017 and evaluating 19 interventions in primary care settings designed to improve care among adult frequent users of health care services who were affected by at least 1 chronic physical condition. In accordance with RS methodology supporting the inclusion of data from various sources, we used a cluster search to identify additional documents relevant to each CM intervention. We emailed the 21 corresponding authors to request unpublished material and searched the associated academic and gray literature, which led to an additional set of 128 documents.

Stage 3. Appraising the Quality of Evidence

Per RS methodology,[20,21] we appraised all of the selected peer-reviewed articles (n = 21) and documents from the gray literature (n = 128) for relevance (ie, contribution of the data to theory building/testing) and robustness (ie, credibility and trustworthiness of the data).[20] On the basis of these criteria, we retained the 21 peer-reviewed articles and 89 of the additional documents, evaluating a total of 19 CM interventions (Figure 1).

Figure 1. Study selection process.



CM = case management; CMO = context, mechanism, and outcome.

Stage 4. Extracting the Data

The extracted data were (1) bibliographic information, (2) study characteristics (location, setting, and design; definition of frequent users; population characteristics;

sample size; type, objective, frequency, and content of the intervention; length of the intervention sessions with patients; duration of follow-up; case-finding process; clinicians involved; intervention offered to the control group; data analysis; outcome characteristics and assessment instruments; and the intervention's effectiveness based on reported outcomes) (details of these findings are reported in the parent systematic review[26]), and (3) data related to the CMO configurations.

Four team members (M.C.C., M.L., O.C., F.F.) were involved in development of CMO configurations. For each intervention, they used an extraction table to systematically extract the relevant data (contexts, mechanisms, outcomes, and associated excerpts) from the included documents. Only CMOs that were clearly reported by the authors were extracted. Outcomes were used as starting points for building CMO configurations. Team members worked together on the first 5 interventions, which served as a learning exercise and to establish common processes and standards. Subsequently, they worked independently, creating data extraction tables of the CMO configurations for each of the 14 remaining interventions. A second team member repeated the process for each intervention, identifying additional CMO configurations. The CMO tables were then circulated to other team members (C.H., M.C.C., M.L., P.L.B., V.S., P.P.), who identified points of agreement and disagreement that were resolved via discussion and consensus. Once all CMO configurations of the interventions had been extracted, all data extraction tables were transferred to NVivo qualitative data analysis software (version 11; QSR International) and synthesized into CMO configurations that were used to refine the initial program theory.

Stage 5. Synthesizing the Evidence

To inform and modify the initial program theory, an abductive reasoning approach (in which there is an iterative back and forth between the theory and the data) was used.[27] The CMOs were analyzed and demiregularities (patterns) identified.[27] Regular discussions with the entire team helped to refine the initial program theory and to identify ways in which it was informed by the data. The iterative process of modification and refinement of the initial theory led to a refined program theory explaining how and why CM works.

RESULTS

Description of the Included Studies

The 19 included CM interventions were evaluated using quantitative methods (n = 16) and mixed methods (n = 3).[26] Thirteen were conducted in the United States and 6 in other countries (Sweden, Canada, Switzerland, Australia, New Zealand, and the United Kingdom). The studies included 17 to 14,140 participants, with an average age range of 20 to 66 years. The proportion of women varied from 25% to 77%.

CMO Configurations and Demiregularities

Eleven CMO configurations were developed (Table 2). They suggested that CM might yield 7 possible positive outcomes (improvements of self-management skills, patient adherence to treatment and recommendations, patient satisfaction, health status, quality of life, and quality of care, and reductions in health care use and costs) when the following mechanisms are triggered: (a) patients feel supported, respected, and accepted; engaged and committed to understanding the care plan and how to access relevant health care services; feel their concerns are heard; are less anxious and more secure; and are more empowered to self-manage; (b) clinicians feel supported and have a deeper understanding of the patient's situation. The ability of each mechanism to trigger a positive outcome was dependent on the context of the intervention, providing patients with easy access to a trusted case manager who provides comprehensive care while maintaining positive interactions with patients. Two demiregularities were identified, as described below.

Demiregularity 1. Developing a Trusting Patient-Clinician Relationship

The relationship developed between the patient and an experienced and trusted case manager appeared to play a key role in the effectiveness of CM for frequent users.[28-33] This relationship influences a patient's motivation to engage in their care (CMOs 2, 3, & 9). Patients' past experiences can affect the interactions they have with clinicians (CMO 3).[28-32,34] A meaningful relationship is built on trust[28-32] and is essential for empowering patients to self-manage their care,[28,30-32] as noted by Grinberg et al[28] in their evaluation of the Camden Coalition of Healthcare Providers, a multidisciplinary CM program for complex frequent users of inpatient service:

> "Participants often drew a connection between this relationship and active motivation. (…) [They] also described genuineness as a key ingredient of their relationship with the members of their Coalition care teams: I loved working with her. I'll work with her any day of the week, she was normal to me; she talked to me as a person, not as a patient. This genuineness in patient interactions was often cited as a catalyst for personal change: [knowing that the care team was] interested in me…it's like wow, me? I felt good, I felt better, I felt somebody really cares about me. I'm living, and I'm not here by myself. And I think that what's made me, you know,

Table 2. CMO Configurations

Theme	CMO Configuration	Evidence (References)
Coordination and health navigation	If frequent users are directed through the health care system and are enabled to connect with clinicians and community services working in close collaboration (C), they have a better understanding of how to access and obtain relevant health care services in appropriate settings. Their knowledge and ability to navigate within the health care system and to communicate with clinicians are strengthened, and they become more engaged in their care (M). This improves their self-management skills and health status and reduces health care use and costs (O). (CMO 1)	Grimmer-Somers et al, 2010[35]; Grinberg et al, 2016[28]; Hudon et al, 2015[29]; Navratil-Strawn et al, 2014[40]; Reinius et al, 2013[33]; Roberts et al, 2015[30]; Shah et al, 2011[38]; Weerahandi et al, 2015[31]
Patient and health care clinician relationship	If case managers are able to develop trusting relationships with frequent users (C), frequent users trust them, feel safe, and develop meaningful relationships with them. This meaningful relationship motivates patients to be engaged in their care (M). In turn, their self-management skills improve, their health condition(s) stabilizes, and health care use and costs are reduced (O). (CMO 2)	Crane et al, 2012[32]; Grinberg et al, 2016[28]; Hudon et al, 2015[29]; Roberts et al, 2015[30]; Weerahandi et al, 2015[31]
	If frequent users have a negative interaction with case managers, feel disrespected, discriminated against, or not connected with them (C), frequent users feel upset, dissatisfied, and frustrated with their encounter. They are unable to develop a trusting relationship with their case managers and are not willing to engage in their care (M). This limits the development of their self-management skills, does not improve their quality of life, and does not change health care use and costs (O). (CMO 3)	Grinberg et al, 2016[28]; Sledge et al, 2006[34]
Patient and health care clinician engagement	If case managers are flexible, able to adapt, and open to change their approach by involving frequent users in their care planning (C), frequent users tend to accept the CM program, tend to understand their role in it, and are willing to engage in their care (M). This improves their self-management skills, health status, and quality of care and reduces health care use and costs (O). (CMO 4)	Adam et al, 2010[36]; Crane et al, 2012[32]; Grimmer-Somers et al, 2010[35]; Grinberg et al, 2016[28]; Hudon et al, 2015[29]; McCarty et al, 2015[37]; Roberts et al, 2015[30]; Weerahandi et al, 2015[31]
	If case managers are willing to be engaged and committed to the program and to take an active role in care planning (C), frequent users accept the program, perceive it to be beneficial, and become more engaged in their health care (M), which improves their self-management skills and reduces health care use (O). (CMO 5)	Adam et al, 2010[36]; Grinberg et al, 2016[28]; Grover et al, 2010[44]; McCarty et al, 2015[37]; Pope et al, 2000[42]; Skinner et al, 2009[43]; Weerahandi et al, 2015[31]
	If frequent users are not involved in their care planning (C), they do not feel engaged and will deviate from their care plan because they do not understand it or do not agree with it (M). Consequently, they will continue to frequently and inappropriately use health care services (O). (CMO 6)	Adam et al, 2010[36]; Bodenmann et al, 2017[39]; Pope et al, 2000[42]
	If clinicians do not follow the care plan that includes restriction of narcotics for frequent users with substance use issues (C), patients are unwilling to follow the care plan (M) and continue to frequently and inappropriately use health care services to obtain narcotics (O). (CMO 7)	Grover et al, 2010[44]; Pope et al, 2000[42]
Patient and health care clinician support	If a comprehensive and holistic approach addressing both medical and social issues is provided to frequent users (C), they feel their concerns are heard and their needs are taken seriously. They feel supported and satisfied with the care received and motivated to be engaged in their care (M). This improves their self-management skills and health status and reduces health care use (O). (CMO 8)	Brown et al, 2005[41]; Grimmer-Somers et al, 2010[35]; Hudon et al, 2015[29]; Pope et al, 2000[42]; Shah et al, 2011[38]
	If frequent users have easy access to case managers who provide regular follow-up meetings (C), frequent users feel supported and cared for in the management of their health issues and trusted by their case managers (M). This improves their self-management skills, health status, and quality of life and reduces health care use and costs (O). (CMO 9)	Crane et al, 2012[32]; Hudon et al, 2015[29]; Reinius et al, 2013[33]; Roberts et al, 2015[30]; Weerahandi et al, 2015[31]
	If clinicians who are overwhelmed by the complex needs of frequent users in an overloaded health care system work in collaboration with an interdisciplinary team (C), they feel supported by the members of the team and satisfied with the program and are willing to engage in the CM program (M). This improves the quality of care they provide to frequent users and reduces patients' health care use (O). (CMO 10)	Adam et al, 2010[36]; Brown et al, 2005[41]; McCarty et al, 2015[37]
Self-management support	If frequent users are involved in their care planning and receive self-management support (C), they develop a greater understanding of their condition, are motivated to take an active role in their care, and feel confident in their ability to obtain medical and social resources (M). This improves their self-management skills, health status, and quality of life and reduces health care use (O). (CMO 11)	Crane et al, 2012[32]; Grimmer-Somers et al, 2010[35]; Grinberg et al, 2016[28]; Hudon et al, 2015[29]; Roberts et al, 2015[30]; Shah et al, 2011[38]; Weerahandi et al, 2015[31]

C = context; CMO = context + mechanism = outcome; M = mechanism; O = outcome.

actually do it. I started takin' my medication, I started, you know, getting out." (p. 250)

Aptitudes and skills of clinicians influence the extent to which patients are engaged in their care (CMO 2).[28,30-32,35] The ability of case managers to develop positive relationships with their patients fosters mutual trust, which in turn motivates both patient and clinician to engage in the CM intervention.[28,30-32] A calm, confident, sensitive, friendly, empathetic, and supportive case manager inspires patients' confidence, increasing their likelihood to be engaged in their care.[28,30-32] Because they work with patients with complex care needs, case managers should take time to listen to them, understand their situation, and be accepting of them.[29,30] Regular follow-up meetings with the same clinician contribute to the development of a trusting relationship (CMO 9),[29-33] and patients are more likely to feel secure, be honest, and to be engaged in their care.[28,31] Patients who are able to self-manage their conditions experience fewer health complications. Thus, our analysis suggests the importance of this demiregularity in reducing inappropriate use of health care services[28,31,32] and thereby related costs.[28,32] In an evaluation of an intensive CM program for frequent users of inpatient services, with chronic conditions and complex care needs, Roberts et al[30] found the following:

> "Key to the success of the work of the CCL [case manager] is the ability to establish trusting relationships with patients, their families, and other caregivers. Many of the high utilizers of Safety-Net hospitals live not only with the challenges surrounding multiple chronic diseases but also with poverty, mental illness, and chaotic life circumstances. The CCLs must understand the context of the lives of their patients and accept those individuals where they are. It is crucial to the CCL's success that we hire those with an aptitude for ongoing professional development regarding effective interactions with patients and dealing with their barriers to self-management." (p. 259)

Demiregularity 2. Engaging Patients and Clinicians in Case Management Interventions

Involving patients in the development of their care plan by considering needs, prioritizing what they want to address, reaching an agreement on care recommendations, explaining their role in their own care, or encouraging them to make their own health-related decisions helps ensure that the patients feel engaged in their care and self-manage their conditions (CMOs 4, 6, and 11).[28-31,35-37] This requires that case managers be open to this process[30,31,35] and to providing self-management support.[28-32,35,38] In addition, educating patients on health condition(s) helps improve understanding of health issues, which in turn increases confidence in the ability to self-manage,[28-30,35,38] improves health status,[31] and decreases health care service use.[31,32,38]

The provision of easy access to and assistance with health care services, particularly navigation services, improves patients' ability to seek and reach appropriate care when needed (CMO 1)[30,33,35,39,40] and helps sustain their engagement in their care. This prevents inappropriate use of health care services.[39,40] Considering that patients' medical and social issues might also influence their engagement, such a comprehensive approach helps patients feel that they are taken seriously, respected, well cared for, satisfied, and motivated to be engaged in their care.[29,35,38,41,42] Hence, they become actively involved in their care and improve their self-management skills.[29,35,38] Again, this can lead to a decrease in inappropriate health care service use.[38,41,42]

The engagement of case managers and clinicians in the CM interventions is also important (CMOs 5, 7, and 10)[28,31,36,37,41-44] because it helps improve patients' self-management skills[28] and reduces inappropriate health care use and costs.[28,31,36,37,42-44] Case managers who are committed to the intervention and take an active role in caring for patients have a positive influence on patients' motivation to engage in their care.[28,31,36,37,42-44] As Green et al[45] reported,

> "Clients have described the motivation they feel to adhere to treatment regimens when they know there are healthcare providers taking an active role in caring for them. The clients engage with the team and become active partners in their own health care." (p. 5)

The 2 demiregularities are intrinsically linked; a trusting patient-clinician relationship is a key element of success for meaningful partnerships and patient engagement. It is necessary for the clinician to gain the patient's trust and to maintain a relationship in which the patient feels engaged in their care, thus triggering mechanisms that generate positive outcomes.

With regard to frequent users with substance use disorders, clinicians' compliance with their care plan is crucial.[42,44] When clinicians do not respect the recommendation of restriction of opioids, frequent users with substance abuse issues tend to use health care services to obtain opioids.

Refined Program Theory Regarding How Case Management Works in Primary Care for Frequent Users With Chronic Conditions

Refinement of our initial theory consisted, for the most part, of further articulating the mechanisms because our initial theory focused more on CM resources. The refined program theory suggests 4 resources (care planning, coordination and health care navigation, self-management support, and support for clinicians) and includes the mechanisms (central arrow, Figure 2) that connect contexts and outcomes of CM for frequent users of health care services with chronic conditions.

DISCUSSION

Our refined program theory of CM proposes that in the context of easy access to an experienced and trusted case manager who provides comprehensive care while maintaining positive interactions with patients, the development of a trusting relationship between the patient and the clinician fosters the engagement of both when the following mechanisms are triggered: (a) patients feel supported, respected, and accepted; are engaged and committed to understanding their care plan and how to access relevant health care services; feel their concerns are heard; are less anxious and more secure; and are empowered to self-manage, and (b) clinicians feel supported and have a deeper understanding of the patient's situation. These relationships provide a causal explanation for the success of CM interventions in improving patient and clinician experiences and overall health outcomes and decreasing health system costs (outcomes) (Figure 2).

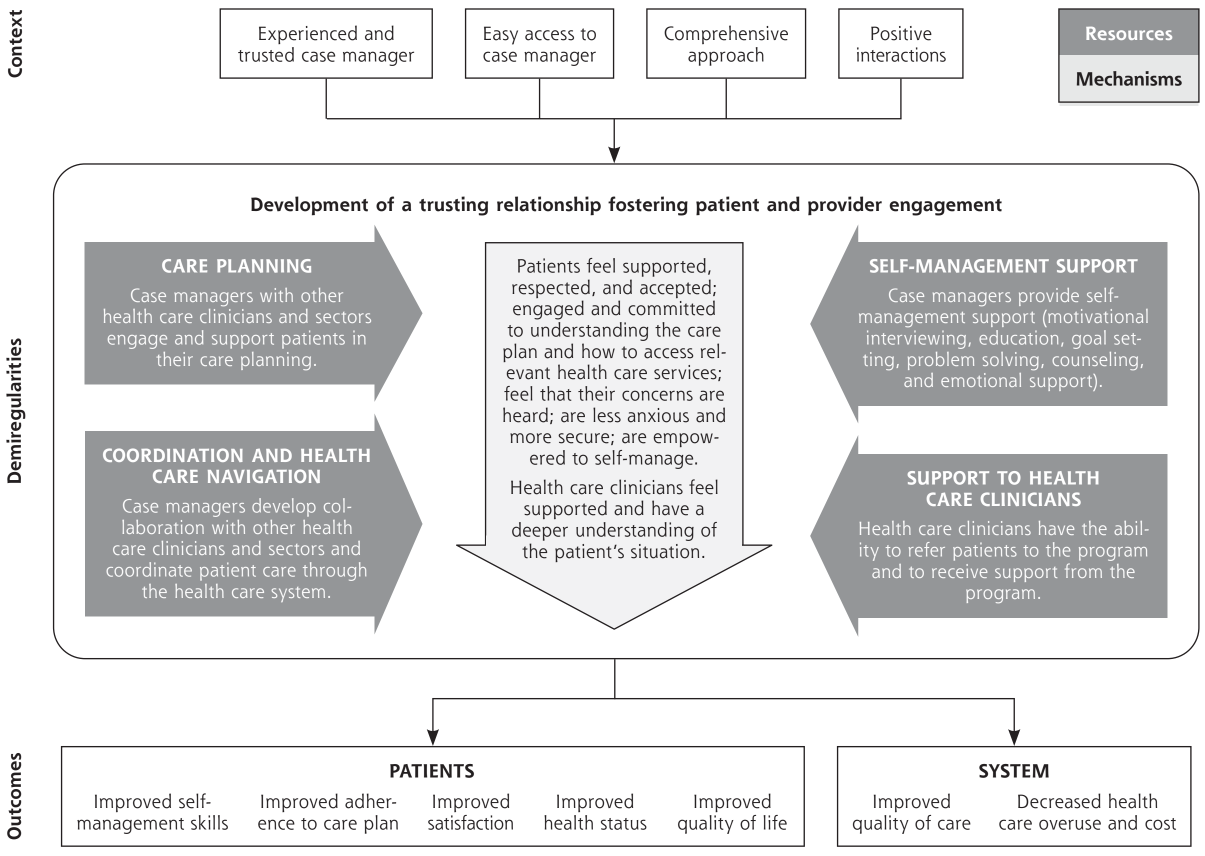
In a study of intensive outpatient care programs for patients with complex care needs, O'Brien et al[46] interviewed clinicians and program leaders and found that patient-clinician relationships built on trust are critical for developing care coordination and treatment plans and these relationships influence patients' engagement in care. With respect to the present RS, we were able to elucidate on the trusting relationship and provide detail regarding this mechanism (central arrow, Figure 2). This detail is an important contribution that can provide clinicians with guidance for exhibiting behavior that can help to build trust with their patients.

These results corroborate those of Elliott et al,[47] who used RS to understand the engagement of older adults in health care decision making. Like us, those authors found that developing trust between the patient and the clinician can help the patient feel engaged in decision making.

Contribution to Research, Clinical Practice, and Policy

Our program theory looks beyond program resources and determination of success and exposes the mechanisms that CM triggers in patients and clinicians in various contexts that generate positive outcomes. It will help clinicians identify essential elements of CM to incorporate into their daily practice. Regarding patients, our program theory might help them recognize the important role they play by engaging in their care planning. Using this theory to frame CM work with patients might be beneficial (and in turn, might help to refine the theory) in clinical settings and might help policy makers design, plan, and implement effective CM programs in their jurisdictions.

Figure 2. Refined program theory.



Strengths and Limitations

Given that CM stakeholders, including patients who are frequent users of health care services, were members of the review team, we are confident that this work is anchored not only in the empirical literature but also in the practical experience of CM stakeholders across Canada. However, although we included all published material regarding the CM interventions, our present results should be critically interpreted in light of the limited descriptions available regarding the CM interventions and how individuals reacted to them. Further research is required to examine if the professional role of the case manager (nurse, social worker, other) or the setting of the CM (clinic, community, home) might have an influence on the development of the relationship. Our theory of CM pertains to frequent users of health care services with chronic conditions. The knowledge base could be improved by testing our theory via realist evaluation of CM in real context.[48]

CONCLUSIONS

With the present RS, we were able to refine what is known about contextual factors of CM in primary care for frequent users with chronic conditions that lead to positive patient and system-level outcomes and to uncover the mechanisms these factors need to trigger to generate the desired outcomes. We propose a program theory that the objective of CM should be to enable an experienced and accessible case manager, a comprehensive approach to patient care, and positive interactions throughout the health care process. This will trigger the development of a trusting relationship that fosters both patient and clinician engagement and will lead to improved patient and clinician experiences, better patient health outcomes, and decreased health care system costs.

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Open access Protocol

BMJ Open

Telehealth and texting intervention to improve HIV care engagement, mental health and substance use outcomes in youth living with HIV: a pilot feasibility and acceptability study protocol

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ABSTRACT

Introduction Youth and young adults living with HIV (YLWH) experience worse clinical outcomes than adults and high rates of behavioural health challenges that impact their engagement in care and adherence to antiretroviral therapy. This study in the San Francisco Bay area aims to evaluate the feasibility, acceptability and preliminary clinical outcomes of a 12-session telehealth counselling series provided to 80 YLWH, including education, motivational enhancement and problem-solving around HIV care, mental health, substance use and other challenges. Findings will provide information about benefits and challenges of telehealth counselling for YLWH and will guide the development of new technology-based strategies for care.

Methods and analysis The Youth to Telehealth and Text to Improve Engagement in Care study is a pilot randomised, crossover trial examining the feasibility and acceptability of a telehealth counselling intervention consisting of twelve 20–30 min weekly sessions focused on identifying and problem-solving around barriers to HIV care access and adherence and on addressing mental health, substance use and/or other issues. Participants also receive text messages for check-ins, appointment reminders and to improve engagement. Participants complete quantitative online surveys at baseline, 4 and 8 months and qualitative exit interviews. Clinical outcomes, including plasma HIV RNA and CD4+ cell count, are collected from medical records. Study staff will explore outcomes of the intervention using quantitative and qualitative methods.

Ethics and dissemination This study and its protocols have been approved by the University of California, San Francisco (UCSF) Institutional Review Board. Study staff will work with the UCSF Center for AIDS Prevention Studies' Community Engagement Core and the Youth Advisory Panel to disseminate results to the community, participants and the academic community.

Trial registration NCT03681145.

Strengths and limitations of this study

- The use of iterative refinement of the intervention manual throughout this pilot study increases the study's potential impact and acceptability among participants.
- The study's counselling intervention is significant in its integrated HIV and behavioural health focus, which is tailored to the participant's baseline HIV knowledge, mental health status and substance use.
- The use of video chat and text messaging modalities for delivery of HIV engagement, mental health and substance use counselling with youth living with HIV is important, reduces the time burden to the clinician and patient and challenges the current delivery of healthcare.
- By examining the acceptability of a fully online versus hybrid in-person online session delivery, we will be able to determine if this intervention can be offered completely remotely, which will in turn increase the geographic reach for the delivery of this intervention.
- This pilot study is limited due to its small sample size, and the data generated from this study may not be generalisable to older individuals and those not living in the San Francisco Bay Area.

BACKGROUND

Youth and young adults aged 18–29 years living with HIV (YLWH) have unique challenges with HIV diagnosis, access and maintenance of care. In 2016, in the USA, youth aged 13–24 years accounted for about 21% of all new HIV infections.[1] Among those aged 13–29 years and living with HIV, only 41% were estimated to be aware of their HIV status. In 2014, of those diagnosed with HIV, only 62% accessed HIV medical care within the first year; of those, 43% were retained in HIV care, and 54% had a suppressed HIV viral load.[2] Access to care and antiretroviral therapy (ART) is crucial for the health of YLWH; high levels of ART adherence is critical for attaining HIV treatment goals including sustaining suppressed HIV viral load, decreasing risk of developing drug-resistant strains of HIV, reducing the risk of HIV transmission to others and improving overall health.[3–5]

Mental health and substance use challenges are prevalent in YLWH, though few studies have been conducted on behavioural health issues in YLWH. One study found that 18% of YLWH who were in care had clinically significant psychological symptoms such as depression or anxiety.[6] Another study of 1706 YLWH found that 42.6% reported mental health concerns at a clinically significant level. Of those reporting these symptoms, only 39.7% reported receiving mental healthcare services in the past year, and 21.9% reported taking medications for mental health conditions.[7] Additionally, in one sample of 12- to 26-year-olds living with HIV, 32% used tobacco, 27% used marijuana, 21% used alcohol, and 22% used other illicit substances.[8]

Mental health and substance use challenges have been shown to negatively impact HIV medication adherence and clinical outcomes across the continuum of HIV care for YLWH.[9 10] For example, in one systematic review and meta-analysis, those with depression symptoms had 42% lower likelihood of achieving 80% or higher ART adherence compared with those without depression.[11] Another found that of those not taking ART, the odds of reporting clinically significant symptoms were three times as high as those on ART, showing the strong relationship between mental illness symptoms and ART uptake and adherence.[12] Another review found that depression and anxiety symptoms in YLWH were strongly associated with ART non-adherence.[13] Additionally, the review found that higher alcohol use in the past week and substance use in the past 3 months were also predictive of poor adherence.

There are few evidence-based counselling interventions for YLWH that address behavioural health factors impacting adherence to HIV care.[13] Interventions developed for adults have shown to be effective in improving depressive symptoms as a method of improving ART adherence.[13] However, young adults differ in multiple ways, including their technology use habits, creating an opportunity for the application of technologies to behavioural health interventions.

As 98% of people aged 18–29 years have a mobile telephone and over 85% have a smartphone, telephone-based interventions are potentially accessible for the majority of YLWH.[14] Most traditional counselling interventions are provided in person and a clinical setting; engaging in these counselling sessions may be a barrier for YLWH who experience transportation or financial issues, stigma or shame around accessing treatment or other challenges.[15] In our formative work, YLWH reported that health-focused mobile interventions could overcome concerns about their ability to effectively and openly communicate with their providers.[16] One survey similarly found that 60% of millennials would be interested in video chat interactions with their medical provider instead of attending in-office appointments.[17]

Several HIV care adherence interventions have been developed for individuals living with HIV, though most are for adults of all ages rather than YLWH. Few of the interventions specifically developed for YLWH use telehealth, texting or other mobile technologies as the platform for intervention delivery.[18] Although these methods have been shown to be promising in improving ART adherence and linkage to care in adults living with HIV, they have been minimally studied in YLWH.[19]

The existing literature on telehealth and texting platforms for HIV-related interventions for YLWH show promising results and highlights the need for additional research in this area.[13] One text message medication reminder system for adolescents and YLWH was shown to be feasible, efficacious and satisfactory to participants.[20] However, a study of 15– to 22-year-old YLWH found that neither a one-way or two-way text messaging intervention significantly improved HIV medication adherence.[21] This highlights the need for additional research on the effectiveness of interventions that combine text messaging with other elements, which may improve efficacy.

In this paper, we describe the protocol for a study to examine the feasibility and acceptability of a novel 12-session telehealth counselling series and accompanying text messages to improve engagement in HIV care, mental health and substance use outcomes. The Youth to Telehealth and Text to Improve Engagement in Care (Y2TEC) intervention is novel in its combination of telehealth and text messaging and strategic integration of three foci (ie, engagement in HIV care, mental health and substance use). We will identify whether these methods are feasible and acceptable to YLWH and will examine preliminary clinical and behavioural outcomes of the intervention. We anticipate that Y2TEC will be feasible and acceptable for counselling YLWH and that participants will show preliminary evidence of improvement in clinical and behavioural outcomes.

METHODS/DESIGN

Study overview and design

The Y2TEC study is a single-site randomised pilot study with the primary aim of examining the feasibility and acceptability of a 12-session telehealth and text message–based counselling series for YLWH. The secondary aim is to evaluate the preliminary impact of the intervention on improved engagement in HIV care, enhanced mental health and reduced substance use for YLWH. The University of California, San Francisco (UCSF) Institutional Review Board (IRB) has reviewed and approved this study. The intervention was designed based on the results of our formative mixed-methods and qualitative research on youth-friendly HIV counselling methods. The intervention is delivered to participants in two condition groups (ie, intervention and waitlist control) via remote telehealth sessions delivered over 4 months, with a crossover design (see table 1). The overall duration of participation is 8 months.

Table 1 Study overview

I=intervention arm participants W=waitlist arm participants X=all participants	Months 0	1	2	3	4	5	6	7	8
Screening/enrolment									
Telephone screening	X								
Informed consent		X							
Assessment surveys									
Baseline survey		X							
Follow-up surveys					X				X
Satisfaction and acceptability questionnaire					I				W
Counselling sessions									
Weekly counselling sessions (12)		I	I	I	I	W	W	W	W
Bidirectional text messages									
Monthly check-ins			W	W	W		I	I	I
Session ratings		I	I	I	I	W	W	W	W
Goal reminders		I	I	I	I	W	W	W	W
Session reminders (24 hours and 15 min before telehealth session)		I	I	I	I	W	W	W	W
Community events and resources		X	X	X	X	X	X	X	X
Exit interviews									
Satisfaction survey					I				W
Qualitative exit interviews					I				W

Study setting

Participants are recruited from the San Francisco Bay Area. Participants consent to the study and complete their initial baseline survey in person in a private office at a community-based location or at UCSF's Center for AIDS Prevention Studies. All other study communications are remote via the video chat platform, text messages and telephone calls.

Study participants

The study sample will consist of 80 individuals aged 18–29 years living with HIV, who live in and receive medical care in the greater San Francisco Bay Area. We have chosen to include young adults in this age range as they are in a distinct developmental phase with unique needs and challenges compared with minors or those aged older than 29 years. Other inclusion criteria include English-speaking, willing and able to provide informed consent and have access to a mobile telephone with text messaging capability. Those planning on moving out of California in the next 8 months or with evidence of severe cognitive impairment or active psychosis that may impede their ability to provide informed consent are excluded.

Sample size justification

NCSS and PASS will be used to compute the minimum detectable effect (MDE) sizes, assuming alpha=0.05, power=0.80 and n=64, reflecting anticipated attrition of 20%.[22] For estimates of means and proportions for feasibility and acceptability measures, the minimum detectable distance from the estimate of the proportion to the upper or lower confidence limit is 12.7%, assuming a target of 70% feasibility and acceptability. For means, the standardised distance to the limit is 0.25. For primary preliminary outcome analyses proposed to compare means of continuous outcomes across the intervention and control groups at 4 months, the minimum detectable standardised mean difference *d* is 0.30. These MDEs are between cutoffs for small (*d*=0.20) and medium (*d*=0.50) standardised mean differences suggesting our study is powered to detect small to medium effects.[23]

Patient and public involvement

Prior to the design of this study, we conducted formative research with healthcare providers and patients (Saberi et al, under review), which helped us refine our research questions, study design and outcome measures. We asked YLWH about optimal methods for intervention delivery and considered the requests of several participants to have an initial session face-to-face with the counsellor. Additionally, we involve participants in study recruitment by encouraging active participants to refer others and providing a $25 incentive to both the referee and referred. We will assess the effects and burden of the intervention by the participants themselves through our quantitative survey and qualitative exist interviews after the intervention. We will work with our Youth Advisory Panel and Community Action Board to disseminate the study's results to participants and the community.

General study procedures

Recruitment methods

Participants are recruited through in-person outreach at clinical and community sites serving YLWH, emails to clinics and providers, flyers posted at health clinics and community-based organisations, targeted online advertisements on Instagram, Craigslist, Facebook and Grindr and recontacting participants from prior studies who had expressed interest in being contacted about future studies. Finally, a participant referral method is used, and a $25 incentive is provided to both the referring participant and new participant.

Eligibility screening

Study staff provide a brief overview of the study to prospective participants, answer any questions and complete an eligibility screening on the telephone. Those who meet the inclusion criteria and are willing to participate in the study are asked for a photo ID to verify their date of birth and proof of HIV status (a letter of diagnosis, laboratory results or HIV medication prescription) via a photo text-messaged to the study telephone or by bringing these documents to the initial in-person visit.

Consent and enrolment procedure

The enrolment visit will be completed in person with a study staff member. Participants review the electronic consent form (see online supplementary appendix A) with a study staff member in a private setting. Individuals who are eligible and agree to participate electronically sign the consent and a medical release form using Qualtrics (Provo, UT, USA; version March 2017) an online survey platform and are provided a copy of the Experimental Subject's Bill of Rights.

Baseline survey

Participants then complete the online baseline survey, which takes approximately 30–45 min. Study staff then help participants download a secure video chat mobile application (ie, Zoom, a (Health Insurance Portability and Accountability Act [HIPAA]–compliant video chat platform) on their telephones. Study staff demonstrate how to set up privacy settings on mobile telephones, such as keeping text message previews from showing up on locked screens and adding a security code to lock the telephone.

Randomisation

Following the baseline survey, research staff randomly assign participants to one of two condition groups (ie, intervention or waitlist control) with a prenumbered sealed envelope. Randomisation is done using SAS (version 9.4) based on randomly permuted block sizes to ensure equal-sized groups, and all study staff are blinded to the randomisation order. Approximately 40 participants will be randomised to the immediate intervention condition and receive their first session in person; about 40 participants will be randomised to the waitlist control condition for 4 months after study enrolment and then cross-over to the treatment arm and receive the study intervention entirely remotely with no in-person session with the counsellor. The counsellor and clinical research coordinator will not be blinded to the randomisation condition, as treatment will be prescribed as a result of the condition.

Participant retention

A number of steps are taken to retain participants throughout the study period. Participants are asked for multiple forms of contact information (including emergency contacts, clinical contacts and social media contacts) at the initial visit to prevent loss of contact. They receive three monthly follow-up text messages during the waiting period to confirm their contact information, appointment reminder text messages 24 hours and 15 min before scheduled counselling sessions, birthday text messages and a weekly text message with free fun local activities to facilitate rapport-building (see table 2).

Participants' Incentives

Participants receive up to $310 for completing all study activities, including payments for each counselling session that gradually increase throughout the study (in $10–$25 increments). Participants are given a ClinCard, a reloadable debit card and instructions for use at the initial visit. Participants are also entered into two raffles for chances to win $25 Amazon gift cards when they confirm their contact information or answer two session rating questions after each telehealth session. Additionally, participants who refer others to the study are paid $25 per successful recruitment.

Risks to participants

All risks to participants are monitored by study staff and documented at each session and study assessment. Study staff are trained to thoroughly explain these risks to participants as well as the steps taken to ensure privacy and confidentiality of all information. Safety-related risks to participants could include discomfort due to the sensitive nature of questions in study surveys including substance use, HIV health-related issues and mental health. Non-clinical study staff conducting interviews and participant communication refer to clinical study staff if participant distress is identified. Clinical staff delivering the intervention are trained to assess distress level of participants and refer to established protocols for any participant crisis. If a participant requires treatment due to distress, this will be determined by clinical staff; they will be referred to appropriate services following the crisis protocol, and the principal investigator (PI) will be informed.

Table 2 Text messages

Message	Schedule	Text and response
24 hours Reminder* (A)	24 hours before appointment	If Y: 'Thank you for confirming, Please text us with any questions'. If N: 'Thank you for replying, we will contact you to reschedule'.
15 min Reminder (A)	15 min before appointment	'UCSF Team: Appointment Reminder: See you in 15 min, here is the link (zoom link)'.
Resource (M)	As needed	'UCSF Team: Resources: Here are the resources you requested (link to resources)'.
Goals* (M)	Three business days after session	'UCSF Team: Goals: Were you able to attempt your goal? Yes Or Not Yet'. Response: 'Got it!'
Free Stuff (A)	Weekly	'UCSF Team: Fun Free Stuff: Enjoy Free Yoga in the Park this Saturday from 10 to 11 am, Downtown Oakland. Here's the link (website)'.
Monthly Check-in* (A)	Monthly during waiting period	'UCSF Study Team: Update or confirm your contact info for a chance to win one of 5 $25 Amazon e- Gift cards at the end of the study. Has your phone number or email address changed? Please reply 1 Yes 0 No' If yes: 'Please send us your updated phone number and email address.________ Thank you! You have been entered in the raffle, good luck!' If No: Thank you! You have been entered in the raffle, good luck!'
Survey Link (M)	Baseline, 4 and 8 months	'UCSF Team: It's time for your survey. Click on the link below to complete the feedback survey and receive $10. Thank you! (Survey Link)'
Session Rating* (A)	After each session	'UCSF Team: Please tell us about the session today for a chance to win one of five $25 Amazon e-Gift cards at the end of the study: 1- I felt heard, understood, and respected by the counselor: a. Strongly agree b. Agree c. Neither agree nor disagree d. Disagree e. Strongly disagree 2- Overall, today's session was right for me: a. Strongly agree b. Agree c. Neither agree nor disagree d. Disagree e. Strongly disagree' Response: 'Thanks for your responses! Please let us know if you have any additional comments by texting us'.
Session Completion (M)	After completion of all sessions	'Congratulations on completing the 1st half of the Y2TEC study! Next, you will receive a survey on xx/xx/xx & a final survey on yy/yy/yy. Please let us know if you have any questions. Thanks!'
Waiting Period Completion (M)	After completing waiting period	'Congratulations, you have finished the 1st half of the Y2TEC study! Next, you will receive a survey on xx/xx/xx & we will contact you to schedule your 1st video chat session after you complete your survey. Please let us know if you have any questions. Thanks!'
Birthday Message (M)	On participant's birthday	'UCSF Team: Happy Birthday, we are sending you all our best wishes for a very happy birthday today, cheers!'
Away Message (A)	After hours and holidays	'Thank you for your message! The Y2TEC Study staff are out of the office until XX/XX/XX and will respond after this date. If this is an emergency, please call 911.'
Study Referral (M)	As needed	'UCSF Team: Participants can receive up to $310 for completing all study activities plus $25 per person they refer who enrolls in the study!'

*Bidirectional.
(A)=Automated message.
(M)=Manually sent message.

Adverse events and auditing

The study staff monitor postsession participant ratings (via text message) as one method for identifying those who may have experienced an adverse event. If a participant reports low satisfaction with the intervention, study staff contact them in a timely manner to determine what occurred in the session. Study staff also provide participants with the study mobile telephone number to spontaneously report any adverse events or unintended effects of the intervention. Any adverse events will be documented on an adverse event form, and follow-up will be tracked. The form along with any session notes with details will be reported to the IRB by the PI within 10 working days. The team of investigators will also meet weekly to audit and discuss general trial conduct–related issues.

Protocol amendments

Protocol amendments will be shared with all stakeholders as they occur. Study staff communicate protocol modifications to investigators during monthly meetings, submit changes to www.clinicaltrials.gov as needed, submit IRB modifications and communicate changes to regulators during meetings every 6 months or via email as needed.

Intervention procedure

The 12-session telehealth series is delivered by a trained behavioural health professional (such a social worker, psychologist or psychotherapist), referred to as the 'counsellor' within the context of this study. Sessions use problem-solving, information-motivation-behavioural skills and motivational interviewing and focus on engagement in HIV care, mental health and substance use.[24–26] Telehealth sessions are completed via a secure video chat platform, Zoom, and text messages are sent via a secure encrypted, HIPAA-compliant platform called Mosio.

Series overview

Participants in the intervention arm meet with the counsellor in person immediately after enrolment, and the waitlist control arm participants meet with the counsellor via video chat after 4 months. Before the first meeting, the counsellor reviews the participant's most recent assessment survey responses to determine the participant's level of acuity and tailor appropriate session dosage. Mental health acuity is determined through the Patient Health Questionnaire (PHQ) 9 and PTSD Checklist (PCL); substance use acuity is determined through the Alcohol Use Disorders Identification Test (AUDIT) and Alcohol, Smoking and Substance Involvement Screening Test (ASSIST); HIV care acuity is calculated by a measure of HIV knowledge as well as current participant utilisation of HIV care services and antiretroviral medications. During the first session, the counsellor assesses the participant's needs and identifies current gaps in knowledge and motivation regarding mental health, substance use and HIV care. The first three to six of the remaining 11 sessions cover core psychoeducational and health literacy–promoting content around engagement in HIV care, mental health and substance use challenges and treatments. Those with higher acuity receive two foundational psychoeducational modules rather than one in each of the three areas, amounting to a maximum of six core educational sessions.

The remaining sessions use an integrated behavioural health and HIV care– focused approach to further the conversations initiated in the core sessions. At the beginning of these sessions, the participant and counsellor choose from a list of topics identified in the first session, including HIV care, mental health, substance use, lifestyle health, social support, family of origin, romantic and sexual relationships, self-identity and disclosure, subsistence needs (housing, money and resources) and education and vocation. These sessions can be done in any order and repeated as needed. If a participant is in crisis and unable to be redirected to these options, a 'wildcard' session focused on crisis response and safety planning may be held. The final session includes reviewing the content covered and goals achieved in the previous sessions, identifying unmet needs, accessing community-based resources and learning strategies for maintaining changes.

Scheduling sessions

Four months are allocated to complete the 12 weekly counselling sessions to allow for missed and rescheduled sessions. Participants are encouraged to contact the counsellor or study staff to reschedule their appointments as needed. Participants receive session reminders via text message 24 hours and 15 min before each session.

Session documentation and fidelity

The counsellor completes session summary notes through a Qualtrics survey form, which includes closed-ended and multiple-choice questions such as session length, participant location, technical issues encountered, session topics selected, educational topics covered, goals set, a session content fidelity checklist and a narrative progress note.

Evaluation and curriculum modifications

The initial version of the Y2TEC intervention will be delivered to participants randomised to the intervention arm. The research team plans to adjust the intervention based on lessons learnt and feedback from participants to develop a modified version of the intervention (ie, intervention manual version 2.0). This version will be provided to all waitlist control participants, and outcome differences between the two arms will be explored during analysis. As a result, the intervention will have gone through an iterative refinement process and will be ready for implementation in a larger randomised controlled trial by the end of the pilot study.

Data collection and management procedure

Clinical data collection

At consent, participants sign a medical release form, and research staff obtain medical records from participants' respective medical clinics at baseline, 4 months and 8 months. Information collected includes appointment

Table 3 Measures in participant surveys

Domain (in order of the survey)	Measure	Baseline survey	Follow-up surveys
Demographics	Original measure	X	
Use of technology	Original measure	X	
HIV treatment outcomes, antiretroviral history and adherence	Original measure	X	X
HIV knowledge	HIV Treatment Knowledge Scale[34]	X	X
Alcohol use	Alcohol Use Disorders Identification Test[35]	X	X
Substance use	Alcohol, Smoking and Substance Involvement Screening Test [36] Q2 , Drug Abuse Screening Test-10[37]	X	X
Depression	Patient Health Questionnaire-9[38]	X	X
Adverse childhood experiences	Adverse Childhood Experience Questionnaire[39]	X	
Trauma/PTSD	PTSD Check List[40]	X	X
Anxiety	Generalised Anxiety Disorder-7[41]	X	X
Sleep	Pittsburgh Sleep Quality Index)[42]	X	X
Resilience	Connor-Davidson Resilience Scale[43]	X	X
Internalised HIV stigma	HIV Stigma Mechanisms[44]	X	X
Mental health and substance use stigma	SAMHSA Mental Health and Alcohol Abuse Stigma Assessment[45]	X	X
Social support	Medical Outcomes Study Social Support Scale[46]	X	X
Social isolation	Patient-Reported Outcomes Measurement Information System[47]		X
Healthcare empowerment	Healthcare Empowerment[48]	X	X
Relationship with healthcare provider	Healthcare Provider[49]	X	X
Unmet subsistence needs and instrumental support	Medical Outcomes Study Short Form[50]	X	X
Satisfaction and acceptability	Original measure		X

PTSD, posttraumatic stress disorder; SAMHSA, Substance Abuse and Mental Health Services Administration.

attendance, medications and laboratory data including plasma HIV RNA and CD4+ cell count. The data point closest to baseline, 4 months and 8 months ± 1 month are used for data analysis.

Assessment data collection

Participants complete assessment surveys at baseline, 4 months and 8 months after enrolment. The surveys collect demographic, technology use, substance use, mental health and HIV care information (see table 3). The baseline surveys are completed online in-person at the initial visit, and the other two are completed remotely on the participants' mobile devices.

Qualitative data collection

A subset of approximately 20 participants who have finished the intervention will be invited to complete an audio-recorded telephone semistructured individual qualitative exit interview with study staff for a $30 payment. Participants will be chosen to reflect a range of levels of engagement and attendance using a question adapted from the Session Rating Scale[27] to determine the level of satisfaction with each telehealth session. Using mean scores of participant satisfaction over 12 telehealth sessions and attendance, participants will be divided into four groups: (1) high attendance, high satisfaction; (2) high attendance, low satisfaction; (3) low attendance, high satisfaction; and (4) low attendance, low satisfaction. Five participants will be randomly selected from each category and interviewed. Participants will receive information and consent for the qualitative interviews during the initial visit, along with the consent for the rest of the study. The interviews will focus on the acceptability of the intervention and participant feedback on the intervention, and the interviews will be audio- recorded and transcribed verbatim.

Table 4 Primary outcome measures: feasibility and acceptability

Primary outcome measures	Metrics	Acceptance criteria
Acceptability	Measure participant satisfaction with the telehealth intervention at completion of intervention by a 30-item questionnaire (1 excellent to 6 unsatisfied) administered through an online survey	Mean satisfaction score≥80%
	Measure participant satisfaction with each telehealth session via 2-item scale (1 strongly agree to 4 strongly disagree) administered via text messaging	Mean satisfaction score≥80% over 12 telehealth sessions
Feasibility	Recruitment	At least 70% of the planned 80 participants (ie, n=56)
	Participant retention at 4 months	At least 80% of participants retained in the study at 4 months
	Participant retention at 8 months	At least 60% of participants retained in the study at 8 months
	Number of telehealth disconnections	Mean of one disconnection per videoconferencing session
	Participant response time to texts	Mean of 3 days between bidirectional text message and participants' response
	Sound quality based on a one item questions using Likert scale (0–10) (0=poor quality; 10=excellent quality) as rated by counsellor	Mean of 7 out of 10 sound quality
	Video quality based on a one item question using Likert scale (0–10) (0=poor quality; 10=excellent quality) as rated by counsellor	Mean of 7 out of 10 video quality

Confidentiality and data protection

All screening and consenting will take place in a private room. Study staff will use a secure, encrypted texting platform for all study text communication. Participants will receive support from study staff who will demonstrate how to set up additional privacy measures using the settings on their personal mobile telephones. Electronic data will be gathered through HIPAA-compliant platforms, stored on a secure network and password protected. Subjects will be coded by numbers and with no names; linking information will be kept in locked files. The data will not be shared unless via a data use agreement including deidentified data. The study has obtained a Certificate of Confidentiality from the National Institutes of Health to protect the privacy of potential and enrolled study participants.

Data monitoring

A Data Monitoring Committee (DMC), interim analyses and stopping guidelines are not needed because the study is a pilot feasibility study that has been classified as minimal risk by the UCSF IRB.

Study outcomes

Feasibility, acceptability and clinical outcomes

Preliminary data on feasibility, acceptability and HIV clinical outcomes will be gathered throughout the study (see tables 4 and 5). Acceptability of the telehealth intervention will be determined throughout the study using several methods. Study staff will administer two-session rating questions via text after each weekly telehealth session, asking if the participant ‘felt heard, understood and respected by the counsellor’ and if the ‘session was right’ for them. Additionally, a 30-item exit survey is administered through Qualtrics after the intervention is completed, including questions pertaining to (1) the overall rating of the study; (2) satisfaction with each study procedure; (3) ease or difficulty with each study procedures; (4) helpfulness of communication with study staff; (5) self-perception of improved ART adherence, mental health and substance use with study participation; (6) recommending a study similar to this to a friend; and (7) participating again in a similar study. Study staff will also conduct qualitative exit interviews with 20 participants to gather in-depth descriptions of participant experiences, perceptions and acceptability of the intervention. Clinical outcomes within the two study arms include HIV RNA, CD4+ cell count, self-reported adherence, appointment attendance, substance use (Drug Abuse Screening Test [DAST] and ASSIST) and mental health (PHQ-9 and PCL-5; see table 5).

Data analysis plan

Quantitative analysis plan

One-way frequency tables will be generated for all baseline and follow-up survey questions, and measures of central tendency and variability will be computed for continuous measures. Results from these analyses will

Table 5 Secondary outcome measures: clinical impact

Secondary outcome measures	Metrics
Alcohol use	Measure participants' alcohol use from baseline to 4 and 8 months using the Alcohol Use Disorder Test (AUDIT), a 10-item questionnaire to measure severity of participants' alcohol use. Responses are summed. Scoring range is 0–20+; 0–7: Low alcohol use, 8–19: Moderate alcohol use, 20+: High alcohol use/dependence.
Depression	Measure participants' depression from baseline to 4 and 8 months using the Patient Health Questionnaire 9, a 9-item Likert scale score (0–3) 0 ‘not at all’, 3 ‘nearly every day’. Responses are summed. Scores will have a range of 0–27. PHQ-9 scores of>10 are associated with moderate to severe depression.
Frequency of Substance Use	Measure participants' change in substance use from baseline to 4 and 8 months using a 10-item questionnaire (ASSIST) to measure frequency of participants' substance use.
Posttraumatic stress disorder (PTSD)	Measure participants' self-reported PTSD from baseline to 4 and 8 months using the PTSD Checklist—revised, a 20-item Likert questionnaire administered through an online survey. Scoring: 0 points for ‘not at all’, 1 point for ‘a little bit’, 2 points for ‘moderately’, 3 points for ‘quite a bit’, 4 points for ‘extremely’. Scores will have a range of 0–80. Responses are summed.
Self-reported medication adherence	Measure changes in participants' self-reported medication adherence based on 1-item adherence rating (1 excellent to 6 poor, lower rating indicates higher adherence) from baseline to 4 and 8 months.
Severity of substance use	Measure participants' changes in substance use from baseline to 4 and 8 months using the Drug Abuse Screening Test, a 10-item questionnaire to measure severity of participants' substance use. Responses are summed. Scoring (0–10); 0–2 low substance use, 9–10 severe substance use.
Measure of participant HIV knowledge using HIV Treatment Knowledge Scale	Assess participants' knowledge of HIV from baseline to 4 and 8 months through the HIV Treatment Knowledge measure, a 15-item self-report questionnaire. Scoring out of 15 (0–12 inadequate, and 13–15 adequate). Scores will have a range of 0–15.

ASSIST, Alcohol, Smoking and Substance Involvement Screening Test .

quantify important sample characteristics and participant use of various telehealth modalities as well as proportions and means of the feasibility and acceptability measures. Primary preliminary outcome analyses will use linear mixed models to compare mean log10 HIV RNA across the intervention and control groups at 4 months relative to baseline. Secondary exploratory preliminary outcome analyses will use the same analytic methods to compare the 8-month time point within the intervention arm to baseline to examine whether the intervention had longer-term effects. A parallel exploratory analysis will compare waitlist controls at 4 months versus 8 months.

Additional secondary exploratory analyses will repeat this set of analyses on other secondary outcomes such as CD4+ cell count, HIV knowledge, self-reported adherence and appointment attendance, PHQ-9 and PCL-5 mental health measures, AUDIT alcohol use measure and the DAST substance use measure. Finally, all analyses described above will be repeatedly stratified by participant gender to explore whether there is any evidence of gender differences in effects. Due to the modest sample size and pilot focus of the study, significance testing will be de-emphasised in favour of performing inferential analyses as a feasibility check to ensure all measures and analysis protocols are in place for a larger formal efficacy trial.[28 29]

Qualitative analysis plan

Study staff will complete, audio- record and transcribe individual in-depth interviews with 20 YLWH following completion of the clinical intervention. The analytic team will identify broad themes from the interview transcripts, discuss and refine them and then enter them into a Microsoft Excel–based matrix with a column for each theme and a row for each case. One coder will initially identify patterns in the themes and code each interview to identify subthemes, and a second coder will double code a random subsample (n=5) of the interview codes within the matrix. Discrepancies in coding will be discussed by the team until a consensus is reached and interrater reliability will be calculated. A sequential mixed-method design will be used to integrate our quantitative and qualitative data analysis.

Dissemination plan

Study staff will work with the UCSF Centre for AIDS Prevention Studies’ Community Engagement Core and the Youth Advisory Board to disseminate results to the community and participants via presentations, community forums, email updates and/or social media. Study staff will conduct town hall presentations and publish findings in peer-reviewed journals to communicate results with healthcare professionals.

DISCUSSION

This study protocol describes the Y2TEC pilot, randomised, cross-over study designed to impact the mental health, substance use and HIV care challenges of YLWH. Few interventions for YLWH currently exist that address these three concerns in an integrated way, and as a result, we had few examples of similar curricula while developing the Y2TEC intervention. Therefore, we relied on formative research including qualitative interviews with healthcare providers and staff serving YLWH, as well as a mixed-methods study examining HIV care engagement, mental health, substance use and technology-based interventions to address these issues with the target population [Saberi *et al*, under review,[15]].

Additionally, in our review of existing telehealth interventions focusing on these areas, we discovered that there were general telehealth guidelines but few specifics for research. For example, telehealth-specific regulations on best practices for responding to mental health crises described general practices for clinicians with little mention of best clinical practices for crisis response within a research setting.[30 31] We also found that there were few sources of information about best practices for using text messaging and telehealth counselling within research settings, as many healthcare providers who are currently holding telehealth appointments are practicing within medical groups that have officially adopted these technologies.[32]

This study has several unique aspects that are worth highlighting. This intervention explores non-traditional methods for care provision that deviate from the adult-care models and may be considered more 'youth friendly'.[33] The intervention was specifically designed to be tailored and adaptable to the participant using the results of the participant's assessment responses to inform the counsellor's decision-making around the number of educational and problem-solving sessions on particular topics. As a result, the counsellor is given the ability to spend more or less time on HIV care, mental health or substance use based on the acuity of the participant's need. Though this adaptive modular structure adds complexity, it has the potential to better meet the needs of participants than a more rigidly structured intervention.

Furthermore, this study simultaneously explores several unique aspects of feasibility and acceptability. In addition to exploring whether this form of intervention will impact HIV, mental health and substance use outcomes, we are also considering the acceptability of a fully online versus hybrid in-person online session delivery. Half of the participants receive the first intervention session with the counsellor in person and the rest of their sessions remotely, and the other half receive the full series remotely. If shown to be similarly acceptable, this intervention can be offered completely remotely.

The Y2TEC counselling series has been designed with replication and scalability in mind. The intervention is unique in the relatively low clinician time burden (6 hours of individual counselling per participant over 4 months) compared with traditional face-to-face counselling, which often involves weekly hour-long sessions (which may total 12–16 hours over 4 months). Additionally, if we find that participants perceive the remote-only counselling option as acceptable, implementing the intervention would require minimal office space and physical materials, limiting factors within healthcare settings. A remote-only counselling intervention would also potentially increase access for those living in rural areas with limited access to transportation or local services.

We anticipate that the findings of our study will show that a telehealth and text message–based counselling series for YLWH will be acceptable and feasible. We expect that the findings from this study will provide information about additional ways of using new mobile technologies to support the HIV care goals and behavioural health needs of YLWH and will help influence the development of additional mobile-based counselling strategies. The results of this pilot study will allow us to conduct a larger multicentre randomised controlled trial to examine the efficacy of this intervention.

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Contributors PS, CDR and MOJ conceived the study and developed the experimental design and measures. ARW and VAG developed the telehealth counselling intervention and manual. DAL and PS developed the main study protocols. ARW and DAL carried out the daily study activities. TBN contributed to the data collection and analysis plan. All authors were involved in the revision of the draft manuscript and have agreed to the final content.

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RESEARCH ARTICLE

The effectiveness of case management interventions for the homeless, vulnerably housed and persons with lived experience: A systematic review

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Abstract

Background

Individuals who are homeless or vulnerably housed are at an increased risk for mental illness, other morbidities and premature death. Standard case management interventions as well as more intensive models with practitioner support, such as assertive community treatment, critical time interventions, and intensive case management, may improve healthcare navigation and outcomes. However, the definitions of these models as well as the fidelity and adaptations in real world interventions are highly variable. We conducted a systematic review to examine the effectiveness and cost-effectiveness of case management interventions on health and social outcomes for homeless populations.

Methods and findings

We searched Medline, Embase and 7 other electronic databases for trials on case management or care coordination, from the inception of these databases to July 2019. We sought outcomes on housing stability, mental health, quality of life, substance use, hospitalization, income and employment, and cost-effectiveness. We calculated pooled random effects estimates and assessed the certainty of the evidence using the GRADE approach. Our search identified 13,811 citations; and 56 primary studies met our full inclusion criteria. Standard case management had both limited and short-term effects on substance use and housing outcomes and showed potential to increase hostility and depression. Intensive case management substantially reduced the number of days spent homeless (SMD -0.22 95% CI -0.40 to -0.03), as well as substance and alcohol use. Critical time interventions and assertive community treatment were found to have a protective effect in terms of rehospitalizations and a promising effect on housing stability. Assertive community treatment was found to be cost-effective compared to standard case management.

Conclusions

Case management approaches were found to improve some if not all of the health and social outcomes that were examined in this study. The important factors were likely delivery intensity, the number and type of caseloads, hospital versus community programs and varying levels of participant needs. More research is needed to fully understand how to continue to obtain the increased benefits inherent in intensive case management, even in community settings where feasibility considerations lead to larger caseloads and less-intensive follow-up.

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Competing interests: David Ponka, Claire Kendall, Vicky Stergiopoulos, Anne Andermann, Peter Tugwell and Kevin Pottie are principal investigators in an ongoing project to develop Canadian evidence-based guidelines for providing social programs and healthcare services to people who are homeless and vulnerably housed. Terry Hannigan was paid an honorarium by the Bruyère Research Institute to provide consultations on this work. This does not alter our adherence to PLOS ONE policies on sharing data and materials. The authors declare no other conflicts of interest.

Introduction

Homeless and vulnerably housed populations have poorer health outcomes including acute and chronic illness [1], traumatic injury [1], mental health and substance use disorders [2–7], and mortality [8]. While often related to individual medical and complex social needs, structural challenges posed by fragmented health and social systems create a potent mix of barriers to access to health care. These include a lack of sufficient language capacity, awareness of affordable healthcare services and their location, transportation services, childcare, and reasonable wait times. When coupled with previous experiences of rejection or discrimination from service providers, these barriers further contribute to individuals failing to access appropriate and available health care [9–11].

To address these barriers, people who are homeless or vulnerably housed may benefit from tailored, patient-centered care with an integrated approach to community and social services [12–14]. Case management (CM) is one such intervention where individual case managers respond to the complexity of navigating the healthcare system by assessing, planning and facilitating access to health and social services [15,16]. While case management interventions are heterogeneous in definition, complexity, target populations served, and modes of delivery [12], among these, four predominant models have evolved in relation to health care: standard case management (SCM), intensive case management (ICM), assertive community treatment (ACT), and critical time intervention (CTI) (See Table 1) [17].

Case management has been shown to improve patient satisfaction [27], quality of life, and the utilization of community-based services among other high-risk populations [28]. However, the evidence base for CM and its implementation among homeless and vulnerably housed populations remains sparse. This review is one of a series of reviews on the effectiveness of providing interventions for homeless and/or vulnerably housed persons. The objective of this review is to assess the effectiveness and cost-effectiveness of four CM models for the health and social outcomes of homeless or vulnerably housed individuals in the following domains: housing stability, mental health, substance use, quality of life, hospitalization, employment and income.

Table 1. Characteristics of case management models- Adapted from de Vet et al. 2013 [15].

	Standard Case Management	Intensive Case Management	Assertive Community Treatment	Critical Time Intervention
Focus of Services	Coordination of services	Comprehensive approach addressing several needs (i.e. housing, physical and mental health, addictions services etc.)	Comprehensive approach addressing several needs (i.e. housing, physical and mental health, addictions services etc.)	Targeted to continuity of care between a period of transition i.e. between precarious housing conditions (i.e. living in a shelter or discharged from hospital) and independent housing arrangements
Target Population	Homeless persons with complex health concerns	Homeless persons with the greatest service need i.e. persons with serious mental illnesses, but typically fewer hospitalizations or less functional impairments [18], and for people experiencing addictions [19].	Homeless persons with the greatest service need i.e. for persons with serious mental illness, often schizophrenia or bipolar disorder, accompanied by a history of multiple psychiatric hospitalizations and functional impairment [20].	Homeless persons at critical transitions in their lives i.e. between a shelter or hospital and independent housing
Access Point	Varies by location. Typically services are accessed through a referral by healthcare professionals (clinician, nurse, social worker, outreach worker). Some locations offer self-referral services where clients can apply for access to services on their own [21].			
Duration of Services	Time limited. once the case manager has brokered the client to a service provider, the service provider to provide ongoing support until a positive outcome is achieved [15].	Ongoing	Ongoing but transfer to lower intensity services is common after a period of stability [22,23].	Time-limited. Usually a period of 9 months after institutional discharge or placement in housing [22].
Availability of case management services		up to 12 hours per day, 7 days a week [24].	24 hours per day, 7 days per week availability [22].	
Where services are offered	Brokering of services to other providers [25].	Case manager accompanies clients to meetings and appointments [24].	Services are offered in a natural setting such as the workplace, home or social setting [15,22].	Worker provides services in the home and helps to strengthen community networks [22].
Coordination of access to services run by other agencies or **service provision** by the agency itself	Coordination	Coordination and service provision	Coordination and service provision	Coordination and service provision
Average Caseload (program intensity)	35	15	15	25
Outreach	No	Yes	Yes	Yes
Responsibility for clients' care	Case managers can originate from several different teams (a mental health team, addictions care team, primary care health team, shelter team, Housing First etc.). Regardless of the team, all case managers play the role of navigator and keep the client's needs at the forefront of their care.			
	Case manager or a navigator role is played by a clinician, nurse, community outreach worker, or social worker [15,26].	Case manager	A multidisciplinary team including case managers, peer support workers, and physicians [20].	Case manager or CTI worker [22].
Case example	Client is homeless or vulnerably housed with no serious mental illness or addictions concerns. Client accesses SCM. Here a clinician, nurse, social worker or outreach worker to play the role of a standard case manager and refer to needed services.	Client is homeless or vulnerably housed with a serious mental illness and/or addiction concern. Client accesses ICM. Here a case manager will arrange for needed assistance and will accompany them to services.	Client is homeless or vulnerably housed with a serious mental illness and/or addiction concern and a history of recurrent hospitalizations. Client accesses ACT. A multidisciplinary team led by a case manager, will offer services in the client's natural setting (home/workplace).	Client is homeless or vulnerably housed and is in a period of transition (i.e. from a shelter or hospital into a housing unit). Client accesses CTI where a case manager or CTI worker will broker or provide services to help with the transition.

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Methods

Protocol registration and reporting

We conducted a systematic review according to a published peer-reviewed protocol [29]. The protocol was not registered in an open-access registry (e.g. PROSPERO) prior to publication.

We followed the PRISMA checklist and SWiM (Synthesis Without Meta-Analysis) reporting guidelines when reporting our findings (see S1 File) [30,31]. Ethical approval was not required for this study.

Selection of priority interventions

We conducted a Delphi consensus process with 84 experienced healthcare practitioners and 76 persons with lived homelessness experience to prioritize person-centered and clinically meaningful priority topics, outcomes, and subgroups [32]. Among these, case management and care coordination were highly prioritized. We then scoped literature using Google Scholar and PubMed to broadly determine a list of interventions and terms relating to each of the Delphi priority topic categories. A working group was formed to arrive at a consensus and inform the final selection of interventions to be included in this review. This working group consisted of medical practitioners, allied health professionals, and community scholars (people with lived experience of homelessness or vulnerable housing) [33]. Our working group deliberated the value of systematic reviews and evidence-based guidelines on various interventions, giving significant weight to the needs and opinions of persons with lived experience of homelessness. Consensus of the working group was to describe case management interventions by level of intensity (Table 1)

Search strategy and selection criteria

A search strategy was developed and peer-reviewed by a health science librarian. We searched MEDLINE, Embase, CINAHL, PsycINFO, Epistemonikos, HTA database, NHSEED, DARE, and the Cochrane Central Register of Controlled Trials (CENTRAL) from the inception of these databases to February 8, 2018, for studies on effectiveness, cost and cost-effectiveness. A combination of indexed terms, free text words, and MeSH headings were used (See S2 File). There were no date or language restrictions. We searched the reference lists of relevant systematic reviews for studies that met our inclusion criteria. We consulted experts in the field of homelessness and people with lived experience to identify any additional studies we may have missed. We updated our search on July 19, 2019 and deduplicated against our previous search to identify trials published since February 2018.

The results were uploaded to Rayyan reference manager software to facilitate the study selection process [34]. Teams of review authors assessed each study for inclusion in duplicate (See Table 2); disagreements were resolved through discussion or a third reviewer. All peer-reviewed studies that assessed case management interventions among homeless or vulnerably housed populations and that reported on relevant outcomes were included. We excluded articles where case management was delivered as a component of a permanent supportive housing intervention as this is covered by a parallel review [35].

Data analysis

We used a standardized data extraction sheet that included the study methodology, population, intervention, control, outcome, study limitations, and funding details. The data were extracted independently by two reviewers. Disagreements were resolved through discussion. To prevent double-counting of outcomes, individual records were carefully screened to identify unique trial studies. Each study was then evaluated for potential overlap using study design, enrollment and data collection dates, authors and their associated affiliations and the reported selection and eligibility criteria in the studies to inform the assessment. Studies deemed to be at risk for double-counting were discussed by the research team and decisions for inclusion in meta-analysis (and any additional analyses) were made. We used the Cochrane Risk-of-Bias tool to assess the quality of each study's methodology, in duplicate [40].

Table 2. Eligibility criteria.

Study Characteristics	Inclusion Criteria	Definitions
Population	People experiencing homelessness and vulnerable housing. If study populations were heterogeneous, we included the study if the population was comprised of >50% homeless or vulnerably housed individuals.	
Interventions	Standard Case Management (SCM)	These allow for the provision of an array of social, healthcare, and other services with the goal of helping the client maintain good health and social relationships. This is done by "including engagement of the patient, assessment, planning, linkage with resources, consultation with families, collaboration with psychiatrists, patient psychoeducation, and crisis intervention" [36].
	Intensive Case Management (ICM)	ICM helps service users maintain housing and achieve a better quality of life through the support of a case manager that brokers access to an array of services. The case manager accompanies the service user to meetings and can be available for up to 12 hours per day, 7 days a week. Case managers for ICM often have a caseload of 15–20 service users each [15].
	Assertive Community Treatment (ACT)	ACT offers team-based care by a multidisciplinary group of healthcare workers in the community. This team has 24 hours per day, 7 days per week availability and provides services tailored to the needs and goals of each service user [15,23].
	Critical Time Intervention (CTI)	CTI is a service that supports continuity of care for service users during times of transition; for example, from a shelter to independent housing or following discharge from a hospital. This service strengthens the person's network of support in the community [37]. It is administered by a CTI worker and is a time-limited service, of usually a period of 6–9 months.
Comparison	No intervention, standard intervention, alternative intervention, treatment as usual.	
Outcomes	Housing stability, mental health, quality of life, substance use, hospitalization, income, and employment-related outcomes.	
Study Characteristics	Primary studies as defined by EPOC criteria [38] Randomized controlled trials Non-randomized controlled trials Controlled before-after studies Interrupted time series and repeated measures studies Cost or cost-consequence studies Full economic evaluation studies: cost-minimization analysis, cost-benefit analysis, cost-effectiveness analysis, and cost-utility analysis. All study designs must include interventions with a comparison/control group and have measured outcomes.	
Study Characteristics	**Exclusion Criteria**	**Justifications**
	Studies taking place in low- middle-income countries [39].	Due to the variability in access to resources and supports in comparison to that in a high-income country vary greatly. We feel that the settings are different and should be synthesized separately
	Studies that exclusively report on Indigenous specific interventions	The analysis of the interventions tailored to this population will be covered by an Indigenous research group.
	Case management delivered as a component of a permanent supportive housing intervention	This is covered by a parallel systematic review [35].

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Where possible, we conducted meta-analysis of measures of effectiveness using random effects models due to their consideration of heterogeneity using RevMan 5.3 software [41]. We verified that the random effects model did not under-estimate the confidence intervals by running parallel fixed effects analyses. We present the summary effects as relative risks or

Table 3. GRADE certainty of evidence and definitions.

Certainty rating	Definition
High	Further research is very unlikely to change our confidence in the estimate of the effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of the effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of the effect and is likely to change the estimate
Very low	Any estimate of the effect is very uncertain

Source: [43]

https://doi.org/10.1371/journal.pone.0230896.t003 standardized mean differences, as appropriate. Where study heterogeneity did not allow for meta-analysis, we employed a narrative synthesis, defined as a "synthesis of findings from multiple studies that relies primarily on the use of words and text to summarise and explain the findings of the synthesis. Whilst it can involve the manipulation of statistical data, the defining characteristic is that it adopts a textual approach to the process of synthesis to 'tell the story' of the findings from the included studies" [42]. We used the GRADE approach to appraise the certainty of the evidence (See Table 3) [43].

Results

We identified 11,934 citations from bibliographic databases and an additional 17 from other sources. After removing duplicates, we screened 7,514 titles and abstracts for eligibility. We assessed 268 citations at full-text, of which 214 were excluded (See Fig 1 and S3 File). Our updated search yielded a total of 1877 additional records, of which 1869 records were screened by title and abstract after removing duplicates. We assessed 36 articles at full text, of which 34 were excluded (See Fig 2). From both searches, we included a total of 56 citations, of which 11 reported on SCM [44–54], 10 on ACT [25,55–63], 17 on ICM [64–80], and 11 on CTI [81–91]. Twelve articles provided evidence on cost-effectiveness; 3 on SCM [50,79,92]; 6 on ACT [56,59,93–96]; 2 on ICM [97,98]; and 1 for CTI [89] (See Figs 1 and 2). Five of the cost-effectiveness articles were included in the effectiveness analysis as well [50,56,59,79,89]. The majority of the included studies were set in the United States, with three studies from Europe and one from Australia. All of the studies focused on homeless and vulnerably housed populations, with varying levels of participant profiles and comorbidities across studies. All trials compared case management interventions to usual care (UC) or an alternative intervention, such as rent vouchers, peer support groups or drop-in services. Appendix S4 lists the characteristics of the included studies on SCM, ICM, ACT, CTI and cost-effectiveness studies.

Characteristics of included studies (SCM)

The effects of all of the case management interventions are summarized in Table 4. In our risk-of-bias assessment (See S5 File), we found that the majority of studies had methodological deficiencies in randomization, allocation concealment and blinding of participants and personnel. The GRADE certainty of the evidence for critical patient-important outcomes is available in S6 File.

Effects of standard case management (SCM)

Of 11 trials on SCM, ten evaluated housing stability [44–48,50–54]. Only three reported significant decreases in homelessness [44,51,52]; an effect that diminished over time in one trial of a time-limited residential case management where participants in all groups accessed significant levels of services [44].

A SCM program tailored to women reduced the odds of depression at 3 months (OR 0.38 95% CI 0.14 to 0.99) but did not show improvements in their overall mental health status (MD 4.50; 95% CI -0.98 to 9.98) [53]. One trial reported *higher* levels of hostility ($p<0.001$) and depression symptoms ($p<0.05$) among female participants receiving nurse-led SCM compared to those receiving standard care, although no significant difference in psychological well-being was reported between these groups [49]. Two additional trials reported no impact on mental health outcomes [44,54]. Two trials reported decreased problematic substance use [44,79], and four others reported no effect on this outcome [48–50,53].

Findings were equivocal for quality of life outcomes. One trial compared health advocate SCM (with or without outreach registration) to usual care [45,46]. While some quality of life

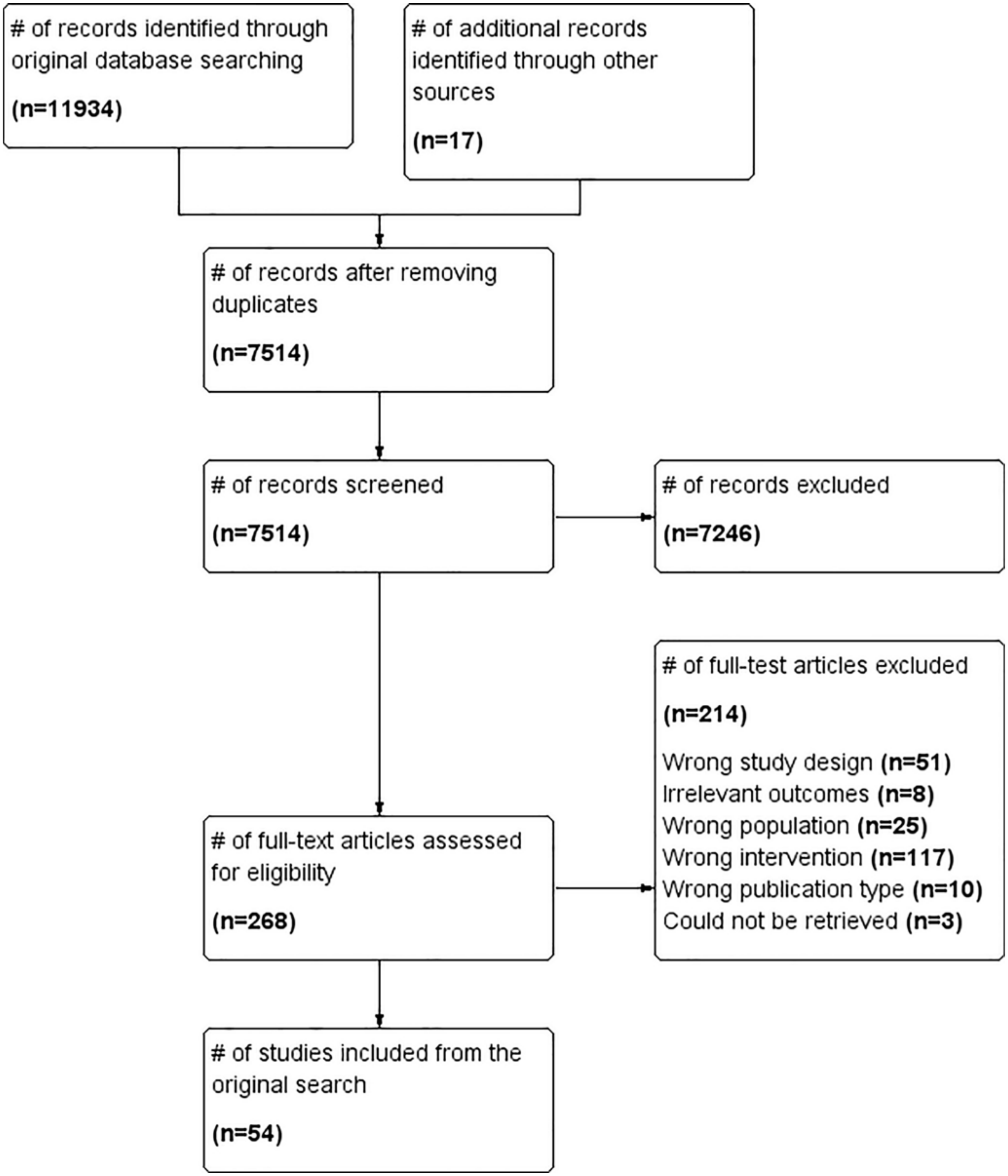

Fig 1. PRISMA flow diagram of search up to February 2018.

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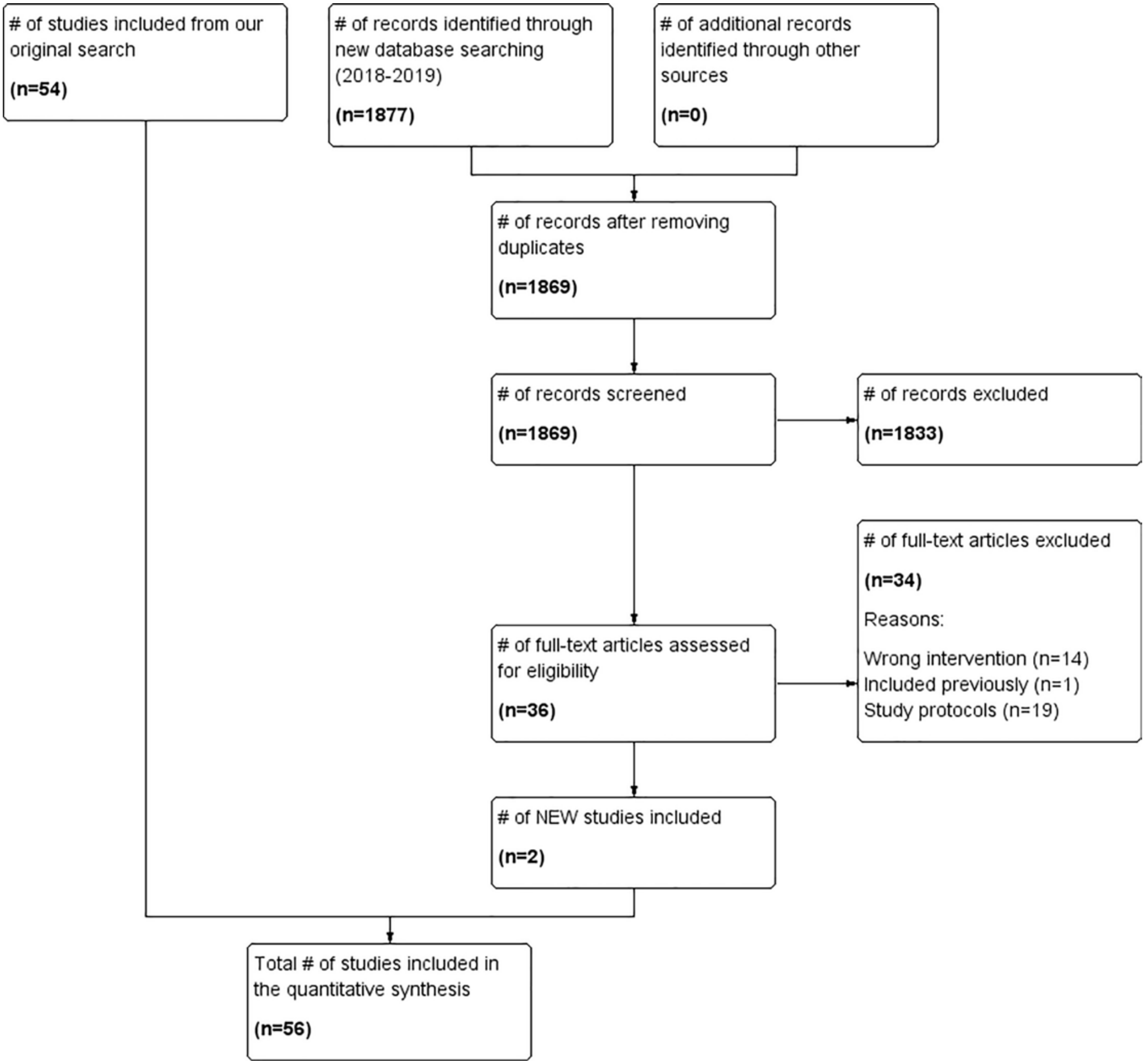

Fig 2. PRISMA flow diagram with updated search up to July 2019.

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domains (e.g. social isolation, sleep) favored health advocate SCM, most effects on quality of life were not significant. Another trial reported no significant benefits of nurse-led SCM on life satisfaction scores [49].

A single trial of health advocate SCM (with or without outreach registration) assessed health service utilization over three months [46]. Only five percent of all participants accessed the emergency department, with no significant difference between health advocacy or usual care groups [46]. Finally, five studies assessed the effectiveness of SCM on employment

Table 4. Results of studies comparing assertive community treatment, intensive case management, critical time interventions, and standard case management to control services.

		Is the between-group difference significantly favouring the case management intervention?						
Intervention*	**Study ID**	**Housing stability**	**Mental health**	**Quality of life**	**Substance use**	**Hospitalization**	**Employment**	**Income**
ACT	[55]	No	-	-	-	No	-	-
ACT	[56]	Yes	No	Yes [1,3]	-	Yes [1,3]	-	No
ACT	[25]	-	No	No	Yes [2]	Yes [2]	-	-
ACT	[57]	Yes [2]	No	-	No	-	-	-
ACT	[58]	Yes [1]	No	Yes [1]	-	Yes	-	-
ACT	[61]	Yes [2]	No	-	No	-	-	No
ACT	[62,63]	Yes [2]	Yes[1]	-	No	-	-	No
ACT	[59,60]	No	No	-	No	-	-	-
ICM	[64]	No	No	No	Yes [1]	-	No	-
ICM	[65]	No	No	-	No	-	-	-
ICM	[66]	-	Yes [1]	Yes [1]	No	-	-	-
ICM	[67]	Yes[2]	-	-	-	-	-	-
ICM	[68,69]	Yes	-	-	Yes [1]	-	No	Yes [1,3]
ICM	[70]	-	No	Yes [1,2]	-	-	-	-
ICM	[71]	No	-	-	-	-	-	No
ICM	[72]	Yes	-	-	-	No	-	-
ICM	[73]	No	No	-	Yes[1]	No		-
ICM	[74]	No	No	No	-	No	No	-
ICM	[75]	Yes [3]	Yes [3]	-	Yes [3]	-	Yes [3]	-
ICM	[76]	No	-	-	No	Yes	-	Yes
ICM	[77]	Yes [1]	Yes [1]	Yes [1]	-	-	-	-
ICM	[78]	Yes [2]	No	-	Yes [2]	-	No	-
ICM	[79]	Yes	No	-	Yes	Yes [2]	-	Yes
ICM	[80]	No	Yes [1]	-	No	-	-	No
CTI	[81]	No	No	No	No	-	-	-
CTI	[82,83]	Yes [1,3]	-	-	-	Yes [1,3]	-	-
CTI	[84]		Yes [1]	No				
CTI	[85,86]	Yes [1]	Yes [1,2]	-	-	-	-	-
CTI	[87–91]	Yes [1]	-	-	-	No	-	No
SCM	[44]	Yes [diminished with time]	No	-	Yes [1] [diminished with time]	-	Yes	-
SCM	[45,46]	No	-	Yes [1]	-	No	-	-
SCM	[47]	No	-	-	-	-	-	-
SCM	[48]	No	-	-	No	-	No	-
SCM	[49]	-	HARMS	No	No	-	-	-
SCM	[50]	No	-	-	No	-	No	-
SCM	[51]	Yes	-	-	Yes	-	No	-
SCM	[52]	Yes	-	-	-	-	-	-
SCM	[53]	No	Yes [1]	-	No	-	-	-
SCM	[54]	No	No	-	-	-	No	-

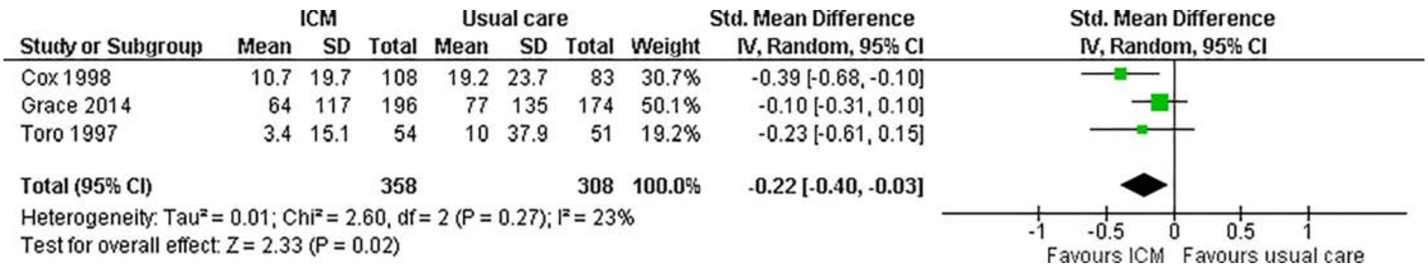
*Assertive Community Treatment; ACT. Intensive Case Management; ICM. Critical Time Intervention; CTI. Standard Case Management; SCM.

1. Depends on sub-outcomes

2. Depends on sub-groups

3. Depends on analysis methodology

https://doi.org/10.1371/journal.pone.0230896.t004



	ICM			Usual care				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Cox 1998	10.7	19.7	108	19.2	23.7	83	30.7%	-0.39 [-0.68, -0.10]
Grace 2014	64	117	196	77	135	174	50.1%	-0.10 [-0.31, 0.10]
Toro 1997	3.4	15.1	54	10	37.9	51	19.2%	-0.23 [-0.61, 0.15]
Total (95% CI)			**358**			**308**	**100.0%**	**-0.22 [-0.40, -0.03]**

Heterogeneity: Tau² = 0.01; Chi² = 2.60, df = 2 (P = 0.27); I² = 23%
Test for overall effect: Z = 2.33 (P = 0.02)

Fig 3. ICM versus usual care pooled analysis of number of days spent homeless (long term, 13+ months follow-up).

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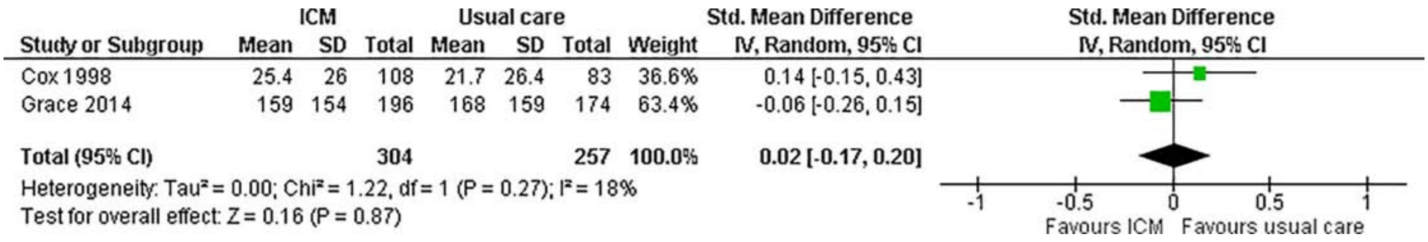
outcomes. One trial reported a significant improvement in employment over 24 months [44], whereas four trials showed no significant difference [48,50,51,54]. While one trial suggests that SCM improves access to income assistance ($p<0.05$) [51], no trials on SCM measured participant income as an outcome.

Effects of intensive case management (ICM)

Fourteen of sixteen trials on ICM assessed housing stability [64,65,67,68,71–80]. Overall, ICM showed small positive effects on housing outcomes, with seven of these fourteen studies [67,68,72,75,77–79] suggesting improvements in housing stability and the other seven reporting no effect (Table 4). A pooled analysis shows that ICM significantly reduced the number of days spent homeless (SMD -0.22 95% CI -0.40 to -0.03; See Fig 3) but had no significant effect on the number of days spent in stable housing compared to usual services (See Fig 4). These findings were unchanged regardless of whether random effects or fixed effects models were used in the analysis (See S7 File). For time-limited interventions, ICM effectively housed more participants [72], reduced time spent in community housing, streets and shelters [77], and reduced the number of moves to different residences [71]. Three other trials reported that ICM was associated with no difference on the number of days in no-rent or privately rented accommodations, better or worse accommodations, stable housing or homelessness compared to standard case management or usual services [74,75,78].

ICM had mixed effects on mental health outcomes. Four trials reported significant reductions in psychological symptoms [66,75,77,80], whereas seven additional trials reported no effect [64,65,70,73,74,78,79]. In two trials, positive mental health outcomes were correlated with improvements in quality of life [66,77], with an additional trial reporting better quality of life despite no significant differences in mental health [70]. Only one trial reported no effect of ICM on quality of life [74].

ICM had a significant benefit in reducing substance use in six of ten trials that measured this outcome [64,68,73,75,78,79]. ICM was associated with significant reductions in alcohol consumption [68,73,75] and reductions in problematic drug use [64,78,79].



	ICM			Usual care				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Cox 1998	25.4	26	108	21.7	26.4	83	36.6%	0.14 [-0.15, 0.43]
Grace 2014	159	154	196	168	159	174	63.4%	-0.06 [-0.26, 0.15]
Total (95% CI)			**304**			**257**	**100.0%**	**0.02 [-0.17, 0.20]**

Heterogeneity: Tau² = 0.00; Chi² = 1.22, df = 1 (P = 0.27); I² = 18%
Test for overall effect: Z = 0.16 (P = 0.87)

Fig 4. ICM versus usual care pooled analysis of number of days spent in stable housing (long term, 13+ months follow-up).

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ICM had mixed effects on participants' hospitalization outcomes. Two studies reported significant reductions in the number of emergency department visits but not in the use of other hospital services compared to usual care [76,79]; while three additional trials reported no significant reductions in the number of days in hospital compared to usual services or support groups [72–74].

Finally, the effect of ICM on income and employment outcomes was small. In one study, ICM was associated with increased number of days paid from employment [75], which was not found in four other trials [64,68,74,78]. Three studies reported that ICM was significantly associated with increased attainment of public income assistance and reduced the incidence of unmet financial need [79] among single adults [68,76]. However, among youth [71], and families [80], ICM had no impact on income obtained from employment or public assistance.

Effects of assertive community treatment (ACT)

Assertive community treatment showed promising effects on housing stability in five of seven trials that measured this outcome [56–58,61,62]. Participants who received ACT reported significantly more days in community housing ($p = 0.006$) [58], and fewer days homeless ($p<0.01$) compared to usual or supportive services [61]. ACT marginally improved the number of days participants spent in stable housing compared to supportive services ($p = 0.032$) [62], and usual services ($p = 0.09$) [57]. However, two trials, one of which included a follow-up study, did not identify any housing-stability benefits of ACT over usual or supportive services [55,59,60].

The effects of ACT on mental health outcomes were moderately positive. In one trial, ACT interventions were associated with fewer psychological symptoms in the areas of unusual activity levels ($p<0.03$) and thought disorder ($p<0.02$) compared to other supportive services [62]. Six other trials reported no additional effects of ACT on mental health compared to usual or supportive services [25,56–59,61]. ACT had equivocal effects on substance use outcomes. One trial showed that ACT participants with more severe alcohol use disorder experienced faster and earlier improvements in substance use compared to those with less severe alcohol-use disorder or those randomized to usual or supportive services ($p<0.01$) [25]; however, this difference was not significant by the end of three years. Four trials reported no additional benefits of ACT on substance use outcomes over usual or supportive services [57,59,61,62].

Findings on quality of life outcomes were mixed. One trial reported that ACT was significantly associated with better overall quality of life over 18 months compared to those receiving SCM ($p<0.05$) [56]. Another trial found no significant improvements for ACT over usual care in objective quality of life measures over 12 months, although ACT participants showed earlier improvement in life satisfaction rates compared to usual care at 6 months ($p = 0.005$) [58]. A third trial found no additional effects of ACT on quality of life outcomes compared to usual and supportive services [25].

Findings on hospitalization outcomes were mostly positive. One trial reported that ACT participants spent approximately half as many days in the hospital compared to those receiving standard case management [56]. No significant differences between groups were found on time to discharge from hospital or length of hospitalization. Another trial showed that ACT was associated with significantly fewer days hospitalized over 3 years compared to other supportive services (MD 19; $p = 0.002$) [25]. One trial reported fewer emergency department visits for ACT participants compared to usual care at 12 months ($p = 0.009$) [58], whereas another trial found no effect of ACT over usual care on either days in hospital or emergency department visits [55].

Finally, three trials reported no effect of ACT on income outcomes over usual or supportive services [56,61,62]. No trials measured employment outcomes.

Effects of critical time interventions (CTI)

Critical time interventions showed a promising effect on housing stability in three of four trials [82,85,87]. In the US context, one trial found that CTI significantly reduced the number of days spent homeless during the final 18 weeks of the study, compared to usual services (OR 0.22; 95% CI 0.06 to 0.88) [82]; however, this effect was not significant over the entire 18 months of the trial. Another trial reported a significant reduction in the average number of nights spent homeless among CTI participants compared to usual services over 18 months (Difference = -61; p = 0.003) [87]. Families that received CTI transitioned from shelter to housing more rapidly than the usual services group (MD -107.9 days; 95% CI -136.2,-79.6) [86]. Conversely, one European trial found that CTI did not have any impact on days rehoused after a 9-month period compared to usual services [81].

CTI showed little effect on mental health outcomes. However, a trial conducted among abused women reported significantly fewer symptoms of PTSD during follow-up (Adjusted MD -7.27, 95% CI -14.31 to -0.22, p = 0.04), but no effect on symptoms of depression or psychological distress [84]. In another RCT [85], families who received CTI showed mixed results on the frequency of children's internalizing and externalizing problems.

Two RCTs examined quality of life outcomes and found no significant impact of CTI over usual services at 9 months [81,84]. As well, when looking at substance-use outcomes, CTI was associated with non-significant reductions in cannabis and alcohol use [81].

One study found that CTI was significantly associated with reduced odds of rehospitalization (OR 0.11, 95% CI 0.01 to 0.96, p = 0.07) and total number of nights hospitalized ($p<0.05$) in the final 18 weeks of the trial [83]. Another trial suggests that CTI reduced the total number of nights of hospitalization over 18 months but not the average length of hospital stays [88].

Finally, one trial showed no significant effect of CTI on income-related outcomes compared to usual services [89]. No trials reported on employment-related outcomes.

Cost and cost-effectiveness of the interventions

Evidence on cost and cost-effectiveness was mixed. The total cost incurred by SCM clients was higher than those receiving usual or standard care [50,79], but lower compared to a US clinical case management program that included housing vouchers and ICM [98]. Cost-effectiveness studies showed that when the benefits gained and costs borne to all payers were considered (also known as a societal perspective) SCM was not cost-effective compared to ACT for persons with serious mental disorders or those with a concurrent substance-use disorder as it was both more expensive [56,94], and was associated with more days in unstable housing [56], and poorer quality of life [94]. SCM was slightly more costly than ACT because SCM clients had nominally more frequent visits to outpatient health care and other community services, more arrest episodes, and incurred higher family time costs compared to ACT clients. For ICM, Stergiopoulos and colleagues showed that the cost of supporting housing with ICM could be partially offset by reductions in the use of emergency shelters and in single-room occupancies [97]. ICM was reported as likely to be cost-effective when all costs and benefits to society are considered [98]. A pre-post study found that when ICM was provided to high users of emergency departments there was a net hospital cost savings of USD$132,726 [92]. For ACT, the included studies that focused on individuals with severe mental illness or dual disorders consistently showed that ACT interventions were associated with lower costs and improved health outcomes compared to the outcomes of usual care [56,59,94–96]. We identified only one study on the cost-effectiveness of CTI which reported that the CTI provided to men with severe mental illness had comparable costs (US$52,574 vs. US$51,749) despite fewer nights spent homeless (508 vs. 450 nights) compared to usual services [89].

Discussion

We conducted a comprehensive systematic review of four case management interventions for people who are homeless or vulnerably housed. The interventions were complex, and the study populations, intervention intensity, and outcomes were heterogeneous, making it challenging to generalize our findings. However, we can make some overarching statements to guide policy and practice. In general, standard case management showed little to no benefit across any of our outcome domains and in one trial [49], implementing SCM was associated with elevated levels of hostility and depression. We found that interventions of greater intensity, such as intensive case management, assertive community treatment and critical time intervention, did improve several outcomes of interest, most notably housing stability. ICM was found to reduce substance use in several studies and CTI to marginally reduce psychological symptoms; however, there was little impact on the quality of life across studies. ICM was associated with a reduced number of emergency department visits but not of hospital admissions, and both ACT and CTI, overall, showed significant reductions in both the number of emergency department visits and days in hospital. Only ICM was found to consistently improve income outcomes, with significant improvements in access to financial assistance and reductions in unmet financial needs. Case management interventions, especially ACT, were cost-effective for persons with complex needs, including those with severe mental illness or dual disorders, if the overall costs and benefits to patients, health care systems and society as a whole were considered.

Our findings suggest that the effectiveness of case management interventions is related both to the intensity of models as well as to their ability to address and advocate for the comprehensive needs of specific groups such as those with severe mental health conditions or those experiencing transitions in care. Findings suggested that the case management needed to be continuous, community-based and intensive so as to maintain and/or increase the gains achieved. For example, in Sosin and colleague's trial [51], improvements in housing stability were attributed to the case worker's advocacy for access to income benefits and help with locating housing. Not surprisingly, higher intensity case management models, which generally have lower caseloads, also include the provision of services above and beyond care coordination and incorporate outreach services, especially in the case of ICM, which is shown to have greater effects compared to other less intensive case-management models. This may be due to their capacity to address some of the underlying social determinants of health that contribute to the cycle of homelessness, such as poverty, which requires longitudinal engagement with case managers. A parallel review also suggests that case management can have significant impacts when provided in conjunction with permanent housing [35]. Given the heterogeneity of these complex interventions, we cannot be certain of the precise mechanisms and key features that promote effectiveness. However, it is likely that a dose-response relationship may explain some of our findings, and that as higher intensity interventions such as ACT and ICM are more precisely defined, there may be greater attention to fidelity in their implementation [19]. Alternatively, it is possible that lower intensity models work predominantly for homeless populations with less acute issues (or for those that are precariously housed), and this would suggest the importance of matching the intensity of the intervention with the acuity of need. Some indicators from a parallel qualitative review point to a case-manager-client relationship built on trust and continuity of care and integrated services as being key factors in the success of case management programs [99]. Many programs include peers and people with lived experience acting in case management roles [100–103], and while this has been identified as important to those confronted with homelessness [104–106], such approaches require formal evaluation.

These findings contribute to an expanding evidence base on effective interventions for people who are homeless or vulnerably housed. Our review builds on a previous review by De Vet [15] as it incorporates evidence up to 2019 and also considers a broader definition of standard case management that includes health advocates, as well as residential and disease-specific case management. Our study includes studies from the US, Europe and Australia, allowing us to make inferences about more diverse health and social systems which are important to address homelessness as an international public health priority [15]. Overall, our findings are congruent with De Vet's conclusions, but with some important differences. Notably, we saw fewer significant results in access to housing among recipients of CTI, likely arising from differences in healthcare and social contexts. The intensity of "usual care" in the Netherlands was high compared to the US context, where follow-up services were not typically available. Additionally, the Netherlands has an extensive social housing system; thus, reducing the short-term risk of recurrent homelessness. More recent CTI studies also suggest lower rates of rehospitalization than was found in our review. Finally, our broader inclusion criteria of SCM interventions allowed us to identify potential harms, such as higher levels of hostility and depression among case management recipients. Overall, our findings are in agreement with other earlier reviews, including those of Coldwell and Bender [23], Hwang [107], Vanderplasschen [28], and Mueser [108]. We also incorporated cost-effectiveness, and while the results were mixed, they provide important evidence on the potential economic impact of case management interventions on health care systems and society.

In the studies reviewed, the quantitative synthesis was complicated by the heterogeneity that exists across interventions. In addition, there is a lack of clarity in and overlap of the nomenclature used to define different case management interventions [12]. Furthermore, few studies provided the level of intervention detail required to make concrete recommendations with respect to the types of activities conducted, the roles and responsibilities of the case managers, and the postulated mechanisms of success that could inform future practice. Such lack of detail can further contribute to challenges in implementation and fidelity across interventions.

To our knowledge, this is the first systematic review to consider a broad range of outcomes and cost-effectiveness of these types of case-management interventions. We used high quality methods to synthesize randomized controlled trials and controlled trials, conducted meta-analyses, and used GRADE methods to assess the certainty of the effects. We integrated persons with lived experience of homelessness into our research team to ensure the relevancy of this work. Limitations include heterogeneous interventions and populations that precluded quantitative synthesis; thus, the studies were too few to allow us to conduct meta-analyses for the many included outcomes. As the majority of studies were conducted in the United States, our findings may not be generalizable to contexts with substantially different health and social systems. Poorly defined control or "usual care" groups further complicates the relative effectiveness of one case management model over another—a particular issue for SCM models. A weakness inherent to a secondary analysis is the potential for bias with respect to the reporting of results for multiple outcomes. Further, we restricted our inclusion criteria to rigorous experimental study designs, thereby, excluding observational studies that may have provided additional evidence in this area. This review is quantitative in nature and we may have excluded important findings related to case management found in the qualitative literature.

In summary, helping people who are homeless and vulnerably housed navigate and access a complex system of services yields positive outcomes in areas such as housing stability and mental health. Case management interventions may be most effective when they target specific complex populations or times of transition with more effective interventions that involve low caseloads, greater intensity and continuity of contact time, and direct service provision in addition to mere coordination. More research is needed on SCM models and their ideal target populations. Further, there is a need to more formally evaluate how to best integrate case management into delivery models such as chronic care management programs [109–111], and patient medical home approaches [112,113]. We postulate that further work is required to understand how to embed such interventions in the primary care setting, given the appeal of its continuous and comprehensive nature [114,115]. We suggest future research should apply a realist lens in order to further understand the critical elements and implementation strategies of case management interventions [116,117].

Supporting information

S1 File. PRISMA checklist.
(PDF)

S2 File. Search strategy.
(PDF)

S3 File. List of excluded studies.
(PDF)

S4 File. Characteristics of included studies.
(PDF)

S5 File. Risk of bias summary.
(PDF)

S6 File. GRADE evidence profiles.
(PDF)

S7 File. Fixed and random effects analyses.
(PDF)

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Integrating Mental Health Care Services Into HIV Comprehensive Care

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ABSTRACT

OBJECTIVES: HIV prevention strategies prioritize medication adherence among people living with HIV (PLWH). Of the 1.1 million PLWH in the United States, more than two-fifths are not virally suppressed and thus experience increased morbidity and mortality as well as transmission risk. Integrated care models are meant to address these gaps and often cite the importance of mental health care services (MHCS). However, research into the impact of integrating MHCS has been limited to those in homogenous treatment.

STUDY DESIGN: This study used an analytic observational cross-sectional design to achieve the above objectives.

METHODS: This study utilized a cross-sectional survey aimed to identify needs among PLWH in the Midwestern region of the United States and to stratify by both MHCS need and receipt. The survey, administered throughout 2018 in 12 HIV service organizations, was completed by PLWH receiving different supportive services. Comparative logistic regression models were calculated to identify the likelihood of nonadherence based on both MHCS receipt and need.

RESULTS: Of the 537 survey respondents, 20% reported receiving integrated MHCS, 8% reported needing but being unable to receive MHCS, and 72% reported not needing or receiving MHCS. Overall, 50% of the sample reported missing at least some HIV medication within the past 30 days. Individuals who needed but did not receive MHCS were more likely to report treatment nonadherence. No significant difference in adherence was identified between those who received MHCS and those who did not need MHCS.

CONCLUSIONS: Results suggest that continued assessment of needs and integration of MHCS into HIV care improves the likelihood of medication adherence. Further, our study highlights how systematically asking PLWH about their needs and connecting them to services may critically affect HIV management.

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HIV treatment adherence plays a critical role in the US National HIV/AIDS Strategy, which is ultimately aimed at reducing the number of new HIV infections by 75% within 5 years.[1] Adherence to antiretroviral therapy results in decreased likelihood of HIV-related morbidity and mortality and a 96% reduction in likelihood of viral transmission.[2,3] However, of the 1.1 million people living with HIV (PLWH) in the United States, only an estimated 63% are virally suppressed (HIV RNA < 200 copies/mL), signifying decreased treatment adherence.[4,5] The HIV integrated care model was developed to address these barriers to continued engagement in care and adherence. This system of care is developed to be individualized and community centered, which may leave PLWH without comprehensive treatment plans.[6-8] Mental health care persists as a common need among PLWH, with limited service availability.[9]

Psychiatric disorders are more prevalent among PLWH; however, those who are able to initiate and engage in active treatment plans often manage their HIV effectively.[10,11] Further, psychological distress symptoms are more common among PLWH who are not virally suppressed compared with those who are virally suppressed.[12] Thus, there are urgent needs to deliver mental health care services (MHCS) among this population. Identifying PLWH who are engaged in MHCS juxtaposed with populations who report needing but not receiving MHCS may help illuminate the role of repeated assessment across the HIV care network.

The aim of this study was to determine the association between reported MHCS need and medication adherence among PLWH to better understand how receipt of care may influence HIV management. Of particular interest were the PLWH who reported the need for MHCS yet did not receive such care.

METHODS

Data for this study utilized 2017 cross-sectional anonymous survey responses completed by PLWH who reside within a 12-county Midwestern region. This annual survey was developed by the region's Ryan White HIV/AIDS Program Planning Council and is distributed

TAKEAWAY POINTS

Mental health care is cited as an important component of integrated HIV care. However, previous studies are often limited to respective samples in homogeneous treatment plans. Among a sample of people living with HIV, our study finds that:

- unique differences exist between those in need of mental health care services and those receiving mental health care services,
- receipt of mental health care services significantly improves likelihood of medication adherence, and
- developing and utilizing methods to identify gaps in integrated HIV care allows for more precise understanding of needs and service delivery.

by HIV case managers within the region. This survey assesses which support service needs are currently important to PLWH in the region.

Inclusion criteria for this study included having previously received a diagnosis of HIV, being 18 years or older at time of survey, and receiving comprehensive HIV case management services funded by the Ryan White HIV/AIDS Program at 1 of 12 case management locations throughout the region. Respondents complete a cross-sectional needs assessment survey annually; thus, they both are familiar with and play an integral role in developing the survey items and protocols. Surveys were conducted as program evaluation of the support services in the region; thus, informed consent was not sought. The data were shared without any identifying information.

Within the survey, MHCS were defined per service guidelines outlined by the Health Resources and Services Administration and the HIV/AIDS Bureau.[13] This includes "psychological and psychiatric treatment and counseling services…provided by a mental health professional licensed or authorized within the State to render such services." Respondents were asked whether (1) they had received MHCS within the past 12 months and (2) mental health care was a service they needed but had not received within the past 12 months. Based on responses, individuals were stratified into 1 of 3 groups by MHCS need and enrollment: group 1, receiving MHCS within the past year; group 2, needing MHCS but have not received them; or group 3, not needing nor receiving MHCS within the past year. Individuals who chose contradictory responses were excluded from analysis. In final predictive modeling, included sociodemographic characteristics were age, gender, race/ethnicity, history of chronic homelessness, and history of incarceration, based on their previously identified modification of HIV medication adherence within current literature.[14,15] In addition, respondents were asked to identify from a list of 26 other medical and social services listed on the survey which services they needed and whether they were receiving them. The numbers of services chosen by each participant were summed and incorporated into the adjusted model to differentiate MHCS from overall gaps in integrated care.

An adapted form of the Basel Assessment of Adherence Scale was used to assess HIV medication adherence. The single-item question is shown to be accurate and reliable among participants who manage chronic disease medication.[16] Further, self-reporting adherence among PLWH is correlated with viral load measurements.[17,18] Respondents were asked to estimate how often they missed doses of prescribed HIV medication during the past 30 days with choices ranging from "none" to "daily." Responses were then dichotomously coded as (1) adherent (no missed doses) or (2) nonadherent (some missed doses). Although a continuous measurement of adherence typically explains a higher proportion of variability, dichotomization is appropriate when categorical data (eg, responses) are skewed and is consistent with similar research.[19]

Descriptive statistical tests of sociodemographics were conducted among the total sample along with each stratified group by MHCS need and receipt to better understand how the groups may differ. Three logistic regression models were completed to determine the crude likelihood of reporting nonadherence based on MHCS group. Models 1 and 2 compared individuals in group 1 and group 2 with group 3, respectively, and model 3 compared adherence differences between groups 1 and 2. A final adjusted model was developed to account for the sociodemographic characteristics previously identified to be associated with adherence. Significance was reported at $\alpha = 0.05$.

RESULTS

Of nearly 6000 PLWH receiving services within the region, 599 participants attempted the survey.[20] Of the total, 55 (9.2%) surveys were excluded from analysis because of missing or incomplete responses. A small portion (n = 7; 1.2%) were excluded because of contradictory responses regarding receipt of mental health care in the past 12 months. A total of 537 (89.6%) participants completed surveys that were included in analysis.

The mean (SD) age among the sample was 43.8 (11.4) years. Most of the sample identified as male (n = 372; 69.3%) and as a racial/ethnic minority (n = 382; 71.1%). One in 5 participants reported ever having experienced chronic homelessness (n = 106; 20%), and 12.5% reported ever having been incarcerated (n = 68). Participants chose a mean (SD) of 2.2 (2.5) services that they needed but were not receiving. Half the sample (n = 269; 50.5%) reported missing 1 or more doses of HIV medication within the past 30 days.

Among the sample, 105 participants reported receiving MHCS within the past year (19.6%), 43 participants reported needing but not receiving MHCS (8.0%), and 389 individuals reported not needing nor receiving MHCS within the past year (72.4%). Additional sample characteristics by MHCS need are detailed in **Table 1**.

Logistic predictive model details and comparisons are depicted in **Table 2**. Crude results reveal no significant difference in medication adherence between group 1 and group 3 (odds ratio [OR], 0.96; 95% CI, 0.62-1.48). Individuals in group 2 were significantly more likely to report nonadherence compared with individuals in group 3 (OR, 3.08; 95% CI, 1.51-6.29) and group 1 (OR, 3.2; 95% CI, 1.46-7.04).

TABLE 1. Sample Characteristics of People Living With HIV According to Mental Health Care Service Need and Receipt

	Group 1[a] (n = 105; 19.6%)	Group 2[b] (n = 43; 8.0%)	Group 3[c] (n = 389; 72.4%)	Total (N = 537)
Number of unmet service needs, mean (SD)	2.1 (1.8)	4.9 (4.8)	2.0 (2.1)	2.2 (2.5)
Age in years, mean (SD)	45.3 (10.3)	39.4 (10.8)	43.9 (11.7)	43.8 (11.4)
Current gender male, n (%)	58 (55.2)	37 (86.0)	277 (71.2)	372 (69.3)
Racial/ethnic minority,[d] n (%)	76 (72.4)	26 (60.5)	280 (72.0)	382 (71.1)
History of chronic homelessness, n (%)	27 (25.7)	15 (34.9)	64 (16.5)	106 (19.7)
History of incarceration, n (%)	17 (16.2)	7 (16.3)	44 (11.3)	68 (12.7)
Missed ≥1 dose of HIV medication in the past 30 days, n (%)	49 (46.7)	32 (74.4)	188 (48.3)	269 (50.1)

[a] Received mental health care services within the past year.

[b] Needed but did not receive mental health care services within the past year

[c] Reported not needing or receiving mental health care services within the past year.

[d] Nonwhite, non-Hispanic.

TABLE 2. Likelihood of Missing HIV Medication Within Past 30 Days Based on Mental Health Care Service Need and Receipt[a]

	Model 1 Crude OR[b]	Model 2 Crude OR[b]	Model 3 Crude OR[b]	Model 4 Adjusted OR[b]
Group 1[c]	0.96 (0.62-1.48)		Reference	0.99 (0.62-1.58)
Group 2[d]		**3.08 (1.51-6.29)**	**3.21 (1.46-7.04)**	**3.09 (1.37-6.97)**
Group 3[e]	Reference	Reference		Reference
Number of unmet service needs				0.95 (0.88-1.03)
Age in years				**0.97 (0.95-0.98)**
Current gender male				1.12 (0.75-1.69)
Racial/ethnic minority				1.23 (0.84-1.92)
History of chronic homelessness				**1.84 (1.14-2.97)**
History of incarceration				1.61 (0.90-2.91)

OR, odds ratio.

[a] Bold entries indicate significance at $\alpha < 0.05$. Model 1 indicates no significant difference in medication adherence between group 1 and group 3. Model 2 indicates group 2 is significantly more likely to report nonadherence compared with group 3. Model 3 indicates group 2 is significantly more likely to report nonadherence compared with group 1.

[b] OR calculated from exponentiated β and 95% CIs.

[c] Received mental health care services within the past year.

[d] Needed but did not receive mental health care services within the past year.

[e] Reported not needing or receiving mental health care services within the past year.

Upon adjusting for age, gender, race/ethnicity, history of homelessness, history of incarceration, and overall unmet service need, individuals in group 2 were significantly more likely to report nonadherence (adjusted OR, 3.09; 95% CI, 1.37-6.97). In addition, older individuals were less likely to report being nonadherent for every year of age increase (adjusted OR, 0.97; 95% CI, 0.95-0.98), and individuals who reported experiencing chronic homelessness were significantly more likely to report nonadherence (adjusted OR, 1.84; 95% CI, 1.14-2.97).

DISCUSSION

These findings suggest the importance of routine assessment and linkage to supportive services to achieve HIV viral suppression. This study identified that PLWH who report needing but not receiving MHCS are significantly more likely to report nonadherence with HIV medication compared with both individuals who received MHCS and individuals who reported not needing MHCS. This increased likelihood of nonadherence among group 2 remained even after adjusting for sociodemographic characteristics and history of homelessness and incarceration. Whereas MHCS need and receipt were found to be significantly associated with medication adherence, other documented unmet service needs were not associated with medication adherence in the adjusted model.

Although HIV integrated treatment plans are meant to address adherence challenges, a large portion of PLWH remain virally unsuppressed.[21] These results identify the importance of routine assessment and integrating an MHCS component into HIV care models. Further, this study found that MHCS need was more relevant to medication adherence than other unmet needs. This highlighted the unique need for MHCS among PLWH, one that will require additional support from integrated care providers to implement. Although our findings are aligned with those of similar studies, we believe our research is unique and adds to the discourse because of the emphasis on routine assessment and referrals in integrated care models.[22,23]

Limitations

Limitations and alternative explanations were explored in an effort to more effectively contextualize our findings. Although self-reported data are commonly utilized in similar research, more vigorous methods of clinical data collection are available, yet not available to the study team.[19] However, by utilizing these self-reported data, we were able to capture and empower the voices and unique experiences of PLWH.[24] Future studies would benefit by comparing our findings with additional sources of data. Further, this study did not distinguish between types of mental health care treatment. However, these findings offer a novel introduction that effectively argues for the inclusion of routine assessments for the need for MHCS and their provision within integrated care models. Insights could be gained from additional research that examines the efficacy of different types of mental health care treatment and the association of those treatments' effectiveness with HIV outcomes.

CONCLUSIONS

Many PLWH continue to struggle with complex challenges and needs that contribute to increased transmission rates among populations.[25] Continuing to identify more effective components of integrated care models will aid in addressing these inequities. This study identifies that MHCS is one of those components. ■

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