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Complete List of Authors:	Eaton, Andrew; University of Toronto, Factor-Inwentash Faculty of Social Work; AIDS Committee of Toronto Chan Carusone, Soo; Casey House; McMaster University, Department of Health Research Methods, Evidence, and Impact Craig, Shelley; University of Toronto, Factor-Inwentash Faculty of Social Work Telegdi, Erin; Casey House McCullagh, John; AIDS Committee of Toronto McClure, David; AIDS Committee of Toronto Wilson, Walter; AIDS Committee of Toronto Zuniga, Leonardo; AIDS Committee of Toronto Berney, Kevin; AIDS Committee of Toronto Ginocchio, Galo; AIDS Committee of Toronto Wells, Gordon; AIDS Committee of Toronto Montess, Michael; AIDS Committee of Toronto Busch, Adam; AIDS Committee of Toronto Boyce, Nick; Ontario HIV and Substance Use Training Program Strike, Carol; University of Toronto, Dalla Lana School of Public Health Stewart, Ann; St. Michael's Hospital
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The ART of conversation: Feasibility and acceptability of a pilot peer intervention to help complex HIV-positive people transition from hospital to community

Andrew D. Eaton[1,2]*, Soo Chan Carusone[3,4], Shelley L. Craig[1], Erin Telegdi[3], John W. McCullagh[2], David McClure[2], Walter Wilson[2], Leonardo Zuniga[2], Kevin Berney[2], Galo F. Ginocchio[2], Gordon A. Wells[2], Michael Montess[2], Adam Busch[2], Nick Boyce[5], Carol Strike[6], Ann Stewart[3,7]

[1]Factor-Inwentash Faculty of Social Work, University of Toronto; Toronto, ON, Canada

[2]AIDS Committee of Toronto (ACT); Toronto, ON, Canada

[3]Casey House (CH); Toronto, ON, Canada

[4]Department of Health Research Methods, Evidence, and Impact; Hamilton, ON, Canada

[5]Ontario HIV and Substance Use Training Program; Toronto, ON, Canada

[6]Dalla Lana School of Public Health, University of Toronto; Toronto, ON, Canada

[7]St. Michael's Hospital; Toronto, ON, Canada

*Corresponding author. Factor-Inwentash Faculty of Social Work, University of Toronto. 246 Bloor St. W., Toronto, ON, Canada, M5S1V4 Phone: +1-416-978-8895. Email: andrew.eaton@utoronto.ca.

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Abstract

Objectives: To pilot test a peer-based intervention for people living with HIV who used substances and had challenges with antiretroviral adherence, and would be discharged from hospital to community.

Study design: A community-based, quasi-experimental pilot intervention study designed to assess feasibility, acceptability, and connection to a community-based HIV organization.

Setting: This study was conducted in Toronto, Canada at Casey House (CH; HIV/AIDS hospital) in collaboration with the AIDS Committee of Toronto (ACT; community-based HIV organization).

Participants: People living with HIV who were: CH inpatient between April 1, 2017 and March 31, 2018; struggled with antiretroviral adherence; actively used substances; and would be discharged to community were eligible. Approximately 40 people met criteria, 19 were approached by an inpatient nurse and 17 consented. Average age was 49 (SD=11), 59% were male, and participants averaged 8 comorbidities (SD=3). Twelve participants completed the intervention and nine connected with ACT.

Intervention: Titled *The ART of Conversation*, the three-pronged personalized intervention was developed through input from CH clients and ACT volunteers, all living with HIV. Intervention components were: a) pre-discharge goal-setting (adherence, substance use, self-identified goal) with the study nurse; b) pre-discharge meeting with an HIV+ peer volunteer (PV); and c) nine post-discharge phone calls between PV and participant, once/day for three days then once/week for six weeks.

Primary Outcomes: Feasibility was measured through proportion of eligible participants recruited, availability of PVs, and connection to ACT. Acceptability was assessed through participant interviews at three times (pre-intervention, post-intervention, 6-week follow-up) and through PV call logs.

Results: Pre-discharge goal-setting and PV meeting were both feasible and acceptable. Phone calls were a challenge following discharge (half of completers missed at least one call), although participants still connected with ACT services.

Conclusions: Although pre-discharge goal-setting and PV meeting were feasible, methods to maintain connection following discharge require further investigation.

Keywords: HIV & AIDS; Substance misuse; Social medicine; Qualitative research

Strengths and limitations of this study

- Patient and public involvement was prioritized throughout this study as people living with HIV co-designed the study and intervention, delivered the intervention, and collected and analyzed data.

- Peer support models have been identified as a priority area by policymakers to improve care transitions for people living with HIV.

- Interventions for a study population with severe medical and psychosocial complexity who are at high-risk of poor health outcomes need to be tested for feasibility and acceptability before launching a larger scale study.

- The key limitations are: the lack of a control group and randomization, which were not possible within our recruitment timeline and sampling frame; a potentially biased sample, as not all eligible participants were approached; and incomplete participation, as half of participants missed at least one post-discharge phone call.

1.0 Introduction

Hospital discharge can result in discontinuity of care, non-adherence to medications, and other negative outcomes [1], especially for people living with HIV [2, 3] who face complex medical and psychosocial challenges [4]. Medical and psychosocial complexity is multiple, overlapping issues that affect a person's health [5]. People living with HIV may experience complex medical issues (e.g., frequent hospitalizations, poor medication adherence, polypharmacy, concurrent comorbidities, etc.) [6, 7]. Psychosocial factors may overlap with health challenges, (e.g., increased substance use, homelessness, unemployment, social isolation, food insecurity, etc.) [8, 9, 10]. These complex difficulties can interrupt the cascade of care and increase the risk of mortality [1]; in particular, substance use is a priority area of focus for care retention interventions [11].

The cascade of care (i.e., HIV treatment cascade or the HIV care continuum) is a framework recommended by UNAIDS for member countries to measure their progress in ending the AIDS epidemic [2]. Individual countries, and individual states and provinces within those countries, have adapted this continuum to fit their local contexts [12, 13] and consulted patients in its local implementation [14]. However, a common end-point is universal amongst these frameworks: retention in care (i.e., attending regular medical appointments, accessing community supports) and maintaining viral suppression (<50 copies of HIV per millilitre of blood, meaning that people living with HIV cannot sexually transmit the virus) [16, 17]. Complex clients living with HIV are often hospitalized to re-adhere to medications and progress on the care cascade; however, the discharge transition can cause cascade regression and poor health outcomes [18]. 'Peer' interventions, provided by trained community members who share lived experience with clients, may be a helpful and cost-effective complement to outpatient clinical care in order to help people living with HIV maintain the health progress that they achieved in hospital [19, 20].

Meaningful involvement of people living with HIV as peers has been central throughout the history of HIV and AIDS [20, 21]. As governments were slow to respond to AIDS in its early years, people living with and affected by HIV formed community-based agencies and implemented peer-based models of care [21, 22]. Yet peer models are understudied amongst people living with both HIV and complex issues; most work focuses on prevention in the HIV-negative population [21, 23, 24, 25] or a single issue (most commonly, medication adherence) in the HIV-positive population [19, 20]. Peer interventions that address the more complex realities that some people living with HIV experience are recommended in policy, especially ones that improve linkages between clinical and community-based care [26, 27].

To design a peer intervention that could help people living with both HIV and complex issues in the transition from hospital to community, we used the theories of Community-Based Participatory Research (CBPR) and Minimally Disruptive Medicine (MDM). CBPR recommends the equitable involvement of the client population in the design and conduct of a study [28], which aligns with this study's aim to pilot a peer intervention. MDM suggests that new interventions may have better results when designed to fit within the context of people's lives [29]. In this study, CBPR was utilized through extensive consultation and involvement of people living with HIV where the recommendation for the study's intervention – goal setting, peer meeting, and post-discharge phone calls – was designed to be as minimally disruptive and acceptable to participants as possible.

With the context of the study's setting at Casey House (CH), a 14-bed HIV hospital with an average 45-day inpatient admission, and funding (one-year CBPR grant), a quasi-experimental pilot was developed to test peer intervention components for feasibility and acceptability.

1.1 Objectives

This study had two objectives. First, to pilot test a peer-based intervention for people living with HIV who had challenges with antiretroviral adherence and substance use and would be discharged from hospital to community; this study of feasibility and acceptability was conducted to determine whether intervention components could be applied in a larger trial. Second, to connect participants to the AIDS Committee of Toronto (ACT) – Canada's largest community-based HIV organization – for further post-discharge support. As this is a peer intervention, patient and public involvement (PPI) was prioritized so that people living with HIV had an active role in the study's design and conduct.

2.0 Methods

This study used primarily qualitative methods to evaluate proof-of-concept of a pilot peer intervention that involved people living with HIV in the study's design and conduct.

2.1 Study design

Participants were enrolled into a personalized three-stage peer-based intervention. Approximately forty people were included in the sampling frame (see participant flow below). Neither randomization nor a control group were feasible.

2.2 Patient and public involvement

People living with HIV became involved in this study as the concept was being developed. First, a community-based exploratory study interviewed CH clients about the discharge transition and found that participants were requesting peer support [18]. Second, two CH client engagement sessions (n=17, all HIV-positive) were held regarding the structure of a post-discharge peer program, including: duration; content; definition of 'peer'; how peers should be trained; and how the pilot should be evaluated. Third, a group consultation was held with ACT volunteers (n=10) who live with HIV and who provide direct service (e.g., support groups). This consultation discussed: the peer program requested by CH clients; program structure; evaluation methods including draft questionnaires; and whether attendees would engage with the study as a peer volunteer (delivering the intervention) or peer researcher (interviewing participants and analyzing data). Finally, one more CH client session (n=6) was facilitated by a peer researcher to continue developing the study questionnaires and intervention details. Based on these consultations, we defined 'peer' as a person living with HIV who has personal or relational experience with substance use.

Five peer researchers attended a 1.5 day, 11.5-hour training; the curriculum has been published elsewhere [30]. The main training component was filmed simulation, where peer researchers were video-recorded conducting simulated interviews to observe their verbal and non-verbal interactions

[31]. Peer researchers refined the study questionnaires, collected all data, and participated in the analysis.

Five peer volunteers (PV) from ACT delivered this intervention. These volunteers completed a total of 44 training hours. The first 22 hours were dedicated to ACT's core skills volunteer training which covers: creating safe and accessible spaces; HIV and health promotion basics; concepts in communication; and anti-oppression and cultural competence. The volunteers then attended 22 hours of training specific to the intervention which focused on: harm reduction; structuring a phone call; communication tools; and self-care.

2.3 Participants

An inpatient nurse at an HIV hospital identified people living with HIV who met inclusion criteria (based on admission details) and approached them regarding their interest in learning more about the three-stage peer program. If people were interested, the principal investigator then met with them for enrolment.

2.3.1 Eligibility criteria

Inclusion criteria: People who are HIV-positive; actively using substances (e.g., cocaine, crystal meth, etc.); inpatient at CH between April 1, 2017 and March 31, 2018; initiated/re-started antiretroviral therapy while they are inpatient at CH; going to be discharged back to the community; English-speaking; can access a phone; and can provide informed consent. Exclusion criteria: People who already participated in this study.

2.3.2 Settings

This study was conducted as a partnership between: a) Casey House (CH), Canada's only standalone HIV/AIDS hospital with fourteen inpatient beds and located in downtown Toronto; and b) the AIDS Committee of Toronto (ACT), Canada's largest community-based HIV/AIDS organization and located in downtown Toronto. CH was responsible for chart abstraction, goal setting and hosting the peer meeting. ACT was responsible for enrolling participants, training and supervision of PVs, and coordinating connection to community-based care.

2.3.3 Participant identification and consent

A study nurse (fourth author) identified participants based on their admission presentation (i.e., identified substance use and ART initiation/re-initiation). The nurse approached participants to introduce the study and, if they were interested in learning more, then referred them to the principal investigator (first author) for consent. To participate in the study, participants consented to the research and to becoming ACT clients. The consent process also involved discussion with participants of preferences regarding PV matches (e.g., schedule).

2.4 Intervention

The intervention consisted of three distinct stages. Participants set discharge goals with the recruiting nurse, then met with a PV prior to discharge. Following discharge, participants scheduled nine phone calls with their PVs over seven weeks.

2.4.1 Goal-setting

The study nurse met with participants during their inpatient admission to help them identify three goals that they wanted to achieve after discharge. One goal was related to their ART adherence, another related to their substance use, and a third personal goal. These goals were written on a Community Transition Planning (CTP) form (see supplementary file) that was designed based on principles of Motivational Interviewing, whereby the facilitators and barriers to a goal are thoroughly discussed [32]. Participants identified the change they wanted to make, the steps necessary to make this change, support people (both personal and professional supports), their importance and confidence at making the change, and significant events that would occur following discharge. Goal-setting occurred one week prior to discharge, and typically lasted half an hour. The forms were shared with PVs prior to their meetings with participants.

2.4.2 Peer volunteer (PV) meeting

The principal investigator matched a PV with a participant and the dyad met at CH to discuss the participant's CTP form, how the participant was feeling about leaving hospital, and the details of phone support (e.g., when to call, what to talk about, etc.). Discharge goals were further refined in this meeting. PVs were encouraged to self-identify shared experiences that might be relevant (e.g., substance use). This meeting occurred in the week leading up to discharge and usually took 45 minutes.

2.4.3 Post-discharge phone calls

The PV phoned the participant once per day for the three days following discharge, then once per week for the following six weeks. This schedule was determined through client consultation; people living with HIV stated that the first 72 hours following discharge were the most difficult and when their risk of relapse was highest. Calls commonly lasted 20-45 minutes and focused on discharge goals and other issues arising for participants, with a focus on connection to community-based services.

2.5 Outcomes

Feasibility was measured through: a) the proportion of eligible participants who were recruited, consented, and completed the study; b) PV availability; and c) connection to ACT (measured as accessing any ACT service within thirteen weeks of discharge). Acceptability was assessed through participant interviews at three times (pre-discharge, post-intervention, and 6-week follow-up) and through logs written by PVs following each phone call.

2.5.1 Measures

The intervention components were assessed qualitatively, with participants scheduled to complete three in-depth, semi-structured interviews with peer researchers (also living with HIV). The first interview occurred at CH following the PV meeting but prior to discharge, with questions on goal-setting and peer meeting components; medication adherence; substance use; community supports; and overall health. The second interview occurred at ACT at conclusion of peer support (week 7 following discharge). Questions from the first interview were repeated alongside probes for feedback on the post-discharge phone calls and the helpfulness of PVs sharing their own experiences. The third interview was held at ACT six weeks after the program's end (week 13 following discharge) and, alongside repeated questions from the first and second interview, focused on supports that the participant had accessed due to the peer program. Interviews were audio-recorded and averaged 00:41:20 in length.

PVs completed a contact log of each call, noting the call's content and rating how they felt the participant was doing individually, interpersonally, socially, and overall. These ratings were completed using the Outcome Rating Visual Analog Scale [33], where PVs placed a mark on a 10cm unnumbered line; instructions stated that marks to the left represented 'not well at all' and marks to the right indicated 'excellent'.

2.6 Sample size

A sample size of fifteen was selected for feasibility as: a) CH has an average 100 admissions per year; b) a clinical estimate based on retrospective chart review found that approximately half of admissions met this study's criteria; c) the hospital moved locations during our recruitment year, disrupting some services; and d) this sample size would allow the team to assess the feasibility and acceptability of intervention components across diverse experiences.

2.7 Data analysis

Research assistants (authors ten to twelve) transcribed interviews and entered data. The entire team held three iterative analysis meetings (four hours each) to read through the data and discuss how findings corresponded to the study's objectives. To qualitatively assess proof-of-concept, illuminating quotes were identified concerning facilitators and barriers of each intervention component. Contact log data is presented as a spaghetti plot; while the sample size limits our ability to interpret these findings, they provide context for the quotes.

3.0 Results

The participant flow and characteristics are presented, followed by numbers analyzed and outcomes concerning the feasibility and acceptability of intervention components. Participant quotes include a unique identifier and gender.

3.1 Participant flow

Figure 1 shows the flow of participants throughout the study. Only half of those eligible were approached due to poor health and risk of mortality for some in hospital.

3.2 Recruitment

A CH nurse approached people who: a) were inpatient at CH during the period of April 1, 2017 to March 31, 2018; b) self-identified substance use and challenges with antiretroviral adherence. Nineteen people were approached and two declined, leaving seventeen consenting to participate. Follow-up occurred seven weeks following discharge (second interview) and thirteen weeks following discharge (interview three), with the final interview occurring on July 11, 2018. The pilot program ended at this time due to the one-year funding agreement.

3.3 Baseline data

Refer to Table 1 for participant characteristics at admission, abstracted from their chart.

Table 1: Participant characteristics (n=17, unless specified otherwise)

Characteristic	N (%) / Mean (SD)
Gender	
Male	10 (59%)
Female	7 (41%)
Age (years)	49 (SD=11)
Income Source	
ODSP	11 (65%)
Other	6 (35%)
Employment Status	
On disability	11 (65%)
Unemployed	6 (35%)
Comorbidities	
Mental health diagnoses	3 (SD=1)
Total comorbidities	8 (SD=3)
Housing prior to admission	
Independent living	9 (53%)
Supportive housing	5 (29%)
Shelter	1 (6%)
Street-involved	1 (6%)
Rooming house	1 (6%)

Housing following discharge	
Independent living	9 (53%)
Supportive housing	6 (35%)
Rooming house	1 (6%
Unknown	1 (6%)
Reason for admission	
ART re-/initiation	7 (41%)
Psychosocial issues	5 (29%)
Acute medical condition	2 (12%)
Respite	2 (12%)
Post-surgical recovery	1 (6%)
Years living with HIV	16 (SD=9)
CD4 (N=14)	
>500	5 (36%)
200-500	4 (29%)
<200	5 (36%)
***Substances** identified	
Crack cocaine	8 (47%)
Opioids	5 (29%)
Crystal meth	5 (29%)
*most common	
Total # of medications at discharge	12 (SD=6)
Post-discharge care	
Family doctor	17 (100%)
Allied health (nursing, psychiatry, social work)	17 (100%)
Substance use program	9 (53%)
HIV specialist	7 (41%)
Adherence reminders	5 (29%)
Length of admission	44 days (SD=42), Median=26

3.4 Numbers analyzed

For feasibility, results are presented against a denominator of 19 (number of participants approached); this includes two people who declined to participate and seven who did not complete the intervention. For acceptability, a denominator of 12 is used as this number participated in all intervention components and completed follow-up interviews.

3.5 Outcomes

The intervention was feasible to recruit and coordinate, and led to participant connection to ACT services. The first two intervention components (goal-setting and peer volunteer meeting) were highly acceptable to participants, while the third (post-discharge phone calls) was well-received by half of completers but the other half had challenges engaging by phone. Patient and Public Involvement (PPI) contributed positively to study outcomes. Throughout the interviews, participants stated how much they appreciated that people living with HIV collaborated in the study's design, delivered the intervention, and conducted their interviews.

3.5.1 Feasibility

Overall, 63% (n=12) of participants who were approached completed the intervention with 57% (n=11) of the total sample connecting to ACT services. Interestingly, two participants who did not complete the intervention (one was lost to follow-up and we were unable to match the other with a peer volunteer) still connected to ACT. ACT services that participants accessed included counselling, support groups, and lunch programs.

Within a one-year recruitment timeline, five PVs were matched with sixteen participants (i.e., each volunteer had approximately three matches); there was only one instance where no volunteer was available to be matched with a participant. PPI may have contributed to ease of recruitment, as potential participants had heard about the study and contributed to its design. PVs received modest compensation at $150 per match.

3.5.2 Acceptability

The goal-setting and peer meeting components were acceptable to participants, with strong participation and positive feedback in interviews. Post-discharge phone calls were a challenge, as half of the participants who participated in this component (n=6) lost their phones, changed their numbers, and/or did not answer at some point over the six weeks of the program. This left six participants completing all nine calls as scheduled. From the twelve participants who engaged with phone calls, the mean number of calls per match was 5.75.

3.5.2.1 Goal-setting results

Most participants (n=15) identified goals for the seven weeks after discharge related to: 1) antiretroviral adherence; 2) substance use; and 3) a personal goal. Participants rated their importance and confidence of each goal on a scale from '1' (not at all) to '10' (very much); figure 2 shows these results.

Participants expressed a high degree of confidence in achieving their adherence goals, despite a reported history of challenges. Substance use goals were primarily abstinence-based and had the lowest confidence of success. Open-ended goals were identified as the most important and primarily focused on improving living space and social connections.

3.5.2.2 Peer volunteer meeting results

Thirteen participants met with an ACT peer volunteer at CH, following goal-setting and prior to discharge, to discuss upcoming discharge, goals, and to make a plan for post-discharge phone calls. Participants appreciated the opportunity to meet with a peer; this was their first non-clinical service interaction during their hospital stay. As one person said, "He told me where he's at…and I shared a bit, [I was] thinking this guy is going to be a counsellor…and then I realized, huh, this guy's on my level" (P3, male).

In the consultations with people living with HIV to design this study, the issue of demographics was raised regarding whether people would be able to connect across ages, genders, etc. Participants felt comfortable connecting with their volunteer regardless of these identities, with one participant saying:

> I wasn't expecting somebody that young to be able to interact with me and understand me...I was even more comfortable when she told me she had HIV. And then I forgot all about [demographics], like we started talking you know she knows how to interact. It's not a thing anybody can do. It's not just about asking the questions it's about making the person feel comfortable and she did that with me (P6, female).

3.5.2.3 Post-discharge phone call results

Peer volunteers phoned participants once per day for the first three days following discharge, then once per week for the following six weeks. The phone calls were the most challenging component of this intervention as half of the participants lost their phones, changed their numbers, and/or did not answer at some point over the program's duration. Participants engaged well while on the phone, speaking with peer volunteers about their discharge goals, other issues in their lives, and how to improve their health and social engagement.

Some participants appreciated the flexibility of phone calls and felt they could engage with a peer volunteer in this manner, as one person said:

> The way we were able to interact, communicate, understand. It was like he understood everything I was saying and I understood everything he was saying. And it was great. I couldn't imagine not having someone like him. Yes, because it made me think, how do I explain it, in the last few years, I've been stuck in a hole. Like it just flew, no one to talk to, not one to help, nowhere to reach out, no nothing. When [Volunteer] came along it was like having a peer in a different type of background and culture (P9, male).

Other participants indicated that the phone calls felt impersonal and that in-person peer support was preferable, with a participant saying "I'm just not a phone person…I don't know, I just can't. It's easier [in-person], you don't really know somebody [over the phone]" (P1, female).

Figure 3 displays the Visual Analog Scale results from the PV call logs. PVs rated how each participant was doing individually, socially, interpersonally, and overall with 0 representing 'not well' and 10 representing 'excellent'. Overall, the most difficult period was 1-2 weeks post-discharge with

participants improving by 5-6 weeks after leaving hospital. Participants who were lost to follow-up were rated lower than people who completed the program.

3.6 Harms

There were no reported study-related harms.

4.0 Discussion

The principal findings of this pilot are that: a) pre-discharge goal-setting and a peer volunteer meeting were feasible and acceptable for a sample of people living with HIV and complex needs; b) while some participants appreciated post-discharge phone calls, others experienced barriers to this method of engagement; and c) a clinical and a community-based HIV organization can partner for improved connection to care.

Compared to other studies, a strength of this study was its substantial involvement of people living with HIV at multiple stages. This PPI approach may have made recruitment easier and contributed towards the positive experience that participants had with multiple intervention components [34]. Another strength was this study's focus on people with complex needs; participants averaged eight comorbidities (e.g., AIDS, cancer, hepatitis C) and are commonly lost to follow-up from outpatient clinical care at CH, so the finding that 65% (n=11) connected with ACT services suggests that peer support can be a helpful catalyst in the discharge transition [20]. This study's primary weaknesses are the lack of randomization and control; other peer support studies have found significant effects in larger samples by focusing on a single issue of concern [19, 20]. A PPI weakness was the mixed results from the post-discharge phone calls, a component of the intervention that was specifically requested from current and former CH clients. In-person peer support has shown better outcomes than post-discharge phone calls in other quasi-experimental studies [35, 36].

For clinicians, this study presents two intervention components – pre-discharge goal setting and peer meeting – that can be feasibly incorporated into practice at low cost and time commitment which may ease the discharge transition for people experiencing complex medical and psychosocial needs. For policymakers, this study responds to a call for greater collaboration between clinical and community-based care [26] by highlighting how a hospital and a community agency can partner to provide peer support.

The goal-setting and peer meeting intervention components need to be tested in a larger trial with greater rigour and a sufficient sample, using standardized measures, to properly ascertain their effectiveness. Future research on post-discharge peer support with a complex population group should be more intensive than weekly phone contact; in-person follow-up, whether meeting in social spaces (such as coffee shops), home visits, or outpatients returning to hospital for post-discharge peer groups could be combined with phone calls as more supportive methods of retaining people in care.

4.1 Limitations

This study has several limitations. Without randomization and control and with a small sample, there remains uncertainty regarding the two promising intervention components (goal-setting and peer meeting). There is a risk of selection bias as eligible participants who were in particularly fragile health were not approached [37]. Incomplete participation amongst a small sample requires that the results be interpreted with some caution.

4.2 Applicability

The goal-setting and peer meeting components show preliminary promise for easing the discharge transition for people living with HIV and complex needs. These components could be more rigorously tested by specialty hospitals, where peers can be adequately trained and supported, to address high rates of lost-to-follow-up and eventual readmission for complex clients.

4.3 Interpretation

While there is some uncertainty regarding this study's benefits, a study of this nature does no harm. Peer support has been found effective on single issues regarding HIV (such as medication adherence); this study's attempt to pilot peer support regarding more complex needs is a first step towards better supporting the more marginalized people living with HIV who require more targeted support than is currently offered. The PPI approach helped facilitate study recruitment and the first two intervention components, yet the third component (post-discharge phone calls) received mixed results despite its PPI influence. This interpretation suggests that in a future definitive trial, post-discharge peer support could combine phone and in-person meetings. Multiple methods of engagement may be more acceptable to participants and contribute to greater completion rates, which could lead to better outcomes.

5.0 Conclusion

This pilot study presents two intervention components (goal-setting and peer volunteer meeting) that have preliminary proof-of-concept in easing the discharge transition and connection to community-based care for people living with HIV and complex needs. More research is needed to determine the ideal form of post-discharge peer support for this population.

Author contributions

ADE oversaw all study activities, supervised personnel, consented participants, led the analysis and interpretation of results, and wrote the first draft of the manuscript. **SCC** led patient engagement activities and co-led analysis and interpretation of results. **SLC** co-led analysis and interpretation of results and met monthly with ADE and SCC to discuss study progress. **ET** facilitated participant goal-setting and coordinated peer volunteer meetings and discharge timing. **JWM, DM, WW, LZ,** and **KB** contributed to study design and collected data. **GFG, GAW,** and **MM** prepared data for analysis through transcription and data entry. **AB** and **NB** trained peer volunteers with ADE. **CS** and **AS** contributed to

study design and analysis. All the authors co-conceptualized the study, contributed to analysis, critically reviewed the manuscript, and approved the final submitted version of the manuscript.

Competing interests

There are no competing interests for any author.

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Data sharing statement

No additional data available. Anyone interested in accessing the data reported in this article can write to the corresponding author who will consult with the University of Toronto's HIV/AIDS Research Ethics Board and respond as appropriate. Requests can be sent to andrew.eaton@utoronto.ca.

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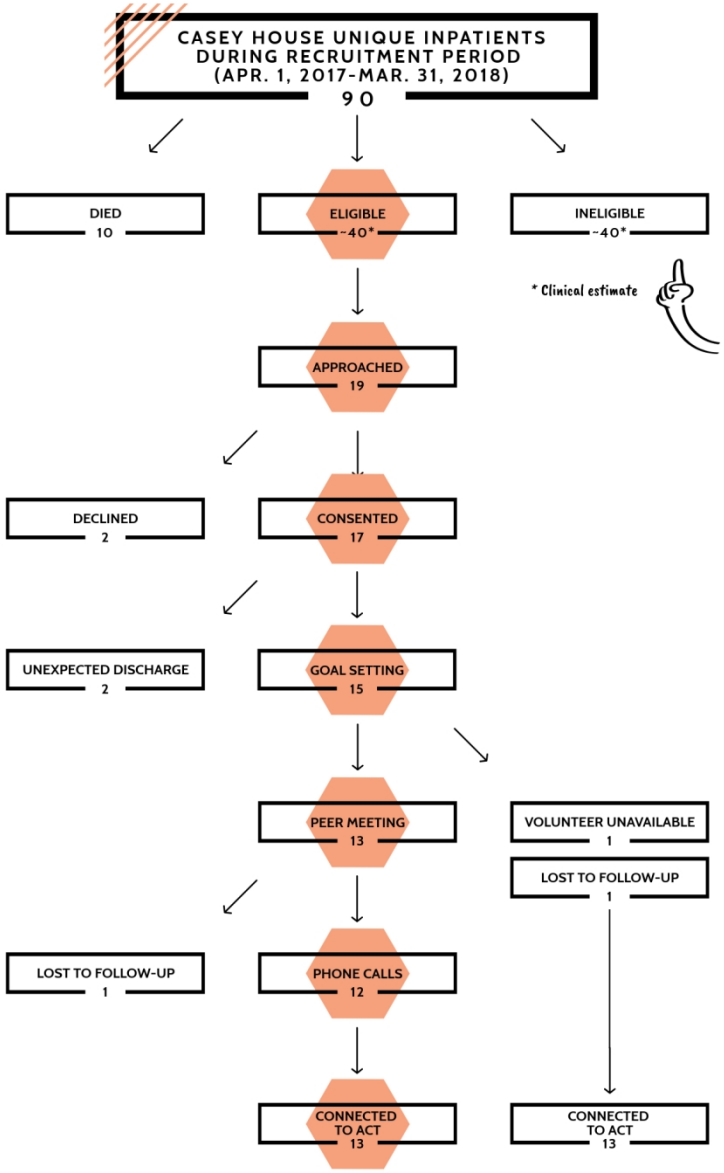

Figure 1: Participant flowchart

564x723mm (72 x 72 DPI)

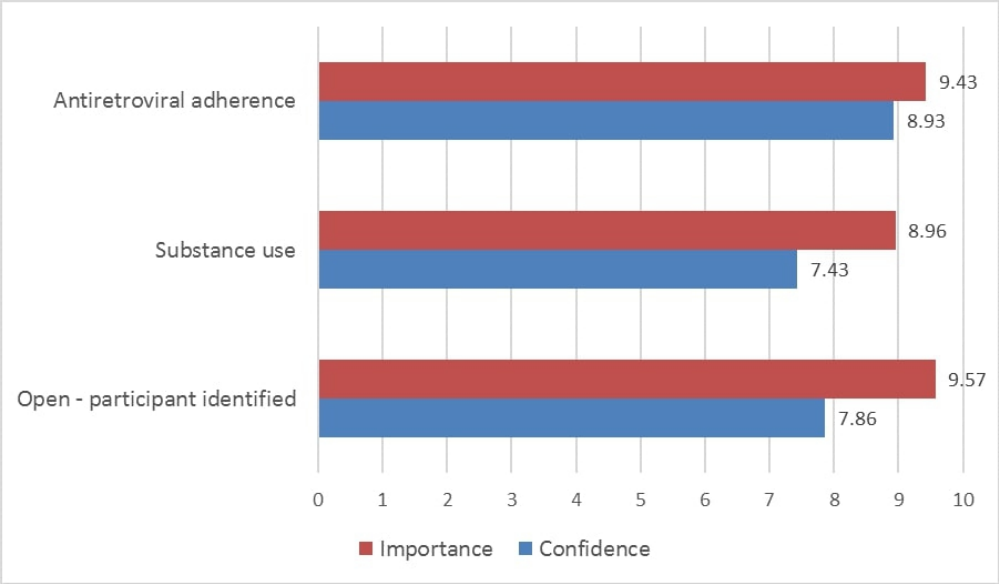

Figure 2: Participant assessment of goal importance and confidence

318x185mm (72 x 72 DPI)

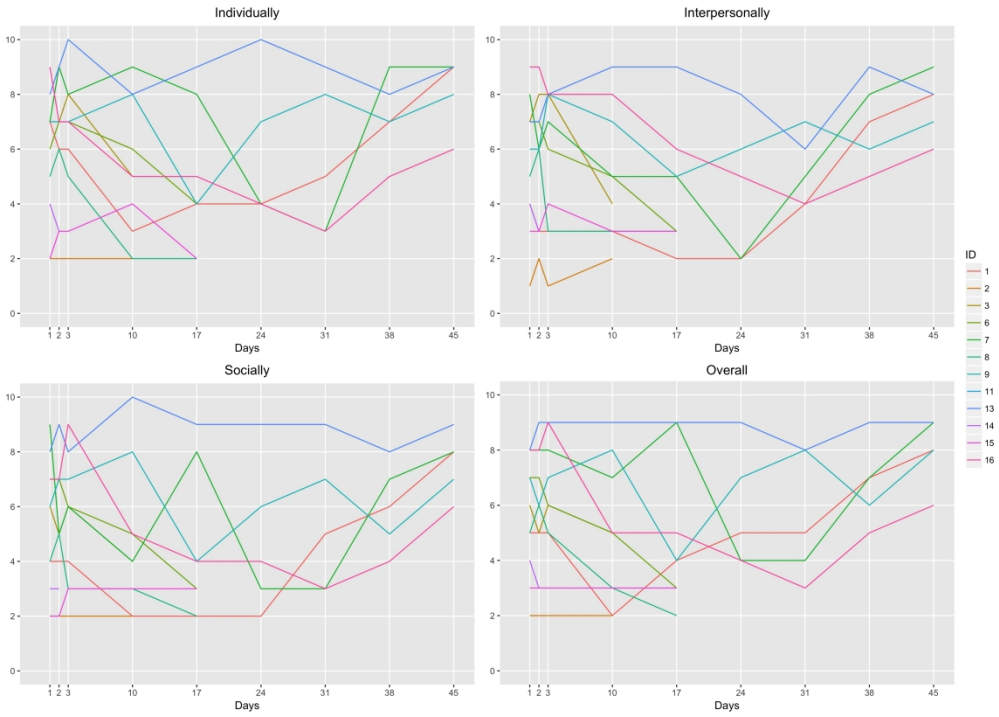

Figure 3: Peer volunteer assessment of participants

1481x1058mm (72 x 72 DPI)

ART of Conversation – Community Transition Planning Forms (CTP)

Community transition change plan

Goal #1: **HIV Medications** **(Note: A CTP form is completed for each area identified by participant)**	
The change I want to make (or continue making) is:	
Some barriers or difficulties that may get in the way are:	
The steps I plan to take in making this change are:	
The person/agency/organization that can support me in making this change is: *Name:* *Contact info:* *How can they help:*	
How important is it to you to make this change? (1-10 scale)	*How confident are you that you can make this change? (1-10 scale)*

Support people/agency/organization

Name	Role	Contact info.
i.e. Chris Smith	**A friend who helps walk my cat.**	**(416) 962-7600**
(Names the person puts forward while in the mind set of discharge transition)		

Significant dates/appointments/events following discharge

Date	Details
i.e. Jan 1st	**My partners birthday**
	(Some significant dates will be in the chart/discharge summary but this completed box can venture beyond medical appts./referrals)

Community transition change plan

Goal #2: **Substance Use** **(Note: A CTP form is completed for each area identified by participant)**	
The change I want to make (or continue making) is:	
Some barriers or difficulties that may get in the way are:	
The steps I plan to take in making this change are:	
The person/agency/organization that can support me in making this change is: *Name:* *Contact info:* *How can they help:*	
How important is it to you to make this change? (1-10 scale)	*How confident are you that you can make this change? (1-10 scale)*

Support people/agency/organization

Name	Role	Contact info.
i.e. Chris Smith	**A friend who helps walk my cat.**	**(416) 962-7600**
(Names the person puts forward while in the mind set of discharge transition)		

Significant dates/appointments/events following discharge

Date	Details
i.e. Jan 1st	**My partners birthday**
	(Some significant dates will be in the chart/discharge summary but this completed box can venture beyond medical appts./referrals)

Community transition change plan

Goal #3: **Open – client-identified** **(Note: A CTP form is completed for each area identified by participant)**	
The change I want to make (or continue making) is:	
Some barriers or difficulties that may get in the way are:	
The steps I plan to take in making this change are:	
The person/agency/organization that can support me in making this change is: *Name:* *Contact info:* *How can they help:*	
How important is it to you to make this change? (1-10 scale)	*How confident are you that you can make this change? (1-10 scale)*

Support people/agency/organization

Name	Role	Contact info.
i.e. Chris Smith	**A friend who helps walk my cat.**	**(416) 962-7600**
(Names the person puts forward while in the mind set of discharge transition)		

Significant dates/appointments/events following discharge

Date	Details
i.e. Jan 1st	**My partners birthday**
	(Some significant dates will be in the chart/discharge summary but this completed box can venture beyond medical appts./referrals)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4-5
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	7-8
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	7-8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	9, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	9, Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the pilot trial ended or was stopped	9
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	9-10
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	10
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	11-13
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	14
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	14
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	14
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	14
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	N/A
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15
	26	Ethical approval or approval by research review committee, confirmed with reference number	15

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Guidance for Reporting Involvement of Patients and the Public 2 – Short Form (GRIPP2-SF)

Section and topic	Item	Reported on page No.
1: Aim	Report the aim of PPI in the study	4
2: Methods	Provide a clear description of the methods used for PPI in the study	5-6
3: Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	11
4: Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	13
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	14

BMJ Open

The ART of conversation: Feasibility and acceptability of a pilot peer intervention to help complex HIV-positive people transition from hospital to community

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The ART of conversation: Feasibility and acceptability of a pilot peer intervention to help complex HIV-positive people transition from hospital to community

Andrew D. Eaton[1,2]*, Soo Chan Carusone[3,4], Shelley L. Craig[1], Erin Telegdi[3], John W. McCullagh[2], David McClure[2], Walter Wilson[2], Leonardo Zuniga[2], Kevin Berney[2], Galo F. Ginocchio[2], Gordon A. Wells[2], Michael Montess[2], Adam Busch[2], Nick Boyce[5], Carol Strike[6], Ann Stewart[3,7]

[1]Factor-Inwentash Faculty of Social Work, University of Toronto; Toronto, ON, Canada

[2]AIDS Committee of Toronto (ACT); Toronto, ON, Canada

[3]Casey House (CH); Toronto, ON, Canada

[4]Department of Health Research Methods, Evidence, and Impact; Hamilton, ON, Canada

[5]Ontario Harm Reduction Network; Toronto, ON, Canada

[6]Dalla Lana School of Public Health, University of Toronto; Toronto, ON, Canada

[7]St. Michael's Hospital; Toronto, ON, Canada

*Corresponding author. Factor-Inwentash Faculty of Social Work, University of Toronto. 246 Bloor St. W., Toronto, ON, Canada, M5S1V4 Phone: +1-416-978-8895. Email: andrew.eaton@utoronto.ca.

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Abstract

Objectives: To pilot test a peer-based intervention for people living with HIV who used substances, had challenges with antiretroviral adherence, and would be discharged from hospital to community.

Study design: A community-based, quasi-experimental pilot intervention study designed to assess feasibility, acceptability, and connection to a community-based HIV organization.

Setting: This study was conducted in Toronto, Canada at Casey House (CH; hospital for people living with HIV) in collaboration with the AIDS Committee of Toronto (ACT; community-based HIV organization).

Participants: People living with HIV who were: CH inpatient between 01/04/2017 and 31/3/2018; struggled with antiretroviral adherence; actively used substances; and would be discharged to community were eligible. Approximately 40 people met criteria, 19 were approached by an inpatient nurse and 17 consented. Average age was 48.8 (SD=11.4), 58.8% were male, and participants averaged 7.8 comorbidities (SD=3.1). Twelve participants completed the intervention and nine connected with ACT.

Intervention: Titled *The ART of Conversation*, the three-pronged personalized intervention was developed through input from CH clients and ACT volunteers, all living with HIV. Intervention components were: a) pre-discharge goal-setting (adherence, substance use, self-identified goal) with the study nurse; b) pre-discharge meeting with an HIV+ peer volunteer (PV); and c) nine post-discharge phone calls between PV and participant, once/day for three days then once/week for six weeks.

Primary Outcomes: Feasibility was measured through proportion of eligible participants recruited, availability of PVs, and connection to ACT. Acceptability was assessed through participant interviews at three times (pre-intervention, post-intervention, 6-week follow-up) and through PV call logs.

Results: Pre-discharge goal-setting and PV meeting were both feasible and acceptable. Phone calls were a challenge following discharge (half of completers missed at least one call), although participants still connected with ACT services.

Conclusions: Although pre-discharge goal-setting and PV meeting were feasible, methods to maintain connection following discharge require further investigation.

Keywords

HIV & AIDS; Substance misuse; Social medicine; Qualitative research

Strengths and limitations of this study

- Patient and public involvement was prioritized throughout this study as people living with HIV co-designed the study and intervention, delivered the intervention, and collected and analyzed data.

- Peer support models have been identified as a priority area by policymakers to improve care transitions for people living with HIV.

- Interventions for a study population with severe medical and psychosocial complexity who are at high-risk of poor health outcomes need to be tested for feasibility and acceptability before launching a larger scale study.

- The key limitations are: the lack of a control group and randomization, which were not possible within our recruitment timeline and sampling frame; a potentially biased sample, as not all eligible participants were approached; and incomplete participation, as half of participants missed at least one post-discharge phone call.

1.0 Introduction

Hospital discharge can result in discontinuity of care, non-adherence to medications, and other negative outcomes [1], especially for people living with HIV [2, 3] who face complex medical and psychosocial challenges [4]. Medical and psychosocial complexity is multiple, overlapping issues that affect a person's health [5]. People living with HIV may experience complex medical issues (e.g., frequent hospitalizations, poor medication adherence, polypharmacy, concurrent comorbidities, etc.) [6, 7]. Psychosocial factors may overlap with health challenges, (e.g., increased substance use, homelessness, unemployment, social isolation, food insecurity, etc.) [8, 9, 10]. These complex difficulties can interrupt the cascade of care and increase the risk of mortality [1]; in particular, substance use is a priority area of focus for care retention interventions [11].

The cascade of care (i.e., HIV treatment cascade or the HIV care continuum) is a framework recommended by UNAIDS for member countries to measure their progress in ending the AIDS epidemic [2]. Individual countries, and individual states and provinces within those countries, have adapted this continuum to fit their local contexts [12, 13] and consulted patients in its local implementation [14, 15]. However, a common end-point is universal amongst these frameworks: retention in care (i.e., attending regular medical appointments, accessing community supports) and maintaining viral suppression (<50 copies of HIV per millilitre of blood, meaning that people living with HIV cannot sexually transmit the virus) [16, 17]. Complex clients living with HIV are often hospitalized to re-adhere to medications and progress on the care cascade; however, the discharge transition can cause cascade regression and poor health outcomes [18]. 'Peer' interventions, provided by trained community members who share lived experience with clients, may be a helpful and cost-effective complement to outpatient clinical care in order to help people living with HIV maintain the health progress that they achieved in hospital [19, 20].

Meaningful involvement of people living with HIV as peers has been central throughout the history of HIV and AIDS [20, 21]. From the first cases of AIDS to the present day, people living with and affected by HIV have been forming community-based agencies and implementing peer-based models of care [21, 22]. Yet peer models are understudied amongst people living with both HIV and complex issues; most work focuses on prevention in the HIV-negative population [21, 23, 24, 25] or a single issue (most commonly, medication adherence) in the HIV-positive population [19, 20]. Peer interventions that address the more complex realities that some people living with HIV experience are recommended in policy, especially ones that improve linkages between clinical and community-based care [26, 27].

To design a peer intervention that could help people living with both HIV and complex issues in the transition from hospital to community, we used the theories of Community-Based Participatory Research (CBPR) and Minimally Disruptive Medicine (MDM). CBPR recommends the equitable involvement of the client population in the design and conduct of a study [28], which aligns with this study's aim to pilot a peer intervention. MDM suggests that new interventions may have better results when designed to fit within the context of people's lives [29]. In this study, CBPR was utilized through extensive consultation and involvement of people living with HIV where the recommendation for the study's intervention – goal setting, peer meeting, and post-discharge phone calls – was designed to be as minimally disruptive and acceptable to participants as possible.

With the context of the study's setting at Casey House (CH), a 14-bed HIV hospital with an average 45-day inpatient admission, and funding (one-year CBPR grant), a quasi-experimental pilot was developed to test peer intervention components for feasibility and acceptability.

1.1 Objectives

This study had two objectives. First, to pilot test a peer-based intervention for people living with HIV who had challenges with antiretroviral adherence and substance use and would be discharged from hospital to community; this study of feasibility and acceptability was conducted to determine whether intervention components could be applied in a larger trial. Second, to connect participants to the AIDS Committee of Toronto (ACT) – Canada's largest community-based HIV organization – for further post-discharge support. As this is a peer intervention, patient and public involvement (PPI) was prioritized so that people living with HIV had an active role in the study's design and conduct.

1.2 Study Settings

This study was conducted as a partnership between Casey House (CH) and the AIDS Committee of Toronto (ACT) in downtown Toronto, Canada. CH is Canada's only standalone hospital for people living with HIV. CH has fourteen inpatient beds for sub-acute, palliative, and respite care. Inpatient admissions average approximately 45 days due to mortality risk amongst most patients. CH also offers community programs, and during the operation of this study launched a day health program to better support adults living with HIV and complex health and psychosocial conditions. ACT is Canada's largest community-based HIV/AIDS organization and offers prevention (i.e., safer sex outreach) and support (i.e., counselling, groups) for people living with and affected by HIV. CH was responsible for chart abstraction, goal setting and hosting the peer meeting. ACT was responsible for enrolling participants, training and supervision of PVs, and coordinating connection to community-based care.

2.0 Methods

This study used descriptive quantitative data and qualitative methods to evaluate feasibility and acceptability a pilot peer intervention that involved people living with HIV in the study's design and conduct.

2.1 Study design

Participants were enrolled into a personalized three-stage peer-based intervention. Approximately forty people were included in the sampling frame (see participant flow below). Neither randomization nor a control group were feasible due to the limited sampling frame and one-year timeline.

2.2 Patient and public involvement

People living with HIV became involved in this study as the concept was being developed and were engaged in four distinct activities. First, a community-based exploratory study interviewed CH clients about the discharge transition and found that participants were requesting peer support [18].

Second, two CH client engagement sessions (n=17, all HIV-positive) were held regarding the structure of a post-discharge peer program, including: duration; content; definition of 'peer'; how peers should be trained; and how the pilot should be evaluated. CH clients living with HIV identified that post-discharge phone support could be easier to access than an in-person peer meeting. Third, a group consultation was held with ACT volunteers (n=10) who live with HIV and who provide direct service (e.g., support groups). This consultation discussed: the peer program requested by CH clients; program structure; evaluation methods including draft questionnaires; and whether attendees would engage with the study as a peer volunteer (delivering the intervention) or peer researcher (interviewing participants and analyzing data). Fourth, one more CH client session (n=6) was facilitated by a peer researcher to continue developing the study questionnaires and intervention details. Based on these consultations, we defined 'peer' as a person living with HIV who has personal or relational experience with substance use. There were two distinct groups of peers on this research team: a) peer researchers; and b) peer volunteers (PVs).

Five peer researchers attended a 1.5 day, 11.5-hour training; the curriculum has been published elsewhere [30]. The main training component was filmed simulation, where peer researchers were video-recorded conducting simulated interviews to observe their verbal and non-verbal interactions [31]. Peer researchers refined the study questionnaires, collected all data, and participated in the analysis.

Five peer volunteers (PV) from ACT delivered this intervention. These volunteers completed a total of 44 training hours. The first 22 hours were dedicated to ACT's core skills volunteer training which covers: creating safe and accessible spaces; HIV and health promotion basics; concepts in communication; and anti-oppression and cultural competence. The volunteers then attended 22 hours of training specific to the intervention which focused on: harm reduction; structuring a phone call; communication tools; and self-care.

2.3 Participants

An inpatient nurse at CH identified people living with HIV who met inclusion criteria (based on admission details) and approached them regarding their interest in learning more about the three-stage peer program. If people were interested, the principal investigator then met with them for enrolment.

2.3.1 Eligibility criteria

Inclusion criteria: People who are HIV-positive; actively using illicit substances (e.g., cocaine, crystal meth, etc.); inpatient at CH between April 1, 2017 and March 31, 2018; initiated/re-started antiretroviral therapy while they are inpatient at CH; going to be discharged back to the community; English-speaking; can access a phone; and can provide informed consent. Exclusion criteria: People at risk of mortality.

2.3.2 Participant identification and consent

A study nurse (fourth author) identified participants based on their admission presentation (i.e., identified substance use and ART initiation/re-initiation). The nurse approached participants to introduce the study and, if they were interested in learning more, then referred them to the principal

investigator (first author) for consent. To participate in the study, participants consented to the research and to becoming ACT clients. The consent process also involved discussion with participants of preferences regarding PV matches (e.g., schedule).

2.4 Intervention

The intervention consisted of three distinct stages. Participants set discharge goals with the recruiting nurse, then met with a PV prior to discharge. Following discharge, participants scheduled nine phone calls with their PVs over seven weeks.

2.4.1 Goal-setting

The study nurse met with participants during their inpatient admission to help them identify three goals that they wanted to achieve after discharge. A nurse was chosen to complete this activity as a means of bridging the clinical care that participants had received in hospital, with the peer support that they would be receiving after discharge. The nurse was trained in Motivational Interviewing (i.e., client-centred counselling to elicit positive goal-setting) [32] and harm reduction principles (i.e., stating that participants could set substance use goals concerning reduced or safer use, not solely abstinence). One goal was related to their ART adherence, another related to their substance use, and a third personal goal. These goals were written on a Community Transition Planning (CTP) form (see supplementary file) that was designed based on principles of Motivational Interviewing, whereby the facilitators and barriers to a goal are thoroughly discussed [32]. Participants identified the change they wanted to make, the steps necessary to make this change, support people (both personal and professional supports), their importance and confidence at making the change, and significant events that would occur following discharge. Goal-setting occurred one week prior to discharge, and typically lasted half an hour. The forms were shared with PVs prior to their meetings with participants.

2.4.2 Peer volunteer (PV) meeting

The principal investigator matched a PV with a participant, based on participant requests (e.g., similar substance use history, length of time living with HIV, gender, etc.). The dyad met at CH to discuss the participant's CTP form, how the participant was feeling about leaving hospital, and the details of phone support (e.g., when to call, what to talk about, etc.). Discharge goals were further refined in this meeting. PVs were encouraged to self-identify shared experiences that might be relevant (e.g., substance use). This meeting occurred in the week leading up to discharge and usually took 45 minutes.

2.4.3 Post-discharge phone calls

The PV phoned the participant once per day for the three days following discharge, then once per week for the following six weeks. This schedule was determined through client consultation; people living with HIV stated that the first 72 hours following discharge were the most difficult and when their risk of relapse was highest. Calls commonly lasted 20-45 minutes and focused on discharge goals and other issues arising for participants, with a focus on connection to community-based services.

2.5 Outcomes

The outcomes and measures are detailed below and in Table 1. Feasibility was measured through: a) the proportion of eligible participants who were recruited, consented, and completed the study; b) PV availability; and c) connection to ACT (measured as accessing any ACT service within thirteen weeks of discharge). Acceptability was assessed through participant interviews at three times (pre-discharge, post-intervention, and 6-week follow-up) and through logs written by PVs following each phone call.

Table 1: Outcomes and measures

Outcomes	Measures	Description
Feasibility	Participant recruitment and retention	Proportion of eligible participants who were recruited, consented, and completed the study
	Peer volunteer (PV) availability	Ability to match PVs with participants
	Connection to ACT	Participants accessing an ACT service (e.g., counselling, groups) within thirteen weeks after discharge
Acceptability	Semi-structured interviews at three times, conducted by peer researchers	Interview 1: Following PV meeting, prior to discharge Interview 2: Program conclusion (seven weeks after discharge) Interview 3: Follow-up (thirteen weeks after discharge)
	Contact logs	Reports from PVs following each phone call

2.5.1 Measures

The intervention components were assessed qualitatively, with participants scheduled to complete three in-depth, semi-structured interviews with peer researchers (also living with HIV). The first interview occurred at CH following the PV meeting but prior to discharge, with questions on goal-setting and peer meeting components; medication adherence; substance use; community supports; and overall health. The second interview occurred at ACT at conclusion of peer support (week 7 following discharge). Questions from the first interview were repeated alongside probes for feedback on the post-discharge phone calls and the helpfulness of PVs sharing their own experiences. The third interview was held at ACT six weeks after the program's end (week 13 following discharge) and, alongside repeated questions from the first and second interview, focused on supports that the participant had accessed due to the peer program. Interviews were audio-recorded and averaged 00:41:20 in length.

PVs completed a contact log of each call, noting the call's content and rating how they felt the participant was doing individually, interpersonally, socially, and overall. These ratings were completed

using the Outcome Rating Visual Analog Scale [33], where PVs placed a mark on a 10cm unnumbered line; instructions stated that marks to the left represented 'not well at all' and marks to the right indicated 'excellent'. PVs were trained to conduct these assessments through instruction on rating participants against how they presented in the initial peer volunteer meeting.

2.6 Sample size

A sample size of fifteen was selected for feasibility as: a) CH has an average 80 discrete admissions annually; b) a clinical estimate based on retrospective chart review found that approximately half of admissions met this study's criteria; c) the hospital moved locations during our recruitment year, disrupting recruitment for approximately one month; and d) based on existing pilot studies, this sample size would allow the team to assess the feasibility and acceptability of intervention components across diverse experiences [34, 35].

2.7 Data analysis

Research assistants (authors ten to twelve) transcribed interviews and entered data. The entire team held three iterative analysis meetings (four hours each) to read through the data and apply content analysis. Content analysis, as used in other qualitative assessments of intervention research [36] included discussion on how findings corresponded to the study's objectives, and which quotes illuminated the facilitators and barriers of each intervention component [37]. Contact log data is presented as a spaghetti plot; while the sample size limits our ability to interpret these findings, they provide context for the quotes.

3.0 Results

The participant flow and characteristics are presented, followed by numbers analyzed and outcomes concerning the feasibility and acceptability of intervention components. Participant quotes include a unique identifier and gender.

3.1 Participant flow

Figure 1 shows the flow of participants throughout the study. Of the ninety discrete inpatient admissions at CH during the recruitment period, 73 were excluded due to: a) an eligibility review of admission presentation, namely mortality risk (n=21) and unidentified substance use (n=40); b) death in hospital (n=10); and c) declining to participate (n=2).

3.2 Recruitment

A CH nurse approached people who: a) were inpatient at CH during the period of April 1, 2017 to March 31, 2018; b) self-identified substance use and challenges with antiretroviral adherence. Nineteen people were approached and two declined, leaving seventeen consenting to participate. Follow-up occurred seven weeks following discharge (second interview) and thirteen weeks following discharge (interview three), with the final interview occurring on July 11, 2018. The pilot program ended at this time due to the one-year funding agreement.

3.3 Baseline data

Participants were predominately male (58.8%, n=10) and had an average age of 48.8 (SD=11.4). Comorbidities (M=7.8, SD=3.1) most commonly were cancer, hepatitis C, and COPD; participants also had mental health diagnoses (M=3.2, SD=1.5), most commonly mood disorders (e.g., bipolar, depression) and organic mental disorders (e.g., HIV-associated neurocognitive disorder). Substances identified were mostly cocaine (47.1%, n=8), opioids (29.4%, n=5), and crystal meth (29.4, n=5). Participants were in hospital for an average of 44.3 days (SD=42.4) and were taking an average of 11.8 (SD=6.2) medications at discharge. Refer to Table 2 for further participant characteristics.

Table 2: Participant characteristics (n=17, unless specified otherwise)

Characteristic	N (%) / Mean (SD)
Gender	
Male	10 (58.8%)
Female	7 (41.2%)
Age (years)	48.8 (SD=11.4)
Income Source	
ODSP	11 (64.7%)
Other	6 (35.3%)
Employment Status	
On disability	11 (64.7%)
Unemployed	6 (35.3%)
Comorbidities	
Mental health diagnoses	3.2 (SD=1.5)
Total comorbidities	7.8 (SD=3.1)
Housing prior to admission	
Independent living	9 (52.9%)
Supportive housing	5 (29.4%)
Shelter	1 (5.9%)
Street-involved	1 (5.9%)
Rooming house	1 (5.9%)
Housing following discharge	
Independent living	9 (52.9%)
Supportive housing	6 (35.3%)
Rooming house	1 (5.9%)
Unknown	1 (5.9%)

Reason for admission	
ART re-/initiation	7 (41.2%)
Psychosocial issues	5 (29.4%)
Acute medical condition	2 (11.8%)
Respite	2 (11.8%)
Post-surgical recovery	1 (5.9%)
Years living with HIV	16.2 (SD=9.1)
CD4 (N=14)	
>500	5 (35.7%)
200-500	4 (28.6%)
<200	5 (35.7%)
***Substances** identified	
Crack cocaine	8 (47.1%)
Opioids	5 (29.4%)
Crystal meth	5 (29.4%)
*most common	
Total # of medications at discharge	11.8 (SD=6.2)
Post-discharge care	
Family doctor	17 (100%)
Allied health (nursing, psychiatry, social work)	17 (100%)
Substance use program	9 (52.9%)
HIV specialist	7 (41.2%)
Adherence reminders	5 (29.4%)
Length of admission	44.3 days (SD=42.4), Median=26

3.4 Numbers analyzed

For feasibility, results are presented against a denominator of 19 (number of participants approached); this includes two people who declined to participate and seven who did not complete the intervention. For acceptability, a denominator of 12 is used as this number participated in all intervention components and completed follow-up interviews.

3.5 Outcomes

The intervention was feasible to recruit and coordinate, and led to participant connection to ACT services. The first two intervention components (goal-setting and peer volunteer meeting) were highly acceptable to participants, while the third (post-discharge phone calls) was well-received by half of completers but the other half had challenges engaging by phone. Patient and Public Involvement (PPI)

contributed positively to study outcomes. Throughout the interviews, participants stated how much they appreciated that people living with HIV collaborated in the study's design, delivered the intervention, and conducted their interviews.

3.5.1 Feasibility

Overall, 63% (n=12) of participants who were approached completed the intervention with 57% (n=11) of the total sample connecting to ACT services. Interestingly, two participants who did not complete the intervention (one was lost to follow-up and we were unable to match the other with a peer volunteer) still connected to ACT. ACT services that participants accessed included counselling, support groups, and lunch programs.

Within a one-year recruitment timeline, five PVs were matched with sixteen participants (i.e., each volunteer had approximately three matches); there was only one instance where no volunteer was available to be matched with a participant. PPI may have contributed to ease of recruitment, as potential participants had heard about the study and contributed to its design. PVs received modest compensation at $150 per match.

3.5.2 Acceptability

The goal-setting and peer meeting components were acceptable to participants, with strong participation and positive feedback in interviews. Post-discharge phone calls were a challenge, as half of the participants who participated in this component (n=6) lost their phones, changed their numbers, and/or did not answer at some point over the six weeks of the program. This left six participants completing all nine calls as scheduled. From the twelve participants who engaged with phone calls, the mean number of calls per match was 5.8 Acceptability results for each intervention component are detailed below.

3.5.2.1 Goal-setting acceptability

Most participants (n=15) identified goals for the seven weeks after discharge related to: 1) antiretroviral adherence; 2) substance use; and 3) a personal goal (most commonly, housing and social connection). Participants rated their importance and confidence of each goal on a scale from '1' (not at all) to '10' (very much); figure 2 shows these results.

Participants expressed a high degree of confidence in achieving their adherence goals, despite a reported history of challenges. Substance use goals were primarily abstinence-based and had the lowest confidence of success. Open-ended goals were identified as the most important and primarily focused on improving living space and social connections. One participant described the goal-setting process thusly:

> [The nurse and I] went over my needs and my goals. Where my frame of mind was at. What things did I think would help me turn this rig around, kinda? [The nurse] figured who I could see to help me along the way…she was top shelf, y'know?... Like hey, yeah, she let me talk and she let me kind of lead the way and then she wrote down [my goals]. It [took] about twenty

> minutes, and then again after she wrote everything down and she filled out her form, then came back and showed me...to verify she had captured everything (P15, male).

Another participant talked about how familiarity with the nurse helped the goal-setting process:

> Me and [nurse] have always gotten along great. Well, I get along with all the nurses but there's a couple that I can talk to about anything and she's one of them…it made me think, let's try this [program]. Give it a fair shot (P16, female).

3.5.2.2 Peer volunteer meeting acceptability

Thirteen participants met with an ACT peer volunteer at CH, following goal-setting and prior to discharge, to discuss upcoming discharge, goals, and to make a plan for post-discharge phone calls. Participants appreciated the opportunity to meet with a peer; this was their first non-clinical service interaction during their hospital stay. As one person said, "He told me where he's at…and I shared a bit, [I was] thinking this guy is going to be a counsellor…and then I realized, huh, this guy's on my level" (P3, male).

In the consultations with people living with HIV to design this study, the issue of demographics was raised regarding whether people would be able to connect across ages, genders, etc. Participants felt comfortable connecting with their volunteer regardless of these identities, with one participant saying:

> I wasn't expecting somebody that young to be able to interact with me and understand me...I was even more comfortable when she told me she had HIV. And then I forgot all about [demographics], like we started talking you know she knows how to interact. It's not a thing anybody can do. It's not just about asking the questions it's about making the person feel comfortable and she did that with me (P6, female).

3.5.2.3 Post-discharge phone call acceptability

Peer volunteers phoned participants once per day for the first three days following discharge, then once per week for the following six weeks. The phone calls were the most challenging component of this intervention as half of the participants lost their phones, changed their numbers, and/or did not answer at some point over the program's duration. Participants engaged well while on the phone, speaking with peer volunteers about their discharge goals, other issues in their lives, and how to improve their health and social engagement.

Some participants appreciated the flexibility of phone calls and felt they could engage with a peer volunteer in this manner, as one person said:

> The way we were able to interact, communicate, understand. It was like he understood everything I was saying and I understood everything he was saying. And it was great. I couldn't imagine not having someone like him. Yes, because it made me think, how do I explain it, in the last few years, I've been stuck in a hole. Like it just flew, no one to talk to, not one to help,

> nowhere to reach out, no nothing. When [Volunteer] came along it was like having a peer in a different type of background and culture (P9, male).

Phone calls occasionally occurred at important times for participants, as shown in the following quote:

> A lot of the time I couldn't get in touch with my [in-person outpatient supports] but my peer would call me every week, she was a big help. I almost had a few relapses, but I didn't [relapse]. Actually it was my peer, once I was about to use and she called me! It was so weird, but in a good way. I told her I really need this call right now (P13, female).

Other participants indicated that the phone calls felt impersonal and that in-person peer support was preferable, with a participant saying "I'm just not a phone person…I don't know, I just can't. It's easier [in-person], you don't really know somebody [over the phone]" (P1, female).

Figure 3 displays the Visual Analog Scale results from the PV call logs. PVs rated how each participant was doing individually, socially, interpersonally, and overall with 0 representing 'not well' and 10 representing 'excellent'. Overall, the most difficult period was 1-2 weeks post-discharge with participants improving by 5-6 weeks after leaving hospital. Participants who were lost to follow-up were rated lower than people who completed the program.

3.6 Harms

There were no reported study-related harms.

4.0 Discussion

The principal findings of this pilot are that: a) pre-discharge goal-setting and a peer volunteer meeting were feasible and acceptable for a sample of people living with HIV and complex needs; b) while some participants appreciated post-discharge phone calls, others experienced barriers to this method of engagement; and c) a clinical and a community-based HIV organization can partner for improved connection to care.

Compared to other studies, a strength of this study was its substantial involvement of people living with HIV at multiple stages. This PPI approach may have made recruitment easier and contributed towards the positive experience that participants had with multiple intervention components [38]. Another strength was this study's focus on people with complex needs; participants averaged eight comorbidities (e.g., AIDS, cancer, hepatitis C) and are commonly lost to follow-up from outpatient clinical care at CH, so the finding that 65% (n=11) connected with ACT services suggests that peer support can be a helpful catalyst in the discharge transition [20].

For clinicians, this study presents two intervention components – pre-discharge goal setting and peer meeting – that can be feasibly incorporated into practice at low cost and time commitment which may ease the discharge transition for people experiencing complex medical and psychosocial needs. For policymakers, this study responds to a call for greater collaboration between clinical and community-based care [26] by highlighting how a hospital and a community agency can partner to provide peer support.

The goal-setting and peer meeting intervention components need to be tested in a larger trial with greater rigour and a sufficient sample, using standardized measures, to properly ascertain their effectiveness. A larger study should consider results from other peer support trials, such as a null effect on antiretroviral adherence due to low-intensity (i.e., phone support) interventions [39] and significant results in adherence and care retention through home visits [40]. Future research on post-discharge peer support with a complex population group should therefore explore more intensive supports than weekly phone contact; in-person follow-up, whether meeting in social spaces (such as coffee shops), home visits, or outpatients returning to hospital for post-discharge peer groups could be combined with phone calls as more supportive methods of retaining people in care.

4.1 Limitations

This study has several limitations. Without randomization and control and with a small sample, there remains uncertainty regarding the two promising intervention components (goal-setting and peer meeting). Other peer support studies have found significant effects in larger samples by focusing on a single issue of concern [19, 20]. A PPI limitation was the mixed results from the post-discharge phone calls. Phone support had been specifically requested from current and former CH clients living with HIV, during our consultations to design this study, as they perceived it to be a convenient and minimally disruptive way of accessing peer support. There is a risk of selection bias as eligible participants who were at risk of mortality were not approached [41]. Measurement error may have occurred as PVs rated their participants; they may have biased these assessments in an attempt to show positive change [42]. Incomplete participation amongst a small sample requires that the results be interpreted with some caution.

4.2 Applicability

The goal-setting and peer meeting components show preliminary promise for easing the discharge transition for people living with HIV and complex needs. These components could be more rigorously tested by other hospitals, where peers can be adequately trained and supported, to address high rates of lost-to-follow-up and eventual readmission for complex clients.

4.3 Interpretation

While there is some uncertainty regarding this study's benefits, a study of this nature does no harm. Peer support has been found effective on single issues regarding HIV (such as medication adherence); this study's attempt to pilot peer support regarding more complex needs is a first step towards better supporting the more marginalized people living with HIV who require more targeted support than is currently offered. The PPI approach helped facilitate study recruitment and the first two intervention components, yet the third component (post-discharge phone calls) received mixed results despite its PPI influence. Given this study's results and in-person peer support showing better outcomes than post-discharge phone calls in other quasi-experimental studies [43, 44], a future post-discharge peer support study could combine phone and in-person meetings. Multiple methods of engagement may be more acceptable to participants and contribute to greater completion rates, which could lead to better outcomes.

5.0 Conclusion

This pilot study presents two intervention components (goal-setting and peer volunteer meeting) that have preliminary proof-of-concept in easing the discharge transition and connection to community-based care for people living with HIV and complex needs. More research is needed to determine the ideal form of post-discharge peer support for this population.

Author contributions

ADE oversaw all study activities, supervised personnel, consented participants, led the analysis and interpretation of results, and wrote the first draft of the manuscript. **SCC** led patient engagement activities and co-led analysis and interpretation of results. **SLC** co-led analysis and interpretation of results and met monthly with ADE and SCC to discuss study progress. **ET** facilitated participant goal-setting and coordinated peer volunteer meetings and discharge timing. **JWM, DM, WW, LZ,** and **KB** contributed to study design and collected data. **GFG, GAW,** and **MM** prepared data for analysis through transcription and data entry. **AB** and **NB** trained peer volunteers with ADE. **CS** and **AS** contributed to study design and analysis. All the authors co-conceptualized the study, contributed to analysis, critically reviewed the manuscript, and approved the final submitted version of the manuscript.

Competing interests

There are no competing interests for any author.

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Data sharing statement

Data not reported in this article (i.e., de-identified interview transcripts) may be available, pending consultation with the University of Toronto's HIV/AIDS Research Ethics Board (REB). Data requests may be sent to the principal investigator at andrew.eaton@utoronto.ca, who will consult with the REB.

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Figure Legend

Figure 1: Participant flowchart

Figure 2: Participant goals: Self-rated importance and confidence

Figure 3: Peer volunteer assessment of participants following each call

Figure 1: Participant flowchart

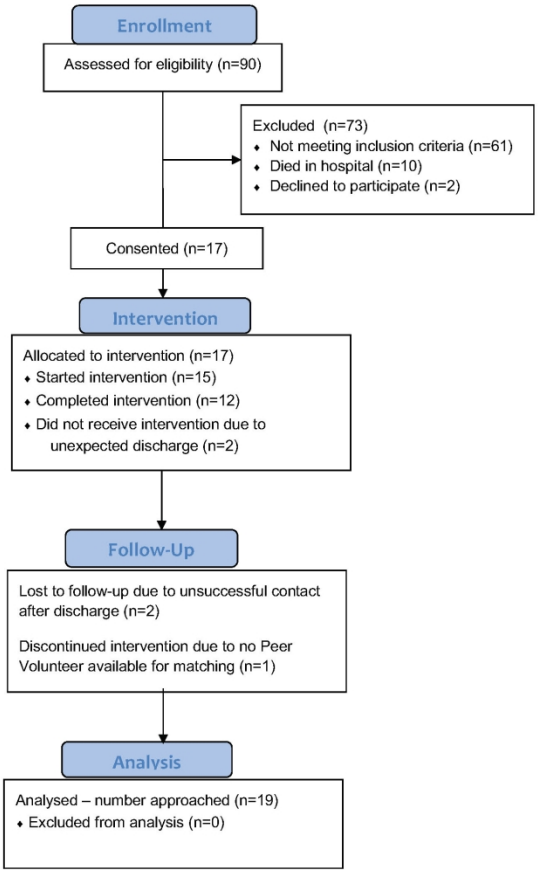

Figure 1: Participant flowchart

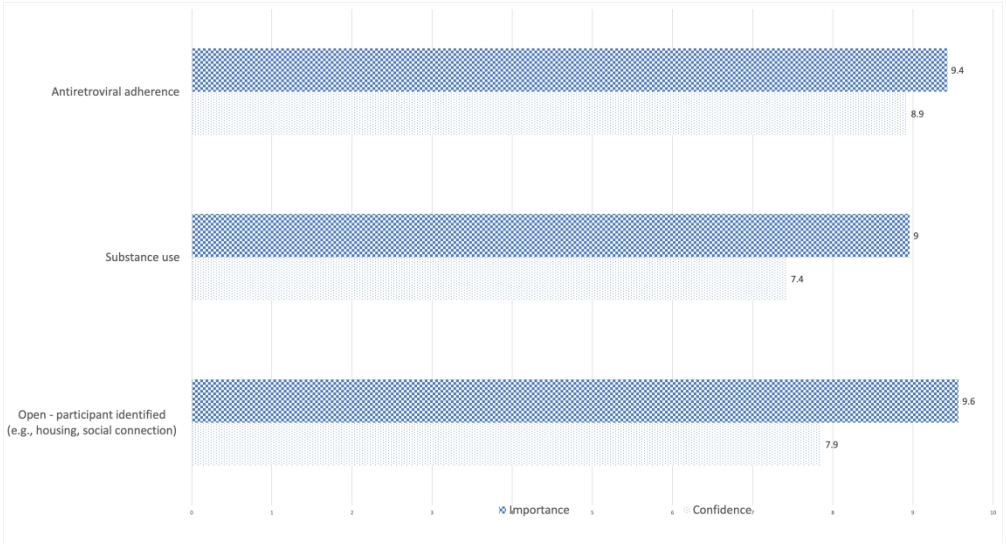

Figure 2: Participant goals: Self-rated importance and confidence

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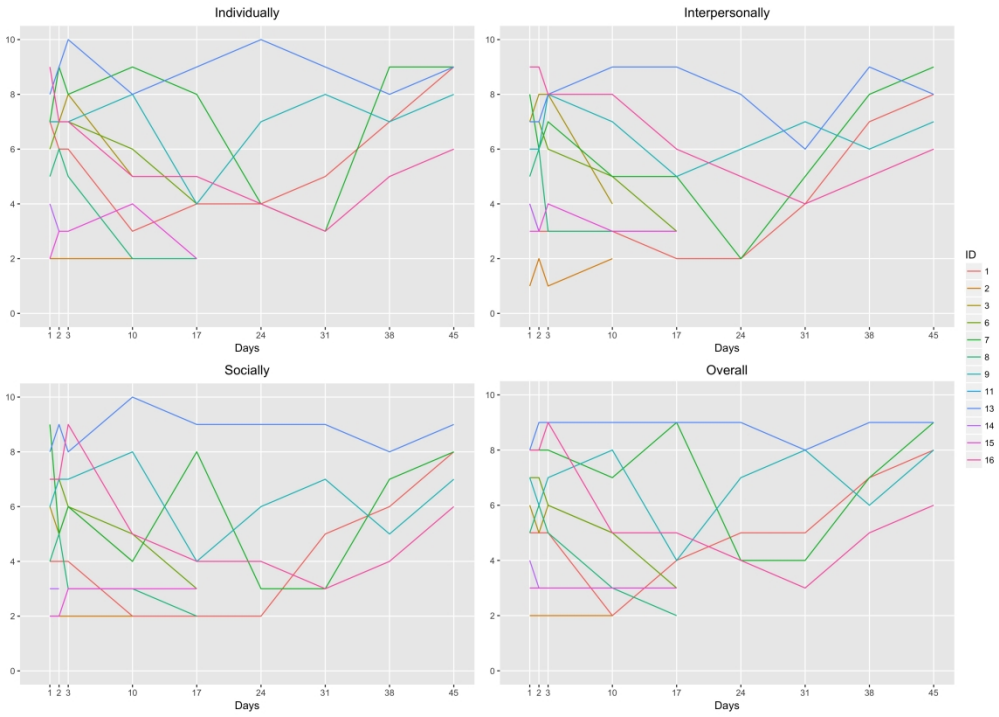

Figure 3: Peer volunteer assessment of participants following each call

ART of Conversation – Community Transition Planning Forms (CTP)

Community transition change plan

Goal #1: **HIV Medications** **(Note: A CTP form is completed for each area identified by participant)**	
The change I want to make (or continue making) is:	
Some barriers or difficulties that may get in the way are:	
The steps I plan to take in making this change are:	
The person/agency/organization that can support me in making this change is: *Name:* *Contact info:* *How can they help:*	
How important is it to you to make this change? (1-10 scale)	*How confident are you that you can make this change? (1-10 scale)*

Support people/agency/organization

Name	Role	Contact info.
i.e. Chris Smith	**A friend who helps walk my cat.**	**(416) 962-7600**
(Names the person puts forward while in the mind set of discharge transition)		

Significant dates/appointments/events following discharge

Date	Details
i.e. Jan 1st	**My partners birthday**
	(Some significant dates will be in the chart/discharge summary but this completed box can venture beyond medical appts./referrals)

Community transition change plan

Goal #2: **Substance Use** **(Note: A CTP form is completed for each area identified by participant)**	
The change I want to make (or continue making) is:	
Some barriers or difficulties that may get in the way are:	
The steps I plan to take in making this change are:	
The person/agency/organization that can support me in making this change is: *Name:* *Contact info:* *How can they help:*	
How important is it to you to make this change? (1-10 scale)	*How confident are you that you can make this change? (1-10 scale)*

Support people/agency/organization

Name	Role	Contact info.
i.e. Chris Smith	**A friend who helps walk my cat.**	**(416) 962-7600**
(Names the person puts forward while in the mind set of discharge transition)		

Significant dates/appointments/events following discharge

Date	Details
i.e. Jan 1st	**My partners birthday**
	(Some significant dates will be in the chart/discharge summary but this completed box can venture beyond medical appts./referrals)

Community transition change plan

Goal #3: **Open – client-identified** **(Note: A CTP form is completed for each area identified by participant)**	
The change I want to make (or continue making) is:	
Some barriers or difficulties that may get in the way are:	
The steps I plan to take in making this change are:	
The person/agency/organization that can support me in making this change is: *Name:* *Contact info:* *How can they help:*	
How important is it to you to make this change? (1-10 scale)	*How confident are you that you can make this change? (1-10 scale)*

Support people/agency/organization

Name	Role	Contact info.
i.e. Chris Smith	**A friend who helps walk my cat.**	**(416) 962-7600**
(Names the person puts forward while in the mind set of discharge transition)		

Significant dates/appointments/events following discharge

Date	Details
i.e. Jan 1st	**My partners birthday**
	(Some significant dates will be in the chart/discharge summary but this completed box can venture beyond medical appts./referrals)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4-5
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8-9, Table 1
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	9, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	9, Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the pilot trial ended or was stopped	9
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10, Table 2
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	11
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	11-14
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	15
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	15
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	15
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	15
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	N/A
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	16
	26	Ethical approval or approval by research review committee, confirmed with reference number	16

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Guidance for Reporting Involvement of Patients and the Public 2 – Short Form (GRIPP2-SF)

Section and topic	Item	Reported on page No.
1: Aim	Report the aim of PPI in the study	4
2: Methods	Provide a clear description of the methods used for PPI in the study	5-6
3: Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	11-12
4: Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	14
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	15

BMJ Open

The ART of conversation: Feasibility and acceptability of a pilot peer intervention to help complex HIV-positive people transition from hospital to community

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The ART of conversation: Feasibility and acceptability of a pilot peer intervention to help complex HIV-positive people transition from hospital to community

Andrew D. Eaton[1,2]*, Soo Chan Carusone[3,4], Shelley L. Craig[1], Erin Telegdi[3], John W. McCullagh[2], David McClure[2], Walter Wilson[2], Leonardo Zuniga[2], Kevin Berney[2], Galo F. Ginocchio[2], Gordon A. Wells[2], Michael Montess[2], Adam Busch[2], Nick Boyce[5], Carol Strike[6], Ann Stewart[3,7]

[1]Factor-Inwentash Faculty of Social Work, University of Toronto; Toronto, ON, Canada

[2]AIDS Committee of Toronto (ACT); Toronto, ON, Canada

[3]Casey House (CH); Toronto, ON, Canada

[4]Department of Health Research Methods, Evidence, and Impact; Hamilton, ON, Canada

[5]Ontario Harm Reduction Network; Toronto, ON, Canada

[6]Dalla Lana School of Public Health, University of Toronto; Toronto, ON, Canada

[7]St. Michael's Hospital; Toronto, ON, Canada

*Corresponding author. Factor-Inwentash Faculty of Social Work, University of Toronto. 246 Bloor St. W., Toronto, ON, Canada, M5S1V4 Phone: +1-416-978-8895. Email: andrew.eaton@utoronto.ca.

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Abstract

Objectives: To pilot a peer-based intervention for people living with HIV who used substances, had challenges with antiretroviral adherence, and would be discharged from hospital to community.

Study design: A community-based, quasi-experimental pilot intervention study designed to assess feasibility, acceptability, and connection to a community-based HIV organization.

Setting: This study was conducted in Toronto, Canada at Casey House (CH; hospital for people living with HIV) in collaboration with the AIDS Committee of Toronto (ACT; community-based HIV organization).

Participants: People living with HIV who were: CH inpatient between 01/04/2017 and 31/3/2018; struggled with antiretroviral adherence; actively used substances; and would be discharged to community were eligible. Forty people met criteria, 19 were approached by an inpatient nurse and 17 consented. Average age was 48.8 (SD=11.4), 58.8% were male, and participants averaged 7.8 physical and mental health comorbidities (SD=3.1).

Intervention: Titled *The ART of Conversation*, the three-pronged personalized intervention was developed through input from CH clients and ACT volunteers, all living with HIV. Intervention components were: a) pre-discharge goal-setting (adherence, substance use, self-identified goal) with the study nurse; b) pre-discharge meeting with an HIV+ peer volunteer (PV); and c) nine post-discharge phone calls between PV and participant, once/day for three days then once/week for six weeks.

Primary Outcomes: Feasibility was measured through proportion of eligible participants recruited and PV availability. Acceptability was assessed through participant interviews at three times (pre-intervention, post-intervention, 6-week follow-up) and through PV call logs. Client records determined connection to ACT within the study timeframe.

Results: Twelve participants completed the intervention and nine connected with ACT. Pre-discharge goal-setting and PV meeting were both feasible and acceptable. Post-discharge phone calls were a challenge as half of completers missed at least one call.

Conclusions: Although pre-discharge goal-setting and PV meeting were feasible, methods to maintain connection following discharge require further investigation.

Keywords

HIV & AIDS; Substance misuse; Social medicine; Qualitative research

Strengths and limitations of this study

- Patient and public involvement was prioritized throughout this study as people living with HIV co-designed the study and intervention, delivered the intervention, and collected and analyzed data.

- Peer support models have been identified as a priority area by policymakers to improve care transitions for people living with HIV.

- Interventions for a study population with severe medical and psychosocial complexity who are at high-risk of poor health outcomes need to be tested for feasibility and acceptability before launching a larger scale study.

- The key limitations are: the lack of a control group and randomization, which were not possible within our recruitment timeline and sampling frame; a potentially biased sample, as not all eligible participants were approached; and incomplete participation, as half of participants missed at least one post-discharge phone call.

1.0 Introduction

Hospital discharge can result in discontinuity of care, non-adherence to medications, and other negative outcomes [1], especially for people living with HIV [2, 3] who face complex medical and psychosocial challenges [4]. Medical and psychosocial complexity is multiple, overlapping issues that affect a person's health [5]. People living with HIV may experience complex medical issues (e.g., frequent hospitalizations, poor medication adherence, polypharmacy, concurrent comorbidities, etc.) [6, 7]. Psychosocial factors may overlap with health challenges, (e.g., increased substance use, homelessness, unemployment, social isolation, food insecurity, etc.) [8, 9, 10]. These complex difficulties can interrupt the cascade of care and increase the risk of mortality [1]; in particular, substance use is a priority area of focus for care retention interventions [11].

The cascade of care (i.e., HIV treatment cascade or the HIV care continuum) is a framework recommended by UNAIDS for member countries to measure their progress in ending the AIDS epidemic [2]. Individual countries, and individual states and provinces within those countries, have adapted this continuum to fit their local contexts [12, 13] and consulted patients in its local implementation [14, 15]. However, a common end-point is universal amongst these frameworks: retention in care (i.e., attending regular medical appointments, accessing community supports) and maintaining viral suppression (<50 copies of HIV per millilitre of blood, meaning that people living with HIV cannot sexually transmit the virus) [16, 17]. Complex clients living with HIV are often hospitalized to re-adhere to medications and progress on the care cascade; however, the discharge transition can cause cascade regression and poor health outcomes [18]. 'Peer' interventions, provided by trained community members who share lived experience with clients, may be a helpful and cost-effective complement to outpatient clinical care in order to help people living with HIV maintain the health progress that they achieved in hospital [19, 20].

Meaningful involvement of people living with HIV as peers has been central throughout the history of HIV and AIDS [20, 21]. From the first cases of AIDS to the present day, people living with and affected by HIV have been forming community-based agencies and implementing peer-based models of care [21, 22]. Yet peer models are understudied amongst people living with both HIV and complex issues; most work focuses on prevention in the HIV-negative population [21, 23, 24, 25] or a single issue (most commonly, medication adherence) in the HIV-positive population [19, 20]. Peer interventions that address the more complex realities that some people living with HIV experience are recommended in policy, especially ones that improve linkages between clinical and community-based care [26, 27].

To design a peer intervention that could help people living with both HIV and complex issues in the transition from hospital to community, we used the theories of Community-Based Participatory Research (CBPR) and Minimally Disruptive Medicine (MDM). CBPR recommends the equitable involvement of the client population in the design and conduct of a study [28], which aligns with this study's aim to pilot a peer intervention. MDM suggests that new interventions may have better results when designed to fit within the context of people's lives [29]. In this study, CBPR was utilized through extensive consultation and involvement of people living with HIV where the recommendation for the study's intervention – goal setting, peer meeting, and post-discharge phone calls – was designed to be as minimally disruptive and acceptable to participants as possible.

With the context of the study's setting at Casey House (CH), a 14-bed HIV hospital with an average 45-day inpatient admission, and funding (one-year CBPR grant), a quasi-experimental pilot was developed to test peer intervention components for feasibility and acceptability.

1.1 Objectives

This study had two objectives. First, to pilot test a peer-based intervention for people living with HIV who had challenges with antiretroviral adherence and substance use and would be discharged from hospital to community; this study of feasibility and acceptability was conducted to determine whether intervention components could be applied in a larger trial. Second, to connect participants to the AIDS Committee of Toronto (ACT) – Canada's largest community-based HIV organization – for further post-discharge support. As this is a peer intervention, patient and public involvement (PPI) was prioritized so that people living with HIV had an active role in the study's design and conduct.

1.2 Study Settings

This study was conducted as a partnership between Casey House (CH) and the AIDS Committee of Toronto (ACT) in downtown Toronto, Canada. CH is Canada's only standalone hospital for people living with HIV. CH has fourteen inpatient beds for sub-acute, palliative, and respite care. Inpatient admissions average approximately 45 days due to mortality risk amongst most patients. CH also offers community programs, and during the operation of this study launched a day health program to better support adults living with HIV and complex health and psychosocial conditions. ACT is Canada's largest community-based HIV/AIDS organization and offers prevention (i.e., safer sex outreach) and support (i.e., counselling, groups) for people living with and affected by HIV. CH was responsible for chart abstraction, goal setting and hosting the peer meeting. ACT was responsible for enrolling participants, training and supervision of PVs, and coordinating connection to community-based care.

2.0 Methods

This study used descriptive quantitative data and qualitative methods to evaluate feasibility, and acceptability, and linkage to community supports of a pilot peer intervention that involved people living with HIV in the study's design and conduct.

2.1 Study design

Participants were enrolled into a personalized three-stage peer-based intervention. Approximately forty people were included in the sampling frame (see participant flow below). Neither randomization nor a control group were feasible due to the limited sampling frame and one-year timeline.

2.2 Patient and public involvement

People living with HIV became involved in this study as the concept was being developed and were engaged in four distinct activities. First, a community-based exploratory study interviewed CH clients about the discharge transition and found that participants were requesting peer support [18].

Second, two CH client engagement sessions (n=17, all HIV-positive) were held regarding the structure of a post-discharge peer program, including: duration; content; definition of 'peer'; how peers should be trained; and how the pilot should be evaluated. CH clients living with HIV identified that post-discharge phone support could be easier to access than an in-person peer meeting. Third, a group consultation was held with ACT volunteers (n=10) who live with HIV and who provide direct service (e.g., support groups). This consultation discussed: the peer program requested by CH clients; program structure; evaluation methods including draft questionnaires; and whether attendees would engage with the study as a peer volunteer (delivering the intervention) or peer researcher (interviewing participants and analyzing data). Fourth, one more CH client session (n=6) was facilitated by a peer researcher to continue developing the study questionnaires and intervention details. Based on these consultations, we defined 'peer' as a person living with HIV who has personal or relational experience with substance use. There were two distinct groups of peers on this research team: a) peer researchers; and b) peer volunteers (PVs).

Five peer researchers attended a 1.5 day, 11.5-hour training; the curriculum has been published elsewhere [30]. The main training component was filmed simulation, where peer researchers were video-recorded conducting simulated interviews to observe their verbal and non-verbal interactions [31]. Peer researchers refined the study questionnaires, collected all data, and participated in the analysis.

Five peer volunteers (PV) from ACT delivered this intervention. These volunteers completed a total of 44 training hours. The first 22 hours were dedicated to ACT's core skills volunteer training which covers: creating safe and accessible spaces; HIV and health promotion basics; concepts in communication; and anti-oppression and cultural competence. The volunteers then attended 22 hours of training specific to the intervention which focused on: harm reduction; structuring a phone call; communication tools; and self-care.

2.3 Participants

An inpatient nurse at CH identified people living with HIV who met inclusion criteria (based on admission details) and approached them regarding their interest in learning more about the three-stage peer program. If people were interested, the principal investigator then met with them for enrolment.

2.3.1 Eligibility criteria

Inclusion criteria: People who were HIV-positive; actively used illicit substances (e.g., cocaine, crystal meth, etc.); inpatient at CH between April 1, 2017 and March 31, 2018; initiated/re-started antiretroviral therapy while they were inpatient at CH; were discharged back to the community; English-speaking; could access a phone; and provided informed consent. Exclusion criteria: People who were at risk of mortality.

2.3.2 Participant identification and consent

A study nurse (fourth author) identified participants based on their admission presentation (i.e., identified substance use and ART initiation/re-initiation). The nurse approached participants to

introduce the study and, if they were interested in learning more, then referred them to the principal investigator (first author) for consent. To participate in the study, participants consented to the research and to becoming ACT clients. The consent process also involved discussion with participants of preferences regarding PV matches (e.g., schedule).

2.4 Intervention

The intervention consisted of three distinct stages. Participants set discharge goals with the recruiting nurse, then met with a PV prior to discharge. Following discharge, participants scheduled nine phone calls with their PVs over seven weeks.

2.4.1 Goal-setting

The study nurse met with participants during their inpatient admission to help them identify three goals that they wanted to achieve after discharge. A nurse was chosen to complete this activity as a means of bridging the clinical care that participants had received in hospital, with the peer support that they would be receiving after discharge. The nurse was trained in Motivational Interviewing (i.e., client-centred counselling to elicit positive goal-setting) [32] and harm reduction principles (i.e., stating that participants could set substance use goals concerning reduced or safer use, not solely abstinence). One goal was related to their ART adherence, another related to their substance use, and a third personal goal. These goals were written on a Community Transition Planning (CTP) form (see supplementary file) that was designed based on principles of Motivational Interviewing, whereby the facilitators and barriers to a goal are thoroughly discussed [32]. Participants identified the change they wanted to make, the steps necessary to make this change, support people (both personal and professional supports), their importance and confidence at making the change, and significant events that would occur following discharge. Goal-setting occurred one week prior to discharge, and typically lasted half an hour. The forms were shared with PVs prior to their meetings with participants.

2.4.2 Peer volunteer (PV) meeting

The principal investigator matched a PV with a participant, based on participant requests (e.g., similar substance use history, length of time living with HIV, gender, etc.). The dyad met at CH to discuss the participant's CTP form, how the participant was feeling about leaving hospital, and the details of phone support (e.g., when to call, what to talk about, etc.). Discharge goals were further refined in this meeting. PVs were encouraged to self-identify shared experiences that might be relevant (e.g., substance use). This meeting occurred in the week leading up to discharge and usually took 45 minutes.

2.4.3 Post-discharge phone calls

The PV phoned the participant once per day for the three days following discharge, then once per week for the following six weeks. This schedule was determined through client consultation; people living with HIV stated that the first 72 hours following discharge were the most difficult and when their risk of relapse was highest. Calls commonly lasted 20-45 minutes and focused on discharge goals and other issues arising for participants, with a focus on connection to community-based services.

2.5 Outcomes

The outcomes and measures are detailed below and in Table 1. Feasibility was measured through: a) the proportion of eligible participants who were recruited, consented, and completed the study; and b) PV availability. Acceptability was assessed through participant interviews at three times (pre-discharge, post-intervention, and 6-week follow-up) and through logs written by PVs following each phone call. Connection to ACT (i.e., linkage to community supports) was determined through a search of client records to see if participants accessed any ACT service (such as counselling or support groups) within thirteen weeks after discharge.

Table 1: Outcomes and measures

Outcomes	Measures	Description
Feasibility	Participant recruitment and retention	Proportion of eligible participants who were recruited, consented, and completed the study
	Peer volunteer (PV) availability	Ability to match PVs with participants
Acceptability	Semi-structured interviews at three times, conducted by peer researchers	Interview 1: Following PV meeting, prior to discharge Interview 2: Program conclusion (seven weeks after discharge) Interview 3: Follow-up (thirteen weeks after discharge)
	Contact logs	Reports from PVs following each phone call
Connection to ACT (i.e., linkage to community supports)	Client records	Participants accessing an ACT service (e.g., counselling, groups) within thirteen weeks after discharge

2.5.1 Measures

The intervention components were assessed qualitatively, with participants scheduled to complete three in-depth, semi-structured interviews with peer researchers (also living with HIV). The first interview occurred at CH following the PV meeting but prior to discharge, with questions on goal-setting and peer meeting components; medication adherence; substance use; community supports; and overall health. The second interview occurred at ACT at conclusion of peer support (week 7 following discharge). Questions from the first interview were repeated alongside probes for feedback on the post-discharge phone calls and the helpfulness of PVs sharing their own experiences. The third interview was held at ACT six weeks after the program's end (week 13 following discharge) and, alongside repeated questions from the first and second interview, focused on supports that the participant had accessed due to the peer program. Interviews were audio-recorded and averaged 00:41:20 in length.

PVs completed a contact log of each call, noting the call's content and rating how they felt the participant was doing individually (i.e., personal well-being), interpersonally (i.e., family and close relationships), socially (i.e., activity engagement, friendships), and overall (i.e., general sense of well-being). These ratings were completed using the Outcome Rating Visual Analog Scale [33], where PVs placed a mark on a 10cm unnumbered line; instructions stated that marks to the left represented 'not well at all' and marks to the right indicated 'excellent'. PVs were trained to conduct these assessments through instruction on rating participants against how they presented in the initial peer volunteer meeting. For example, a PV would assess the interpersonal domain based on a participant's progress on reconnecting with their daughter, if the participant identified this goal in the initial meeting.

2.6 Sample size

A sample size of fifteen was selected for feasibility as: a) CH has an average 80 discrete admissions annually; b) a clinical estimate based on retrospective chart review found that approximately half of admissions met this study's criteria; c) the hospital moved locations during our recruitment year, disrupting recruitment for approximately one month; and d) based on existing pilot studies, this sample size would allow the team to assess the feasibility and acceptability of intervention components across diverse experiences [34, 35].

2.7 Data analysis

Research assistants (authors ten to twelve) transcribed interviews and entered data. The entire team held three iterative analysis meetings (four hours each) to read through the data and apply content analysis. Content analysis, as used in other qualitative assessments of intervention research [36] included discussion on how findings corresponded to the study's objectives, and which quotes illuminated the facilitators and barriers of each intervention component [37]. Contact log data is presented as a spaghetti plot; while the sample size limits our ability to interpret these findings, they provide context for the quotes.

3.0 Results

The participant flow and characteristics are presented, followed by numbers analyzed and outcomes concerning the feasibility and acceptability of intervention components. Participant quotes include a unique identifier and gender.

3.1 Participant flow

Figure 1 shows the flow of participants throughout the study. Of the ninety discrete inpatient admissions at CH during the recruitment period, 73 were excluded due to: a) an eligibility review of admission presentation, namely mortality risk (n=21) and unidentified substance use (n=40); b) death in hospital (n=10); and c) declining to participate (n=2). Mortality risk was determined by an admission for palliative care or when the clinical team determined than a person was too medically unstable to participate. Unidentified substance use means that inpatients themselves nor their referring clinician identified substance use at admission.

3.2 Recruitment

A CH nurse approached people who: a) were inpatient at CH during the period of April 1, 2017 to March 31, 2018; b) self-identified substance use and challenges with antiretroviral adherence. Nineteen people were approached and two declined, leaving seventeen consenting to participate. Follow-up occurred seven weeks following discharge (second interview) and thirteen weeks following discharge (interview three), with the final interview occurring on July 11, 2018. The pilot program ended at this time due to the one-year funding agreement.

3.3 Baseline data

Participants were predominately male (58.8%, n=10) and had an average age of 48.8 (SD=11.4). Comorbidities (M=7.8, SD=3.1) most commonly were cancer, hepatitis C, and Chronic Obstructive Pulmonary Disease (COPD); participants also had mental health diagnoses (M=3.2, SD=1.5), most commonly mood disorders (e.g., bipolar disorder, depressive disorders) and organic mental disorders (e.g., HIV-associated neurocognitive disorder). Substances identified were mostly cocaine (47.1%, n=8), opioids (29.4%, n=5), and crystal meth (29.4, n=5). Participants were in hospital for an average of 44.3 days (SD=42.4) and were taking an average of 11.8 (SD=6.2) medications at discharge. Refer to Table 2 for further participant characteristics.

Table 2: Participant characteristics (n=17, unless specified otherwise)

Characteristic	N (%) / Mean (SD)
Gender	
Male	10 (58.8%)
Female	7 (41.2%)
Age (years)	48.8 (SD=11.4)
Income Source	
ODSP	11 (64.7%)
Other	6 (35.3%)
Employment Status	
On disability	11 (64.7%)
Unemployed	6 (35.3%)
Comorbidities	
Mental health diagnoses	3.2 (SD=1.5)
Total comorbidities	7.8 (SD=3.1)
Housing prior to admission	
Independent living	9 (52.9%)
Supportive housing	5 (29.4%)
Shelter	1 (5.9%)

Street-involved	1 (5.9%)
Rooming house	1 (5.9%)
Housing following discharge	
Independent living	9 (52.9%)
Supportive housing	6 (35.3%)
Rooming house	1 (5.9%)
Unknown	1 (5.9%)
Reason for admission	
ART re-/initiation	7 (41.2%)
Psychosocial issues	5 (29.4%)
Acute medical condition	2 (11.8%)
Respite	2 (11.8%)
Post-surgical recovery	1 (5.9%)
Years living with HIV	16.2 (SD=9.1)
CD4 (N=14)	
>500	5 (35.7%)
200-500	4 (28.6%)
<200	5 (35.7%)
***Substances** identified	
Crack cocaine	8 (47.1%)
Opioids	5 (29.4%)
Crystal meth	5 (29.4%)
*most common	
Total # of medications at discharge	11.8 (SD=6.2)
Post-discharge care	
Family doctor	17 (100%)
Allied health (nursing, psychiatry, social work)	17 (100%)
Substance use program	9 (52.9%)
HIV specialist	7 (41.2%)
Adherence reminders	5 (29.4%)
Length of admission	44.3 days (SD=42.4), Median=26

3.4 Numbers analyzed

For feasibility, results are presented against a denominator of 19 (number of participants approached); this includes two people who declined to participate and five who did not complete the

intervention. For acceptability, a denominator of 12 is used as this number participated in all intervention components and completed follow-up interviews.

3.5 Outcomes

The intervention was feasible to recruit and coordinate, and led to participant connection to ACT services. The first two intervention components (goal-setting and peer volunteer meeting) were highly acceptable to participants, while the third (post-discharge phone calls) was well-received by half of completers but the other half had challenges engaging by phone. Patient and Public Involvement (PPI) contributed positively to study outcomes. Throughout the interviews, participants stated how much they appreciated that people living with HIV collaborated in the study's design, delivered the intervention, and conducted their interviews.

3.5.1 Feasibility

Overall, 63.1% (n=12) of participants who were approached completed the intervention. Within a one-year recruitment timeline, five PVs were matched with sixteen participants (i.e., each volunteer had approximately three matches); there was only one instance where no volunteer was available to be matched with a participant. PPI may have contributed to ease of recruitment, as potential participants had heard about the study and contributed to its design. PVs received modest compensation at $150 per match.

3.5.2 Acceptability

The goal-setting and peer meeting components were acceptable to participants, with strong participation and positive feedback in interviews. Post-discharge phone calls were a challenge, as half of the participants who participated in this component (n=6) lost their phones, changed their numbers, and/or did not answer at some point over the six weeks of the program. This left six participants completing all nine calls as scheduled. From the twelve participants who engaged with phone calls, the mean number of calls per match was 5.8 Acceptability results for each intervention component are detailed below.

3.5.2.1 Goal-setting acceptability

Most participants (n=15) identified goals for the seven weeks after discharge related to: 1) antiretroviral adherence; 2) substance use; and 3) a personal goal (most commonly, housing and social connection). Participants rated their importance and confidence of each goal on a scale from '1' (not at all) to '10' (very much); figure 2 shows these results.

Participants expressed a high degree of confidence in achieving their adherence goals, despite a reported history of challenges. Substance use goals were primarily abstinence-based and had the lowest confidence of success. Open-ended goals were identified as the most important and primarily focused on improving living space and social connections. One participant described the goal-setting process thusly:

> [The nurse and I] went over my needs and my goals. Where my frame of mind was at. What things did I think would help me turn this rig around, kinda? [The nurse] figured who I could see to help me along the way…she was top shelf, y'know?... Like hey, yeah, she let me talk and she let me kind of lead the way and then she wrote down [my goals]. It [took] about twenty minutes, and then again after she wrote everything down and she filled out her form, then came back and showed me...to verify she had captured everything (P15, male).

Another participant talked about how familiarity with the nurse helped the goal-setting process:

> Me and [nurse] have always gotten along great. Well, I get along with all the nurses but there's a couple that I can talk to about anything and she's one of them…it made me think, let's try this [program]. Give it a fair shot (P16, female).

3.5.2.2 Peer volunteer meeting acceptability

Thirteen participants met with an ACT peer volunteer at CH, following goal-setting and prior to discharge, to discuss upcoming discharge, goals, and to make a plan for post-discharge phone calls. Participants appreciated the opportunity to meet with a peer; this was their first non-clinical service interaction during their hospital stay. As one person said, "He told me where he's at…and I shared a bit, [I was] thinking this guy is going to be a counsellor…and then I realized, huh, this guy's on my level" (P3, male).

In the consultations with people living with HIV to design this study, the issue of demographics was raised regarding whether people would be able to connect across ages, genders, etc. Participants felt comfortable connecting with their volunteer regardless of these identities, with one participant saying:

> I wasn't expecting somebody that young to be able to interact with me and understand me...I was even more comfortable when she told me she had HIV. And then I forgot all about [demographics], like we started talking you know she knows how to interact. It's not a thing anybody can do. It's not just about asking the questions it's about making the person feel comfortable and she did that with me (P6, female).

3.5.2.3 Post-discharge phone call acceptability

Peer volunteers phoned participants once per day for the first three days following discharge, then once per week for the following six weeks. The phone calls were the most challenging component of this intervention as half of the participants lost their phones, changed their numbers, and/or did not answer at some point over the program's duration. Participants engaged well while on the phone, speaking with peer volunteers about their discharge goals, other issues in their lives, and how to improve their health and social engagement.

Some participants appreciated the flexibility of phone calls and felt they could engage with a peer volunteer in this manner, as one person said:

> The way we were able to interact, communicate, understand. It was like he understood everything I was saying and I understood everything he was saying. And it was great. I couldn't imagine not having someone like him. Yes, because it made me think, how do I explain it, in the last few years, I've been stuck in a hole. Like it just flew, no one to talk to, not one to help, nowhere to reach out, no nothing. When [Volunteer] came along it was like having a peer in a different type of background and culture (P9, male).

Phone calls occasionally occurred at important times for participants, as shown in the following quote:

> A lot of the time I couldn't get in touch with my [in-person outpatient supports] but my peer would call me every week, she was a big help. I almost had a few relapses, but I didn't [relapse]. Actually it was my peer, once I was about to use and she called me! It was so weird, but in a good way. I told her I really need this call right now (P13, female).

Other participants indicated that the phone calls felt impersonal and that in-person peer support was preferable, with a participant saying "I'm just not a phone person…I don't know, I just can't. It's easier [in-person], you don't really know somebody [over the phone]" (P1, female).

Figure 3 displays the Visual Analog Scale results from the PV call logs. Overall, the most difficult period was 1-2 weeks post-discharge with participants improving by 5-6 weeks after leaving hospital. Participants who were lost to follow-up were rated lower than people who completed the program.

3.5.3 Connection to ACT

Over half (57.9%, n=11) of the total sample connected to ACT services. Interestingly, two participants who did not complete the intervention (one was lost to follow-up and we were unable to match the other with a peer volunteer) still connected to ACT. ACT services that participants accessed included counselling, support groups, and lunch programs.

3.6 Harms

There were no reported study-related harms.

4.0 Discussion

The principal findings of this pilot are that: a) pre-discharge goal-setting and a peer volunteer meeting were feasible and acceptable for a sample of people living with HIV and complex needs; b) while some participants appreciated post-discharge phone calls, others experienced barriers to this method of engagement; and c) a clinical and a community-based HIV organization can partner for improved connection to care.

Compared to other studies, a strength of this study was its substantial involvement of people living with HIV at multiple stages. This PPI approach may have made recruitment easier and contributed towards the positive experience that participants had with multiple intervention components [38]. Another strength was this study's focus on people with complex needs; participants averaged eight comorbidities (e.g., AIDS, cancer, hepatitis C) and are commonly lost to follow-up from outpatient

clinical care at CH, so the finding that 65% (n=11) connected with ACT services suggests that peer support can be a helpful catalyst in the discharge transition [20].

For clinicians, this study presents two intervention components – pre-discharge goal setting and peer meeting – that can be feasibly incorporated into practice at low cost and time commitment which may ease the discharge transition for people experiencing complex medical and psychosocial needs. For policymakers, this study responds to a call for greater collaboration between clinical and community-based care [26] by highlighting how a hospital and a community agency can partner to provide peer support.

The goal-setting and peer meeting intervention components need to be tested in a larger trial with greater rigour and a sufficient sample, using standardized measures, to properly ascertain their effectiveness. A larger study should consider results from other peer support trials, such as a null effect on antiretroviral adherence due to low-intensity (i.e., phone support) interventions [39] and significant results in adherence and care retention through home visits [40]. Future research on post-discharge peer support with a complex population group should therefore explore more intensive supports than weekly phone contact; in-person follow-up, whether meeting in social spaces (such as coffee shops), home visits, or outpatients returning to hospital for post-discharge peer groups could be combined with phone calls as more supportive methods of retaining people in care.

4.1 Limitations

This study has several limitations. Without randomization and control and with a small sample, there remains uncertainty regarding the two promising intervention components (goal-setting and peer meeting). Other peer support studies have found significant effects in larger samples by focusing on a single issue of concern [19, 20]. A PPI limitation was the mixed results from the post-discharge phone calls. Phone support had been specifically requested from current and former CH clients living with HIV, during our consultations to design this study, as they perceived it to be a convenient and minimally disruptive way of accessing peer support. There is a risk of selection bias as eligible participants who were at risk of mortality were not approached [41]. PV assessments of participants may have been biased, likely in the direction of showing positive change [42]. Incomplete participation amongst a small sample requires that the results be interpreted with some caution.

4.2 Applicability

The goal-setting and peer meeting components show preliminary promise for easing the discharge transition for people living with HIV and complex needs. These components could be more rigorously tested by other hospitals, where peers can be adequately trained and supported, to address high rates of lost-to-follow-up and eventual readmission for complex clients.

4.3 Interpretation

While there is some uncertainty regarding this study's benefits, we found no evidence of study harm. Peer support has been found effective on single issues regarding HIV (such as medication

adherence) [19, 20]; this study's attempt to pilot peer support regarding more complex needs is a first step towards better supporting the more marginalized people living with HIV who require more targeted support than is currently offered. This study's positive results with connection to ACT services aligns with other studies that found improved care engagement as a result of a peer intervention [40, 43, 44]. Qualitatively, this study's participants expressed views similar to other peer intervention studies regarding the ease of speaking with a peer and the benefit of shared experience [19, 45, 46]. However, this study found that PVs and participants were able to connect despite differences in age, health status, and other demographics, which differs from other studies that recommend peers share as many subgroup characteristics as possible [45, 47].

The PPI approach helped facilitate study recruitment and the first two intervention components, yet the third component (post-discharge phone calls) received mixed results despite its PPI influence. Given this study's results and in-person peer support showing better outcomes than post-discharge phone calls in other quasi-experimental studies [48, 49], a future post-discharge peer support study could combine phone and in-person meetings. Multiple methods of engagement may be more acceptable to participants and contribute to greater completion rates, which could lead to better outcomes.

5.0 Conclusion

This pilot study presents two intervention components (goal-setting and peer volunteer meeting) that have preliminary proof-of-concept in easing the discharge transition and connection to community-based care for people living with HIV and complex needs. More research is needed to determine the ideal form of post-discharge peer support for this population.

Author contributions

ADE oversaw all study activities, supervised personnel, consented participants, led the analysis and interpretation of results, and wrote the first draft of the manuscript. **SCC** led patient engagement activities and co-led analysis and interpretation of results. **SLC** co-led analysis and interpretation of results and met monthly with ADE and SCC to discuss study progress. **ET** facilitated participant goal-setting and coordinated peer volunteer meetings and discharge timing. **JWM, DM, WW, LZ,** and **KB** contributed to study design and collected data. **GFG, GAW,** and **MM** prepared data for analysis through transcription and data entry. **AB** and **NB** trained peer volunteers with ADE. **CS** and **AS** contributed to study design and analysis. All the authors co-conceptualized the study, contributed to analysis, critically reviewed the manuscript, and approved the final submitted version of the manuscript.

Competing interests

There are no competing interests for any author.

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Data sharing statement

Data not reported in this article (i.e., de-identified interview transcripts) may be available, pending consultation with the University of Toronto's HIV/AIDS Research Ethics Board (REB). Data requests may be sent to the principal investigator at andrew.eaton@utoronto.ca, who will consult with the REB.

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Figure Legend

Figure 1: Participant flowchart

Figure 2: Participant goals: Self-rated importance and confidence

Figure 3: Peer volunteer assessment of participants following each call

CONSORT
TRANSPARENT REPORTING of TRIALS

Figure 1: Participant flowchart

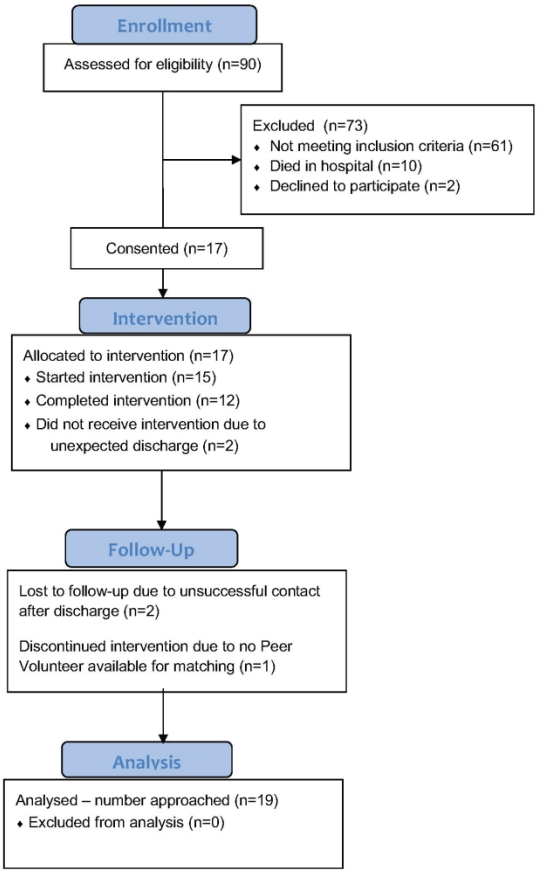

Figure 1: Participant flowchart

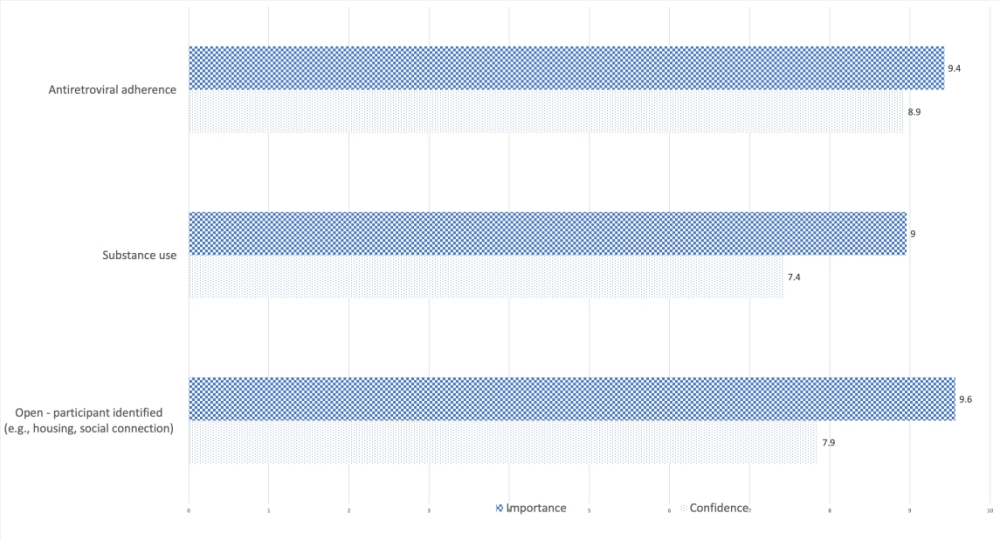

Figure 2: Participant goals: Self-rated importance and confidence

275x149mm (300 x 300 DPI)

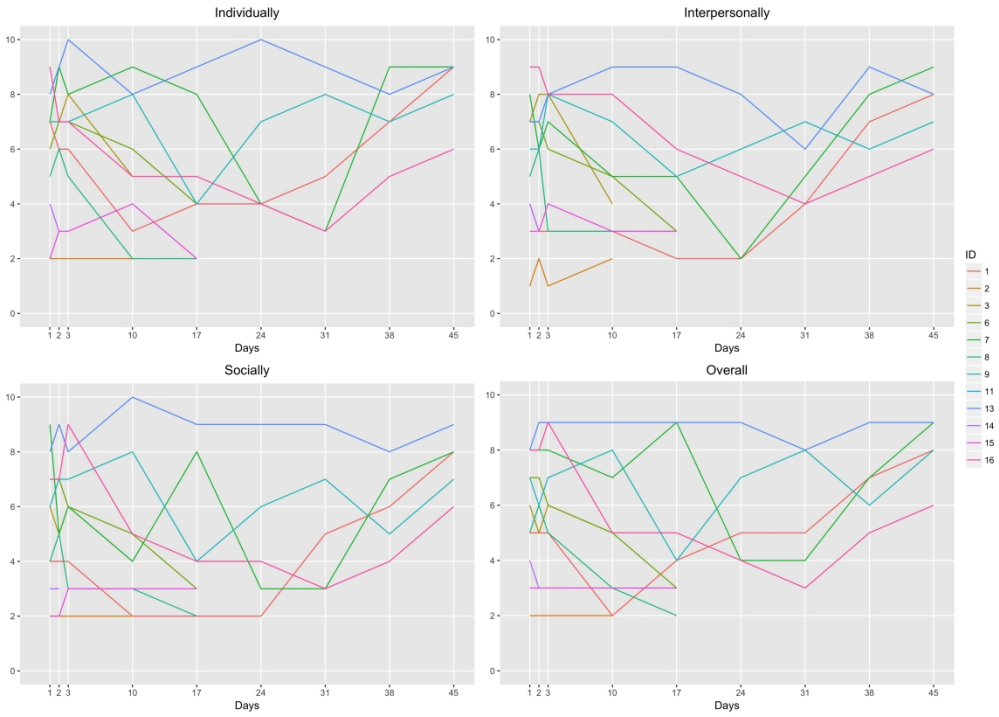

Figure 3: Peer volunteer assessment of participants following each call

ART of Conversation – Community Transition Planning Forms (CTP)

Community transition change plan

Goal #1: **HIV Medications** **(Note: A CTP form is completed for each area identified by participant)**	
The change I want to make (or continue making) is:	
Some barriers or difficulties that may get in the way are:	
The steps I plan to take in making this change are:	
The person/agency/organization that can support me in making this change is: *Name:* *Contact info:* *How can they help:*	
How important is it to you to make this change? (1-10 scale)	*How confident are you that you can make this change? (1-10 scale)*

Support people/agency/organization

Name	Role	Contact info.
i.e. Chris Smith	**A friend who helps walk my cat.**	**(416) 962-7600**
(Names the person puts forward while in the mind set of discharge transition)		

Significant dates/appointments/events following discharge

Date	Details
i.e. Jan 1st	**My partners birthday**
	(Some significant dates will be in the chart/discharge summary but this completed box can venture beyond medical appts./referrals)

Community transition change plan

Goal #2: **Substance Use** **(Note: A CTP form is completed for each area identified by participant)**	
The change I want to make (or continue making) is:	
Some barriers or difficulties that may get in the way are:	
The steps I plan to take in making this change are:	
The person/agency/organization that can support me in making this change is: *Name:* *Contact info:* *How can they help:*	
How important is it to you to make this change? (1-10 scale)	*How confident are you that you can make this change? (1-10 scale)*

Support people/agency/organization

Name	Role	Contact info.
i.e. Chris Smith	**A friend who helps walk my cat.**	**(416) 962-7600**
(Names the person puts forward while in the mind set of discharge transition)		

Significant dates/appointments/events following discharge

Date	Details
i.e. Jan 1st	**My partners birthday**
	(Some significant dates will be in the chart/discharge summary but this completed box can venture beyond medical appts./referrals)

Community transition change plan

Goal #3: **Open – client-identified** **(Note: A CTP form is completed for each area identified by participant)**	
The change I want to make (or continue making) is:	
Some barriers or difficulties that may get in the way are:	
The steps I plan to take in making this change are:	
The person/agency/organization that can support me in making this change is: *Name:* *Contact info:* *How can they help:*	
How important is it to you to make this change? (1-10 scale)	*How confident are you that you can make this change? (1-10 scale)*

Support people/agency/organization

Name	Role	Contact info.
i.e. Chris Smith	**A friend who helps walk my cat.**	**(416) 962-7600**
(Names the person puts forward while in the mind set of discharge transition)		

Significant dates/appointments/events following discharge

Date	Details
i.e. Jan 1st	**My partners birthday**
	(Some significant dates will be in the chart/discharge summary but this completed box can venture beyond medical appts./referrals)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4-5
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8-9, Table 1
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	9, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	9, Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the pilot trial ended or was stopped	10
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10, Table 2
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	11-12
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	12-14
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	15
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	15
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	15-16
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	16
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	N/A
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	16-17
	26	Ethical approval or approval by research review committee, confirmed with reference number	17

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Guidance for Reporting Involvement of Patients and the Public 2 – Short Form (GRIPP2-SF)

Section and topic	Item	Reported on page No.
1: Aim	Report the aim of PPI in the study	4
2: Methods	Provide a clear description of the methods used for PPI in the study	5-6
3: Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	11-12
4: Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	14-15
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	16