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Author/s:

Papaluca, T;Craigie, A;McDonald, L;Edwards, A;Winter, R;Hoang, A;Pappas, A;Waldron, A;McCoy, K;Stoove, M;Doyle, J;Hellard, M;Holmes, J;MacIsaac, M;Desmond, P;Iser, D;Thompson, AJ

Title:

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Date:

2022-08-01

Citation:

Papaluca, T., Craigie, A., McDonald, L., Edwards, A., Winter, R., Hoang, A., Pappas, A., Waldron, A., McCoy, K., Stoove, M., Doyle, J., Hellard, M., Holmes, J., MacIsaac, M., Desmond, P., Iser, D. & Thompson, A. J. (2022). Care Navigation Increases Initiation of Hepatitis C Treatment After Release From Prison in a Prospective Randomized Controlled Trial: The C-LINK Study. *Open Forum Infectious Diseases*, 9 (8), <https://doi.org/10.1093/ofid/ofac350>.

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Care Navigation Increases Initiation of Hepatitis C Treatment After Release From Prison in a Prospective Randomized Controlled Trial: The C-LINK Study

Timothy Papaluca,^{1,2} Anne Craigie,^{1,2} Lucy McDonald,¹ Amy Edwards,¹ Rebecca Winter,^{1,2} Annabelle Hoang,¹ Alex Pappas,¹ Aoife Waldron,¹ Kelsey McCoy,¹ Mark Stooze,^{2,3} Joseph Doyle,^{2,3,4} Margaret Hellard,^{2,3,4} Jacinta Holmes,^{1,2} Michael Maclsaac,^{1,2} Paul Desmond,^{1,2} David Iser,^{1,2} and Alexander J. Thompson^{1,2}

¹Department of Gastroenterology, St Vincent's Hospital, Melbourne, Victoria, Australia, ²Burnet Institute, The University of Melbourne, Melbourne, Victoria, Australia, ³Department of Epidemiology and Preventative Medicine, Monash University, Melbourne, Victoria, Australia, and ⁴Department of Infectious Diseases, The Alfred and Monash University, Melbourne, Victoria, Australia

Background. Prison-based hepatitis C treatment is safe and effective; however, many individuals are released untreated due to time or resource constraints. On community re-entry, individuals face a number of immediate competing priorities, and in this context, linkage to hepatitis C care is low. Interventions targeted at improving healthcare continuity after prison release have yielded positive outcomes for other health diagnoses; however, data regarding hepatitis C transitional care are limited.

Methods. We conducted a prospective randomized controlled trial comparing a hepatitis C care navigator intervention with standard of care for individuals released from prison with untreated hepatitis C infection. The primary outcome was prescription of hepatitis C direct-acting antivirals (DAA) within 6 months of release.

Results. Forty-six participants were randomized. The median age was 36 years and 59% were male. Ninety percent ($n = 36$ of 40) had injected drugs within 6 months before incarceration. Twenty-two were randomized to care navigation and 24 were randomized to standard of care. Individuals randomized to the intervention were more likely to commence hepatitis C DAAs within 6 months of release (73%, $n = 16$ of 22 vs 33% $n = 8$ of 24, $P < .01$), and the median time between re-entry and DAA prescription was significantly shorter (21 days [interquartile range {IQR}, 11–42] vs 82 days [IQR, 44–99], $P = .049$).

Conclusions. Care navigation increased hepatitis C treatment uptake among untreated individuals released from prison. Public policy should support similar models of care to promote treatment in this high-risk population. Such an approach will help achieve hepatitis C elimination as a public health threat.

Keywords. DAA; elimination; hepatitis C; prison; transitional care.

The World Health Organization has proposed elimination targets for hepatitis C infection [1]. To achieve these targets, treatment must be prioritized to high-transmitting populations including people who inject drugs (PWID) [2]. Because PWID experience a high lifetime risk of incarceration, prisons are an important setting to engage and treat people living with hepatitis C [3]. Prison-based hepatitis C treatment is effective, cost effective, and can reduce intraprison incident infection by interrupting transmission [4–7]. However, even in areas where prison treatment programs are available, short sentence durations and resource constraints mean many individuals are released untreated.

After release from prison, individuals are faced with multiple competing social, financial, and medical priorities, and this period is defined by high rates of morbidity and mortality [8–13]. In this setting, we have previously shown that only 25% of individuals released from prison with untreated hepatitis C commenced treatment within 6 months [14]. Data from North America similarly demonstrates a low likelihood of linkage to hepatitis C care after prison release [15, 16].

Multiple interventions designed to enhance healthcare continuity among individuals leaving prison have demonstrated favorable outcomes [17–22]. In a recent prospective, single-arm study, 31% of individuals with hepatitis C infection who received transitional care coordination and patient navigation were linked to hepatitis C care within 180 days of release [23]. However, there is no randomized controlled data investigating the effect of transitional interventions on linkage to hepatitis C care after community re-entry.

METHODS

We conducted a randomized controlled trial to compare the likelihood of commencing hepatitis C DAA treatment within

Received 18 May 2022; editorial decision 13 July 2022; accepted 27 July 2022; published online 28 July 2022

Correspondence: Alexander J. Thompson, MBBS, PhD, Director of Gastroenterology, St Vincent's Hospital Melbourne, 35 Victoria Parade, Fitzroy, Victoria, Australia, 3065 (alexander.thompson@svha.org.au).

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6 months of prison release between untreated individuals who received case-management using a care navigator model (hereafter “care navigation”) and those who received standard of care.

Study Design and Setting

We have previously established a nurse-led, statewide, hepatitis, prison in-reach program (hereafter “Statewide Hepatitis Program”) that provides prison-based hepatitis C management in Victoria, Australia [4]. This program assesses high volumes of individuals with a focus on providing treatment during incarceration. However, it is not possible to treat every person living with hepatitis C during their incarceration, particularly those with imminent release to community. Individuals in prison assessed by the Statewide Hepatitis Program between October 1, 2018 and March 15, 2020 who had an anticipated release date within 4 weeks of their initial assessment were eligible for inclusion. The study was discussed with potential participants who then verbally consented to participate and provided community contact details for themselves and/or community associates (eg, family members, community healthcare providers, and peers). They also provided written consent for the release of pharmaceutical claims information for 6 months after community re-entry to determine hepatitis C treatment status. This record captures every hepatitis C DAA prescription generated in Australia. All participants were provided with a toll-free number at their prison-based assessment and were encouraged to contact the care navigator after community re-entry. Once prison release was confirmed using the prison electronic record, participants were randomized to care navigation or standard of care.

Participants

Inclusion criteria included the following: (1) active hepatitis C infection, defined as a positive hepatitis C ribonucleic acid (RNA) polymerase chain reaction (PCR); (2) ability to provide 1 or more telephone numbers for community contact postrelease; (3) age 18 to 65 years; and (4) ineligibility for prison-based hepatitis C treatment (anticipated release within 4 weeks of initial assessment). Individuals were excluded if as follows: (1) they were cirrhotic (liver stiffness measurement [LSM] of ≥ 12.5 kPa, or aspartate aminotransferase-to-platelet index > 1.0 where LSM was unavailable); (2) they were released under the authority of the Victorian Department of Justice and Community Safety; and/or (3) treatment was commenced in prison.

Standard of Care

In Victoria, standard in-prison protocols include creation of a healthcare summary for an individuals’ community primary care provider. If an individual is prescribed opioid substitution therapy (OST) during incarceration, they are linked with a community prescriber/pharmacy. The OST is reimbursed for Australian citizens through the Australian Pharmaceutical

Benefits Scheme (PBS); however, a weekly dispensing fee of ~\$35.00 Australian Dollars (AUD) is charged by pharmacies. Normal procedure in Victoria is that community pharmacies are reimbursed by the Victorian Government to dispense an individual’s OST for 4 weeks after community re-entry.

Standard Statewide Hepatitis Program discharge protocols for individuals with hepatitis C who are assessed while incarcerated but released untreated include creating a comprehensive hepatitis C summary for the individuals’ community healthcare provider. This includes blood-based results including hepatitis C virus (HCV) RNA PCR and genotype, hepatitis B virus (HBV) serology, and transient elastography results, where available. Information on DAA prescribing is included. An alert is created in the participant’s prison-based electronic record to indicate that they remained untreated and should be referred to the Statewide Hepatitis Program in the event of reincarceration.

After community re-entry, if a standard-of-care participant initiated contact with the care navigator via the toll-free number, they were directed to their local healthcare provider to commence treatment. We attempted to contact standard-of-care participants 6 months after release irrespective of whether hepatitis C DAA had been prescribed (evidenced by PBS records) to determine treatment completion and outcome status. Standard-of-care participants who remained untreated were eligible to receive care navigation equivalent to participants in the intervention arm.

Study Intervention: Care Navigation

In addition to the standard discharge protocols described, participants randomized to care navigation were offered an additional healthcare and support intervention. The care navigator (a gastroenterologist) was responsible for delivering the intervention, which included telephone-based consultations, prescription of hepatitis C DAA medications, and reimbursements for (1) DAA medication copayments (\$16.80–\$116.40 AUD) and (2) study participation time (supermarket vouchers at baseline, end of treatment [EOT], and sustained virologic response week 12 [SVR12]; \$20, \$50, and \$100 AUD, respectively). Where applicable, OST-dispensing fees were reimbursed for the duration of the participants’ hepatitis C treatment. This was paid directly to the dispensing pharmacy (\$140–\$280 AUD).

Participants randomized to care navigation were contacted via telephone within 2 weeks of prison release. If the participant could not be reached, their nominated associates were contacted to ascertain updated contact details. If contact was not established within 6 weeks of community re-entry, no further attempts were made. If contact was successful, the care navigation model was described to the participant who reconsented for participation. A toll-free number was provided to study participants, and telephone contact could be initiated by the study coordinator or the participants.

Hepatitis C DAAs were prescribed via the PBS and dispensed at St Vincent's Hospital. Medications were packaged into monthly blister packs and sent via registered post to participants' home address or their community pharmacy for collection.

The prison database was screened intermittently to determine whether participants had been reincarcerated, and, if so, a Statewide Hepatitis Program nurse was informed so that treatment could be commenced or continued within the prison.

Outcomes for Analysis

The primary endpoint was the number of participants prescribed HCV DAAs within 6 months of prison release. Secondary endpoints included time to DAA prescription, proportion of community- and prison-based treatment initiations, completion of treatment, and SVR12 outcomes.

Sample Size

Anticipating that 25% of participants in the standard of care and 55% in the care navigation groups would commence HCV DAAs within 6 months, a priori power calculation identified a target of 96 participants to achieve a power of 80% to detect a significant difference between groups ($\alpha = 0.05$). Participants were randomized using an electronic key generated by nonstudy personnel to care navigation or standard of care on a 1:1 basis, stratified by OST prescription status.

Data Collection

Baseline data were collected during participants' prison-based Statewide Hepatitis Program assessments. Self-reported variables included information regarding injecting drug use (IDU) practices and medical comorbidities. A history of IDU was defined as having ever injected an illicit substance. Recent IDU was defined as injecting within 6 months of incarceration. Transient elastography was performed at the assessment. Blood-based results were recorded from the prison medical record and included full blood count, liver and renal biochemistry, HCV RNA and genotype, and human immunodeficiency virus/HBV serology. Medications were recorded from the prison record.

The time interval between prison release and (1) successful participant contact and (2) DAA prescription were recorded. Data from the national drug reimbursement schedule was the final source of truth for confirmation and date of DAA prescription for participants prescribed treatment by nonstudy personnel. Self-reported commencement of DAA medications and completion of treatment, defined as EOT, were recorded. Laboratory forms for blood draw were mailed to participants before the SVR12 timepoint, enabling them to access their local pathology provider. Participants in the intervention group continued to be followed until an HCV PCR test 12 weeks after

completion of therapy was performed. Hepatitis C virus cure was defined as no detectable HCV RNA on PCR testing at least 12 weeks after completion of therapy. The occurrence/frequency of adverse events and instances of reincarceration were recorded.

Data Analysis

Categorical variables were applied to χ^2 tests (or Fisher's exact tests for samples less than 5) while continuous variables were applied to (parametric) t tests and (non-parametric) Mann-Whitney/Kruskal-Wallis tests. We considered the primary outcome of DAA initiation by intention-to-treat analysis using Fisher's exact test. The time data relating to intervals between release and DAA prescription was subjected to Mann-Whitney/Kruskal-Wallis test analysis. Statistical analyses were performed using STATA v12.0 (StataCorp, Texas).

Patient Consent Statement

This research protocol was approved by St Vincent's Hospital Human Research Ethics Committee (REF HREC/17/SVHM/282). Formal informed consent was provided by all study participants, which included either written consent or audio recording of participants verbally consenting to each statement included in the consent form, as stipulated by the reviewing research committee.

RESULTS

Participant Characteristics

In total, 46 participants were randomized. Baseline characteristics are presented in [Table 1](#). Participants were predominantly male ($n = 27$, 59%), median age was 36 years, and 20% identified as Aboriginal and/or Torres Strait Islander. All participants reported a lifetime history of IDU, which was recent for most ($n = 36$ of 40, 90%). Twenty (43%) participants were reincarcerated within 6 months.

Recruitment was paused in March 2020 due to the severe acute respiratory syndrome coronavirus 2 (SAR-CoV-2) pandemic that resulted in the suspension of prison-based, face-to-face assessments. At this time, an interim analysis determined that the primary endpoint had been met and recruitment was terminated.

Likelihood of Hepatitis C Treatment Initiation

Primary Outcome: Hepatitis C Treatment Initiation

Care navigation was associated with a higher likelihood of hepatitis C treatment prescription postrelease from prison. Sixteen of the 22 participants (73%) randomized to care navigation commenced treatment within 6 months, compared with 8 of 24 participants (33%) in the standard-of-care arm ($P = .01$). Among those prescribed DAAs, the median time between community re-entry and DAA prescription was 21 days (interquartile range [IQR], 11–42 days) for care navigation and 82 days

Table 1. Baseline Characteristics

Characteristics	Total (n=46)	Care Navigation (n=22)	Standard of Care (n=24)
Age, years, median [IQR]	36 [32–41]	35 [31–41]	36 [32–41]
Male sex, n (%)	27 (59)	13 (59)	14 (58)
Body mass index, kg/m ² , median [IQR]	26.3 [21.5–29.1]	26.6 [22.1–29.2]	25.4 [21.4–29.8]
Indigenous Australian, n (%)	9 (20)	5 (23)	4 (17)
HCV genotype, n (%)			
1	19 (41)	9 (41)	10 (42)
2	2 (5)	2 (9)	0 (0)
3	14 (30)	7 (32)	7 (29)
4	1 (2)	1 (4)	0 (0)
NA	10 (22)	3 (14)	7 (29)
ALT, U/mL, median [IQR]	63 [37–102]	62 [35–142]	63 [37–87]
Platelet count, median [IQR]	270 [213–326]	269 [214–323]	278 [199–353]
HBV serology, n (%)			
HBsAg	0 (0)	0 (0)	0 (0)
Anti-HBs	33 (72)	16 (72)	17 (71)
Anti-HBc	8 (17)	3 (18)	5 (21)
HIV coinfection, n (%)	1 (2)	1 (5)	0 (0)
LSM, n (%) (n=36) ^a			
<6 kPa	18/36 (50)	8/15 (53)	10/21 (48)
6–9 kPa	14/36 (39)	7/15 (47)	7/21 (33)
9–12.5 kPa	4/36 (11)	0 (0)	4/21 (19)
>12.5 kPa	0/36 (0)	0 (0)	0/21 (0)
APRI <1.0 for participants without LSM available, n (%)	10/10 (100)	7/7 (100)	3/3 (100)
Cirrhosis, n (%)	0 (0)	0 (0)	0 (0)
Injecting drug use, n (%)			
PWID, ever	46 (100)	22 (100)	24 (100)
PWID, 6 months before incarceration	36/40 (90)	18/21 (86)	18/19 (95)
Comorbid psychiatric illness, n (%)	23 (50)	16 (73)	9 (38)
Psychotropic medication, n (%)	20 (43)	13 (59)	7 (29)
OST at prison release	13 (28)	7 (32)	6 (25)
Reincarceration ^b , n (%)	20 (43)	11 (50)	9 (38)
DAA regimens, n (%)			
Glecaprevir/Pibrentasvir	19/24 (79)	13/16 (81)	6/8 (75)
Sofosbuvir/Velpatasvir	5/24 (21)	3/16 (19)	2/8 (25)

Abbreviations: ALT, alanine aminotransferase; APRI, aspartate aminotransferase-to-platelet index; DAA, direct-acting antiviral; HBc, hepatitis B core antibody; HBs, hepatitis B surface antibody; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; IQR, interquartile range; LSM, liver stiffness measurement; NA, not applicable; OST, opioid substitution therapy; PWID, person who injects drugs.

^aLiver stiffness measurements were not available for 10 participants due to access limitations.

^bReincarceration was defined as re-entering the Victorian prison system within 6 months of the participants' index community re-entry episode.

(IQR, 44–99 days) for standard-of-care participants ($P = .049$) (Figure 1).

Of the 16 participants randomized to care navigation who commenced treatment, 15 (94%) did so via the intervention (Figure 2). This included 13 treated directly in the community by the care navigator and 2 who were fast tracked for prison-based treatment after reincarceration. One participant was prescribed treatment in the community via an alternate healthcare provider. Of the 8 participants who commenced treatment in the standard-of-care arm, 5 were prescribed DAAs in the community and 3 commenced therapy in the prison after reincarceration. The proportion of participants retained in hepatitis C care at each treatment milestone is displayed in Figure 3.

Care Navigator Intervention Arm: Cascade of Care

Thirty-eight points of contact were recorded for the 22 participants (Supplementary Table 1). Overall, 15 participants were contactable. Although the participant or a nominated associate was contactable for 20 (91%) participants, 5 associates were unable ($n = 4$) or unwilling ($n = 1$) to facilitate onward contact with the participant. Participants most commonly provided a personal telephone number ($n = 12$); however, successful contact was more commonly achieved via a family member ($n = 11$ of 15, 73%) than with the participant directly ($n = 4$ of 15, 27%). Of the 13 who commenced treatment, 7 (54%) changed telephone number during follow up (range 0–2). The DAAs were mailed to the participants' community pharmacy for

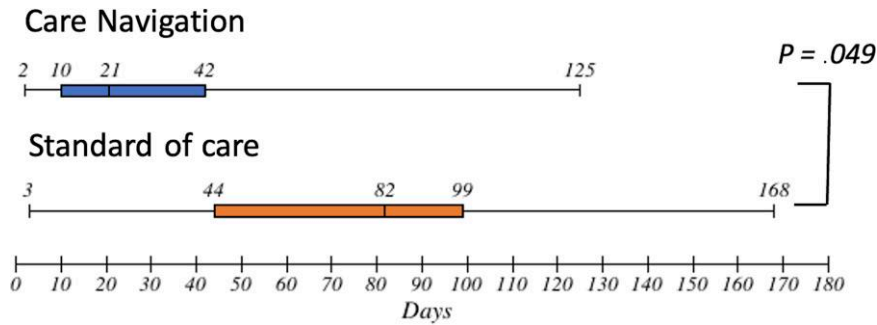


Figure 1. Time to direct-acting antivirals entry after community re-entry.

collection ($n=7$) or to their home ($n=4$) or were collected in person ($n=2$).

Two participants in the care navigator intervention arm commenced hepatitis C treatment in prison after reincarceration, and another one commenced treatment in the community independently. Treatment was well tolerated. One participant

reported nausea and one developed Bell's Palsy at treatment week 4, which was not deemed treatment related.

Standard of Care Arm

Per the study protocol, participants in the control arm were not contacted until 6 months postrelease. Five participants

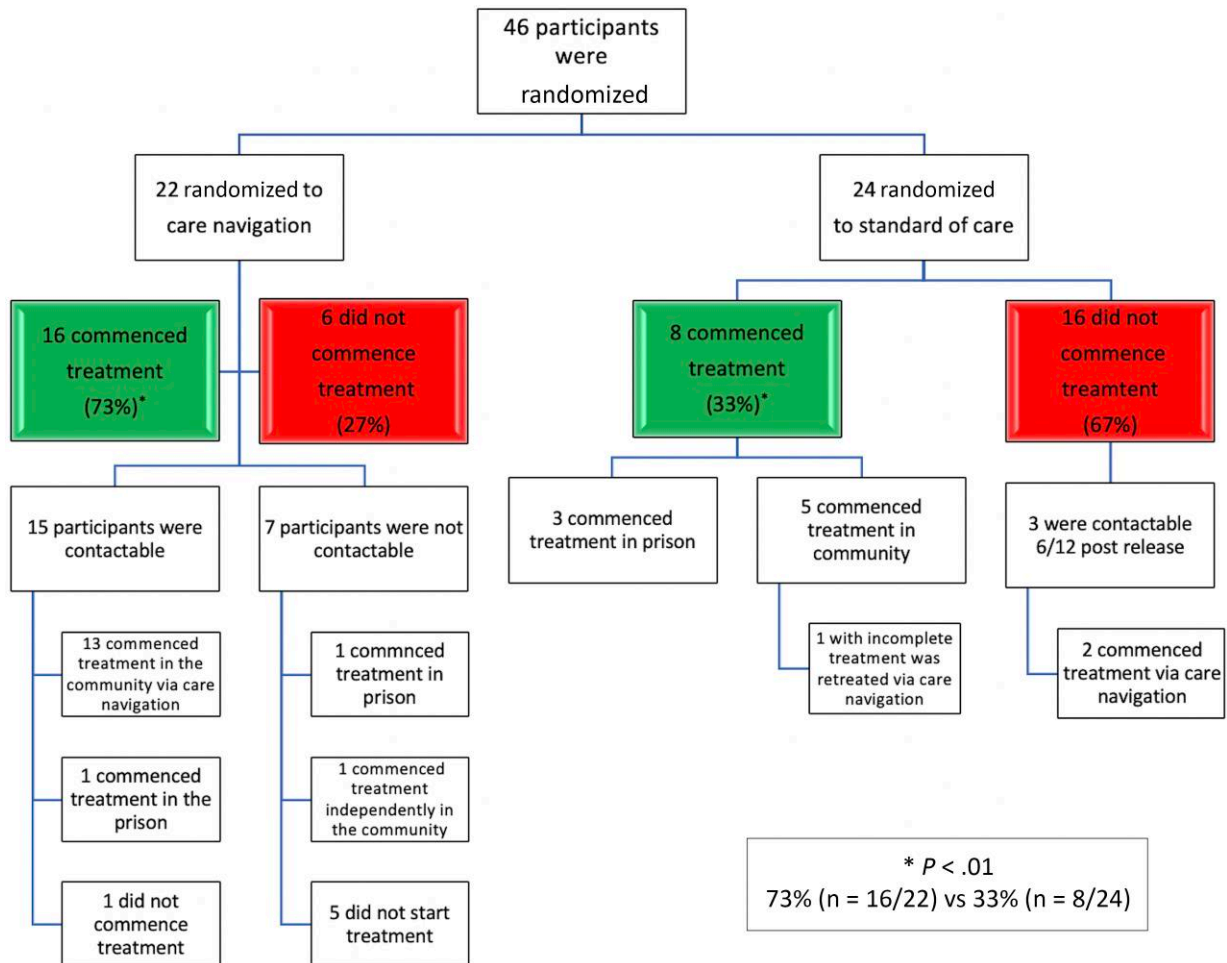


Figure 2. Participant consort diagram. *There was a higher likelihood of participants randomised to care navigation compared to standard of care would be prescribed hepatitis C treatment ($n = 16/22, 73\%$ vs $n = 8/24, 33\%$ $p < 0.01$).

Proportion of participants engaged in care at hepatitis C treatment milestones

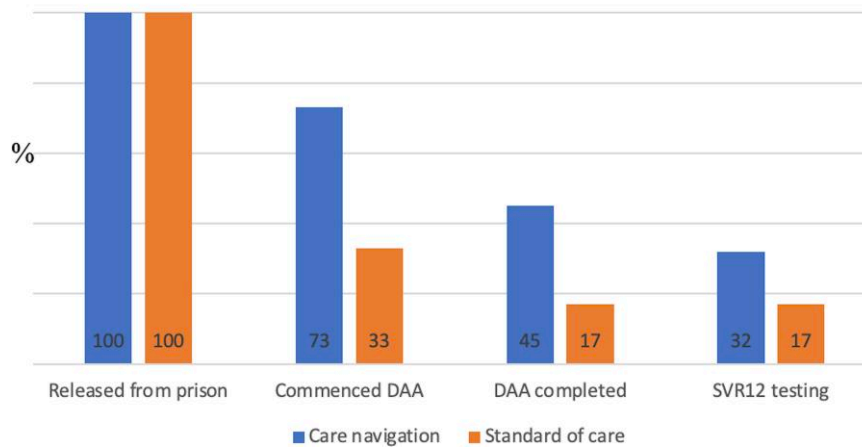


Figure 3. Proportion of participants engaged in care at hepatitis C treatment milestones. DAA, direct-acting antiviral; SVR12, sustained virologic response 12 weeks after end of treatment.

randomized to standard of care initiated treatment in the community, 2 of whom were treated by their primary physician: 1 via a supervised injecting facility outreach program, and 1 through a hospital outpatient clinic. One participant's treatment was registered by the national database, but details of the treatment setting were not available. Three participants were treated in prison after reincarceration. Only 1 participant in the standard-of-care arm initiated contact with the study team using the toll-free number provided before community re-entry.

All participants randomized to standard of care were eligible to switch to care navigation at 6 months postrelease, if they remained untreated. Six of 24 participants were contactable at 6 months. Of the 16 untreated participants, only 3 were contactable. Two subsequently commenced treatment via care navigation.

Community-Based Versus Prison-Based Hepatitis C Treatment Initiations According to Treatment Arm

Participants randomized to care navigation were more likely to commence treatment in the community than standard-of-care participants ($n = 14$ of 22, 64% vs $n = 5$ of 24, 21% $P = .01$).

Overall, 20 (43%) participants were reincarcerated during the 6-month follow up. The rate of reincarceration was similar between groups ($n = 11$ of 22, 50% vs $n = 9$ of 24, 38%, $P = .55$). When participants who had already commenced treatment in the community before reincarceration were excluded, a comparable proportion of participants in both arms initiated treatment in prison ($n = 2$ of 5, 40% vs $n = 3$ of 9, 33% $P = 1.0$).

Correlates of Treatment Initiation

Correlates of treatment initiation were considered on univariate analysis for both groups (Table 2). The only factor

associated with a higher likelihood of DAA commencement among care navigation participants was successful participant contact after release ($n = 14$ of 15, 93% vs $n = 2$ of 7, 29%, $P = .01$).

DISCUSSION

This is the first randomized controlled trial demonstrating the effectiveness of postprison release care navigator-led hepatitis C management. Care navigation was associated with a significant improvement in DAA initiation rates among untreated hepatitis C-positive individuals after release from prison. Overall, 73% of participants enrolled in care navigation commenced DAAs within 6 months. The time interval between prison release and DAA prescription in the care navigator arm was also shorter. The model achieved high rates of treatment initiation despite a range of competing needs common for re-entering individuals. In light of these competing priorities, it is not surprising that only 33% of participants randomized to standard of care commenced treatment during follow up. These results are in keeping with our previous findings in a retrospective audit in which only 25% of individuals commenced DAAs in 6 months after release and are similar to other international data, highlighting the utility of and need for dedicated transitional support [14, 15, 24].

We observed a higher likelihood of DAA initiation in participants in our intervention arm than the 20% reported by Akiyama et al [23], who performed a single-arm study evaluating hepatitis C care coordination for recently released individuals. The higher DAA prescription rate among our participants is likely multifactorial. First, we were able to successfully contact a greater proportion of participants after community

Table 2. Correlates of Treatment Initiation for Participants Randomized to Care Navigation and Standard of Care

Variable	Care Navigation (n = 22)		P Value	Standard of Care (n = 24)		P Value
	Treated (n = 16)	Not Treated (n = 6)		Treated (n = 8)	Not Treated (n = 16)	
Male sex	9 (56)	4 (67)	1.0	6 (75)	8 (50)	.39
Age [IQR]	35 [31–41]	38 [34–43]	.36	33 [31–40]	38 [32–42]	.48
Aboriginal or Torres Strait Islander	2 (13)	3 (50)	.1	1 (13)	3 (19)	1.0
Reincarceration within 6 months	8 (50)	3 (50)	1.0	3 (38)	6 (38)	1.0
Released from prison on OST	6 (38)	1 (17)	.62	1 (13)	5 (31)	.62
Psychiatric comorbidity	13 (81)	3 (50)	.28	2 (25)	7 (44)	.66
IDU during 6 months before incarceration (n = 36/40)	n = 15/16 (94)	n = 3/5 (60)	.13	n = 6/7 (86)	n = 12/12 (100)	.37
Successful participant contact within 6 weeks after prison release	14 (88)	1 (17)	.01	

Abbreviations: IDU, injecting drug use; IQR, interquartile range; OST, opioid substitution therapy. Being able to successfully contact a participant within 6 weeks of prison release was associated with a higher likelihood of DAA prescriptions (n = 14/16, 88% vs n = 1/6, 17%, p = 0.01).

re-entry, which our data identifies as key for transitional care engagement. Second, we created a model of care that facilitated immediate treatment initiation, rather than supporting an individual through existing healthcare pathways. Finally, although numbers in this pilot study are small due to the challenges of recruiting and after up re-entering individuals, by including a control arm, we were able to confirm for the first time that care navigation is associated with increased treatment uptake compared with standard of care.

The ability to contact participants after community re-entry was key to engaging individuals in care. Although only a minority of untreated participants randomized to standard of care were contactable at 6 months postrelease, again, 2 of 3 commenced treatment through care navigation. This further endorses the model’s ability to overcome functional barriers to care on community re-entry and engage those poorly served by existing healthcare pathways. Associates, most commonly family members, were key in facilitating contact with participants in the community, and therefore future transitional interventions should prioritize collecting an individual’s contact information as well as their trusted social network.

However, we did encounter difficulties maintaining contact with participants during follow up, most frequently due to a change in contact details. The difference between an individual’s anticipated and actual contact details and social networks before and after prison release is also evidenced by 80% of standard of care participants being uncontactable at 6 months post-release. Successful engagement in hepatitis C transitional care is therefore dependent on early contact after release from prison when there appears to be more certainty about an individual’s contact information. Furthermore, given only 1 participant-initiated contact after prison release, assertive follow up by a care coordinator is required to achieve a level of engagement required to justify resourcing.

The time to hepatitis C treatment was also shorter among care navigation participants. Australian data demonstrates that almost half of individuals with an IDU history resumed IDU within 6 months of community re-entry [10]. As such, reducing time between community re-entry and DAA initiation may also have important implications in reducing incident infection.

Overall, 43% of the participants were reincarcerated during follow up, reinforcing (1) the close association between PWIDs and detention and (2) the cyclical movements between community and prison. Enhanced collaboration between prison and community healthcare providers is therefore important to manage the complex needs of people across typically siloed medical services. Our study highlights that care navigation during these critical transitions can improve healthcare engagement among this population. Given the frequent interaction between PWID and the prison sector, we must also (1) continue to advocate for prison-based hepatitis C management internationally where this is not standard practice and (2) continue to evaluate systems to improve hepatitis C treatment throughput when this is in place.

Limitations of this study include the intensive nature and multiple financial components of the intervention, which may limit its implementation in other regions. In addition, because of these multiple components included in the intervention, we cannot confidently conclude which specific aspect of the model contributed to the high treatment rates achieved. Furthermore, because this study was coordinated by a gastroenterologist undertaking a higher degree, the care navigator was also a prescriber. However, this model of care is continuing in our jurisdiction with a clinical nurse consultant care navigator with similar efficiencies; therefore, it is not believed to impact the applicability of this model in other regions. Finally, the onset of the SARS-CoV-2 pandemic led to suspension of

face-to-face, prison-based assessments and therefore participant recruitment. Although the primary outcome remains significant on statistical analysis, we acknowledge that the target sample size was not reached.

CONCLUSIONS

In summary, care navigation increases the likelihood that individuals living with hepatitis C are successfully engaged in care after release from prison and reduces the time to treatment. Treatment rates among unsupported individuals are otherwise low. Similar programs should be developed and implemented to make a meaningful contribution to improving health outcomes among this marginalized population and promoting the elimination of hepatitis C.

Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Acknowledgments

Author contributions. All authors made a substantial contribution to the concept or design of the work and/or the acquisition, analysis, or interpretation of the data. In addition, all authors were involved in drafting or revising the work, gave final approval of the version to be published, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Financial support. This study funded by the St Vincent's Hospital Melbourne Research Endowment Fund. T. P. received funding from an Australian Government Research Training Program Scholarship and the Department of Gastroenterology, St Vincent's Hospital Melbourne. A. J. T. and M. H. received funding from the National Health and Medical Research Council of Australia (NHMRC) Practitioner Fellowships Grants 1142976 and 1112297. This work was supported by NHMRC Program Grant 1132902 and Partnership Grant 1116161.

Potential conflicts of interest. J. D. reports investigator-initiated research funding to institution from Gilead and AbbVie and honoraria to institution from Gilead. M. H. reports investigator-initiated research funding from Gilead Sciences and AbbVie. D. I. reports honoraria for speaking duties from AbbVie. A. J. T. reports the following: involvement in advisory boards for AbbVie, Gilead Sciences, Roche Diagnostics, BMS, Merck, Immunocore, Janssen, Assembly Biosciences, Arbutus, Vir Biotechnology, Eisai, Ipsen, and Bayer; honoraria for speaking duties from AbbVie, Gilead Sciences, Roche, and BMS; and investigator-initiated research funding from Gilead Sciences, BMS, AbbVie, and Roche Molecular Systems. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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