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Abstract

Objectives: To describe: (1) cardiac rehabilitation (CR) referral across cardiac units in a tertiary centre with eReferral; (2) characteristics associated with CR referral and enrolment; and (3) the effects of peer navigation (PN) on referral and enrolment. This pilot was a 2 parallel-arm, randomized, single-blind trial with allocation concealment.

Setting: 3 cardiac units (i.e., interventional, general cardiology, and cardiac surgery) in 1 of 2 hospitals of a tertiary centre.

Participants: CR-eligible adult cardiac inpatients were randomized to PN or usual care. 94 (54.7%) patients consented, of which 46 (48.9%) were randomized to PN. Outcomes were ascertained in 76 (80.9%) participants.

Intervention: The PN: (1) visited the participant at the bedside, (2) mailed a card reminding about CR to the participant's home, and (3) called the participant 2 weeks post-discharge to discuss CR barriers.

Outcome Measures: The primary outcome of enrolment was defined as participant attendance at a scheduled CR intake appointment (yes/no). The secondary outcome was referral. Blinded outcome assessment was conducted 12 weeks post-discharge, via CR chart extraction.

Results: Those who received care on the cardiac surgery unit (77.9%) were more likely to be referred than those treated on the general cardiology (61.1%) or interventional unit (33.3%; p=.04). Patients who had cardiac surgery, hypertension and hyperlipidemia were significantly more likely, and those with congenital heart disease, cancer and a previous cardiac diagnosis were less likely, to be referred. Participants referred to a site closer-to-home (76.2% of those referred) were more likely to enrol than those not (23.7%, p<.05). PN had no effect on referral (77.6%, p=0.45) or enrolment (46.0%, p=0.24).

Conclusions: There is wide variability in CR referral, even within academic centres, and despite eReferral. Referral was quite high, and thus PN did not improve CR utilization. Results support triaging patients to the CR program closest to their home.

Trial registration: Clinicaltrials.gov NCT02204449

Strengths and Limitations of this Study

· This is one of the few studies to investigate inter-institutional variability in cardiac rehabilitation referral practices by ward, and to investigate the effects of patient referral triage to the cardiac rehabilitation program closest-to-home on their subsequent enrolment.

· With regard to limitations, first, a comparison group exposed to traditional cardiac rehabilitation referral approaches was not included in the design, therefore it is unknown whether the CR referral and enrolment rates observed herein are truly higher than what would be observed without eReferral.

· Second, the relatively low response rate suggests there may be some selection bias.

· Third, the primary outcomes were ascertained via self-report for those re-referred closer to home but via chart report for those who attended the within-institution CR program.

· Fourth, the study was conducted at a single institution (albeit with 2 hospitals), which while appropriate for a pilot study, limits generalizability of findings.

Cardiovascular disease (CVD) is among the leading causes of morbidity globally.[1] With advances in acute treatment, patients are surviving their events, but remain at high risk of recurrence and subsequent mortality. Cardiac rehabilitation (CR) is an outpatient secondary prevention program composed of structured exercise training, comprehensive education, and counseling, which has been shown reduce recurrence and increase survival.[2] Despite its proven benefits, CR remains grossly under-utilize.[3-5]

Emphatic calls to promote greater CR utilization have been sounded by learned societies.[6, 7] Systematic CR referral has been demonstrated to significantly increase referral, and discussion with patients about CR at the bedside prior to discharge have been shown to increase their subsequent enrolment.[8, 9] Accordingly, targets of 85% inpatient CR referral and 70% enrolment have been established.[10] Systematic referral strategies have the ancillary benefit of mitigating bias in patient referral.[11]

There is variability in institutional approaches to referral and patient communication regarding CR.[12] To minimize costs associated with the referral process, our institution recently established electronic CR referral (eReferral), such that referral to CR appears as an option in the electronic discharge summary for all indicated cardiac patients (Figure 1). To assess the potential added effect of patient education regarding CR at the bedside, in accordance with a recent successful trial of peer navigation (PN),[13,14] our institution recently expanded and augmented a peer visiting program for coronary artery bypass graft surgery patients to all wards treating patients indicated for CR.

The objectives of the current study were to: (1) describe CR referral rates across cardiac units in a tertiary cardiac centre with eReferral; (2) describe patient sociodemographic and clinical characteristics associated with referral and enrolment in such a centre; and (3) describe the effects of PN on CR referral and enrolment. It was hypothesized that eReferral would achieve high absolute rates of referral across both PN and usual care groups, and that PN would achieve significantly higher rates of enrolment among referred patients than usual care.

METHOD

Design and procedure

A pilot randomized controlled trial entitled "Cardiac Rehabilitation PEer navigation to promote Enrolment and Referral" (CR-PEER) was undertaken to test the feasibility of a PN intervention (independent variable) in increasing cardiac patients' referral to and enrolment in CR (dependent variables). This trial design was pragmatic,[15] 2 parallel-arm, randomized (1:1), allocation-concealed, and single-blind. The protocol was reviewed and approved by the University Health Network (UHN) Research Ethics Board and also the Committee on Research Involving Human Subjects at Stony Brook University.

Upon consent, clinical data were extracted from inpatient charts to confirm CR eligibility. Included participants were then randomized to either receive the PN intervention (see below) or usual care (eReferral, see below). The randomization sequence was generated by a statistician unaffiliated with the study, and was stratified by sex in random blocks of four, eight, and 12. Random assignment was concealed through the use of opaque envelopes.

CR enrolment and referral were the primary and secondary outcome measures, respectively. They were ascertained by a research assistant blinded to random assignment 12 weeks post-discharge through extraction from the CR chart.

Setting

Participants were recruited from three cardiac units (i.e., interventional cardiology, general cardiology, and cardiac surgery) in one of two hospitals of an Academic Health Sciences Centre (UHN) in Toronto, Canada between July and December 2014. CR is offered to patients at no charge in Ontario.

The eReferral system was instituted as part of usual care in June 2014. As shown in Figure 1, when healthcare providers (i.e., nurse-practitioners, hospitalists, cardiologists or cardiac specialists depending on the cardiac unit) are completing the electronic discharge summary for patients with a cardiac diagnosis or procedure indicated for CR, they must click 'yes' or 'no' whether they wish to refer the patient to CR. Therefore, eReferral is available on all the cardiology units. Where 'yes' is selected, the electronic discharge summary is copied into a

queue which is managed by the CR staff. The CR staff then reviews the discharge summaries, and triages the patients accordingly.

As a tertiary cardiac care centre, non-local patients are frequently treated. Inpatient staff were instructed to refer all patients to the CR program within the institution, regardless of their location of residence (see text in Figure 1). This served to mitigate referral failure due to lack of inpatient staff awareness of CR program locations proximate to patients' homes. Thereafter, CR program staff reviewed the addresses of all referred patients, so that non-local patient referrals could be re-directed to a program closer to their place of residence (where available). Upon discussion with patients, referral information was faxed to the program closer to their home.

Participants

Participants were adult cardiac inpatients eligible for CR, with one or more of the following CR-indicated diagnoses or procedures: acute coronary syndrome, percutaneous coronary intervention (PCI), coronary artery bypass graft surgery ± valve surgery, arrhythmia, stable heart failure, congenital heart disease, and/or non-disabling stroke. In addition participants had to be proficient in English. Patients were excluded if: (1) they had any major musculoskeletal, neuromuscular, visual, cognitive or non-dysphoric psychiatric condition, or any serious or terminal illness not otherwise specified which would preclude CR eligibility based on CR guidelines as outlined by the Canadian Association of Cardiovascular Prevention and Rehabilitation,[16] (2) they were being discharged to long-term care, (3) were unable to ambulate (i.e., walk unaided at 2 mph and hence undergo a pre-CR exercise stress test), and/or (4) did not reside in Ontario where CR services are reimbursed.

Intervention

The PN intervention was based on the approach previously tested in the United States by Benz Scott et al.,[13,14] with modifications to accommodate the local healthcare context. As the UHN hospitals had an eReferral system in place as part of usual care, the primary focus of the current intervention was to increase CR enrolment.

The intervention was delivered by two female CR PNs, who were UHN CR graduates and formal volunteers at the participating hospital. The navigators completed training with UHN

Volunteer Services, and were trained by the study team to deliver CR-focused education and support. Training included review of scripts for all points of contact with participants.

The intervention consisted of three points of contact between participants and PNs. First, participants were visited at the bedside by the CR PN to build rapport, provide written materials about the benefits of CR, and encourage the participant to obtain a CR referral from their healthcare provider before discharge from the hospital. The second point of contact occurred one week post-discharge, when a "get well soon" card was mailed by the CR navigator to the participant's home, including the phone number of the UHN CR centre. For those not referred, the card included a message encouraging the participant to secure a referral from any of their physicians. The third and final point of contact occurred two weeks after discharge; the CR navigator called the participant to discuss any barriers to CR enrolment. Each point of contact was documented on a piloted form to establish consistency and fidelity.

Measures

Participant sociodemographic and clinical characteristics were extracted from participants' medical charts. These included age, sex, admission and discharge dates, cardiovascular diagnoses/procedures, risk factors, comorbidities, previous cardiac diagnoses, and contact information. The independent variable was study arm (i.e., intervention versus usual care).

The primary outcome of enrolment was defined as participant attendance at a scheduled CR intake appointment (i.e., risk factor assessment, exercise stress testing, goal-setting; yes/no). This was ascertained through blind review of CR charts for local participants referred to the institution's CR program. For participants referred to a program closer to their home (re-referral), enrolment was ascertained via self-report through a phone call, again by a research assistant blind to random assignment.

The secondary outcome of referral (yes/no) was confirmed by reviewing the list of those received at UHN's program. Referral was defined as CR program receipt of documentation from a healthcare provider to refer the participant dated during or subsequent to the index participant admission, whether it was a formal referral form, eReferral or a discharge summary from the

hospital stay. Where no referral was found at the local UHN program, participants were called to ascertain whether they had been referred to or enrolled in any other CR programs, again by a research assistant blind to random assignment. Re-referral was evident by a fax cover sheet attached to the referral form, addressed to another CR program.

Statistical analyses

First, the equivalence of participant sociodemographic and clinical characteristics by arm were tested using chi-square or t-tests, as appropriate. To test the first objective, CR referral was described by cardiac ward.

To test the second objective, CR referral and enrolment (yes/no) were compared by participant sociodemographic and clinical characteristics using Fisher's exact tests or t-tests, as applicable. To test the final objective, Fisher's exact tests were used to compare CR referral and enrolment by trial arm. IBM SPSS v.20 was used for all analyses.

RESULTS

Respondent characteristics

As shown in Figure 2, 172 patients were approached, of which 26 (15.1%) were ineligible, for the following reasons: 15 (8.7%) were not proficient in English, nine (5.2%) either did not live in Ontario or were leaving the province after discharge from hospital, and two (1.2%) had a medical condition which rendered them ineligible for CR. Overall, 94 patients consented and were randomized (1 patient consented but withdrew before randomization), resulting in a study enrollment rate of 54.7%. One patient withdrew consent after randomization and one patient died prior to outcome assessment, resulting in a final sample of N=92.

Table 1 displays participant sociodemographic and clinical characteristics. As shown, there were no significant differences in these characteristics by arm.

Table 1. Sociodemographic and clinical characteristics by arm.

Characteristic	Intervention n=46 (48.9%)	Usual Care n=48 (51.1%)	Total N=94
Sociodemographic			
Age (mean ±SD)	62.6 ±13.1	62.7 ±16.5	62.7 ±14.8
Female sex	14 (30.4)	15 (31.3)	30 (31.9)
Non-white	8 (17.4)	8 (17.0)	16 (17.0)
Clinical			
Cardiac Rehabilitation Indication (% yes)†			
Valve surgery	19 (41.3)	22 (45.8)	41 (43.6)
Coronary artery bypass graft surgery	19 (41.3)	16 (33.3)	35 (37.2)
Arrhythmia or rhythm device	16 (34.8)	11 (22.9)	27 (28.7)
Acute coronary syndrome	10 (21.7)	14 (29.1)	24 (25.5)
Percutaneous coronary intervention	9 (19.6)	9 (18.8)	18 (19.1)
Heart failure	3 (6.5)	4 (8.3)	7 (7.4)
Congenital heart disease	0 (0.0)	2 (4.2)	2 (2.1)
Non-disabling stroke	0 (0.0)	1 (2.1)	1 (1.1)
Risk factors (% yes)			
Hyperlipidemia	29 (63.0)	24 (50.0)	58 (61.7)
Hypertension	28 (60.9)	25 (52.1)	53 (56.4)

Diabetes	7 (15.2)	14 (29.1)	21 (22.3)
Smoking	4 (8.7)	10 (29.2)	14 (14.9)
Obesity	2 (4.3)	3 (6.3)	5 (5.3)
Previous history of cardiac disease (% yes)	42 (91.3)	38 (79.2)	80 (85.1)
Comorbidities (% yes)			
Arthritis	7 (15.2)	4 (8.3)	11 (11.7)
Cancer	3 (6.5)	6 (12.5)	9 (9.6)
Chronic Obstructive Pulmonary Disease	2 (4.3)	2 (4.2)	4 (4.3)
Osteoporosis	2 (4.3)	0	2 (2.1)
Hip/knee replacement	1 (2.2)	1 (2.1)	2 (2.1)
Length of stay (mean days ±SD)	9.3 ±4.6	10.8 ±9.4	10.0 ±7.4
Discharged on weekend	9 (19.6)	8 (17.0)	17 (18.1)

Abbreviations: SD, standard deviation.
† indications are not mutually exclusive (e.g., bypass surgery patients had concomitant valve repair).

As shown in Figure 2, CR referral was ascertained for 84 (91.3%) participants and enrolment for 76 (82.6%) participants. There was no referral form received at UHN CR for eight (16.7%) participants randomized to usual care, who could not subsequently be reached by phone to confirm they were not referred to another program. Nine (9.8%) participants could not be reached by phone to confirm enrollment.

There was no difference in whether outcomes were ascertained by randomized arm (p=0.25). With regard to sociodemographic and clinical characteristics, participants for whom

outcomes were ascertained were not significantly different than participants for whom outcomes were not ascertained (data not shown).

CR referral and enrolment

Overall, 59 (77.6%) of the 76 study participants were referred (66/92 assuming no referral in those for whom outcomes were not ascertained; 71.7%), of which 45 (76.3%) were re-referred to a CR site closer to their home. Physicians were as likely to refer participants regardless of whether the CR program ultimately re-referred them to a site closer to their home or not (p=0.29).

Overall, 35 (46.1%) of the 76 participants enrolled (or 35/92 assuming no enrolment in those for whom outcomes were not ascertained, 38.0%), with 30 (66.7%) of those re-referred to a site closer to home enrolling. Of the 59 referred, 59.3% enrolled. As shown in Table 2, participants re-referred to a CR program closer to their home were significantly more likely to enroll than those who were not (p=0.04).

Table 2. Participant Characteristics by Cardiac Rehabilitation Referral and Enrolment.

	Referred (N = 92)		**Enrolled (N=76)**	
Characteristic	**Yes n = 66 (78.6%)**	**No n =26 (28.3%)**	**Yes n = 35 (46.0%)**	**No n = 41 (53.9%)**
Sociodemographic				
Age (mean ±SD)	63.1 ±13.8	61.0 ±17.2	61.5 ±14.0	62.9 ±16.0
Female sex	21 (31.8)	7 (26.9)	12 (34.3)	10 (24.4)
Non-white	13 (19.7)	4 (15.4)	8 (22.9)	6 (14.6)

Clinical				
Cardiac Rehabilitation Indication (% yes)				
Valve surgery	29 (43.9)	10 (38.5)	18 (51.4)	16 (39.0)
Coronary artery bypass graft surgery	29 (43.9)	6 (23.1)	14 (40)	14 (34.1)
Arrhythmia or Rhythm Device	18 (27.2)	9 (34.6)	10 (28.8)	9 (22.0)
Acute coronary syndrome	20 (30.3)	4 (15.4)	8 (22.9)	11 (26.8)
Percutaneous coronary Intervention	14 (21.2)	4 (15.4)	7 (20.0)	8 (19.5)
Heart failure	2 (3.0)	5 (19.2)*	2 (5.7)	3 (7.3)
Congenital heart disease	0	2 (7.7)	0	2 (4.9)
Non-disabling stroke	1 (1.5)	0	0	1 (2.4)
Risk factors (% yes)				
Hypertension	40 (60.6)	12 (46.2)	21 (60)	22 (53.7)
Hyperlipidemia	41 (62.1)	11 (42.3)	21 (60.0)	25 (61.0)
Smoking (% current)	12 (18.2)	2 (7.7)	5 (14.3)	6 (14.6)

Diabetes	17 (25.8)	4 (15.4)	7 (20.0)	11 (26.8)
Obesity	4 (6.1)	1 (3.8)	4 (11.4)	1 (2.4)
Previous history of cardiac disease (% yes)	56 (84.8)	23 (88.5)	30 (85.7)	36 (87.8)
Comorbidities				
Arthritis	9 (13.6)	2 (7.7)	5 (14.3)	4 (9.8)
Cancer	3 (4.5)	5 (19.2)*	2 (5.7)	5 (12.2)
Chronic Obstructive Pulmonary Disease	3 (4.5	1 (3.8)	2 (5.7)	2 (4.9)
Osteoporosis	2 (3.0)	0	1 (2.9)	0
Hip/knee replacement	2 (3.0)	0	1 (2.9)	1 (2.4)
Length of stay (mean days ±SD)	9.2 ±4.7	11.3 ±10.9**	9.4 ±4.4	8.2 ±4.8
Discharged on weekend	12 (18.2)	6 (23.1)	9 (25.7)	6 (14.6)
Referred to site closer to home	-	-	30 (85.7)*	15 (36.6)

*p<.05, **p<.01; Abbreviations: SD, standard deviation.

With regard to objective 1, there were significant differences in CR referral depending on the cardiology unit from which a participant was discharged (p=0.04). Participants who received

inpatient care on the cardiac surgery unit (77.9%) were more likely to be referred than those treated on the general cardiology (61.1%) or the interventional cardiology unit (33.3%).

With regard to the second objective, sociodemographic and clinical characteristics associated with CR referral are shown in Table 2. As displayed, there were no differences in the sociodemographic characteristics of those referred versus not, but differences were observed based on clinical characteristics. With regard to cardiac indication for CR, participants with heart failure were less often referred (p=0.02). With regard to comorbidities, participants with cancer were significantly less likely to be referred than those without (p<0.05). Finally, those who were referred to CR had a shorter length of stay in the hospital than those not (p<0.01). Sociodemographic and clinical characteristics associated with CR enrolment are also shown in Table 2. As displayed, there were no significant differences in these characteristics among those who enrolled versus not.

Effects of peer navigation on CR utilization

Intervention fidelity. Of the 46 participants randomized to the navigation intervention, 38 (82.6%) received all 3 contacts. One (2.2%) participant did not receive the bedside visit and 7 (15.2%) participants did not receive the post-discharge phone call. In addition, four (8.7%) participants did not receive their initial bedside contact prior to hospital discharge, but instead the content was delivered via a telephone call to the participant at their home within three days of discharge.

Among the sample for whom outcomes were ascertained (n=76), CR referral did not significantly differ between the navigated group (n=31, 79.5%) and usual care (n=28, 75.7%; p=0.45). Enrolment also did not significantly differ between groups (n=20, 51.3% in the PN arm; n=15, 40.5% for usual care, p=0.27).

If we assume no referral or enrolment among those for whom there was no referral form at UHN yet they could not be reached by phone (n=92), referral still did not significantly differ between the navigated group (n=37, 80.4%) and usual care (n=29, 63.0%; p=0.05). Enrolment also did not significantly differ between groups in this larger sample (n=20, 51.3% in the PN arm; n=15, 40.5% for usual care, p =0.24).

DISSCUSSION

There is wide variability in CR referral practices even within academic institutions by cardiac wards, which could be due to cultural norms, healthcare provider practice variation, or the severity of illness (e.g., surgical patients vs. non-invasive procedures). Despite institution of an eReferral strategy across the academic institution, patients on the surgery unit were more likely to be referred than those on other units, and this finding is consistent with previous studies.[17,18] Indeed, there was a 40% difference in the proportion of patients referred by unit in the same institution. The eReferral strategy did however appear to mitigate sociodemographic biases oft-observed in CR referral,[19] and patient referral was consistent on weekends as well as weekdays. Moreover, this is one of the first studies to our knowledge to document higher rates of CR enrolment where patients are triaged to CR sites closer to their home.

Prior studies have demonstrated that systematic referral strategies can decrease referral bias.[11] Although a larger sample than reported here is required to be conclusive, there did not appear to be age, sex or ethnocultural biases in referral or enrolment patterns. This is a positive sign and suggests that eReferral has potential to mitigate bias in physician decisions related to these non-clinical characteristics.

There were differences in the clinical characteristics of patients referred however. Patients with heart failure were less likely to be referred than those without, although this finding should be interpreted with caution due to the low number of participants with this indication in the sample. This is disconcerting given the established benefits of CR for heart failure patients,[20] and that Canadian CR guidelines promote heart failure as an indication for CR.[16] Moreover, heart failure is now a reimbursed indication for CR in the United States,[21,22] and in Ontario where this study was undertaken, there are recommendations for CR referral for heart failure patients.[23] Greater awareness of the evidence of benefit and these policy changes may be needed before we see changes in referral practice.

Second, patients with comorbid cancer were less often referred than those without. This may be appropriate, depending on the stage of cancer and therapy. Finally, patients who had a shorter length of inpatient hospital stay were more likely to be referred than those with a longer

stay. This is somewhat surprising given that patients on the bypass unit, which traditionally has longer lengths of stay were more often referred than angioplasty patients, who have a shorter stay. Patients with a longer length of stay may have complications, more comorbidities, or more severe or complex disease, which would preclude participation in CR.

Due to the high rate of inpatient referral observed at over three-quarters of patients, the addition of PN did not have a significant impact on patient enrolment as hypothesized, although firm conclusions cannot be drawn as this was a pilot study. A larger sample may be needed to observe differences in enrolment by PN exposure, particularly in the context of eReferral. Thus, the first hypotheses in this pilot was confirmed, but the second was disconfirmed. Potential explanations for the lack of replication of findings from the PN trial by Benz Scott et al.[13] include the eReferral strategy implemented at the institution as outlined previously. In the trial in the United States, there was no referral strategy in the usual care arm. In the intervention arm, the PNs facilitated contact between the patient and the CR centre. Based on the results of this pilot, the decision has been made not to proceed to a full-scale trial.

Implications

There are three key policy implications of these findings. First, re-referring patients to programs closer to home should be a 'best practice' for cardiac care, as it may improve patient enrolment rates. There may be financial disincentive to re-refer where CR programs are reimbursed based on patient volumes. However, there are so many patients who do not access CR, that programs should always have sufficient patients to ensure financial soundness. Second, system-wide CR referral strategies, such as eReferral, should be broadly instituted as a means of ensuring high CR referral rates.

On a related note, third and finally, given the variation in CR referral between wards despite eReferral, education of healthcare providers will still be required to ensure consistent CR referral practices. There is a need to provide repeated education / in-services to cardiac healthcare providers, feedback on the proportion of patients referred in relation to targets, and reminders about the benefits of CR participation for patients and recommendations to refer patients in clinical practice guidelines, particularly on interventional cardiology units. If the high

rates of CR referral observed on cardiac surgery units could be replicated across all cardiac units, we would be much closer to achieving the 85% target.[10]

Limitations

Caution is warranted in interpreting these results. First, a comparison group exposed to traditional CR referral approaches was not included in the design, therefore it is unknown whether the CR referral and enrolment rates observed herein are truly higher than what would be observed without eReferral. Second, the relatively low response rate (54.7%) suggests there may be some selection bias. Third, the primary outcomes were ascertained via self-report for those re-referred closer to home but via chart report for those who attended the within-institution CR program. This may have biased findings. Fourth, the study was conducted at a single institution (albeit with 2 hospitals), which while appropriate for a pilot study, limits generalizability of findings. Finally, generalizability is limited to academic cardiac centres in jurisdictions where CR is available at no charge to patients.

In conclusion, CR referral across cardiac units in the same institution vary by 40% despite an eReferral strategy, with the rates highest observed on the cardiac surgery unit. Patients with heart failure, comorbid cancer and longer lengths of inpatient stay were less often referred than those without. With regard to enrolment, those who had their referral redirected to a site located closer to their home were more likely to enrol. Finally, likely due to the eReferral system implemented institution-wide, the PN intervention did not impact CR referral or enrolment.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

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Author Contributions

Sobia F Ali-Faisal made substantial contributions to the acquisition and analysis of the data, drafting the work

Lisa Benz Scott made substantial contributions to the conception and design of the work, revised the manuscript critically for important intellectual content, and gave final approval of the manuscript

Lauren Johnston acquired the outcome data, revised the manuscript critically for important intellectual content, and gave final approval of the manuscript

Sherry L Grace made substantial contributions to the design of the work and interpretation of the data, drafted and gave final approval of the manuscript

Data Sharing Statement

No additional data available.

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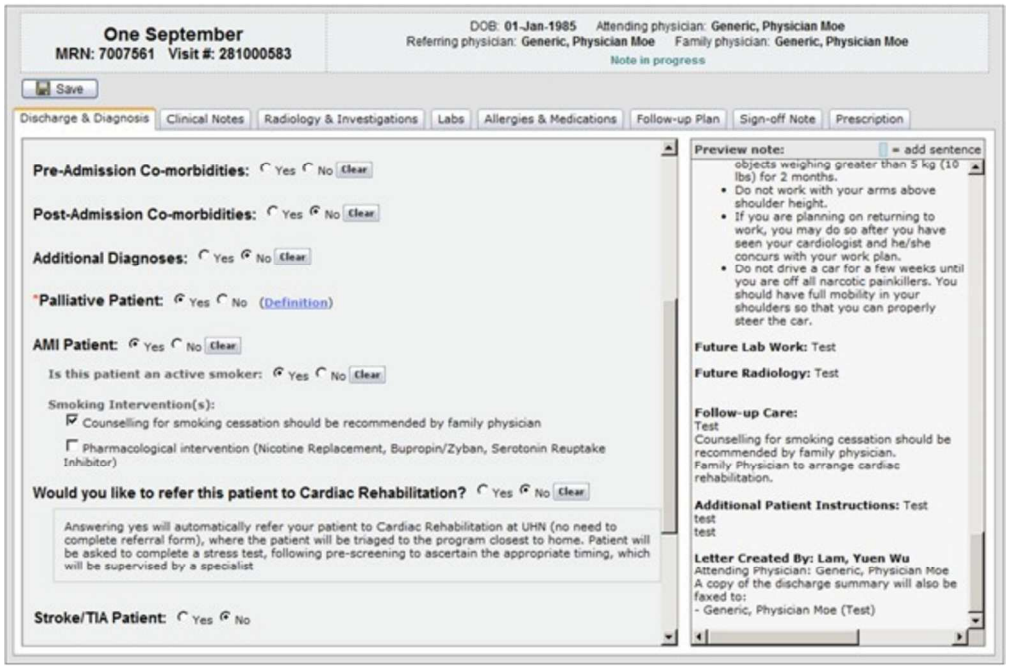
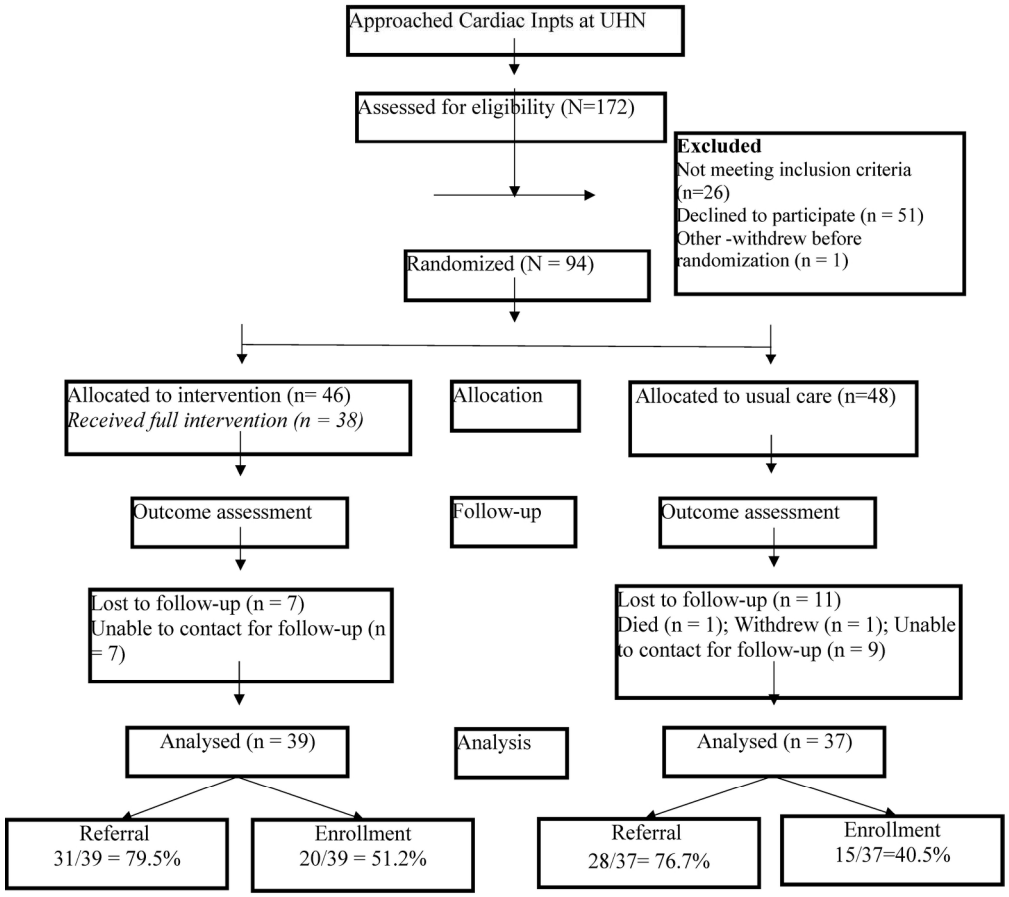
Figure 1. eReferral Screenshot from Electronic Discharge Summary



107x75mm (300 x 300 DPI)

Figure 2. Participant Recruitment Flow Diagram



190x183mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	
	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	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
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	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7
	13b	For each group, losses and exclusions after randomisation, together with reasons	7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5-6
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8-9
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	12-13
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12-13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full 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	17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 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.

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Cardiac rehabilitation referral and enrolment across an academic health sciences centre with eReferral and peer navigation: A randomized controlled pilot trial

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Keywords:	Physical and Rehabilitation Medicine, Health Services Research, Referral, Patient Navigation

Title: Cardiac rehabilitation referral and enrolment across an academic health sciences centre with eReferral and peer navigation: A randomized controlled pilot trial

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Running Head: CR-PEER

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Text Word Count: 3574

Abstract

Objectives: To describe: (1) cardiac rehabilitation (CR) referral across cardiac units in a tertiary centre with eReferral; (2) characteristics associated with CR referral and enrolment; and (3) the effects of peer navigation (PN)on referral and enrolment. This pilot was a 2 parallel-arm, randomized, single-blind trial with allocation concealment.

Setting: 3 cardiac units (i.e., interventional, general cardiology, and cardiac surgery) in 1 of 2 hospitals of a tertiary centre.

Participants: CR-eligible adult cardiac inpatients were randomized to PN or usual care. 94 (54.7%) patients consented, of which 46 (48.9%) were randomized to PN. Outcomes were ascertained in 76 (80.9%) participants.

Intervention: The PN: (1) visited participant at the bedside, (2) mailed a card reminding about CR to participant's home, and (3) called participant 2 weeks post-discharge to discuss CR barriers.

Outcome Measures: The primary outcome of enrolment was defined as participant attendance at a scheduled CR intake appointment (yes/no). The secondary outcome was referral. Blinded outcome assessment was conducted 12 weeks post-discharge, via CR chart extraction.

Results: Those who received care on the cardiac surgery unit (77.9%) were more likely to be referred than those treated on the general cardiology (61.1%) or interventional unit (33.3%; p=.04). Patients who had cardiac surgery, hypertension and hyperlipidemia were significantly more likely, and those with congenital heart disease, cancer and a previous cardiac diagnosis were less likely, to be referred. Participants referred to a site closer-to-home (76.2% of those referred) were more likely to enrol than those not (23.7%, p<.05). PN had no effect on referral (77.6%, p=0.45) or enrolment (46.0%, p=0.24).

Conclusions: There is wide variability in CR referral, even within academic centres, and despite eReferral. Referral was quite high, and thus PN did not improve CR utilization. Results support triaging patients to the CR program closest to their home.

Trial registration: Clinicaltrials.gov NCT02204449

Strengths and Limitations of this Study

· This is one of the few studies to investigate intra-institutional variability in cardiac rehabilitation referral practices by ward, and to investigate the effects of patient referral triage to the cardiac rehabilitation program closest-to-home on their subsequent enrolment.

· The design of this study is a strength: This was a randomized controlled trial, with allocation concealment and blinded outcome assessment.

· With regard to limitations, first, a comparison group exposed to traditional cardiac rehabilitation referral approaches was not included in the design, therefore it is unknown whether the CR referral and enrolment rates observed herein are truly higher than what would be observed without eReferral.

· Second, the relatively low response rate suggests there may be some selection bias.

· Third, the primary outcomes were ascertained via self-report for those re-referred closer to home but via chart report for those who attended the within-institution CR program.

Cardiovascular disease is among the leading causes of morbidity globally.[1] With advances in acute treatment, patients are surviving their events, but remain at high risk of recurrence and subsequent mortality. Cardiac rehabilitation (CR) is an outpatient secondary prevention program composed of structured exercise training, comprehensive education, and counseling, which has been shown reduce recurrence and increase survival.[2]

Despite its proven benefits, CR remains grossly under-utilized.[3,4] Multi-factorial barriers to both CR referral by providers and enrolment among eligible patients have been established.[5] In their systematic review, Clark et al.[6] reported the key issues at the health system-level included insufficient time and workload capacity to make the referral, and at the provider-level included over-reliance on physicians as gatekeepers and judgments that patients were not likely to participate. In another systematic review by this group,[7] lack of patient knowledge regarding CR services was associated with lower enrolment rates. Finally, in their systematic review, Cortes and Arthur[5] found cardiac indication, older age, being a non-English speaker, being a woman, being unmarried, and being non-white were all associated with lower referral rates.

Emphatic calls to promote greater CR utilization have been sounded by learned societies.[8,9] Systematic CR referral has been demonstrated to significantly increase referral, and discussion with patients about CR at the bedside prior to discharge have been shown to increase their subsequent enrolment.[10,11] Accordingly, targets of 85% inpatient CR referral and 70% enrolment have been established.[12] Systematic referral strategies have the ancillary benefit of mitigating bias in patient referral.[13]

There is variability in institutional approaches to referral and patient communication regarding CR.[14] To minimize costs associated with the referral process, our institution recently established electronic CR referral (eReferral), such that referral to CR appears as an option in the electronic discharge summary for all indicated cardiac patients (Figure 1). To assess the potential added effect of patient education regarding CR at the bedside, in accordance with a recent successful trial of peer navigation,[15,16] our institution recently expanded and augmented a

peer visiting program for coronary artery bypass graft surgery patients to all wards treating patients indicated for CR.

Peer navigation (also referred to as patient navigation) is a patient-centric intervention designed to eliminate barriers to timely health care.[17] It is a one-on-one relationship between navigators, usually a trained layperson, and patients in which the navigator provides education about the healthcare process and support.[18] It has been implemented and tested in a variety of healthcare populations,[19–21] including cardiac.[15,16] Prior reviews of peer navigation interventions provide evidence that it may reduce health system barriers,[22–26] such as those experienced by patients eligible for CR. Indeed, it has been recommended as an approach to overcoming barriers to CR use.[27,28]

Accordingly, the objectives of the current study were to: (1) describe CR referral rates across cardiac units in a tertiary cardiac centre with eReferral; (2) describe patient sociodemographic and clinical characteristics associated with referral and enrolment in such a centre; and (3) describe the effects of peer navigation on CR referral and enrolment. It was hypothesized that eReferral would achieve high absolute rates of referral across both peer navigation and usual care groups, and that peer navigation would achieve significantly higher rates of enrolment among referred patients than usual care.

METHOD

Design and procedure

A pilot randomized controlled trial entitled "Cardiac Rehabilitation PEer navigation to promote Enrolment and Referral" (CR-PEER) was undertaken to test the feasibility of a peer navigation intervention (independent variable) in increasing cardiac patients' referral to and enrolment in CR (dependent variables). This trial design was pragmatic,[29] 2 parallel-arm, randomized (1:1), allocation-concealed, and single-blind. A power calculation was deemed inappropriate as this was a pilot study.[30] The protocol was reviewed and approved by the University Health Network Research Ethics Board and also the Committee on Research Involving Human Subjects at Stony Brook University.

Upon obtaining written informed consent, clinical data were extracted from inpatient charts to confirm CR eligibility. Included participants were then randomized to either receive the peer navigation intervention (see below) or usual care (eReferral, see below). The randomization sequence was generated by a statistician unaffiliated with the study, and was stratified by sex in random blocks of four, eight, and 12. Random assignment was concealed through the use of opaque envelopes.

CR enrolment and referral were the primary and secondary outcome measures, respectively. These outcomes were ascertained by a research assistant (LJ) blinded to random assignment 12 weeks post-discharge through extraction from the CR chart.

Setting

Participants were recruited from three cardiac units (i.e., interventional cardiology, general cardiology, and cardiac surgery) in one of two hospitals of an Academic Health Sciences Centre (University Health Network) in Toronto, Canada between July and December 2014. CR is offered to patients at no charge in Ontario, as it is reimbursed by the provincial government health insurance (i.e., single-payer).

The eReferral system was instituted as part of usual care in June 2014. As shown in Figure 1, when healthcare providers (i.e., nurse-practitioners, hospitalists, cardiologists or cardiac specialists depending on the cardiac unit) are completing the electronic discharge summary for patients with a cardiac diagnosis or procedure indicated for CR, they must click 'yes' or 'no' whether they wish to refer the patient to CR. Therefore, eReferral is available on all the cardiology units. Where 'yes' is selected, the electronic discharge summary is copied into a queue which is managed by the CR staff. The CR staff then reviews the discharge summaries, and triages the patients accordingly.

As a tertiary cardiac care centre, non-local patients are frequently treated. Inpatient staff were instructed to refer all patients to the CR program within the institution, regardless of their location of residence (see text in Figure 1). This served to mitigate referral failure due to lack of inpatient staff awareness of CR program locations proximate to patients' homes. Thereafter, CR program staff reviewed the addresses of all referred patients, so that non-local patient referrals

could be re-directed to a program closer to their place of residence (where available). Upon discussion with patients, referral information was faxed to the program closer to their home.

Participants

Participants were adult cardiac inpatients eligible for CR, with one or more of the following CR-indicated diagnoses or procedures: acute coronary syndrome, percutaneous coronary intervention, coronary artery bypass graft surgery ± valve surgery, arrhythmia, stable heart failure, congenital heart disease, and/or non-disabling stroke. In addition participants had to be proficient in English. Patients were excluded if: (1) they had any major musculoskeletal, neuromuscular, visual, cognitive or non-dysphoric psychiatric condition, or any serious or terminal illness not otherwise specified which would preclude CR eligibility based on CR guidelines as outlined by the Canadian Association of Cardiovascular Prevention and Rehabilitation,[31] (2) they were being discharged to long-term care, (3) were unable to ambulate (i.e., walk unaided at 2 mph and hence undergo a pre-CR exercise stress test), and/or (4) did not reside in Ontario where CR services are reimbursed.

Intervention

The peer navigation intervention was based on the approach previously tested in the United States by Benz Scott et al.,[15,16] with modifications to accommodate the local healthcare context. As the University Health Network hospitals had an eReferral system in place as part of usual care, the primary focus of the current intervention was to increase CR enrolment.

The intervention was delivered by two female CR peer navigators, who were University Health Network CR graduates and formal volunteers at the participating hospital. The navigators completed training with University Health Network Volunteer Services, and were trained by the study team to deliver CR-focused education and support. Training included review of scripts for all points of contact with participants.

The intervention consisted of three points of contact between participants and peer navigators. First, participants were visited at the bedside by the CR peer navigator to build rapport, provide written materials about the benefits of CR, and encourage the participant to obtain a CR referral from their healthcare provider before discharge from the hospital. The

second point of contact occurred one week post-discharge, when a "get well soon" card was mailed by the CR navigator to the participant's home, including the phone number of the University Health Network CR centre. For those not referred, the card included a message encouraging the participant to secure a referral from any of their physicians. The third and final point of contact occurred two weeks after discharge; the CR navigator called the participant to discuss any barriers to CR enrolment. Each point of contact was documented on a piloted form to establish consistency and fidelity.

Measures

Participant sociodemographic and clinical characteristics were extracted from participants' medical charts. These included age, sex, admission and discharge dates, cardiovascular diagnoses/procedures, risk factors, comorbidities, previous cardiac diagnoses, and contact information. The independent variable was study arm (i.e., intervention versus usual care).

The primary outcome of enrolment was defined as participant attendance at a scheduled CR intake appointment (i.e., risk factor assessment, exercise stress testing, goal-setting; yes/no). This was ascertained through blind review of CR charts for local participants referred to the institution's CR program. For participants referred to a program closer to their home (re-referral), enrolment was ascertained via self-report through a phone call, again by a research assistant blind to random assignment.

The secondary outcome of referral (yes/no) was confirmed by reviewing the list of those received at University Health Network's program. Referral was defined as CR program receipt of documentation from a healthcare provider to refer the participant dated during or subsequent to the index participant admission, whether it was a formal referral form, eReferral or a discharge summary from the hospital stay. Where no referral was found at the local University Health Network program, participants were called to ascertain whether they had been referred to or enrolled in any other CR programs, again by a research assistant blind to random assignment. Re-referral was evident by a fax cover sheet attached to the referral form, addressed to another CR program.

Statistical analyses

First, the equivalence of participant sociodemographic and clinical characteristics by trial arm were tested using chi-square or t-tests, as appropriate. To test the first objective, CR referral was described by cardiac ward.

To test the second objective, CR referral and enrolment (yes/no) were compared by participant sociodemographic and clinical characteristics using Fisher's exact tests or t-tests, as applicable. To test the final objective, Fisher's exact tests were used to compare CR referral and enrolment by trial arm. IBM SPSS v.20 was used for all analyses.

RESULTS

Respondent characteristics

A diagram of patient flow is shown in Figure 2. One hundred and seventy-two patients were approached, of which 26 (15.1%) were ineligible, for the following reasons: 15 (8.7%) were not proficient in English, nine (5.2%) either did not live in Ontario or were leaving the province after discharge from hospital, and two (1.2%) had a medical condition which rendered them ineligible for CR. Overall, 94 patients consented and were randomized (1 patient consented but withdrew before randomization), resulting in a study enrollment rate of 54.7%. One patient withdrew consent after randomization and one patient died prior to outcome assessment, resulting in a final sample of N=92.

Table 1 displays participant sociodemographic and clinical characteristics. As shown, there were no significant differences in these characteristics by trial arm.

Table 1. Sociodemographic and clinical characteristics by trial arm.

Characteristic	Intervention n=46 (48.9%)	Usual Care n=48 (51.1%)	Total N=94
Sociodemographic			
Age (mean ±SD)	62.6 ±13.1	62.7 ±16.5	62.7 ±14.8

Female sex	14 (30.4)	15 (31.3)	30 (31.9)
Non-white	8 (17.4)	8 (17.0)	16 (17.0)
Clinical			
Cardiac Rehabilitation Indication (% yes)†			
Valve surgery	19 (41.3)	22 (45.8)	41 (43.6)
Coronary artery bypass graft surgery	19 (41.3)	16 (33.3)	35 (37.2)
Arrhythmia or rhythm device	16 (34.8)	11 (22.9)	27 (28.7)
Acute coronary syndrome	10 (21.7)	14 (29.1)	24 (25.5)
Percutaneous coronary intervention	9 (19.6)	9 (18.8)	18 (19.1)
Other (Heart failure, congenital heart disease, non-disabling stroke)	3 (6.5)	7 (14.5)	10 (10.6)
Risk factors (% yes)			
Hyperlipidemia	29 (63.0)	24 (50.0)	58 (61.7)
Hypertension	28 (60.9)	25 (52.1)	53 (56.4)
Diabetes	7 (15.2)	14 (29.1)	21 (22.3)
Smoking	4 (8.7)	10 (29.2)	14 (14.9)
Previous history of cardiac disease (% yes)	42 (91.3)	38 (79.2)	80 (85.1)
Comorbidities (% yes)			
Arthritis	7 (15.2)	4 (8.3)	11 (11.7)
Cancer	3 (6.5)	6 (12.5)	9 (9.6)

Length of stay (mean days ±SD)	9.3 ±4.6	10.8 ±9.4	10.0 ±7.4
Discharged on weekend	9 (19.6)	8 (17.0)	17 (18.1)

Abbreviations: SD, standard deviation.
† indications are not mutually exclusive (e.g., bypass surgery patients had concomitant valve repair).

As shown in Figure 2, CR referral was ascertained for 84 (91.3%) participants and enrolment for 76 (82.6%) participants. There was no referral form received at University Health Network CR for eight (16.7%) participants randomized to usual care, who could not subsequently be reached by phone to confirm they were not referred to another program. Nine (9.8%) participants could not be reached by phone to confirm enrollment.

There was no difference in whether outcomes were ascertained by randomized arm (p=0.25). With regard to sociodemographic and clinical characteristics, participants for whom outcomes were ascertained were not significantly different than participants for whom outcomes were not ascertained (data not shown).

CR referral and enrolment

Overall, 59 (77.6%) of the 76 study participants were referred (66/92 assuming no referral in those for whom outcomes were not ascertained; 71.7%), of which 45 (76.3%) were re-referred to a CR site closer to their home. Physicians were as likely to refer participants regardless of whether the CR program ultimately re-referred them to a site closer to their home or not (p=0.29).

Overall, 35 (46.1%) of the 76 participants enrolled (or 35/92 assuming no enrolment in those for whom outcomes were not ascertained, 38.0%), with 30 (66.7%) of those re-referred to a site closer to home enrolling. Of the 59 referred, 59.3% enrolled. As shown in Table 2, participants re-referred to a CR program closer to their home were significantly more likely to enroll than those who were not (p=0.04).

Table 2. Participant Characteristics by Cardiac Rehabilitation Referral and Enrolment.

	Referred (N = 92)		Enrolled (N=76)	
Characteristic	**Yes n = 66 (78.6%)**	**No n =26 (28.3%)**	**Yes n = 35 (46.0%)**	**No n = 41 (53.9%)**
Sociodemographic				
Age (mean ±SD)	63.1 ±13.8	61.0 ±17.2	61.5 ±14.0	62.9 ±16.0
Female sex	21 (31.8)	7 (26.9)	12 (34.3)	10 (24.4)
Non-white	13 (19.7)	4 (15.4)	8 (22.9)	6 (14.6)
Clinical				
Cardiac Rehabilitation Indication (% yes)				
Valve surgery	29 (43.9)	10 (38.5)	18 (51.4)	16 (39.0)
Coronary artery bypass graft surgery	29 (43.9)	6 (23.1)	14 (40)	14 (34.1)
Arrhythmia or Rhythm Device	18 (27.2)	9 (34.6)	10 (28.8)	9 (22.0)
Acute coronary syndrome	20 (30.3)	4 (15.4)	8 (22.9)	11 (26.8)
Percutaneous coronary Intervention	14 (21.2)	4 (15.4)	7 (20.0)	8 (19.5)

Heart failure	2 (3.0)	5 (19.2)*	2 (5.7)	3 (7.3)
Risk factors (% yes)				
Hypertension	40 (60.6)	12 (46.2)	21 (60)	22 (53.7)
Hyperlipidemia	41 (62.1)	11 (42.3)	21 (60.0)	25 (61.0)
Smoking (% current)	12 (18.2)	2 (7.7)	5 (14.3)	6 (14.6)
Diabetes	17 (25.8)	4 (15.4)	7 (20.0)	11 (26.8)
Previous history of cardiac disease (% yes)	56 (84.8)	23 (88.5)	30 (85.7)	36 (87.8)
Comorbidities				
Arthritis	9 (13.6)	2 (7.7)	5 (14.3)	4 (9.8)
Cancer	3 (4.5)	5 (19.2)*	2 (5.7)	5 (12.2)
Length of stay (mean days ±SD)	9.2 ±4.7	11.3 ±10.9**	9.4 ±4.4	8.2 ±4.8
Discharged on weekend	12 (18.2)	6 (23.1)	9 (25.7)	6 (14.6)
Referred to site closer to home	-	-	30 (85.7)*	15 (36.6)

*p<.05, **p<.01; Abbreviations: SD, standard deviation.

With regard to objective 1, there were significant differences in CR referral depending on the cardiology unit from which a participant was discharged (p=0.04). Participants who received

inpatient care on the cardiac surgery unit (77.9%) were more likely to be referred than those treated on the general cardiology (61.1%) or the interventional cardiology unit (33.3%).

With regard to the second objective, sociodemographic and clinical characteristics associated with CR referral are shown in Table 2. As displayed, there were no differences in the sociodemographic characteristics of those referred versus not, but differences were observed based on clinical characteristics. With regard to cardiac indication for CR, participants with heart failure were less often referred (p=0.02). With regard to comorbidities, participants with cancer were significantly less likely to be referred than those without (p<0.05). Finally, those who were referred to CR had a shorter length of stay in the hospital than those not (p<0.01).

Sociodemographic and clinical characteristics associated with CR enrolment are also shown in Table 2. As displayed, there were no significant differences in these characteristics among those who enrolled versus not.

Effects of peer navigation on CR utilization

Intervention fidelity. Of the 46 participants randomized to the navigation intervention, 38 (82.6%) received all 3 contacts. One (2.2%) participant did not receive the bedside visit and 7 (15.2%) participants did not receive the post-discharge phone call. In addition, four (8.7%) participants did not receive their initial bedside contact prior to hospital discharge, but instead the content was delivered via a telephone call to the participant at their home within three days of discharge.

Among the sample for whom outcomes were ascertained (n=76), CR referral did not significantly differ between the navigated group (n=31, 79.5%) and usual care (n=28, 75.7%; p=0.45). Enrolment also did not significantly differ between groups (n=20, 51.3% in the peer navigation arm; n=15, 40.5% for usual care, p=0.27).

If we assume no referral or enrolment among those for whom there was no referral form at University Health Network yet they could not be reached by phone (n=92), referral still did not significantly differ between the navigated group (n=37, 80.4%) and usual care (n=29, 63.0%; p=0.05). Enrolment also did not significantly differ between groups in this larger sample (n=20, 51.3% in the peer navigation arm; n=15, 40.5% for usual care, p =0.24).

DISSCUSSION

There is wide variability in CR referral practices even within academic institutions by cardiac wards, which could be due to cultural norms, healthcare provider practice variation, or the severity of illness (e.g., surgical patients vs. non-invasive procedures). Despite institution of an eReferral strategy across the academic institution, patients on the surgery unit were more likely to be referred than those on other units, and this finding is consistent with previous studies.[32,33] Indeed, there was a 40% difference in the proportion of patients referred by unit in the same institution. The eReferral strategy did however appear to mitigate sociodemographic biases oft-observed in CR referral,[5] and patient referral was consistent on weekends as well as weekdays. Moreover, this is one of the first studies to our knowledge to document higher rates of CR enrolment where patients are triaged to CR sites closer to their home.

Prior studies have demonstrated that systematic referral strategies can decrease referral bias.[13] Although a larger sample than reported here is required to be conclusive, there did not appear to be age, sex or ethnocultural biases in referral or enrolment patterns. This is a positive sign and suggests that eReferral has potential to mitigate bias in physician decisions related to these non-clinical characteristics.

There were differences in the clinical characteristics of patients referred however. Patients with heart failure were less likely to be referred than those without, although this finding should be interpreted with caution due to the low number of participants with this indication in the sample. This is disconcerting given the established benefits of CR for heart failure patients,[34] and that Canadian CR guidelines promote heart failure as an indication for CR.[31] Moreover, heart failure is now a reimbursed indication for CR in the United States,[35,36] and in Ontario where this study was undertaken, there are recommendations for CR referral for heart failure patients.[37] Greater awareness of the evidence of benefit and these policy changes may be needed before we see changes in referral practice.

Second, patients with comorbid cancer were less often referred than those without. This may be appropriate, depending on the stage of cancer and therapy. Finally, patients who had a shorter length of inpatient hospital stay were more likely to be referred than those with a longer

stay. This is somewhat surprising given that patients on the bypass unit, which traditionally has longer lengths of stay were more often referred than angioplasty patients, who have a shorter stay. Patients with a longer length of stay may have complications, more comorbidities, or more severe or complex disease, which would preclude participation in CR.

Due to the high rate of inpatient referral observed at over three-quarters of patients, the addition of peer navigation did not have a significant impact on patient enrolment as hypothesized, although firm conclusions cannot be drawn as this was a pilot study. A larger sample may be needed to observe differences in enrolment by peer navigation exposure, particularly in the context of eReferral. Thus, the first hypotheses in this pilot was confirmed, but the second was disconfirmed. Potential explanations for the lack of replication of findings from the peer navigation trial by Benz Scott et al.[15] include the eReferral strategy implemented at the institution as outlined previously. In the trial in the United States, there was no referral strategy in the usual care arm. In the intervention arm, the peer navigators facilitated contact between the patient and the CR centre. Based on the results of this pilot, the decision has been made not to proceed to a full-scale trial.

Implications

There are three key policy implications of these findings. First, re-referring patients to programs closer to home should be a 'best practice' for cardiac care, as it may improve patient enrolment rates. There may be financial disincentive to re-refer where CR programs are reimbursed based on patient volumes. However, there are so many patients who do not access CR, that programs should always have sufficient patients to ensure financial soundness. Second, system-wide CR referral strategies, such as eReferral, should be broadly instituted as a means of ensuring high CR referral rates.

On a related note, third and finally, given the variation in CR referral between wards despite eReferral, education of healthcare providers will still be required to ensure consistent CR referral practices. There is a need to provide repeated education / in-services to cardiac healthcare providers, feedback on the proportion of patients referred in relation to targets, and reminders about the benefits of CR participation for patients and recommendations to refer

patients in clinical practice guidelines, particularly on interventional cardiology units. If the high rates of CR referral observed on cardiac surgery units could be replicated across all cardiac units, we would be much closer to achieving the 85% target.[12]

Strengths and Limitations

The current study is one of the few to investigate both intra-institutional variability in CR referral practices by ward, and the effects of referral triage to the CR program closest-to-home on subsequent patient enrolment. Therefore, a strength of this research is its' novel contribution to the literature. A second strength is the use of a randomized controlled design, as well as allocation concealment, with blinded outcome assessment.

Nonetheless, caution is warranted in interpreting these results. First, a comparison group exposed to traditional CR referral approaches was not included in the design, therefore it is unknown whether the CR referral and enrolment rates observed herein are truly higher than what would be observed without eReferral. Second, the relatively low response rate (54.7%) suggests there may be some selection bias. Third, the primary outcomes were ascertained via self-report for those re-referred closer to home but via chart report for those who attended the within-institution CR program. This may have biased findings. Fourth, the study was conducted at a single institution (albeit with 2 hospitals), which while appropriate for a pilot study, limits generalizability of findings. Finally, generalizability is limited to academic cardiac centres in jurisdictions where CR is available at no charge to patients.

In conclusion, CR referral across cardiac units in the same institution vary by 40% despite an eReferral strategy, with the rates highest observed on the cardiac surgery unit. Patients with heart failure, comorbid cancer and longer lengths of inpatient stay were less often referred than those without. With regard to enrolment, those who had their referral redirected to a site located closer to their home were more likely to enrol. Finally, likely due to the eReferral system implemented institution-wide, the peer navigation intervention did not impact CR referral or enrolment.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

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Author Contributions

Sobia F Ali-Faisal made substantial contributions to the acquisition and analysis of the data, drafting the work

Lisa Benz Scott made substantial contributions to the conception and design of the work, revised the manuscript critically for important intellectual content, and gave final approval of the manuscript

Lauren Johnston acquired the outcome data, revised the manuscript critically for important intellectual content, and gave final approval of the manuscript

Sherry L Grace made substantial contributions to the design of the work and interpretation of the data, drafted and gave final approval of the manuscript

Data Sharing Statement

No additional data available.

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Figure 1. eReferral Screenshot from Electronic Discharge Summary

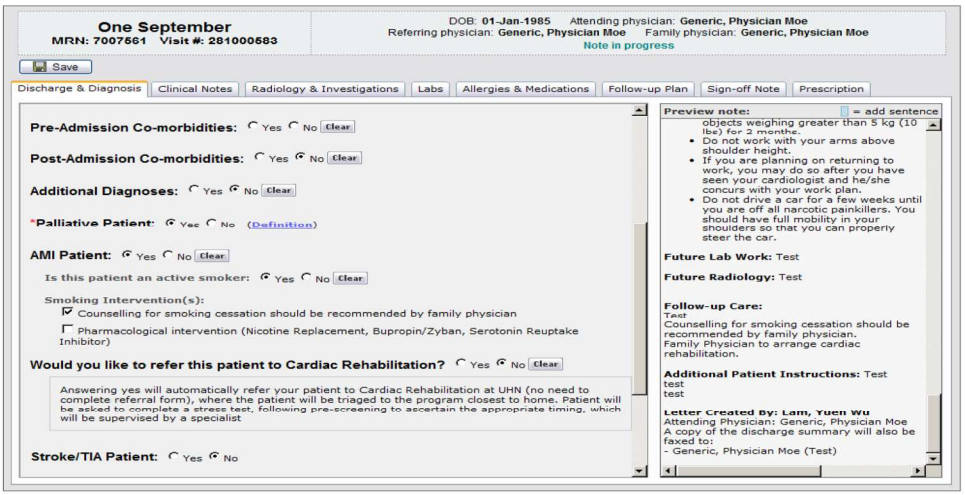

Figure 1. eReferral Screenshot from Electronic Discharge Summary
172x95mm (300 x 300 DPI)

Figure 2: Participant Recruitment Flow Diagram

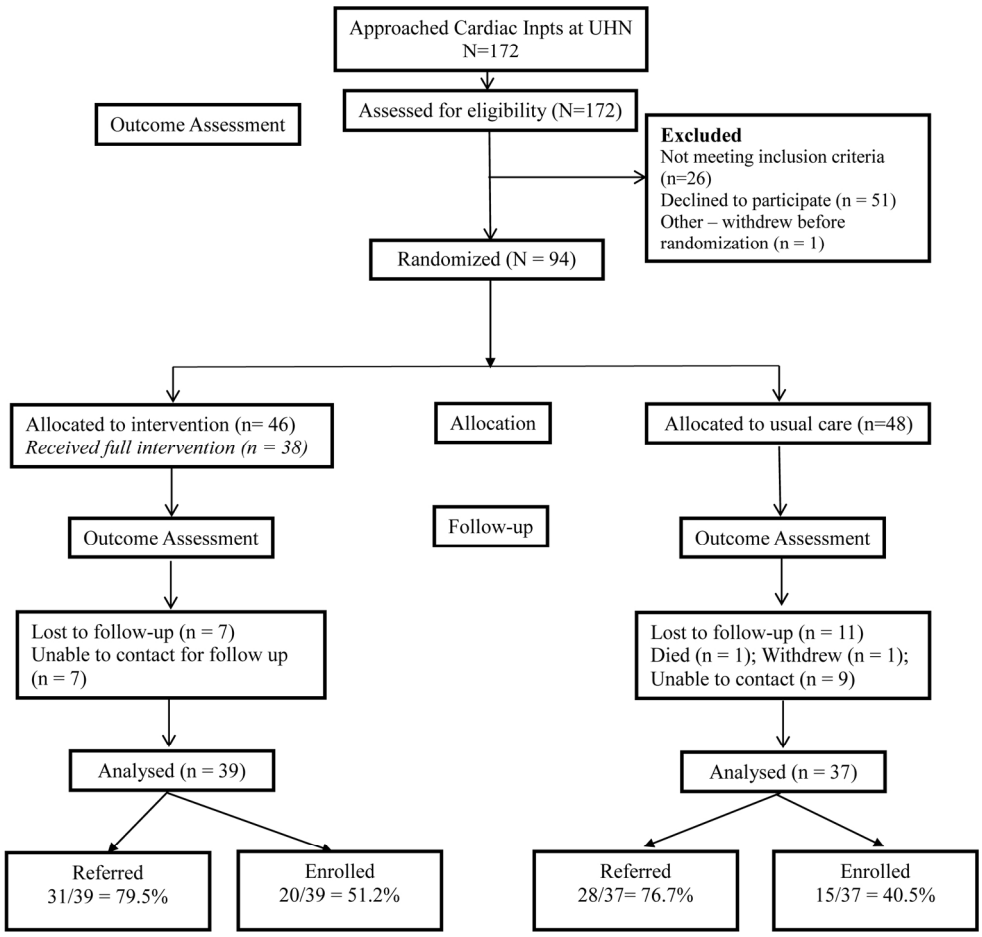

Figure 2: Participant Recruitment Flow Diagram
173x173mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	
	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	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
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	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7
	13b	For each group, losses and exclusions after randomisation, together with reasons	7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5-6
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8-9
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	12-13
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12-13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full 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	17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 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.