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Original Article

A Randomized Trial of Video-based Education in Patients With Heart Failure: The Congestive Heart Failure Outreach Program of Education (COPE)

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ABSTRACT

Background: Heart failure (HF) exacerbations often relate to poor self-care. Education programs improve outcomes, but are resource-intensive. We developed a video-based educational intervention and evaluated it in patients with HF.

Methods: Congestive Heart Failure Outreach Program of Education was a pragmatic multicenter randomized trial. We included subjects with HF if they were hospitalized, seen in the emergency department (ED), or high-risk outpatients, and randomized them to intervention or control. Intervention included a 20-minute video, supplementary booklet, and 3 bimonthly newsletters focusing on salt and fluid

RÉSUMÉ

Introduction : L'exacerbation de l'insuffisance cardiaque (IC) est souvent liée à une mauvaise prise en charge autonome des soins. Les programmes d'enseignement améliorent les résultats cliniques, mais exigent beaucoup de ressources. Nous avons conçu une intervention éducative par vidéo et l'avons évaluée auprès de patients atteints d'IC.

Méthodes : Le Congestive Heart Failure Outreach Program of Education était une étude pragmatique multicentrique à répartition aléatoire. Nous avons sélectionné les sujets atteints d'IC s'ils étaient hospitalisés, vus au service des urgences (SU) ou patients en consultation externe exposés à un risque élevé, et les avons répartis de

Heart failure (HF) is a common complication of cardiovascular disease and one of the most common causes of cardiovascular hospital admissions.[1] For example, in Canada, HF was associated with approximately 106,000 hospitalizations involving more than 85,000 patients and 1.4 million hospital days in fiscal year 2000[2] and approximately 1 million hospitalizations per year in the United States.[3] Notably, approximately one-third of hospitalizations were readmissions, with an in-hospital mortality of approximately 16%.[2] The cost of hospital admissions for HF in Canada has been estimated to be CAD$482 million in 2013[4] and USD$31 billion (overall direct and indirect costs) in the United States.[5] As such, interventions to reduce the burden of HF related hospitalizations are clearly needed.

A number of precipitants of HF exacerbations have been described.[6-10] Of these, excessive sodium and fluid intake and poor medication adherence appear to be the most frequent causes of worsening of HF symptoms. As such, many of the

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Ethics Statement: The study protocol was registered (NCT00371085) a priori, and all participating centers received local research ethics approval.

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restriction, daily weights, and medications. Subjects watched the video and were encouraged to review it at home, along with the booklet/newsletters. Control subjects received the booklet only. The primary outcome was the difference in cardiovascular hospitalizations or ED visits between groups at 6 months. Secondary outcomes included clinical events and in-hospital days.

Results: We recruited 539 subjects from 22 centers in Canada and the United States. Baseline characteristics were similar in both groups: 64% were male and had a mean age of 66 (± 13) years, mean ejection fraction 31% (± 13.5), and 65% New York Heart Association Functional Classification III/IV. The primary outcome occurred in 57 subjects (21%) in the intervention group compared with 61 subjects (23%) in the control group ($P = 0.66$). There were no significant differences in prespecified secondary outcomes; however, death occurred in 18 subjects (7%) in the intervention group and 33 subjects (12%) in the control group ($P = 0.03$).

Conclusion: Video education on self-care did not reduce hospitalizations or ED visits in patients with HF. Of note, mortality was lower in the intervention group.

manière aléatoire au groupe d'intervention ou au groupe témoin. L'intervention a consisté en une vidéo de 20 minutes, un livret supplémentaire et 3 bulletins bimensuels portant sur la restriction du sel et des liquides, les mesures quotidiennes du poids et les médicaments. Après que les sujets eurent regardé la vidéo, nous les avons encouragés à la revoir à la maison, en plus de lire le livret et les bulletins. Les sujets témoins ont reçu seulement le livret. Le critère de jugement principal était la différence dans les hospitalisations en raison d'une maladie cardiovasculaire ou les visites au SU entre les groupes après 6 mois. Les critères de jugement secondaires étaient les événements cliniques et les jours d'hospitalisation.

Résultats : Nous avons recruté 539 sujets de 22 centres au Canada et aux États-Unis. Les caractéristiques initiales étaient similaires dans les 2 groupes : 64 % étaient des hommes et avaient un âge moyen de 66 ans (± 13), une fraction d'éjection moyenne de 31 % (± 13,5), et 65 % avaient une classification fonctionnelle III/IV de la New York Heart Association. Le critère de jugement principal est survenu chez 57 sujets (21 %) dans le groupe d'intervention et chez 61 sujets (23 %) dans le groupe témoin ($P = 0,66$). Il n'y a eu aucune différence significative dans les critères secondaires prédéfinis. Toutefois, 18 sujets (7 %) du groupe d'intervention et 33 sujets (12 %) du groupe témoin sont morts ($P = 0,03$).

Conclusion : L'enseignement sur les autosoins par vidéo n'a pas réduit les hospitalisations ou les visites au SU des patients atteints d'IC. Notamment, la mortalité a été plus faible dans le groupe d'intervention.

precipitants of HF may be thought of as failure of self-care by the patient. Because of this, numerous studies have attempted to address knowledge gaps in patients with HF, comprehensively reviewed by Jonkman et al.[11] As an example, our group conducted the REACT Study, a 2-stage multicentre trial in 768 patients who were hospitalized for HF.[12] During the first stage of this study, a nurse or pharmacist assessed consecutive patients with HF for angiotensin-converting enzyme (ACE) inhibitor illegibility/dosage titration while in the hospital. The intervention increased ACE inhibitor use from 58% at baseline to 83% at discharge ($P < 0.001$). Before discharge, 278 patients were randomized to a patient support program or usual care. The patient support program consisted of education on HF and medications, self-monitoring, adherence counseling, monthly newsletters, and ongoing support. Patients were contacted by telephone at 2 and 4 weeks and monthly thereafter to reinforce educational issues concerning HF and medications and to assess study end points. Usual care patients received only a pamphlet on heart disease without formal counseling. A total of 276 patients were enrolled in this stage of the study and followed for 6 months. Patients randomized to the patient support program showed a reduction in cardiovascular-related emergency department (ED) visits and hospital days as well as cost of care, compared with usual care.[12] Although educational and support programs such those examined in the REACT study appear to improve HF outcomes, they are generally labor-intensive (and therefore, expensive) to provide. Therefore, we wondered if the essence of self-care could be distilled into a video-based educational program that would be more practical to administer to patients (ie, take less staff time). As such, the objective of the **C**ongestive Heart Failure **O**utreach **P**rogram of **E**ducation (COPE) study was to determine the effect of a video-based educational intervention for patients with HF on clinical outcomes.

Methods

COPE was a pragmatic, randomized controlled trial conducted in 22 centers in Canada and the United States. These centers included both academic and community hospitals, and were selected on the basis of their expressed interest in patient self-care interventions or professional networks of the investigators. None of the centers had formal HF self-care programs for their patients at the time of the study. The study protocol was registered (NCT00371085) a priori, and all participating centers received local research ethics approval.

We included patients with symptomatic HF $\geq$ 18 years of age and admitted to the hospital, presenting to the ED, or seen in an outpatient clinic (the latter must have had a HF hospitalization within the previous 6 months). We excluded patients who already required professional assistance for self-care, were unable to communicate, were cognitively impaired, had serious mental illness, or were on chronic dialysis. Patients were recruited from hospital wards, EDs, or outpatient clinics.

The intervention was based on an educational video produced by our research group. The content of the video was based on our previous surveys and focus groups with patients with HF,[13] as well as our previous research experience in developing educational materials for patients with HF.[13,14] We also called on the expertise of experienced HF educators who work in HF clinics to distill the most important elements of HF education into the video. The focus of the video was on

Table 1. Baseline characteristics of the study population

Characteristic	Intervention (n = 270)	Usual care (n = 269)
Age, y (mean ± SD)	65 (13)	67 (13)
Male, n (%)	168 (62)	175 (65)
Education, n (%)		
Grade school	52 (19)	68 (25)
High school	92 (34)	99 (37)
Postsecondary	124 (46)	101 (38)
Resides at home with support, n (%)	94 (35)	101 (38)
Duration of HF, n (%)		
New onset	105 (39)	99 (37)
≤ 12 mo	68 (25)	78 (29)
13-48 mo	16 (6)	28 (10)
> 48 mo	79 (29)	64 (24)
Medical history, n (%)		
Hypertension	185 (69)	176 (65)
Dyslipidemia	155 (57)	165 (61)
Diabetes mellitus	112 (42)	95 (35)
Myocardial infarction	110 (41)	122 (45)
Atrial fibrillation	107 (40)	104 (39)
Angina	74 (27)	95 (35)
Medications, n (%)		
ACE inhibitor	180 (67)	183 (68)
Angiotensin receptor blocker	41 (15)	34 (13)
β-Blocker	206 (76)	205 (76)
Spironolactone	81 (30)	72 (27)
Digoxin	76 (28)	63 (23)
Furosemide	199 (74)	206 (77)
Health resource use, n (%)		
At least 1 cardiovascular hospitalization or ED visit in the previous year	90 (33%)	89 (33%)
CHF knowledge		
PaKSAC knowledge survey score (mean ± SD)	28 (7.2)	28 (6.7)

ACE, angiotensin-converting enzyme; CHF, congestive heart failure; ED, emergency department; HF, heart failure; SD, standard deviation.

No comparisons reached $P < 0.05$.

3 simple self-care messages that were repeated often: avoiding salt, recording of daily weights and symptoms, and adhering to medications (all of which relate to acute precipitants of HF). Of note, the messages were all delivered from real patients with HF from our clinic. Our previous experience with HF educational videos was that mostly they consisted of a clinician "talking head" espousing a long list of things that patients with HF should not do. We thought patients would relate better to education from their peers. The video was edited to extract messages from these real patients on how they coped with their HF, focusing on these 3 important messages. The 20-minute video is available at www.epicore.ualberta.ca/cope.

Once patients provided written informed consent, they underwent our previously used "PaKSAC" knowledge survey to measure baseline knowledge about HF and HF-related self-care activities[15] (Supplemental Appendix S1). Patients were then randomly assigned to the intervention (educational video) or control (usual care) study groups via a secure internet randomization service (to ensure allocation concealment) at the EPICORE Centre. The sequence for randomization was generated by a computer using variable block design and stratified by study site.

Intervention: Patients randomized to the intervention group met with a research coordinator (pharmacist or nurse) and watched a 20-minute educational video on a portable DVD player during their hospital or clinic stay. They were also given a copy of the video to take home and were encouraged to review the video often. They also received an educational booklet, which outlined the same educational messages as in the video (and used the same graphic design). This is available at www.epicore.ualberta.ca/cope. Patients were provided a diary to facilitate the tracking of relevant study end points (eg, ED visits and hospitalizations) after their enrollment. Finally, a reminder card and 3 newsletters were mailed to their home at 2 weeks and then at 1, 3, and 5 months after study enrollment, respectively. The newsletters reinforced the 3 key messages from the video, reminded patients to complete the diary, to watch the video again, gave some lifestyle tips such as low sodium recipes, and encouraged patients to discuss their condition with their physician (these are available at www.epicore.ualberta.ca/cope). The fidelity of the study intervention was assessed and summarized according to the domains suggested by Borelli et al[16] in Supplemental Appendix S2. In addition, we monitored a random sample of patients at all participating sites.

Control: Patients randomized to the control group received usual care, which included the education that is typically provided for patients with HF when they present to that particular institution. They were also given the identical educational booklet as the intervention group; however, the research coordinator did not review it with the patient. In the control group, patients were also encouraged to have a dialogue with their physician regarding their HF.

Baseline data were collected through patient survey and medical chart review methods by the research coordinator using standardized data-collection forms. Baseline data included information on sociodemographics, clinical history (including current medication), and New York Heart Association Functional Classification (NYHA-FC) at the time of enrollment. The research coordinator contacted patients 6 months after enrollment (via telephone) for assessment of outcomes. When necessary, patients' medical records were also reviewed. The HF knowledge survey was again used to evaluate knowledge on HF and HF-related self-care activities (Supplemental Appendix S1); health-related outcomes included ED visits or hospitalizations for cardiovascular (including HF) or noncardiovascular conditions.

The primary outcome measure was difference in cardiovascular hospitalizations or cardiovascular ED visits between the intervention and control groups. Secondary outcomes included the differences between the intervention group and the control group in all-cause hospitalizations, HF hospitalizations, number of days in hospital, and change in HF knowledge (6 month vs baseline scores). A panel of clinicians (EEL and MCS), who were blinded to the intervention allocation, adjudicated all the clinical events following predefined conventions and standardized forms.

The statistical analyses followed the intention-to-treat principle; including all patients in the groups to which they were randomized regardless of whether they received the intervention or were lost to follow-up. Categorical variables were summarized using proportions and compared using chi-square tests; continuous variables were summarized using means (with ± standard deviations or medians (with interquartile ranges) and compared using independent t tests or Mann−Whitney U tests, as appropriate. The change in the

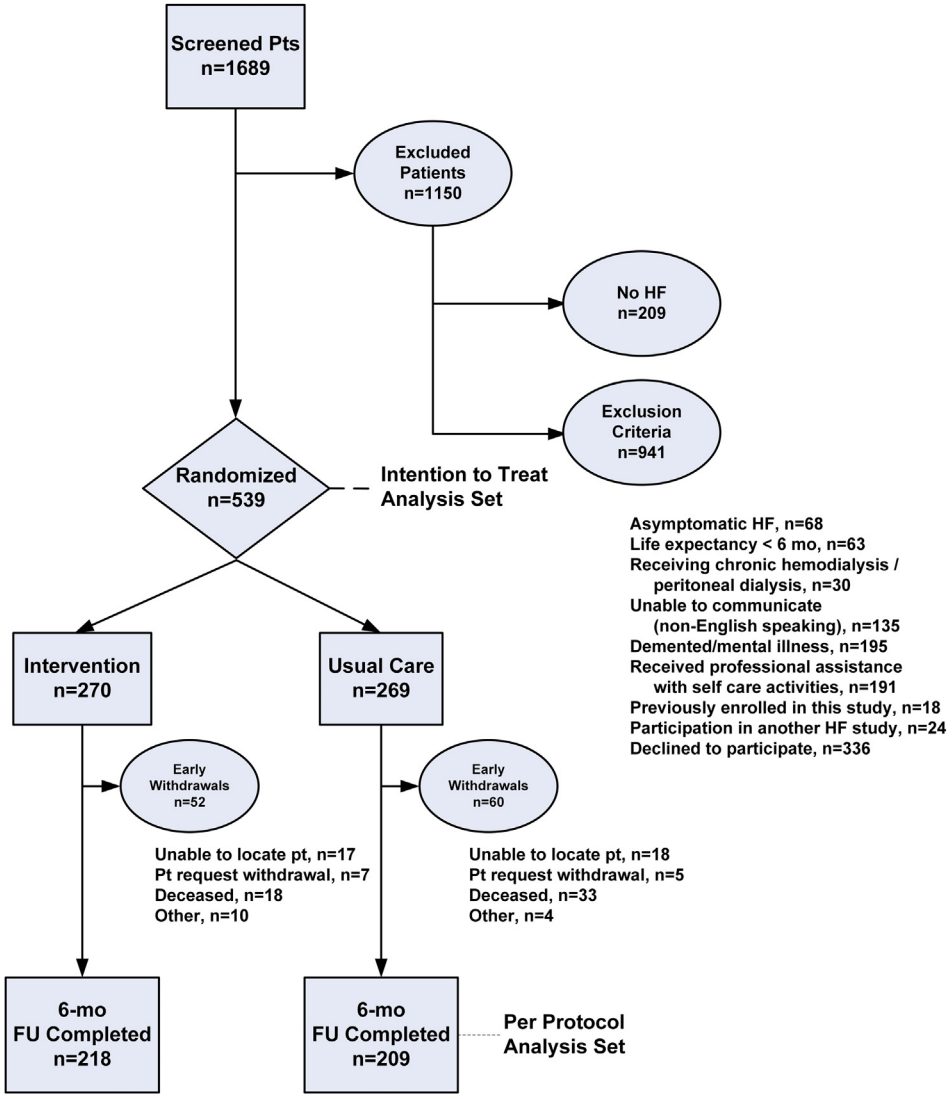

Figure 1. Trial flow. FU, follow-up; HF, heart failure.

HF knowledge scores was evaluated using a random-effects model.

Results

Baseline characteristics of the subjects enrolled are shown in Table 1. Subjects were enrolled from mid 2004 to 2010 in 22 clinical centers in Canada and the United States. A total of 1689 patients were screened, 1150 of whom were excluded for various reasons (Fig. 1), resulting in a total of 539 patients being randomized and analyzed, 270 to intervention and 269 to control groups. Most of the participants were recruited from inpatient units, and the recruitment among the study sites (ED = 28.2%, inpatient units = 58.4% and outpatient clinics = 13.4%) did not differ. There were 52 early withdrawals in the intervention group (19%), which included 18 deaths, and there were 60 early withdrawals in the control group (22%), including 33 deaths. Details on the fidelity of the study intervention according to the domains suggested by Borrelli et al[16] are shown in Supplemental Appendix S2.

Characteristics of study subjects are shown in Table 1. The average age of patients in the study was 66 (±13) years, 63% were male, and 36% resided at home with support. Forty-two percent had postsecondary education. Onset of HF was new in 38% of patients, with 27% having a duration of HF of greater than 4 years. A history of patients enrolled is fairly typical of patients with HF, with a high prevalence of hypertension, dyslipidemia, diabetes, myocardial infarction, and atrial fibrillation. Most patients were in NYHA-FC III (38% in the intervention group and 45% in the control group). Baseline medications are also shown in Table 1, with most patients receiving an ACE inhibitor/angiotensin receptor blocker and β-blocker. Approximately one-third of patients were receiving spironolactone and approximately one-quarter were receiving digoxin.

For the primary outcome of cardiovascular hospitalization or cardiovascular ED visit, there was no difference between the intervention group (21%) and the control group (23%, $P = 0.66$) (Table 2). Likewise, there was no statistical difference in terms of all-cause hospitalizations, HF hospitalizations,

Table 2. Study outcomes 6 months after enrollment

Outcome	Intervention (n = 270) N (%)	Usual care (n = 269) N (%)	*P* value
CV hospitalization or CV ED visit*	57 (21)	61 (23)	0.66†
CV hospitalization*	34 (13)	39 (15)	0.52†
CV ED visit*	34 (13)	33 (12)	0.91†
All-cause hospitalization*	48 (18)	55 (21)	0.43
HF hospitalization*	22 (8)	22 (8)	0.99
All-cause hospital days, median [IQR]	12 [4, 25]	10.5 [4.5, 20]	0.80‡
CV hospital days, median [IQR]	15 [7, 26]	9.5 [4.5, 16.5]	0.15‡
Any hospitalization or death	68 (25)	86 (32)	0.08†
CV hospitalization or death*	53 (20)	71 (26)	0.06†
HF hospitalization or death*	40 (15)	54 (20)	0.11†
Death*	18 (7)	33 (12)	0.03†
PaKSAC knowledge survey score, (mean ± SD)	35 (6.0)	23 (6.5)	< 0.01

CV, cardiovascular; ED, emergency department; ED, HF, heart failure; IQR, interquartile range; SD, standard deviation.

* Externally adjudicated.

† Pearson Chi Square test.

‡ Mann Whitney Test.

all-cause hospital days, or cardiovascular hospital days. Other standard HF trial outcomes were not different between groups in terms of end points of any hospitalization or death, cardiovascular hospitalization or death, or HF hospitalization or death. However, there was a statistically significant reduction in mortality between the intervention (18 deaths, 7%) vs control (33 deaths, 12%; $P = 0.03$).

Six months after study enrollment, most patients were in NYHA-FC II (45% in the intervention group and 39% in the control group); patients' medication profile (based on self-report) was similar. There was a statistically significant average increase in the PaKSAC HF knowledge score assessed at 6 months compared with the baseline measures in the intervention group vs the control group (6.7 ± 0.5 vs 5.2 ± 0.5; $P = 0.024$).

Discussion

Patient self-care is a cornerstone of the management of HF: The practical question is how to deliver it efficiently. In our study of high-risk patients with HF, a multifaceted video-based educational intervention focusing on 3 simple self-care messages did improve HF knowledge, but did not reduce hospitalizations or ED visits compared with usual care. We did observe a statistically significant and clinically meaningful reduction in mortality in favour of the intervention. Although we recommend educating patients with HF, further work is needed to determine the ideal delivery method for this intervention.

Jonkman and the TASTE Investigators[11] systematically reviewed the literature and performed an individual patient meta-analysis of patient self-care interventions. In this comprehensive review of 20 studies and 5624 patients, self-management interventions significantly reduced the risk of HF hospitalization or all-cause death by 20% and HF hospitalization by 20%, and improved quality of life. In a separate analysis by the same group, no particular component of successful interventions was identified other than duration of the intervention.[17] This likely highlights the variability of patient needs and the complexity of behavioural change.

Although this was a randomized controlled trial conducted in multiple centers and with a well-structured, reproducible intervention delivered with high fidelity, a number of limitations do arise. First, we had lower than anticipated event rates of approximately 22% (we had assumed an event rate of 50%, resulting in lower statistical power). This may be due to patient selection issues, contamination, or other factors. We also noted that at 6 months, approximately half of the patients in both groups were attending a specialized HF clinic, which would be expected to reduce event rates as well (perhaps we activated patients to seek out a HF clinic). There may have been significant contamination of the control group, because we did provide the same written educational materials to the control group (this was a requirement from our research ethics committees). The ability to assimilate educational information may have varied among the study participants; however, we did not anticipate substantial differential effect in the intervention exposure because most were recruited from inpatient units. There were also losses to follow-up of approximately 20%; however, this was even between the groups and included patients who were deceased, which is to be expected in an HF trial. Finally, there may be some volunteer bias in this study whereby patients who are most interested in their disease will consent to participate and those who are not at all interested in their condition, but those needing the intervention the most might not consent to participate. This is common for studies of this type and is difficult to avoid.

It may also be that "dose" of our intervention was too low. Perhaps more in-depth education is necessary than we provided by video and the reminder newsletters. Nevertheless, the level of education we provided was consistent with that recommended by most major HF societies and guidelines. It is also possible that a video-based education is not the ideal delivery method to affect our health care use; simply providing knowledge does not necessarily lead to behaviour changes.[18] It is also possible that differential effects of certain factors not explored in depth in this study, such as limited health care access (eg, no linkage with a primary care provider, deficient ambulatory care), could have prompted acute care visits and influenced mortality. As such, we would recommend further study on the paradigm of knowledge and behavior change including a more detailed exploration of the postacute care context. Of note, since the COPE intervention was developed, theoretical frameworks and a taxonomy for behavioural change interventions have been developed that could help to develop better interventions.[18,19]

Most, if not all, HF guidelines recommend patient education on self-management. Although a number of trials have now suggested that more intensive educational interventions do not reduce clinical events,[20] the same educational messages delivered through HF clinics do improve clinical outcomes.[21,22] Perhaps it is the one-on-one interaction between the patient and the clinician in an outpatient clinic setting (and follow-up visits) that ultimately takes the educational messages toward actual behavioural change, and perhaps this cannot be simply reproduced by a video and follow-up phone calls. This area requires further study.

An interesting and clinically relevant observation was that mortality was significantly reduced in our intervention group. Although this was unexpected, it is not completely incongruous with other studies providing patient education and support, such as COACH (a patient education and support program delivered by nurses in a protocolized fashion,[20] and EFFECT (hospitals received report cards on aspects of HF care, including provision of patient education[23]), both of which showed trends toward reductions in mortality. Why mortality would be reduced when other HF-related clinical events are not remains an area for further investigation.

Conclusions

A video-based educational intervention aimed at high-risk patients with HF did not improve nonmortality clinical outcomes compared with usual care. Mortality was lower in patients who received the intervention; however, the numbers were small.

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Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2018.12.001.