

A randomized controlled trial of women's early use of a novel undergarment following sternotomy: The Women's Recovery from Sternotomy Trial (WREST)

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Background Despite a lack of randomized trial evidence, clinicians often suggest that women use a brassiere to reduce poststernotomy pain and discomfort. We tested the effect of women's use of a special (compression) undergarment after sternotomy on pain, discomfort, and functional status.

Methods Women (n = 481) having first-time sternotomy in 1 of 10 Canadian centers were randomized to receive the intervention or usual care. Pain and discomfort data (using numeric rating scales) were collected in person while participants were hospitalized. Thereafter, pain, discomfort, and functional status data (using Health Assessment Questionnaire) were collected by standardized telephone interview until 12 postoperative weeks.

Results Overall, and until at least 6 weeks postoperatively, fewer women in the intervention than usual care group reported having incision and breast pain and discomfort. Breast pain scores were lower in the intervention than the usual care group at 2 weeks postoperatively ($P = .04$), and over time (OR 0.65 [95% CI 0.45-0.94], $P = .02$). For women discharged within 14 postoperative days, post hoc analyses revealed intervention group patients had a significantly reduced likelihood of breast pain (OR 0.46 [95% CI 0.32-0.66], $P < .001$) and breast discomfort (OR 0.62 [95% CI 0.44-0.86], $P = .01$) but not incision pain (OR 0.99 [95% CI 0.72-1.37], $P = .95$) or discomfort (OR 0.77 [95% CI 0.55-1.02], $P = .06$). There was no difference between groups in functional status. The effects were not influenced by age or brassiere size.

Conclusions Using a supportive undergarment during the early postoperative reduces breast pain. This finding is amplified and extends to include a reduction in breast discomfort, when women are discharged within 14 postoperative days. (Am Heart J 2006;152:1187-93.)

Approximately one third of cardiac surgeries are performed on women.^{1,2} Cardiac surgery patients experience moderate to severe pain postoperatively to which sternotomy pain is a major contributor.³⁻⁸ Compared to men, women describe more poststernotomy incision and breast sensations and discomforts (eg, aching, shooting and sharp pain to breasts, breast tingling, and numbness), as well as slower sternal

wound healing.⁸⁻¹⁶ Qualitatively, women associate much of their incision discomfort with uncomfortable sensations in their breasts and suggest the need for appropriate breast and sternal incision support.^{9,10,14,15}

We described previously¹⁷ that splinting or supporting the sternal wound may decrease pain and discomfort associated with movement.⁴ We hypothesized that a well-supporting undergarment may provide such a splinting function for women. Although women are typically advised to bring a comfortable brassiere to hospital, wearing one early in recovery after sternotomy can interfere with chest tube, central line, and electrocardiographic lead placements; disrupt x-ray imaging; may be uncomfortable because of poor fit (due to breast swelling or weight loss); and result in irritation to the incision.^{7,9,15} Finally, the activity of fastening a brassiere or donning a one-piece "sport bra" is virtually impossible at this time.^{10,13} Current thinking suggests that women's pain, discomfort, and possibly, wound complications are reduced with the use of a supportive undergarment post sternotomy.^{9,11,13,14,18-20} However, randomized trial evidence is lacking to support this recommendation.

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The primary purpose of this study was to determine the effect of early use of a special (compression) undergarment on pain, discomfort, and functional status in women poststernotomy over 12 weeks postoperatively. A secondary purpose of this study was to monitor the safety (including wound healing) of the undergarment during the early poststernotomy recovery period.

Methods

Participants and study design

As previously described,¹⁷ English-speaking women, 18 years and older, who were having first-time cardiac surgery through median sternotomy between March 2003 and December 2004 at 1 of 10 Canadian centers (see Appendix A) were approached to participate in this study. Exclusion criteria included having a brassiere size >52 in (study undergarment was then unavailable), previous breast surgery, mastectomy or radiotherapy to the chest, or a cognitive/mental disability that would hinder response to study questions.

Upon scheduling for surgery or hospital admission, demographic data were collected and all eligible women were measured for brassiere size by specially trained research assistants. Study participants were then randomized to either early use of a compression undergarment (intervention) or usual care through a secure internet site at the Epidemiology Coordinating and Research Centre, Division of Cardiology, University of Alberta. The randomization sequence was computer-generated, blocked (with variable block size), and stratified by brassiere cup size (A/B and C/D+) and study site.

Participants randomized to the intervention group were given 2 undergarments (see Figure 1).^c The undergarment was donned as soon as these women were clinically stable postoperatively (usually within 4 to 6 hours, although one site placed the undergarment while in the operating room). Undergarments were then worn at the discretion of the participant. Participants randomized to the control group were exposed only to the usual care of the institution (ie, wear a comfortable brassiere of their own, usually donned ≥ 2 days postoperatively). Binding of breasts was not permitted.

The protocol received institutional ethics approval at all participating sites. Written informed consent was obtained from each participant. The WREST investigators all contributed to the design of the study. All authors contributed to drafts, revisions, or review of this manuscript.

Follow-up and data collection

While participants were hospitalized, data were collected in person by site research assistants. Sternal incision and breast pain and discomfort, analgesic use (a potential confounder), as well as sternal wound healing (a measure of safety) data were collected on the first and every other postoperative day, as well as at discharge. Pain and discomforts were measured using

11-point numeric rating (Likert-type) scales that were anchored with descriptors (0 = none, 10 = worst). Pain was scored as rated in the single-item question. The descriptors of discomforts (tingling, dull ache, numbness, itchiness, tenderness, other patient-identified factor) were consistent with those generated qualitatively and used in studies (including our pilot study)¹⁷ focusing on women's recovery and discomfort following cardiac surgery.^{10,14-16} Discomforts were measured using the same numeric rating scale and anchors used to measure pain. Given that discomfort may stem from only one or all of the descriptors, the discomfort score was generated by counting the highest score given to any one of the descriptors. Analgesic use data (generic name, dose, number of doses) for the preceding 24 hours (8 AM to 8 AM) were collected at each point in time. Sternal wound healing data were collected using Society of Thoracic Surgeons-based descriptors on ordinal scales for sternal wound drainage (5-point scale; 0 = none, 4 = large amount requiring dressing changes >2 per day), sternal stability (3-point scale; 0 = stable, 2 = palpable movement without cough), and sternal incision proximation (5-point scale; 0 = closed, 4 = gaping). Participants were successfully taught how to "score" their sternal wounds in our pilot work and in this study.¹⁷ Clinical data were collected through a health record audit at the time of discharge.

Once discharged, data were collected from participants over the telephone by centrally located research assistants who were blinded to the extent possible. Pain, discomfort, analgesic use, and sternal wound healing data were collected at each contact. Functional status data, using the Health Assessment Questionnaire²¹ (HAQ), were collected at the first home telephone contact and during postoperative weeks 3, 6, and 12. At the last interview, intervention participants were asked, "How strongly would you recommend this undergarment be used by a friend having heart surgery?" (0 [not at all] to 10 [absolutely]).

Data analyses

All analyses were based on intention-to-treat principles. Wilcoxon tests, Student *t* tests, and χ^2 tests were used as appropriate to compare the characteristics (demographic, clinical) of participants assigned to the intervention and control groups. Pain and discomfort data were then compared using Wilcoxon tests, and *P* values were adjusted for multiple comparisons at each prespecified point in time (5 days and 2, 6, and 12 weeks postoperatively). Upon inspection of the data, we observed that pain and discomfort scores were positively skewed. Thus, we dichotomized these scores. A score of $\geq 3/10$ indicated some moderate pain and $\leq 2/10$ indicated no pain.^{22,23} We examined treatment by time interactions and main effects of time and treatment using logistic regression. Generalized estimating equations were used to account for lack of independence among observations.²⁴ Finally, we tested whether the effects of the undergarment were modified or confounded by age or brassiere cup size.

We planned to use a last observation-carried-forward strategy. However, we noted that the pain and discomfort scores escalated markedly at the 2-week postoperative point in time (by which the majority of participants had been discharged from hospital). Thus, to reduce bias introduced by time of discharge, if the observation was missing before discharge, the prior predischARGE observation was carried forward. Similarly, if the observation was missing following discharge, only the

^c The undergarment was initially designed as a compression undergarment for use after reduction mammoplasty. Certain modifications were made to enable more flexibility in the sizing (eg, to accommodate women's changing shape), to reduce friction on the sternal wound, to accommodate postoperative monitoring lines and chest tubes, and to enable quick access for regular (eg, x-ray, auscultation) or emergent care.

Figure 1



Model

Patient (within 6 hours post-operatively)*

WREST undergarment. *Consent obtained.

prior postdischarge observation was carried forward. This strategy resulted in a reduction in missing data, and the missing data pattern was identical for each of the outcome variables.

We categorized medications taken for pain as nonnarcotic analgesics (acetaminophen, acetylsalicylic acid), mild narcotic analgesics (acetaminophen with codeine), and strong narcotic analgesics (opiates). Participants' medication use was scored based on the highest "level" of medication taken in the past 24 hours by health record audit (in-hospital) or by recall (after discharge). These data were then compared using Pearson χ^2 test. Scores from the three wound healing elements (wound drainage, sternal stability, and sternal incision proximation) were summed to form a "wound healing score." We observed that these scores were also positively skewed. Thus, we dichotomized the scores (≥ 3 indicating wound healing difficulty, ≤ 2 indicating no wound healing difficulty) and made between-group comparisons using Fisher exact test. Functional status data (HAQ)²¹ were analyzed using repeated measures analysis of variance. All data were analyzed using R version 2.1.0 (2005) (R Foundation for Statistical Computing, Boston, MA) software.

This trial was designed to have 80% power to detect an intervention effect of 20% on pain scores, assuming a sample size of 376 (188 per group).¹⁷ A Data Safety Monitoring Committee met at 3 prespecified times to examine data and assure no harms were associated with the undergarment use (wound healing and cause of death were carefully monitored). The trial was funded by the Canadian Institutes of Health Research after peer review. The funder had no influence on the trial design or conduct. The investigators had no proprietary interest in the undergarment. The registration number for this clinical trial was ISRCTN 47669580.

Results

Main findings

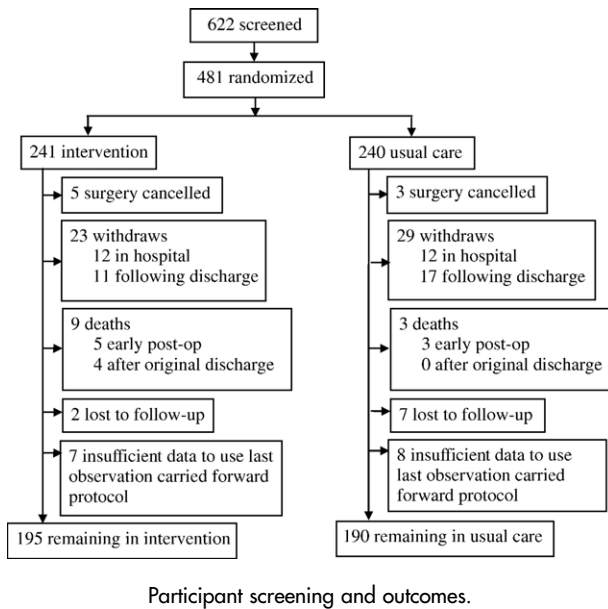
We enrolled 481 women (241 to intervention and 240 to usual care). The randomized participants did not differ

significantly on any relevant demographic or clinical variables. The loss of some participants rendered a final sample of 385 (Figure 2); 9.5% (23/241) of the intervention and 12.1% (29/240) of the usual care participants withdrew. We used a last observation-carried-forward strategy in our data analysis, rendering complete data at each prespecified point in time for the data set that we used ($n = 385$). The proportion of patients with data filled in using the last observation-carried-forward strategy was lowest at day 5 (1.5% and 2.6% in intervention and usual care groups, respectively) and highest at week 6 (12.3% and 14.7% for intervention and usual care groups, respectively). There was no evidence of a difference between groups ($P = .4417$) in the amount of "filled-in" data nor evidence that pattern of filled-in data differed for the 2 groups over time ($P = .8989$). Participants who remained in the final data set did not differ significantly, based on their randomization, on demographic or clinical variables (Table 1).

Although our analysis plan was based on intention-to-treat principles, we examined undergarment "hours of wear" data at the first 2 prespecified points in time for the intervention and usual care groups. On day 5 and 2 weeks postoperatively, 69% (134/195) and 45% (88/195) of women in the intervention group wore the study undergarment >12 hours per day. However, the minority of women in the usual care group tended to wear their own brassiere >12 hours per day at day 5 and 2 weeks postoperatively (15% [29/190] and 22% [41/190], respectively).

The proportions of women who experienced incision and breast pain and discomfort (ie, scores ≥ 3) at the prespecified points in time are presented in Figure 3. Overall and until at least 6 weeks postoperatively, fewer

Figure 2



women in the intervention than usual care group reported having incision and breast pain and discomfort. Incision pain and discomfort peaked at 2 weeks postoperatively. However, breast pain and discomfort peaked differentially in the intervention (6 weeks postoperatively) and usual care (2 weeks postoperatively) groups. Participants in the intervention group reported significantly less breast pain than those in the usual care group at 2 weeks postoperatively (Wilcoxon test; Hochberg adjusted $P = .04$).

When the incision and breast pain and discomfort scores were examined using logistic regression models (with generalized estimating equations that take account of all time points in a single analysis), there was no evidence of treatment by time interactions for the pain and discomfort outcomes. Overall, there was a significant treatment effect of the undergarment in the reduction of breast pain. Women in the intervention group were significantly less likely than those in the usual care group to report breast pain (OR 0.65 [95% CI 0.45-0.94], $P = .02$). There was no significant effect of the intervention on sternal incision pain (OR 0.85 [95% CI 0.64-1.13], $P = .27$) or discomfort (OR 0.90 [95% CI 0.68-1.18], $P = .44$), or breast discomfort (OR 0.75 [95% CI 0.54-1.03], $P = .08$). Furthermore, there was no evidence that the intervention effects were affected by age or cup size.

There were no significant differences between the intervention and usual care groups in the proportion of participants receiving pain medications (Table II).

Table I. Characteristics of all 385 women in the final data set

Variable	Intervention	SD/%	Usual care	SD/%
Age (mean)	66.65	11.09	64.67	11.55
BMI (mean)	29.09	6.60	28.82	5.14
Chest circumference* (in) (mean)	39.15	3.96	38.87	4.24
Brassiere cup size				
A	15/195	7.7%	10/190	5.3%
B	64/195	32.8%	55/190	28.9%
C	72/195	36.9%	71/190	37.4%
D+	44/195	22.6%	54/190	28.4%
Study brassiere size				
XS (32")	2/195	1.0%	1/190	0.5%
S (34")	7/195	3.6%	2/190	1.1%
M (36")	16/195	8.2%	23/190	12.1%
L (38")	29/195	14.9%	29/190	15.3%
XL (40")	45/195	23.1%	44/190	23.2%
XXL (42"-44")	50/195	25.6%	46/190	24.2%
XXXL (44"-46")	29/195	14.9%	29/190	15.3%
XXXXL (48"+)	17/195	8.7%	16/190	8.4%
Surgery type				
CABG	112/195	57.4%	109/190	57.4%
Valve	64/195	32.8%	48/190	25.3%
CABG + valve	13/195	6.7%	20/190	10.5%
Other	6/195	3.0%	12/190	6.8%
Donor graft site				
Right IMA	10/125	8.0%	15/129	11.6%
Left IMA	102/125	81.6%	109/129	84.5%
Saphenous	96/125	76.8%	87/129	67.4%
Other site	21/125	16.8%	15/129	11.6%
Wound closure				
Staples	41/195	21.0%	37/190	19.5%
Sutures	137/195	70.3%	133/190	70.0%
Retention sutures	4/195	2.1%	5/190	2.6%
Postoperative course				
CPR	0/195	0.0%	0/190	0.0%

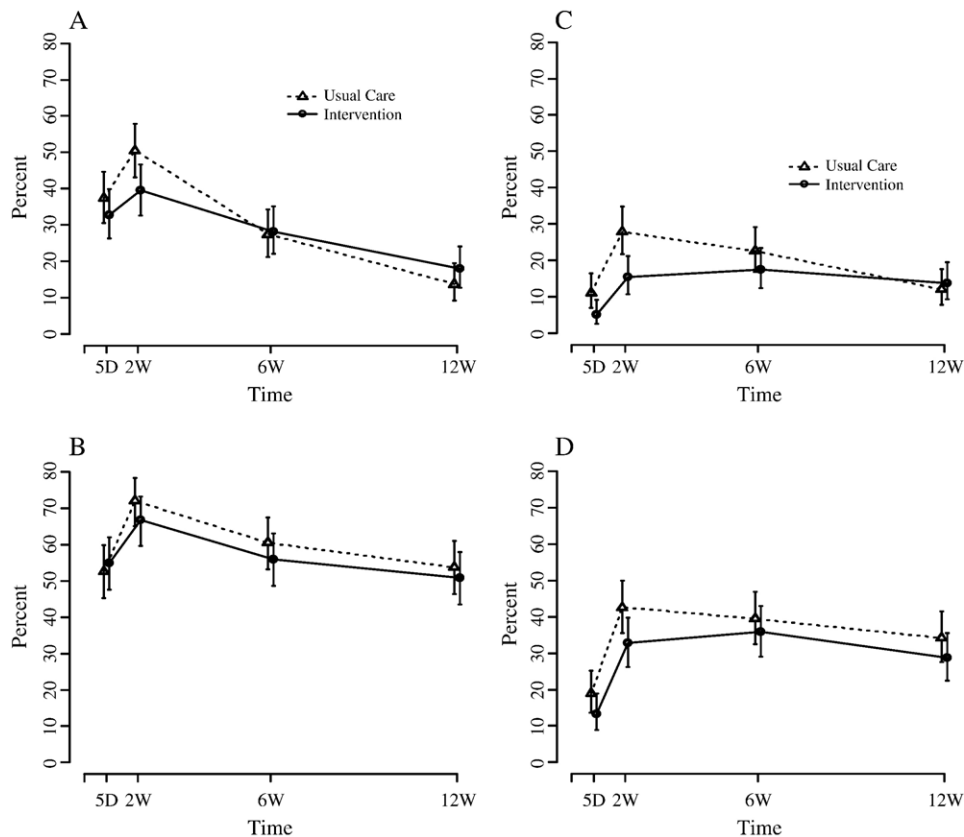
BMI, Body mass index; CABG, coronary artery bypass graft; IMA, internal mammary artery; CPR, cardiopulmonary resuscitation.

*Add 4" if even number and 5" if odd number to determine brassiere band size.

Neither were there significant differences in difficulty with sternal wound healing between participants in the intervention and usual care groups, respectively (day 5, 3.6% vs 2.6%, $P = .80$) (week 2, 7.7% vs 5.3%, $P = .45$) (week 6, 2.6% vs 7.4%, $P = .05$) (week 12, 1.5% vs 2.6%, $P = .69$). Although there were significant increases in functional status scores over the postoperative period ($F_{3,870} = 811.57$, $P < .001$), there were no significant between group differences in HAQ²¹ scores at any point in time ($F_{1,289} = 0.8384$, $P = .36$). The subjective response to the undergarment use was favorable: 78% (140/180) of responders indicated they would highly (score ≥ 8) recommend it to a friend having heart surgery.

Finally, no significant deleterious effects of the undergarment use were documented throughout the study or by the Data Safety Monitoring Committee in their deliberations.

Figure 3



Percentage of women with incision pain and discomfort (**A** and **B**) and breast pain and discomfort (**C** and **D**) scores ≥ 3 by group over time. Horizontal bars represent exact binomial 95% CIs.

Post hoc analysis of scores before and after discharge

The time course of postoperative pain, which had not been well characterized previously, indicated an intriguing increase in the proportion of women who reported incision and breast pain and discomfort at the 2-week postoperative relative to the day 5 postoperative point in time (see Figure 3). We hypothesized this might represent the influence of hospital discharge. Therefore, we performed a post hoc analysis to examine the proportion of women experiencing pain and discomfort scores ≥ 3 immediately before and after discharge. For participants discharged within 14 days (discharge times ranged from 4-70 days postoperatively), the timing of data collection intervals allowed us to align measures of pain and discomfort on day of discharge with scores at 1, 2, and 3 weeks post discharge (approximately 4-5 weeks postoperatively). This analysis included 93% of women in both the intervention and usual care groups. Logistic regression models with generalized estimating equations were used for the analysis, as described above, but also

included time of discharge as an independent variable. There was no evidence of treatment by time interactions for any of the pain or discomfort scores. Participants in the intervention group were significantly less likely than those in the usual care group to report breast pain (OR 0.46 [95% CI 0.32-0.66], $P < .001$) and breast discomfort (OR 0.62 [95% CI 0.44-0.86], $P = .005$) but not sternal incision pain (OR 0.99 [95% CI 0.72-1.37], $P = .95$) or discomfort (OR 0.77 [95% CI 0.55-1.02], $P = .06$) over the 3-week period after discharge.

Discussion

We empirically investigated the effect of women's use of a novel undergarment during the poststernotomy period. Although incision pain and discomfort scores were consistently higher than breast pain and discomfort scores, we demonstrated only a significant reduction in breast pain (and discomfort) for those who were randomized to receive the study undergarment. There were no adverse effects of using the undergarment.

Table II. Pain medication use (by category) at prespecified points in time

Time	Medication category	Intervention	%	Usual care	%	P
Day 5	Nonnarcotic	40/195	20.5%	39/190	20.5%	.42
	Mild narcotic	118/195	60.5%	105/190	55.3%	
	Strong narcotic	37/195	19.0%	46/190	24.2%	
Week 2	Nonnarcotic	72/195	36.9%	71/190	37.4%	.41
	Mild narcotic	96/195	49.2%	84/190	44.2%	
	Strong narcotic	27/195	13.8%	35/190	18.4%	
Week 6	Nonnarcotic	131/195	67.2%	131/190	68.9%	.69
	Mild narcotic	46/195	23.6%	46/190	24.2%	
	Strong narcotic	18/195	9.2%	13/190	6.8%	
Week 12	Nonnarcotic	169/195	86.7%	164/190	86.3%	.62
	Mild narcotic	18/195	9.2%	21/190	11.1%	
	Strong narcotic	8/195	4.1%	5/190	2.6%	

Moreover, most women randomized to receive the study undergarment wore it regularly (ie, >12 h/d) during their early surgical recovery and indicated they would recommend the study undergarment to a friend undergoing sternotomy.

To our knowledge, this is the first study to undertake an adequately powered randomized trial of this kind. Only two other investigations have been reported of sternal support following cardiac surgery.^{25,26} The sample sizes were small; 10 intervention and 10 control in one randomized pilot study of a brassiere for women²⁵ and 14 in one nonrandomized descriptive study of a sternal support for men and women.²⁶ Neither study had sufficient power to demonstrate a benefit to using the intervention.

Poststernotomy pain and discomfort management has been a focus of concern for healthcare providers^{3-8,15,16} and has been limited, in most part, to in-hospital management, likely because of the need to mobilize postoperative patients. Indeed, our findings suggest that study participants' sternal incision and breast pain and discomforts were reasonably well managed while hospitalized. Our findings also reveal that women randomized to the usual care group tended not to wear their own brassiere while hospitalized. The relatively low initial pain and discomfort scores might account for our finding of no significant intervention effect during hospitalization. Our inspection of the pain and discomfort data revealed an unexpected and striking increase in scores at the 2-week relative to the day 5 postoperative point in time. We attributed this increase in scores to the participants' discharge from hospital and their subsequent increase in activity. It is well documented that when women are discharged home after cardiac surgery, they are recovering "in their place of work" and this "work" is the yardstick that they use to measure their recovery.^{13,27} For women discharged within 14 postoperative days, our post hoc analysis of scores before and after discharge revealed that using the undergarment after sternotomy did not reduce sternal incision pain or

discomfort but significantly reduced breast pain (54%) and discomfort (38%) experienced in this subgroup over a period of up to 5 weeks postoperatively.

Limitations

There were some challenges to designing and implementing this trial. First, there was no reasonable placebo control. The only meaningful solution was to compare the intervention to usual care. Second, data collection was not blinded while participants were hospitalized. However, randomization was concealed, the site-based research assistants (who were rigorously trained, using a standardized protocol, to elicit subjective responses from study participants) and data analysts were blinded to the extent possible. Third, the outcome measures were subjective. The outcomes of interest were those well known to be important to women having sternotomy—incision and breast pain and discomfort.^{9-11,13-15} More objective measures, such as use of pain medication, could not reasonably be used because of pain protocols used in participating institutions. Moreover, many of the women were already taking pain medications for other ailments (arthritis for example) that would have also had an effect on postoperative pain. Fourth, there were postrandomization losses to follow-up. Some of these losses were unavoidable (ie, surgery cancelled, death) and those who withdrew were often too ill to reasonably expect they continue. The losses were not differentiated by study group, and >90% data collection calls were completed with those who remained in the study.²⁸ Despite these limitations, our design decisions rendered findings that we believe are applicable to real world practice.

Conclusions

To our knowledge, this is the first clinical trial to test a practical intervention for women's use following sternotomy. Study findings provide an evidence base for healthcare providers to recommend that women wear a supportive (ie, compression) undergarment

during the poststernotomy period to reduce their longer-term breast pain and enhance their breast comfort as they become more active following surgery. Importantly, most women would recommend the use of such an undergarment to others having sternotomy. The next phases of work will include an economic analysis and further examination of the characterization and time course of poststernotomy pain and discomfort.

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Appendix A. Site Investigators and Research Assistants

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