Orthopaedic Section of the APTA
Grant Program
Final Report Form

Date: October 24, 2022
Name of Investigators: Rogelio A. Coronado, Kristin R. Archer, Clinton Devin
Name of Grant: Early Postoperative Exercise after Anterior Cervical Discectomy and Fusion: A Pilot, Randomized Controlled Trial
Award Period: May 25, 2016 to April 30, 2019

1. Briefly summarize major accomplishments of this project:
   Over the funding period, we completed enrollment and all follow-up sessions for our clinical trial sample of 30 individuals undergoing anterior cervical discectomy and fusion. Participants were randomized to receive an early home exercise program or usual care after surgery. Outcomes were collected up to 12 months after surgery. The primary results of our project were published in *Spine* (2020). We have attached the copy of our publication. Prior to our trial, we completed a case series piloting our early home program intervention. The case series was described in our publication in *Physiotherapy Theory and Practice* (2021).

2. Provide a one-paragraph summary of results or abstract suitable for posting on the Orthopaedic Section website. (The following abstract is from our published paper in *Spine*):

Study design: Pilot randomized controlled trial.
Objective: To examine the acceptability and preliminary safety and outcome effects of an early self-directed home exercise program (HEP) performed within the first 6 weeks after anterior cervical discectomy and fusion (ACDF).
Summary of background data: Little is known regarding optimal postoperative management after ACDF.
Methods: Thirty patients (mean ± standard deviation, age = 50.6 ± 11.0 years, 16 women) undergoing ACDF were randomized to receive an early HEP (n = 15) or usual care (n = 15). The early HEP was a 6-week self-directed program with weekly supportive telephone calls to reduce pain and improve activity. Treatment acceptability was assessed after the intervention period (6 weeks after surgery). Safety (adverse events, radiographic fusion, revision surgery) was determined at routine postoperative visits. Disability (Neck Disability Index), pain intensity (Numeric Rating Scale for neck and arm pain), physical and mental health (SF-12), and opioid use were assessed preoperatively, and at 6 weeks and 6 and 12 months after surgery by an evaluator blinded to group assignment.
Results: Participants reported high levels of acceptability and no serious adverse events with the early HEP. No difference in fusion rate was observed between groups ($P > 0.05$) and no participants underwent revision surgery. The early self-directed HEP group reported lower 6-week neck pain than the usual care group ($F = 3.3$, $P = 0.04$, $r = 0.3$, mean difference = -1.7 [-3.4; -0.05]) and lower proportion of individuals (13% vs. 47%) using opioids at 12 months ($P = 0.05$). No other between-group outcome differences were observed ($P > 0.05$).
Conclusion: An early self-directed HEP program was acceptable to patients and has the potential to be safely administered to patients immediately after ACDF. Benefits were noted for short-term neck pain and long-term opioid utilization. However, larger

trials are needed to confirm safety with standardized and long-term radiograph assessment and treatment efficacy.

3. Attach a list of your publications published or accepted during the past year, or currently being written. Send reprints when available. List presentations made and abstracts accepted for presentation based on this work. Indicate with an asterisk (*) those publications support by Orthopaedic Section funding.

The following presentations and publications were based on this work:

Publications:

Coronado RA, Devin CJ, Pennings JS, Vanston SW, Fenster DE, Hills J, Aaronson OS, Schwarz JP, Stephens BF, Archer KR. Early self-directed home exercise program after anterior cervical discectomy and fusion: a pilot study. **Spine**, 2020; 45(4):217-225. PMID: 31490861.

Coronado RA, Devin CJ, Pennings J, Aaronson OS, Haug CM, Van Hoy EE, Vanston SW, Archer KR. Safety and feasibility of an early telephone-supported home exercise program after anterior cervical discectomy and fusion: a case series. **Physiotherapy Theory and Practice**, 2021; 37(10):1096-1108. PMID: 31663795.

Presentations:

Coronado RA, Devin CJ, Van Hoy EE, Haug CM, Vanston SW, Aaronson OS, Archer KR. A randomized trial of early home exercise versus usual care after anterior cervical decompression and fusion for degenerative cervical spine conditions. Cervical Spine Research Society Annual Meeting, Toronto, Ontario, Canada, December 8, 2016.

Coronado RA, Devin CV, Van Hoy EE, Haug CM, Vanston S, Aaronson OS, Archer K. Clinical efficacy and safety of an early home exercise program after anterior cervical discectomy and fusion: a case series. American Physical Therapy Association Combined Sections Meeting, San Antonio, TX, February 2017. ***Abstract published in Journal of Orthopaedic & Sports Physical Therapy, 2017; 47(1):A79.***

Coronado RA, Devin CJ, Pennings JS, Vanston SW, Fenster DE, Hills J, Aaronson O, Schwarz JP, Stephens BF, Archer KR.* Safety and efficacy of an early exercise program after anterior cervical discectomy and fusion: a pilot randomized controlled trial. Cervical Spine Research Society 46th Annual Meeting, Scottsdale, AZ, December 8, 2018.

Coronado RA, Devin C, Pennings JS, Fenster D, Vanston S, Hills J, Aaronson O, Schwarz J, Stephens B, Archer K. The safety and feasibility of an early physical therapist-delivered, telephone-based home exercise program after anterior cervical discectomy and fusion: a randomized controlled trial. American Physical Therapy Association Combined Sections Meeting, Washington, DC, January 24, 2019. ***Abstract published in Journal of Orthopaedic & Sports Physical Therapy, 2019; 49(1):CSM84.***

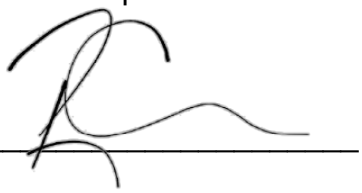
4. Provide a budget, using the original approved budget. Indicate total funds spent to date per major categories. If there was ≥ 25% deviation (greater or less spent) of use of funds for any of the budget category, please BRIEFLY indicate the rationale.

Expense Category	Total Budget	Amount Spent in Year 1	Amount Spent in Year 2 and NCE	Total Spent	Rationale for categorical differences
		5/25/2016-4/30/2017	5/1/2017-4/30/2019		
Personnel	$8,940	$7,657.81	$17,265.39	$24,923.20	Consultant and statistical costs included in this line item
Participant compensation	$7,200		$4,150.00	$4,150.00	Enrollment less than anticipated
Materials & Supplies	$6,249	$329.00	$597.80	$926.80	Purchased accelerometer accessories only
Consultant	$1,000				Included in personnel
Other Expenses-Statistical Costs	$6,610				Included in personnel
Total	$30,000	$7,986.81	$22,013.19	$30,000.00	

Budget variation from the initial plan was due to 1) consultant and statistical costs being placed within personnel costs, 2) lower than anticipated enrollment that reduced participation compensation, and 3) shift in amount spent on coordinator effort to increase enrollment over the NCE period.

5. Please send out a final print-out from your institution indicating monies spent per major categories.

Budget sent as requested.

Signature: 

Date: 10/24/2022

Spine

SPINE Volume 45, Number 4, pp 217–225
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RANDOMIZED TRIAL

Early Self-directed Home Exercise Program After Anterior Cervical Discectomy and Fusion

A Pilot Study

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Study Design. Pilot randomized controlled trial.

Objective. To examine the acceptability and preliminary safety and outcome effects of an early self-directed home exercise program (HEP) performed within the first 6 weeks after anterior cervical discectomy and fusion (ACDF).

Summary of Background Data. Little is known regarding optimal postoperative management after ACDF.

Methods. Thirty patients (mean ± standard deviation, age = 50.6 ± 11.0 years, 16 women) undergoing ACDF were randomized to receive an early HEP (n = 15) or usual care (n = 15). The early HEP was a 6-week self-directed program with weekly supportive telephone calls to reduce pain and improve activity. Treatment acceptability was assessed after the intervention period (6 weeks after surgery). Safety (adverse events, radiographic fusion, revision surgery) was determined at routine postoperative visits. Disability (Neck Disability Index), pain intensity (Numeric Rating Scale for neck and arm pain), physical and mental health (SF-12), and opioid use were assessed preoperatively, and at 6 weeks and 6 and 12 months after surgery by an evaluator blinded to group assignment.

Results. Participants reported high levels of acceptability and no serious adverse events with the early HEP. No difference in fusion rate was observed between groups ($P > 0.05$) and no participants underwent revision surgery. The early self-directed HEP group reported lower 6-week neck pain than the usual care group ($F = 3.3$, $P = 0.04$, $r^2 = 0.3$, mean difference = −1.7 [−3.4; −0.05]) and lower proportion of individuals (13% *vs.* 47%) using opioids at 12 months ($P = 0.05$). No other between-group outcome differences were observed ($P > 0.05$).

Conclusion. An early self-directed HEP program was acceptable to patients and has the potential to be safely administered to patients immediately after ACDF. Benefits were noted for short-term neck pain and long-term opioid utilization. However, larger trials are needed to confirm safety with standardized and long-term radiograph assessment and treatment efficacy.

Key words: exercise therapy, neck pain, radiculopathy, spinal fusion, surgical decompression.

Level of Evidence: 2

Spine 2020;45:217–225

Anterior cervical discectomy and fusion (ACDF) is the most common cervical spine surgery.[1,2] The number of ACDF procedures has steadily increased over the last two decades,[1–4] with approximately 120,000 performed in the United States each year.[2,5] Average hospital charges for ACDF are estimated at more than $50,000 and rising,[5,6] resulting in more than $5 billion in total charges annually.[6] Despite the increased utilization, persistent neck and arm pain and disability are reported in up to 50% of patients.[7,8] Variability in the utilization of rehabilitation after ACDF may contribute to these poor outcomes.[9]

Rehabilitation is often initiated 4 to 6 weeks after surgery.[9] However, two systematic reviews highlight a lack of evidence for guiding postoperative rehabilitation.[10,11] One randomized trial has shown rigid collars improve function and pain after ACDF, but the quality of evidence was very low.[12] Wibault *et al*[13] randomized patients to structured

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Acknowledgment date: May 20, 2019. First revision date: July 30, 2019. Acceptance date: August 7, 2019.

The manuscript submitted does not contain information about medical device(s)/drug(s).

The Cervical Spine Research Society and Academy of Orthopaedic Physical Therapy, and a Vanderbilt Clinical and Translational Science Award (UL1 TR000445) from the National Center for Advancing Translational Sciences/National Institutes of Health grant funds were received in support of this work.

Relevant financial activities outside the submitted work: consultancy, grants, expert testimony.

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DOI: 10.1097/BRS.0000000000003239

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rehabilitation or usual care at 6 weeks after ACDF and reported better 6-month outcomes following rehabilitation for expectation fulfillment and neck pain, but not in the primary outcome of disability. It is unknown if 4 to 6 weeks after surgery is the optimal time to initiate exercise. During the immediate postoperative period, there is reduced neck motion from fusion, pain, and postoperative restrictions (*e.g.*, collar),[14–16] which affects neck muscle function and can lead to atrophy and deconditioning.[17] The loss of strength may not spontaneously recover and can persist several years after surgery.[18] Early initiation of exercise may counteract these deleterious effects.[19,20]

The purpose of this pilot study was to examine the acceptability and preliminary safety and outcome effects of an early self-directed home exercise program (HEP) performed during the first 6 weeks after ACDF. Our hypothesis was that the HEP would be acceptable to patients, show preliminary safety through no adverse events and revision surgery and comparable fusion rates, and demonstrate improvements in disability, pain, physical and mental health, and opioid utilization at 12 months after surgery compared to usual postoperative care. This study is informed by the lumbar spine surgery literature, which supports early postfusion rehabilitation that includes walking, education, neuromobilization, and core strengthening.[21,22] Results of this study will provide clinicians with a better understanding of early exercise benefits and inform future rehabilitation efforts.

METHODS

Study Design

This study was a single-blind pilot randomized controlled trial. Data were assessed preoperatively and 6 weeks, 6 months, and 12 months after surgery. The Institutional Review Board at Vanderbilt University Medical Center approved this study. The trial protocol was published on ClinicalTrials.gov (NCT02720172). Trial conduct and reporting were in accordance with CONSORT.[23,24]

Procedures

Consecutive patients were screened from April 2016 to July 2017. The inclusion criteria were patients aged 21 years and older; English-speaking; and undergoing ACDF for cervical stenosis, spondylosis, degenerative spondylolisthesis, or disc herniation. Exclusion criteria were patients having surgery secondary to trauma, fracture, tumor, infection, or spinal deformity; undergoing cervical corpectomy; with a worker's compensation claim; diagnosed with severe psychiatric disorder such as schizophrenia or other psychotic disorder; with a documented history of alcohol and/or drug abuse; and unable to return to clinic for follow-up visits or provide a stable telephone or physical address.

Enrolled participants provided written informed consent and completed a preoperative assessment containing demographic and clinical characteristics, and validated outcome measures for disability, pain, and physical and mental health. Medical record data included baseline information on prior neck surgery, comorbidities (Functional Comorbidity Index),[25] surgical indication, and number of fusion levels, and surgeon instructions at hospital discharge. Randomization to early self-directed HEP or usual care was conducted in a concealed manner by personnel not responsible for recruitment using a computer-generated scheme in a 1:1 ratio in blocks of assignments stratified by age (21–59; 60–90) and number of fusion levels (1 or 2; 3 or more). After the intervention (6 weeks) and at 6 and 12 months after surgery, participants completed the validated outcome measures and answered questions about opioid use, physical therapy (PT) utilization, and revision surgery. Questionnaires were completed remotely by participants through paper or Web-based survey (Research electronic data capture: REDCap[26]) or in-person at a 6- or 12-month clinic visit. Medical records were reviewed for revision status at 18 to 24 months after surgery. All outcomes were assessed by study personnel blinded to group assignment.

Intervention

Early Home Exercise Program

Participants received usual postoperative care plus a self-directed HEP to decrease pain and promote movement and activity during the initial 6-week recovery period (Table 1).[27] The HEP included daily walking and sleeping instructions, and range of motion and strengthening exercises. Cognitive-behavioral strategies based on the work by Archer *et al*[28] in patients undergoing lumbar spine surgery included relaxation, deep breathing, and distraction. Specific therapeutic exercises included (1) neck range of motion (limited to approximately 30° in all directions); (2) shoulder (*i.e.*, shrugs, scapular retraction, circles) and upper back range of motion; and (3) neck (*i.e.*, isometrics, chin tuck), shoulder (*i.e.*, theraband flexion, internal/external rotation, wall push-up), and core/trunk strengthening (*i.e.*, abdominal tightening with extremity movements) (Appendix 1, http://links.lww.com/BRS/B466). Therapeutic exercises were progressed in difficulty over three 2-week phases as participants tolerated and as directed by a licensed physical therapist (S.W.V.) over weekly phone calls. In addition to progressing exercise, the therapist tracked patient adherence and documented adverse events. Participants were provided a manual for the HEP program and completed an HEP diary to record days performing exercise. Before the current randomized trial, the early HEP protocol was tested in eight participants to assess feasibility.[29] Refinement of the program included the addition of sleeping tips.

Usual Care

Patients received usual postoperative care from their surgeon. Usual care included medication, cervical collar as indicated, and driving or lifting restrictions. Referral to PT was typically ordered at the 6-week postoperative visit.

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TABLE 1. Home Exercise Program Description Based on the Template for Intervention Description and Replication (TIDieR)[27]

Item	Description
1. Intervention name	Early home exercise program (HEP)
2. Rationale, theory, or goal of intervention elements	The early HEP includes exercise and pain management strategies to reduce pain (deep breathing, relaxation, distraction) and improve activity (walking, stretching, strengthening).
3. Materials used	The early HEP used a detailed written manual that participants used to perform and progress daily exercise. Resistance bands were used to adjust intensity of strengthening exercise.
4. Procedures	Brief supportive phone calls were made to offer encouragement, assess compliance, and progress exercises as indicated.
5. Provider	The early HEP is a self-directed program. Weekly phone calls were made by a licensed physical therapist with 15 years' experience working with patients with musculoskeletal pain. Training on the intervention procedures was performed at a single session prior to study enrollment.
6. Delivery mode	The early HEP was a home-based program performed individually and supported through weekly telephone calls with a physical therapist.
7. Location	Participant's home
8. Duration and frequency	The early HEP lasted 6 weeks, beginning immediately after surgery. Exercises were performed daily. The early HEP contained three phases progressing in intensity every 2 weeks.
9. Tailoring	Personalized progression or adaptation occurred through weekly phone calls with a physical therapist. Example tailoring could include slower or quicker progression through phases or adjustments to individual exercises.
10. Modifications	No modifications were made to the early HEP during the study.
11. Intervention adherence	Participant adherence was encouraged with a written exercise diary and through weekly phone calls.

Acceptability

Acceptability was assessed through adherence and an intervention assessment at 6 weeks. Participants were asked to rate the helpfulness of the program and the likelihood of recommending the program to a friend using an 11-point numeric rating scale (NRS) with 0 meaning "not at all helpful or likely" and 10 "extremely helpful or likely." Participants were asked to rate the overall benefit considering the effort put into it, and the importance of changes in pain and activity using a 5-point Likert scale. Open-ended questions were asked regarding ideal start time.

Safety

Safety was determined through adverse events, imaging, and revision surgery at 12 months. Adverse events were recorded weekly during the intervention phase. Fusion status was determined by review of postoperative computed tomography when available,[30] or by interspinous motion analysis on dynamic flexion-extension radiographs as described by Song *et al*.[31] All radiographs were assessed by a single evaluator (J.M.H.) blinded to group assignment. Images were obtained at routine clinic visits at the discretion of the surgeon. Revision surgery was determined at 18 to 24 months *via* patient self-report and electronic medical record review.

Outcomes

Outcomes included disability, pain, general health, and opioid utilization. Disability was assessed with the 10-item Neck Disability Index (NDI).[32] The NDI has demonstrated good to excellent psychometric properties in patients undergoing cervical spine fusion.[33] The minimum clinically important difference (MCID) for the NDI is 7.5 points in patients after ACDF.[33] Neck and arm pain intensity were assessed with an 11-point NRS.[34] The NRS is a reliable and valid measure of pain intensity in older adults and patients with chronic pain.[35,36] The MCID for the NRS is 2.6 points in patients after ACDF.[37] Physical and mental health was assessed with the SF-12.[38] The SF-12 is a reliable and valid measure of general health.[39,40] The MCID for the SF-12 physical health subscale is 8.1 points and for the mental health subscale is 4.7 points in patients after ACDF.[41] Opioid utilization was assessed with the question "are you currently taking opioid medications" at 6 weeks, and 6 and 12 months.

Statistical Analysis

Baseline comparisons were assessed with *t* tests or Fisher exact tests. The primary analyses were intent-to-treat. Change scores with 95% confidence intervals (CIs) were computed for each group. Separate multivariable linear regression analyses were performed to determine the independent impact of early HEP compared to usual care on each outcome at 6 weeks, 6 months, and 12 months. Covariates included the baseline outcome score and number of comorbidities. Regression output was interpreted based on significance level, beta value, and 95% CI. Alpha was set at an *a priori* level of 0.05 for statistical significance.

RESULTS

Participants

One hundred thirteen patients were assessed for eligibility (Figure 1). Of these, 35 participants (31%) were consented.

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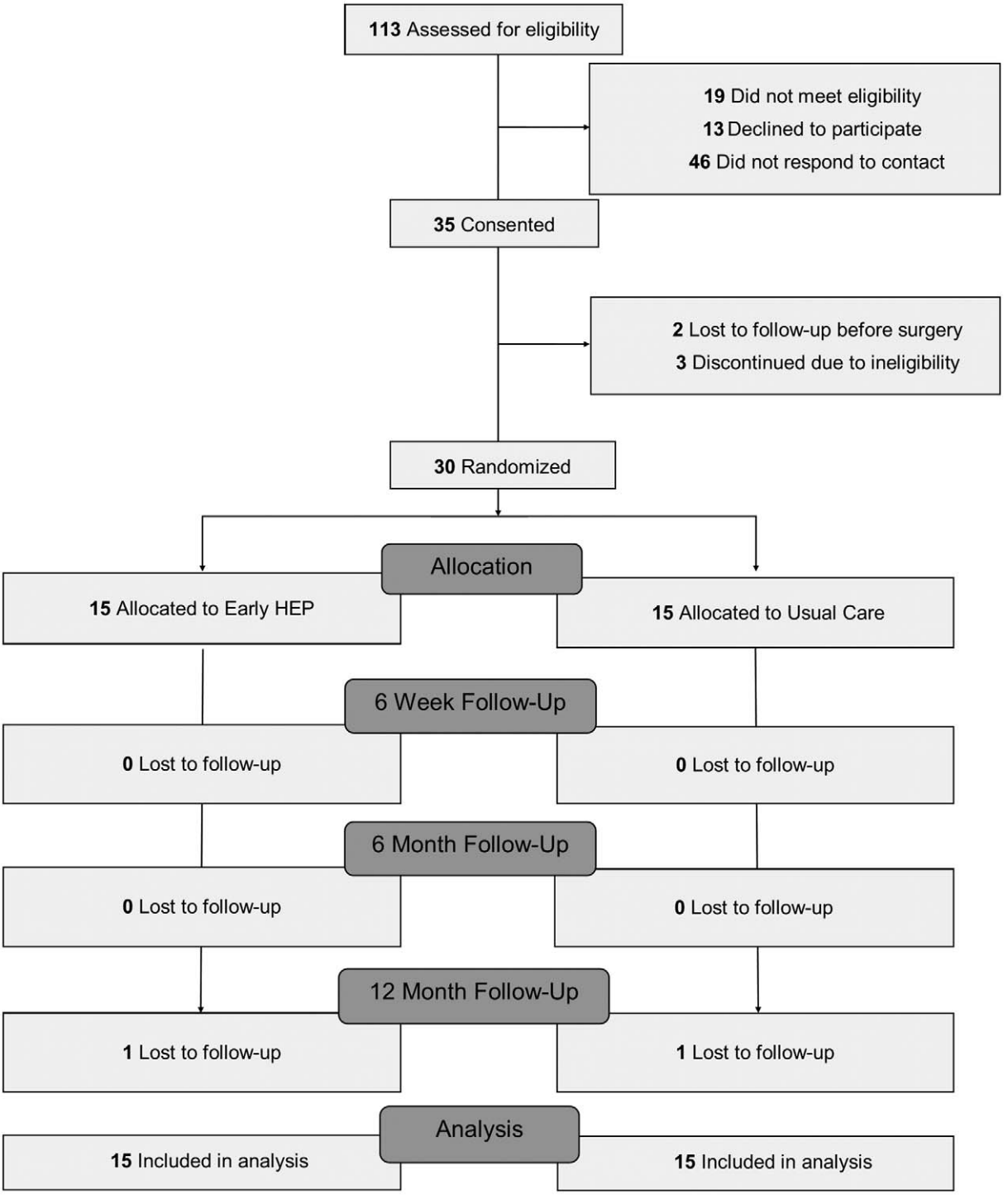

Figure 1. CONSORT flow diagram. HEP indicates home exercise program.

Five participants were excluded after enrollment and before randomization for not completing the preoperative assessment (n = 3), cancelling surgery (n = 1), and having a documented history of drug abuse (n = 1). Thirty participants (mean ± standard deviation [SD]; age = 50.6 ± 11.0 years; 16 [53%] female; 25 [83%] White) were randomized to receive early HEP (n = 15) or usual care (n = 15) (Table 2). Twenty-eight (93%) participants completed all outcome assessments at 12 months. No group differences in baseline characteristics were observed, except early HEP participants had more comorbidities (mean ± SD = 4.3 ± 1.6) than usual care (mean ± SD = 2.7 ± 1.4) ($P = 0.01$).

For discharge instructions, all participants were instructed not to lift more than 15 pounds or perform sudden or extreme neck movements. Driving restrictions varied from 2 to 6 weeks after surgery. Twenty (67%) participants were given a soft collar, with no difference between groups (early HEP = 9 (60%) *vs.* usual care = 11

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TABLE 2. Baseline Sociodemographic and Clinical Characteristics of Study Sample

Characteristic	Total N = 30	Early HEP n = 15	Usual Care N = 15
Sociodemographic			
Mean ± SD age (yr)	50.6 ± 11.0	51.8 ± 10.3	49.3 ± 11.9
Sex			
Male	14 (46.7)	6 (40.0)	8 (53.3)
Female	16 (53.3)	9 (60.0)	7 (46.7)
Race			
White	25 (83.3)	12 (80.0)	13 (86.7)
Non-White	5 (16.7)	3 (20.0)	2 (13.3)
Ethnicity			
Hispanic or Latino	2 (6.7)	1 (6.7)	1 (6.7)
Not Hispanic or Latino	28 (93.3)	14 (93.3)	14 (93.3)
Education			
High school or less	11 (36.7)	6 (40.0)	5 (33.3)
Some college or more	19 (63.3)	9 (60.0)	10 (66.7)
Marital status			
Married	23 (76.7)	12 (80.0)	11 (73.3)
Not married	7 (23.3)	3 (20.0)	4 (26.7)
Tobacco status			
Current use	5 (16.7)	1 (6.7)	4 (26.7)
Not current use	25 (83.3)	14 (93.3)	11 (73.3)
Employment status			
Currently working	11 (36.7)	5 (33.3)	6 (40.0)
Not currently working	19 (63.3)	10 (66.7)	9 (60.0)
Clinical			
Mean ± SD pain duration (mo)	14.9 ± 11.8	16.7 ± 15.5	13.2 ± 7.2
Prior neck surgery			
Yes	7 (23.3)	4 (26.7)	3 (20.0)
No	23 (76.7)	11 (73.3)	12 (80.0)
Mean ± SD comorbidities (FCI)	3.5 ± 1.7	4.3 ± 1.6	2.7 ± 1.4
Radiculopathy			
Yes	15 (50.0)	6 (46.2)	7 (46.7)
No	15 (50.0)	7 (53.8)	8 (53.3)
Myelopathy			
Yes	22 (73.3)	12 (75.0)	10 (66.7)
No	8 (26.7)	3 (25.0)	5 (33.3)
Number of fusion levels			
1 or 2	26 (86.7)	13 (86.7)	13 (86.7)
3 or more	4 (13.3)	2 (13.3)	2 (13.3)

All values are N (%) unless otherwise indicated.
FCI indicates Functional Comorbidity Index; HEP, home exercise program.

(73%), $P = 0.35$). After 6 weeks, 13 (43%) participants, with 8 (53%) from the early HEP group and 5 (33%) from usual care, reported attending postoperative PT ($P = 0.46$).

Treatment Acceptability

The mean ± SD days with a valid report of adherence was 38.4 ± 4.4 and for performing exercise was 29.2 ± 11.9, corresponding to an adherence rate of 0.75 (95% CI: 0.60; 0.92). Participants reported high levels of helpfulness, likelihood to recommend program, and perceived benefits (Table 3). Other benefits included quicker recovery (''*I recovered faster and felt better after my first week*''), greater feasibility (''*easier to do than going to PT*'' and ''*It's a good program. Especially since I used all my PT visits allowed prior to surgery*''), and enhanced confidence for activity (''*The program gave me the confidence to start exercising and not be afraid to move my head*''). The ideal start time was reported as immediately after to within 2 weeks after surgery by 12 (80%) participants, whereas 2 (13%) participants stated before surgery.

Safety

No serious adverse events were reported. Two (13%) participants from the early HEP group reported minor neck

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TABLE 3. Acceptability of Early Home Exercise Program to Participants (n = 15)	
Item	**Value**
1. Helpful to overall recovery (0–10), mean ± SD	8.8 ± 1.5
2. Likely to recommend (0–10), mean ± SD	8.9 ± 1.8
3. Overall benefit, taking account effort put into it, N (%)	
Benefits far outweighed the effort	6 (40.0)
Benefits somewhat outweighed the effort	1 (1.7)
Benefits equaled the effort	8 (53.3)
Effort somewhat outweighed the benefits	0 (0.0)
Effort far outweighed the benefits	0 (0.0)
4. Importance of changes in pain, N (%)	
Pain decreased a meaningful amount	8 (53.3)
Some decrease in pain, but not enough to be meaningful	4 (26.7)
No change in pain	2 (13.3)
Some increase in pain, but not enough to be meaningful	0 (0.0)
Pain increased a meaningful amount	1 (6.7)
5. Importance of changes in activity, N (%)	
Activity increased a meaningful amount	6 (40.0)
Some increase in activity, but not enough to be meaningful	8 (53.3)
No change in activity	0 (0.0)
Some decrease in activity, but not enough to be meaningful	1 (6.7)
Activity decreased a meaningful amount	0 (0.0)

pain or muscle soreness. Seventeen (57%) participants had adequate imaging to assess fusion status at follow-up and there was no statically significant difference between the two groups ($P = 0.54$) (Table 4). No participants underwent revision surgery based on self-report and a review of medical records.

TABLE 4. Individual Imaging Findings and Revision Rate by Group (n = 17*)			
Study ID	**Fusion Levels**	**Imaging: Months After Surgery**	**Fusion Status**
Early HEP			
1	2	5.3	Fused
7	2	13.8	Not fused
13	2	8.7	Not fused
15	3	13.9	Fused
45	1	7.8	Fused
85	1	10.0	Fused
88	2	4.9	Fused
Usual care			
4	1	5.8	Fused
9	1	13.7	Fused
22	1	5.1	Fused
35	1	2.3	Fused
41	1	9.3	Fused
49	1	3.9	Fused
53	1	21.8	Fused
58	2	10.8	Fused
86	1	12.2	Fused
89	4	12.1	Not fused

**Seventeen of the 30 participants received appropriate imaging (e.g., computed tomography of dynamic radiographs) for determining fusion status.*
HEP indicates home exercise program.

Outcomes

Immediate improvements at 6 weeks were noted in the early HEP group for disability (mean change [95% CI] = −7.7 [−11.6; −3.7]), neck pain (mean change [95% CI] = −4.5 [−6.1; −3.0]), arm pain (mean change [95% CI] = −4.1 [−5.9; −2.2]), physical health (mean change [95% CI] = 4.9 [0.3; 9.6]), and mental health (mean change [95% CI] = 5.6 [0.7; 10.5]) ($P < 0.05$, Table 5). These changes exceeded MCID for disability, neck and arm pain, and mental health. Significant improvements were maintained for all outcomes at 12 months ($P < 0.05$), except for mental health. The usual care group demonstrated an immediate improvement in all outcomes ($P < 0.05$), except for physical health. The immediate change in neck pain (mean change [95% CI] = −2.7 [−3.4; −2.0]) and mental health (mean change [95% CI] = 8.1 [0.1; 16.2]) exceeded MCID. Significant improvements were noted in all outcomes at 12 months ($P < 0.05$). Multivariable regression analyses revealed a greater effect on 6-week neck pain in the early HEP group compared to usual care ($F = 3.3$, $P < 0.05$, $r^2 = 0.3$, Table 5). This corresponded to a −1.7 (95% CI = −3.4; −0.5) point difference on the NRS. No other between-group differences were noted ($P > 0.05$).

There were no group differences in the proportion of participants currently taking opioid medication at 6 weeks (early HEP = 3 [20%] *vs.* usual care = 8 [53%], $P = 0.06$) or 6 months (early HEP = 4 [27%] *vs.* usual care = 7 [47%], $P = 0.23$). At 12 months, there was a fewer proportion of participants in the early HEP group (13%) on opioid medication compared to usual care (47%, $P = 0.05$).

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TABLE 5. Patient-Reported Outcomes for Disability, Pain, and Physical and Mental Health for Early Home Exercise Program and Usual Care Groups

		Baseline	6 wk		6 mo		12 mo	
Outcome	Group	Mean ± SD	Mean ± SD	Beta (95% CI)	Mean ± SD	Beta (95% CI)	Mean ± SD	Beta (95% CI)
Disability (NDI)	Usual care	25.3 ± 7.6	19.5 ± 10.6	-	15.4 ± 9.6	-	12.6 ± 10.1	-
	Early HEP	26.5 ± 8.5	18.9 ± 10.1	−3.1 (−13.9; 5.9)	16.9 ± 10.4	1.9 (−4.6; 8.4)	15.9 ± 13.5	3.4 (−4.1; 11.0)
Neck pain (NRS)	Usual care	6.3 ± 2.0	3.5 ± 1.9	-	2.7 ± 1.8	-	3.0 ± 2.2	-
	Early HEP	7.0 ± 2.0	2.5 ± 2.5	−1.7* (−3.4; −0.5)	2.9 ± 2.7	0.1 (−1.7; 1.8)	2.9 ± 2.9	−0.7 (−2.7; 1.2)
Arm pain (NRS)	Usual care	5.5 ± 2.7	3.1 ± 2.9	-	3.1 ± 3.2	-	3.1 ± 2.8	-
	Early HEP	7.0 ± 2.3	2.9 ± 2.8	−1.6 (−3.7; 0.4)	3.4 ± 2.6	−0.8 (−2.7; 1.2)	4.0 ± 3.0	−0.3 (−2.6; 1.9)
Physical health (SF-12)	Usual care	31.7 ± 11.4	33.9 ± 10.6	-	39.8 ± 12.0	-	42.6 ± 11.5	-
	Early HEP	29.1 ± 8.4	34.0 ± 11.7	2.2 (−3.9; 8.4)	35.4 ± 13.4	−3.5 (−12.6; 5.7)	38.7 ± 12.5	−1.6 (−8.1; 4.9)
Mental health (SF-12)	Usual care	38.5 ± 10.7	46.6 ± 10.3	-	47.9 ± 12.8	-	49.0 ± 7.7	-
	Early HEP	38.3 ± 13.5	44.0 ± 13.1	−2.5 (−11.5; 45.4)	45.5 ± 14.4	−1.9 (−12.5; 8.7)	42.1 ± 13.3	−6.3 (−14.5; 1.9)

Regression (beta [95% CI]) results were obtained from multivariate linear regression with adjustment for baseline (preoperative) outcome score and number of comorbidities.

**Significance at P value less than 0.05.*

CI indicates confidence interval; HEP, home exercise program; NDI, Neck Disability Index (range = 0–50, higher scores reflect higher disability, minimal clinically important difference [MCID] = 7.5); NRS, Numeric Rating Scale (range = 0–10, higher scores reflect higher pain, MCID = 2.6); SF-12, Short Form Health Survey (range = 0–100, higher scores reflect higher health, MCID = 8.1 for physical health and 4.7 for mental health).

DISCUSSION

An early HEP was found to be acceptable, appeared safe, and offered an immediate benefit in neck pain. This pain modulating effect was not maintained at the 6- and 12-month follow-up timepoints. Early HEP participants were, however, less likely to be taking opioid medication at 12 months. Disability, arm pain, and physical and mental health were comparable between groups. These results appear to indicate that exercise during the immediate postoperative period is a potentially safe nonpharmacologic approach to postoperative pain management.

The early HEP was acceptable to study participants through high ratings on helpfulness and likelihood to recommend the program. None of the participants felt the efforts outweighed the benefits. Moreover, most (80%) participants in the current trial felt initiating exercise within 2 weeks after surgery was ideal. The dominant preference for early exercise initiation is a possible reason for 13 of the 15 participants adhering to the program. Patient preference is an important component of patient-centered medicine and shared decision making.[42] In nonoperative settings of patients with neck and back pain, preferences can shape expectations of benefit from exercise.[43,44] A greater understanding of preference and expectation for postoperative management is needed in patients undergoing ACDF.

The most common time to begin PT is 4 to 6 weeks after ACDF,[9] likely reflecting safety considerations. The current study, however, offers preliminary data on early exercise safety. In addition to the lack of group differences in fusion status, no participants required revision surgery for pseudarthrosis and there were no differences in neck pain that would suggest a higher rate of symptomatic pseudarthrosis in the early HEP group. Abbott *et al*[22] conducted a randomized trial of an early progressive psychomotor therapy program after lumbar fusion and found no increased risks in reoperation or pseudoarthrosis. In an observational cohort study, Machino *et al*[19] initiated early daily motion exercises immediately after cervical laminoplasty and found early mobilization may have contributed to preserved cervical alignment and motion. In other orthopedic populations, Villalta and Peiris[45] conducted a systematic review of early aquatic mobilization after shoulder, hip, and knee surgeries and found no increased risk and a potential benefit on physical functioning. Collectively, our pilot work and these previous studies show early rehabilitation strategies may be appropriate immediately after surgery. Further work is needed to confirm the safety of early post-ACDF exercise.

To date, one trial has examined the effect of postoperative exercise after ACDF. Wibault *et al*[13] compared a structured PT program that delivered neck-specific exercises and cognitive-behavioral strategies starting 6 weeks after surgery to usual care. Both the current pilot study and the trial by Wibault *et al*[13] showed no differences in primary outcomes at 6 months with intent-to-treat analyses. The current pilot study did report an immediate benefit in neck pain following the early HEP at 6 weeks. The immediate pain effect in the early HEP group compared to usual care was small and was not maintained at 12 months. Interestingly, secondary outcomes related to patient perceptions of the importance of changes after intervention were favorable in both studies. Wibault *et al*[13] suggest that these outcomes

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may capture domains not currently represented in the other measures.

Lower opioid utilization was found at 12 months for the early HEP compared to usual care. This finding may be due to the early introduction of pain management strategies, which may influence downstream medication use. In patients seeking nonoperative care for neck pain, Horn and Fritz[46] found early PT was associated with lower risk of receiving an opioid prescription at 1-year from the index visit compared to patients receiving late PT. Future research will need to definitively establish whether postoperative strategies can not only improve outcomes, but also suppress the overutilization of opioids.

The strengths of this study include the randomized trial design, novelty of examining an early HEP, and long-term patient-reported outcome assessment. There were notable limitations that need to be considered. First, the study was not a fully powered and definitive randomized trial. The intent of the study was to describe patient acceptability and preliminary safety and outcome effects. It is possible the lack of differences in outcome measures between the early HEP and usual care groups was due to the small sample size. In addition, treatment differences in neck pain and opioid utilization may be due to multiple outcome comparisons. This pilot project provides necessary preliminary data for larger multicenter trials to establish the safety and efficacy of early exercise for ACDF. Second, the evaluation of fusion status was determined at variable time points after surgery and at the direction of the evaluating surgeon. Only 17 patients received imaging appropriate for fusion determination. Although this evaluation likely reflects current surgeon practice, a standardized approach for determining fusion will be needed to properly evaluate safety. The safety findings of the current pilot study should be interpreted with caution. Third, adherence was determined with a written exercise diary and weekly phone calls. Written diaries are a common adherence strategy, however, may not be as accurate compared to other methods.[47]

CONCLUSION

An early HEP program was found to be acceptable to patients and has the potential to be safely implemented during the immediate postoperative period. Pilot study findings suggest that exercise may be an effective pain management approach in the short-term, with potential for long-term reductions in opioid utilization.

➢ Key Points

- ❑ There is no consensus on the value or optimal timing of postoperative rehabilitation after ACDF.
- ❑ An early self-directed HEP performed within the first 6 weeks after surgery may be an acceptable and safe rehabilitation option for improving pain and disability outcomes.
- ❑ An early HEP is acceptable to patients with high levels of helpfulness and perceived benefits.
- ❑ An early HEP appears safe with no increased risk for adverse events, fusion status, or revision surgery.
- ❑ An early HEP may offer immediate pain-reducing benefits, with potential for mitigating long-term opioid use.

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