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Automated, Internet-based Pain Coping Skills Training to Manage Osteoarthritis Pain: A Randomized Controlled Trial

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Osteoarthritis (OA) is a leading cause of disability in the United States and globally, [14; 39] and the burdens it causes are expected to increase as the world's population ages [14; 23]. Non-pharmacological treatments are a recommended component of current guidelines for treating OA pain [53]. Although evidence is mixed that people benefit from non-pharmacological treatments such self-management interventions and patient education [e.g., 17; 25; 38; 45], one non-pharmacological therapy—pain coping skills training (PCST)—has demonstrated more consistently positive outcomes [38]. PCST focuses specifically on

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educating people about cognitive and behavioral pain coping skills and helping them master those skills so they can become more actively involved in managing their pain--the most common and debilitating OA symptom [33]. It includes two main components: 1) a rationale linking pain to patterns of cognitive, emotional, and behavioral pain responses, and 2) training in skills such as attention diversion (e.g., relaxation), cognitive restructuring (to address catastrophizing and other maladaptive cognitive patterns), and activity patterns (e.g., activity-rest cycling). It has traditionally been delivered in-person by a trained therapist over 10-12 weeks. Randomized controlled trials demonstrate that PCST significantly improves pain and other outcomes [e.g., 24; 29; 30; 31; 63]. Moreover, interventions such as PCST have fewer adverse effects than pharmacological pain treatments and are well-received by patients.

Thus, research supports the efficacy of in-person PCST. However, access to this intervention is limited by barriers such as lack of trained therapists, the substantial resources needed to deliver it, and the need for people to travel to in-person training held at scheduled times [22; 59] There is a clear need for an approach that makes PCST more accessible. The Internet—a proven method for delivering behavioral interventions—provides an avenue for meeting this need [15; 42; 58; 65], especially given older adults' increasing use of the Internet [69].

The present pilot study was a two-arm randomized controlled trial conducted to evaluate the potential efficacy and acceptability of an eight-week, automated, Internet-based version of PCST called PainCOACH. This program was designed to retain key therapeutic features of the in-person PCST protocol, simulating in-person PCST while presenting training in an easy-to-use format with guided instruction, individualized feedback, interactive exercises, and animated demonstrations [57]. We hypothesized that: (1) PainCOACH would reduce pain (primary outcome) and improve pain-related interference with functioning, pain-related anxiety, self-efficacy for pain management, and positive and negative affect; and (2) acceptability would be high. Our overarching goal was to use findings from this early-stage research to refine the program and study protocol in preparation for a larger-scale trial.

Additionally, we explored sex differences in responses to PainCOACH, based on evidence in our own lab and others showing significant sex differences in pain, pain responses, pain behavior, and pain coping in people with OA [e.g., 1; 19; 27; 32; see 54; 62; 67]. The potential for men and women to respond differently to pain interventions is important but rarely evaluated in research.

Methods

Participants

Participants were recruited from two study sites from October 2012 to May 2013. At the University of North Carolina at Chapel Hill (UNC), individuals with knee or hip OA were recruited for screening from the Johnston County Osteoarthritis Project (JoCo OA), a community-based cohort of non-institutionalized men and women from six townships in Johnston County, North Carolina. This area is largely rural and, on average, low income [26], suggesting that these participants might have low access to services such as in-person PCST. The JoCo OA study established OA using radiographs with Kellgren-Lawrence (KL)

radiographic grade of 2 or more in at least one knee or hip and affirmative responses to the following question for each joint separately: “On most days, do you have pain, aching, or stiffness in your [right, left] [knee, hip].” Symptomatic OA required the presence of pain, aching or stiffness and radiographic OA in the same joint. At Duke University Medical Center, potentially eligible individuals were identified for screening using medical or research records. They were individuals with clinically confirmed OA in one or both knees and/or hips who received care through Duke medical or surgical clinics or the Duke Pain and Palliative Care Clinic. Two additional individuals at Duke were recruited through participant referrals; their OA diagnosis was verified by their physicians. Screening was implemented with a telephone screening interview conducted by trained staff at the potential participant’s study site.

Inclusion/exclusion criteria

Participants were adults (≥18 years old) with knee or hip OA, confirmed radiographically (KL grade ≥2, with pain in the affected joint), with American College of Rheumatology clinical criteria [3; 4], or by their physician. They had to speak English and report having frequent OA pain (defined as pain on most days of the month for each of the prior three months). Individuals were excluded from participating if they had significant cognitive impairment (3 or more incorrect responses on a validated six-item screener) [9]; less than 7th grade reading proficiency (three-item health literacy screener) [10]; or medical comorbidities that interfered with their ability to complete the intervention or that indicated they had a pain-related condition in addition to OA (uncorrectable moderate or severe hearing or vision deficits, Parkinson’s disease, cancer pain, rheumatoid arthritis, fibromyalgia, diabetic neuropathy, arthroscopic surgery or total knee- or hip- replacement surgery in the past six months, fractures in the past six months, history of falls in the past three months, or vertigo in the past month).

Trial design and randomization

This study used a multi-center, balanced (1:1) randomization, assessor-blinded, parallel-group design. It included assessments at baseline (prior to randomization), midway through the intervention period (midpoint assessment), and after completion of the intervention (post-intervention assessment, approximately 9 to 11 weeks after randomization). The midpoint assessment was included to evaluate the possibility that participants could begin experiencing benefits before completing the full program. The study was registered at ClinicalTrials.gov (registration number: NCT01638871).

Randomization was implemented using computer-generated permuted block randomization (with random block sizes varying from 2 to 12) stratified by sex and site. Participants were randomly assigned to one of two treatment conditions (PainCOACH or assessment only control) using a 1:1 ratio. Sequentially-numbered opaque envelopes were used to conceal allocation until after the baseline assessment.

Study flow

Figure 1 shows a CONSORT flow diagram depicting participants’ progression through the study design. As shown, 400 individuals were approached for recruitment into screening. Of

the 131 who declined screening, 21% of them (*n*=28) provided information that indicated they would have been ineligible (e.g., a reason for declining that involved having no arthritis, little or no joint pain in hips/knees, serious hearing/vision problems, self-reported low literacy, recent or scheduled hip/knee surgery, or a health problem that would exclude them). The remaining 103 gave one or more reasons for declining screening, mostly involving not having time (*n*=33), health problems (*n*=28), not being interested (*n*=25), and not wanting to use a computer (*n*=24). Potential participants who declined screening or enrollment were significantly older than those who agreed to screening and/or enrollment (*M*=72.6, *SD*=8.8 vs. *M*=69.0, *SD*=9.8, respectively, p=.001) and men tended to be more likely than women to decline (38.1% of men vs. 27.6% of women; *p*=.05). There were no significant race/ethnicity differences in agreement to be screened.

Of the 269 individuals who completed screening, 139 were not eligible. Because screening ended after certain ineligibility criteria were met, it is not possible to report all reasons for ineligibility. However, hip/knee pain was the first criterion in the interview and 53% of those screened reported insufficiently frequent arthritis pain in their hips or knees to be eligible. In addition, 10 individuals were eligible but declined to continue, 3 were lost to follow-up after screening, and 4 did not attend the baseline visit at which enrollment occurred and could not be rescheduled. Thus, 113 participants were enrolled, completed the baseline assessment, and were randomized to the PainCOACH group (*n* = 58) or assessment only control group (*n* = 55). The unequal group sizes resulted from our use of blocking in the randomization. The attrition rate from baseline to post-intervention was 3.5%; two participants did not attend their post-intervention visit and then could not be contacted to reschedule, one did not complete the post-intervention assessment because of a painful shoulder condition and impending surgery, and one was withdrawn from the study due to serious illness. Five PainCOACH participants did not complete some (*n*=2) or all (*n*=3) intervention sessions but did complete the post-intervention assessment. Accordingly, their post-intervention data were analyzed (i.e., we used an intent-to-treat approach). Participants who completed study activities did not differ significantly from non-completers (those who dropped out of the study or who did not complete all PainCOACH sessions) on any sociodemographic, medical, or outcome variable.

Procedures

Trained research staff telephoned potential participants for recruitment into the screening protocol. A scripted description was used to explain that the study was for people with arthritis pain in their hips or knees and that it focused on teaching people to use pain coping skills using a computer program. The time commitment was explained, as was the fact that a tablet computer would be loaned to people who needed it. Participants who were eligible based on screening and who agreed to continue were scheduled for an in-person baseline visit at their study site.

The baseline visit took place at participants' study site and began with informed consent procedures. After signed consent was obtained, a blinded, trained staff member led participants through completion of the baseline questionnaire. Following completion of the questionnaire, the staff member revealed participants' randomized study assignment,

becoming unblinded in the process, and provided instructions appropriate to the assigned treatment condition. For PainCOACH participants, those instructions included receiving a loaned tablet computer and being shown how to use it to access the PainCOACH program. PainCOACH participants also completed a brief supplementary questionnaire only relevant to study participants using the program. To reduce the probability of compliance problems observed in some Internet-based interventions [18; 52], the staff member then used motivational interviewing techniques [50] to ask questions designed to enhance participants' motivation to complete the entire PainCOACH program. Specifically, the supplementary questionnaire included a question asking participants to rate how important it was to them to complete the PainCOACH program. Participants who provided an answer other than "extremely important" were asked their reasons for their response and what it would take to get their response closer to "extremely important." The staff member led them in a brief discussion during which they generated reasons for completing the program, barriers to doing so, and solutions. The discussion was then summarized by the staff member in a manner consistent with a motivational interviewing approach.

Before ending the baseline visit, participants in both treatment conditions were given instructions in how and when they would complete the midpoint and post-intervention assessments. They left with a midpoint questionnaire sealed in an envelope, with instructions not to open and complete it until a staff member phoned to instruct them to do so. A date and time for that call was scheduled for approximately 5 weeks from the date of the baseline visit (corresponding to the time at which PainCOACH participants would have completed four of the eight program training modules). Participants were also asked not to tell any other staff members their randomized study assignment unless specifically asked to do so.

For the midpoint assessment, an unblinded staff member phoned participants at the scheduled time and, using scripted instructions that ensured the call would be brief and highly structured, asked them to open the midpoint assessment packet, complete the questionnaire, and return it using the postage paid return envelope provided in the packet.

The post-intervention assessment occurred in-person at participants' study sites approximately 9-11 weeks after baseline (about a week after PainCOACH participants completed the last of the program's eight training modules). Several steps were taken to ensure that the staff conducting this visit were blind to the participants' randomized study assignment. First, at the time the visit was scheduled, participants were reminded not to mention their group assignment during the visit and not to provide any information that would reveal it until specifically asked to do so. Additionally, PainCOACH participants were met by an unblinded staff member who collected their tablet computer before meeting with a blinded staff member who administered the follow-up questionnaires.

Compensation was provided to participants as follows: $40 for the baseline assessment, $40 for the midpoint assessment, and $80 for the post-intervention assessment. The study was conducted in accordance with the Institutional Review Boards of UNC, Duke University, and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (sponsor).

Treatment conditions

Internet-based PCST (PainCOACH)—Participants in this condition used the PainCOACH program, which translated an in-person PCST protocol [28] for delivery via the Internet. The translation processes used procedures designed to ensure the program retained key therapeutic components of the in-person protocol. It included eight modules completed in a self-directed manner (i.e., without therapist contact) at the rate of one per week. Each module took 35-45 minutes to complete and provided interactive training in a cognitive or behavioral pain coping skill. As in the in-person PCST protocol, participants were asked to practice each new skill after learning it. Their completion of and experiences with practices were reviewed at the beginning of the next module. A summary of the content and flow of the modules is provided in Table 1.

Participants were led through the program by a female "virtual coach" who greeted participants at the beginning of each module and provided verbal instruction, feedback, and encouragement throughout each module. Important points in her dialogue were accentuated with onscreen text or illustrated with graphics. Learning was also reinforced with theoretically-based methods drawn from social cognitive theory [5; 6], adult learning theory [36; 37], and principles of multimedia instruction [e.g., 46]. For instance, program elements based on social cognitive theory included interactive exercises to enhance mastery of new skills, persuasive arguments regarding participants' ability to complete tasks (social persuasion), and observation of similar others (characters that represented average members of the target population who modeled use of pain coping skills). The modules and other program features were accessed through a home page (see online supplement). Other features included the ability to review all or part of completed modules (e.g., accessed through a toolbox icon on the home page menu next to completed modules), optional automated practice reminders, encouraging messages, badges earned by completing training modules and selected tasks (e.g., practices), self-monitoring (i.e., a section called COACHtrack used to manage practice reminders, log and view graphs showing progress, and set/revise practice goals), and a section of the website that enabled participants to read about others' experiences using pain coping skills and to post their own experiences (COACHchat). Program modules and features were controlled by programming that used decision rules to customize participants' experience based on their responses and progress through the program (e.g., offering suggestions to practice more and tips for doing so when participant responses indicated no or little practice). Features of this programming are described elsewhere [57]; it used an "expert systems approach" in that its tailoring and algorithms were guided by the expertise of therapists with extensive experience delivering in-person PCST.

Participants accessed the program at home through a wireless high-speed broadband connection or a 4G LTE high-speed Internet connection provided by the study. They also received a companion hard-copy workbook that reviewed how to use the tablet computer and PainCOACH, provided an overview of modules and features, and included worksheets.

Assessment only (control)—Participants in this condition completed the baseline, midpoint, and post-intervention assessments on the same schedule and using the same

procedures as participants in the PainCOACH condition. They were not offered access to PainCOACH at any point during or after the study.

Primary outcome measure

Pain in the prior month was assessed with the Arthritis Impact Measurement Scale 2 (AIMS2) 5-item arthritis pain subscale [49]. Respondents reported the severity of their usual arthritis pain (1=*severe* to 5=*none*) as well as the frequency of severe pain, pain in two or more joints at the same time, morning stiffness lasting more than one hour after waking, and difficulty sleeping due to pain (1=*no days* to 5=*all days*). The first item was reverse coded and responses were summed and normalized to produce possible scores ranging from 0 to 10, with higher scores indicating greater pain. Internal reliability was adequate at all study assessments (Cronbach's alphas of .74 to .78)

Secondary outcome measures

Self-efficacy for pain management was measured with the 8-item version of the Arthritis Self-Efficacy Scale [40], which assesses participants' confidence in their ability to manage their arthritis pain and its effects on functioning on a scale from 1 (*very uncertain*) to 10 (*very certain*). Responses were averaged so that higher scores indicated greater self-efficacy. Internal reliability was good at all assessments (alphas of .89 to .93).

Pain-related interference with functioning was assessed with AIMS2 subscales relevant to lower extremity functioning [43] including mobility level (5 items), walking and bending (5 items), self-care (4 items), and household tasks (4 items). Responses for mobility level and walking and bending were provided on a scale from 1 (*no days*) to 5 (*all days*) and responses for self-care and household tasks were provided on a scale from 1 (*never*) to 5 (*always*). They were recoded as necessary then summed and normalized to produce possible scores ranging from 0 to 10, with higher scores indicating worse functioning. Internal reliability was good at all assessments (alphas of .84 to .86).

Pain-related anxiety was assessed with the 20-item Pain Anxiety Symptoms Scale [47], which measures fear of pain, cognitive anxiety, avoidance, and physiological symptoms of anxiety on a scale from 0 (*never*) to 5 (*always*). Responses were summed so that higher scores indicated greater anxiety. Internal reliability was good (α=.92, all assessments).

Positive and negative affect was assessed with the 20-item Positive and Negative Affect Scale [68], which assesses positive (10 items) and negative affect (10 items) during the past few weeks on a scale from 0 (*not at all*) to 5 (*extremely*). Responses for each subscale were summed so that higher scores indicated greater positive or negative affect. Internal reliability was good at all assessments (alphas of .87 to .89 for positive affect, alphas of .81 to .90 for negative affect).

Sociodemographics were self-reported and included participant sex, age, race/ethnicity, marital status, education, work status, and annual household income.

Medical variables included self-reported medical co-morbidities assessed with the AIMS2 comorbidities subscale [49], which asks respondents whether their health is currently

affected by 11 medical conditions (e.g., diabetes, cancer). We added three conditions (vision problems, hearing problems, and arthritis of the hand or wrist) that may affect completion of PainCOACH. Conditions endorsed as being present were summed to yield a score from 0 to 14.

Retention plan

All participants were phoned to remind them of study appointments. Additionally, because many participants had little experience using computers, participants randomized to the PainCOACH treatment condition were phoned by a trained staff member several days after baseline to verify they had been able to connect their tablet computer to the Internet and log on to the program. In addition, participants received a brief phone call to encourage continued use of the program and to resolve questions or problems that could be hindering program use if they: (1) did not sign into the first PainCOACH module within 10 days of joining the study or (2) did not sign into the next scheduled module within 10 days of completing the prior module. Of the 58 participants in the PainCOACH condition, 43.1% needed no prompts to log in, 34.5% needed one prompt, 12.1% needed two prompts, and 10.3% needed three or more prompts.

Power

This small-scale trial was not intended to have statistical power to test the efficacy of the PainCOACH program, but rather to evaluate the intervention's potential for efficacy and its acceptability. Consistent with recommendations for conducting pilot studies to inform larger trials [60], the sample size was selected to yield precise parameter estimates, including effect sizes (e.g., to inform later sample size estimation). Consequently, we report Cohen's *d* effect sizes for analyses evaluating potential efficacy regardless of the significance of the mixed models. In general, a Cohen's *d* of ≤ .20 is considered to be a small effect, .50 is considered to be a medium effect, and ≥ .80 is considered to be a large effect [12].

Statistical analysis plan

Analyses focused on evaluating the potential efficacy of the PainCOACH program (as indicated by its effects on primary and secondary outcomes) and its acceptability. *Potential efficacy* (i.e., effects on primary and secondary outcomes at post-intervention) was evaluated with linear mixed models using V. 9.2 of the SAS procedure MIXED. Before beginning these analyses, the distribution and psychometric properties of all measures were evaluated and the success of randomization was evaluated with bivariate analyses examining whether the PainCOACH and control groups differed with respect to sociodemographic variables, medical variables, or study outcomes. As a first step, initial models for each outcome examined changes in the outcome over time. Second, any covariates identified as having an effect on the outcome being evaluated ($p \leq 0.25$) were added to the models. For these analyses, some covariates were represented by dummy-coded variables, including sex, race/ethnicity (non-Hispanic White vs. other), marital status (married/partnered vs. other), education (4-year college degree or higher education vs. other), and work status (working full-/part-time vs. other). Third, the main effect for treatment condition (PainCOACH vs. control) was evaluated, followed by the interaction of time by treatment condition. Finally,

the interaction of sex by treatment condition was evaluated to examine sex differences in responses to the intervention. Analyses used an "Intent to Treat" approach because the statistical procedures used all information participants provided even if some of it was missing. As a consequence, all 113 participants were included in all analyses.

Analyses evaluating the *acceptability* of pain coping skills training to this population used descriptive statistics to examine retention, adherence (completion of PainCOACH modules), and participants' use of program features.

Results

Table 2 shows the baseline sociodemographic and clinical characteristics of the 113 participants. The sample was mostly female and married, with an average age of 67 years (range 38 to 90). Thirty-one percent were from racial/ethnic minority groups other than non-Hispanic White. Annual household income ranged from less than $15,000 to greater than $135,000; however, the median fell below the United States 2012 median household income of $51,017 [16]. Educational attainment also varied substantially; 30% of the sample had a high school education or less and 39% had a four-year college degree or more. Most participants had both hip and knee OA. Participants in the two treatment conditions did not differ at baseline in terms of sociodemographic, medical, or study outcome variables.

PainCOACH potential efficacy

Table 3 shows descriptive statistics for all outcome variables by treatment condition and time of assessment. Analyses examining the potential efficacy of PainCOACH (as indicated by its effects on primary and secondary outcomes) are described below. Although we report significance levels, this study was not designed to provide sufficient statistical power to detect expected effects. Effect sizes are therefore reported to evaluate potential efficacy.

Pain—Based on the criterion described in the statistical analysis plan, the covariates for this outcome were age, sex, and work status. Results showed a significant sex by treatment interaction, $F(1,107)=12.96$; $p<.001$. This finding led us to test a linear mixed model that included women only, retaining age and work status as covariates. (A similar model for men was not tested because of the small number of men in the study). Results revealed effects of time, $F(2,88)=8.25$, $p=.001$, and treatment condition $F(1,88)=4.99$, $p=.028$, but their interaction did not reach significance, $F(2,88)=0.93$, $p=.40$. Examination of adjusted means (see Figure 2) showed that women in the PainCOACH and control conditions did not differ in mean pain at baseline, Tukey adjusted $p=.692$. However, women in the PainCOACH condition had significant reductions in pain from baseline ($M=4.74$) to midpoint ($M=4.11$; Tukey adjusted $p=.028$) and from baseline to post-intervention ($M=4.02$; Tukey adjusted $p=.036$). The main effect of treatment and pattern of means indicated that positive effects of the intervention on pain occurred between baseline and midpoint and were maintained through post-intervention. There were not corresponding significant reductions in pain for women in the control condition (Ms=5.26, 5.06, and 4.73 for baseline, midpoint, and post-intervention, respectively), although change from baseline to post-intervention was marginally significant (Tukey adjusted $p=.09$). The Cohen's d effect size [12] for the group difference at post-intervention was .33.

Self-efficacy—The only covariate for this outcome was number of medical comorbidities. There was a significant effect of treatment such that participants in the PainCOACH condition (*M*=7.11) reported significantly higher levels of self-efficacy than participants in the control condition (*M*=6.49; Tukey adjusted *p*=.038). The time by treatment interaction was not significant, $F(2,110) = .95$, $p=.388$. Thus, collapsing across time, PainCOACH participants had higher self-efficacy for pain management. Examination of adjusted means showed that there was no group difference in self-efficacy at baseline (Tukey adjusted *p*=.925), indicating that group differences in self-efficacy emerged after the baseline assessment. Furthermore, in the control group, self-efficacy did not change over time (*M*s=6.31, 6.39, and 6.70 for baseline, midpoint, and post-intervention, respectively). In contrast, in the PainCOACH group, self-efficacy increased significantly from baseline (*M*=6.66) to post-intervention (*M*=7.52; Tukey adjusted *p*=.023), although increases from baseline to midpoint (M=7.21) and from midpoint to post-intervention did not reach significance (Tukey adjusted *p*s=.193 and .650, respectively). Taken together, the main effect of treatment and pattern of means indicated that positive effects of the intervention on self-efficacy occurred between baseline and midpoint and were maintained through post-intervention. The Cohen's *d* effect size [12] for the group difference at post-intervention was .43.

Pain-related interference with functioning—Covariates for this outcome included sex, race/ethnicity, education, income, and number of medical comorbidities. There was no significant effect of treatment, $F(1,102)=1.55$, $p=.216$. Furthermore, the time by treatment interaction was not significant, $F(2,207)=.06$, $p=.9376$, nor were any interactions between the covariates and treatment condition. The Cohen's *d* effect size [12] for the group difference at post-intervention was .13.

Pain anxiety—The covariates for this outcome included race/ethnicity, marital status, education, income, and number of medical comorbidities. The effect of treatment was not significant, $F(1,102)=1.55$, $p=.216$, nor was the time by treatment interaction, $F(2,207)=.06$, $p=.938$. The Cohen's *d* effect size [12] for the group difference at post-intervention was .20.

Negative Affect—No covariates were required for this outcome. There was no significant effect of treatment, $F(1,111)=.05$, p=.820. Furthermore, the time by treatment interaction was not significant, $F(2,214)=.23$, $p=.796$. The Cohen's *d* effect size [12] for the group difference at post-intervention was .10.

Positive Affect—The covariates for this outcome included sex and education. The main effect for treatment was not significant, $F(1,109) = 1.42$, $p=.236$; however, there was a marginally significant time by treatment interaction, $F(2,214) = 2.53$, $p=.082$. Examination of the adjusted means suggested that positive affect increased among participants in the PainCOACH condition from baseline to midpoint and post-intervention (*M*s=35.51, 36.15, and 36.30, respectively) whereas this pattern was not observed among participants in the control condition (Ms=35.49, 33.40, and 34.17, respectively). However, these differences were not significant using a Tukey adjusted *p* value. The Cohen's *d* effect size for the group difference at post-intervention was .24.

We note that the foregoing analyses did not reveal any findings that would indicate concerns about the safety of the intervention. Likewise, no adverse events occurred that were related to completion of the PainCOACH program.

PainCOACH acceptability

Of 113 participants randomized, 97% (n=110) completed the midpoint assessment and 96% (*n*=109) completed the post-intervention assessment. Attrition was 5% (*n*=3) in the control group and 2% (*n*=1) in the PainCOACH group. Among PainCOACH participants, adherence to the program was high: 53 of the 58 (91%) completed all eight training modules.

Many participants used resources provided in PainCOACH to increase engagement and learning: most used the workbook to take notes (85.5%) or complete worksheets (79.6%); 81.8% read other people's stories in COACHchat, and 25.5% shared their own stories; over half used COACHtrack to log practices (54.5%), view their progress in practices and/or self-efficacy (65.5%), change their practice goals (68.5%), manage automated practice reminders (56.4%), and record their self-efficacy (51.9%).

Discussion

This early-stage trial evaluated PCST delivered via an automated Internet intervention called PainCOACH. Results generally supported the program's promise among people with hip and/or knee OA. Overall, effect sizes ranged from trivial to medium across outcomes, with the most notable effects on pain and self-efficacy for pain management. Specifically, women who used PainCOACH reported lower pain than women in the control group, with an effect size in a range considered to be clinically significant [55; 61]. Additionally, PainCOACH users' self-efficacy for pain management increased from baseline to post-intervention compared to the control group, suggesting potential for sustained benefits. These findings, along with strong evidence for the program's acceptability, highlight the clinical promise of delivering PCST via the Internet and support continued development and evaluation of the PainCOACH program to strengthen its effects.

These findings were especially encouraging in light of the fact that participants were a racially diverse sample of older adults, some with low income, living in a rural area, and/or with little experience using computers or the Internet. Although some investigators may have concerns about using a technology-based intervention in a population like this, the number of older adults accessing the Internet is growing steadily [69] and evidence supports the general acceptability of Internet-based interventions among older adults [13; 48].

Indeed, at baseline 50% of our participants expressed a preference for learning pain coping skills at home on a computer and adherence to PainCOACH was very high: 91% of participants who began PainCOACH completed all eight modules. This finding offers a striking contrast with high rates of non-adherence observed for many other behavioral Internet interventions [see 18]. A recent review of Internet-based behavioral health promotion interventions found average adherence of about 50% [34], and a study investigating an Internet-based physical activity intervention for people with hip or knee OA

found that only 19% completed all nine intervention modules and 46% completed six modules (defined as adequate adherence) [8].

A variety of factors may have contributed to our high adherence. First, at baseline we used motivational interviewing techniques to enhance motivation to complete PainCOACH. Second, the program was designed to simulate features of in-person PCST that make it engaging and effective [57], including the sense of being understood within a responsive, empathetic relationship with a therapist. For instance, carefully crafted tailoring algorithms and wording were used to ensure that PainCOACH's virtual coach presented information and responded to participants' actions in a manner consistent with how a trained, expert therapist would do these things in person. Third, the program was designed to engage a sense of accountability [51]. For instance, the virtual coach engaged participants in interactive exercises that mimicked social interactions about important intervention activities (e.g., verifying appointments for completing subsequent modules). Fourth, we used an iterative development process to gather extensive feedback from our target audience to enhance the program's usability and content [57]. Further research will be needed to determine the extent to which these or other factors or others contributed to the unusually high adherence observed in this study.

Yet it is also the case that 23% of our potential participants declined screening because they did not want to use a computer. This finding underscores the fact that programs such as PainCOACH should not be viewed as supplanting in-person training, but rather as supplementing it by increasing access and offering an Internet-based alternative to people who prefer it. Yet, there may be ways to increase older adults' interest in trying Internet interventions even when they have concerns about using computers. For instance, they may be persuaded to try these programs if peers suggest and model their use. Furthermore, positive initial experiences with an easy-to-use Internet intervention may address some concerns about using computers and encourage continued use. In fact, preference for completing PCST on a computer increased from 50% at baseline to 62% post-intervention among participants who used PainCOACH.

Findings from this study will be used to refine PainCOACH, with the goal of enhancing its efficacy. For instance, although large percentages of participants used PainCOACH resources such as COACHchat and COACHtrack, the lowest usage was for features intended to remind participants to practice skills and to self-monitor their practices and program benefits. Improving these features to increase their use should enhance the program's efficacy [e.g., 35; 44].

We will also refine study protocols to improve our ability to evaluate the program's efficacy. For instance, we could not adequately evaluate reduction in pain among men; they had significantly lower pain than women at entry into the study, especially if they were in the control group. Accordingly, we do not believe our findings indicate that PainCOACH should only be tested among women in the future. PCST has been found to be effective in samples that include both men and women [24; 29], and although women report greater OA pain than men [66], millions of men are burdened by OA pain. Our planned larger-scale trial will use more rigorous screening to ensure participants have sufficiently high pain to require

intervention, especially in light of the fact that our participants' baseline pain scores (even women's) were somewhat lower than those reported in other OA interventions [e.g., 2; 63; 64], limiting our ability to detect improvements in pain.

Several other effects were smaller than expected. For instance, effects on pain-related interference with functioning were trivial. However, our participants' pain-related interference with functioning at baseline was low (a mean of 1.79 on a possible scale from 0-10, with lower scores indicating better functioning). Thus, on average, our participants had little pain-related impairment when they entered the study and little room for improvement. A more rigorous test will require testing PainCOACH in a sample with greater impairment. Similarly, the program's trivial effect on negative affect was unexpected, but low average levels of negative affect at baseline (a mean of less than 10 out of a possible score of 50) likely limited our ability to evaluate effects on this outcome. Effects on positive affect were stronger, albeit still small. Although not as well-studied as negative affect, this finding is interesting given growing evidence linking positive affect with adaptive cognitive, behavioral, and emotional processes [11; 20; 41].

One limitation of the study is that it lacked an attention control group. A key distinction has been made between control and comparison functions of control groups [21]. In the present study, the assessment only control group (in conjunction with rigorous methods) controlled for alternative causal explanations for study findings. It was therefore useful for evaluating internal validity in this early-stage trial. Moreover, our control group's OA treatments were not constrained or enhanced in any way, so the group's outcomes should reflect those that may occur in a community setting without access to PainCOACH. Nonetheless, a worthy goal for future work will be to use an active comparison group to evaluate effects of theorized therapeutically-active components of PainCOACH and to rule out attention and expectancy factors (e.g., a group that receives Internet-based education about OA and its treatment) [56].

A second limitation of the study is that it did not include equal numbers of men and women, precluding planned examination of sex differences. More women than men were available for recruitment in our pools of potential participants, and more men than women declined to join the study. Prior to conducting a larger-scale trial, it will be necessary to ensure the refined program and study protocol address the needs of both men and women.

Despite these limitations, this study also made strong contributions. First, PainCOACH is the only Internet-based behavioral pain intervention that we know of to focus specifically on OA pain with an automated approach designed to increase its scalability and cost-effectiveness [cf., 7]. Second, findings demonstrated the potential for an automated, Internet-based intervention to produce benefits despite involving no contact with a therapist. Third, PainCOACH's potential scalability and cost-effectiveness should make it easier to implement in clinical settings than in-person training, supporting increased clinical use of an empirically-based non-pharmacological pain therapy. Fourth, these benefits occurred in a racially diverse sample of older adults, including many low income individuals and those living in a rural area, suggesting that PainCOACH could reach people whose access to interventions is currently limited. Fifth, adherence to this automated program was

exceptionally high, suggesting that participants valued their experience with the program and found it engaging. This is especially notable given that many of our participants had little prior experience with computers or the Internet. The contributions came from a study using an initial version of PainCOACH, which will now be refined to make it more efficacious prior to evaluating it in a larger-scale trial. Some important unanswered questions to address in the future include: 1) What are longer-term effects of the intervention?; 2) Can the number of PainCOACH modules be reduced without sacrificing efficacy?; 3) How can use of the program's features (e.g., COACHtrack) be improved?; 4) What is the best way to integrate the program into clinical care?; and 5) Does the program's impact differ by participant sex?

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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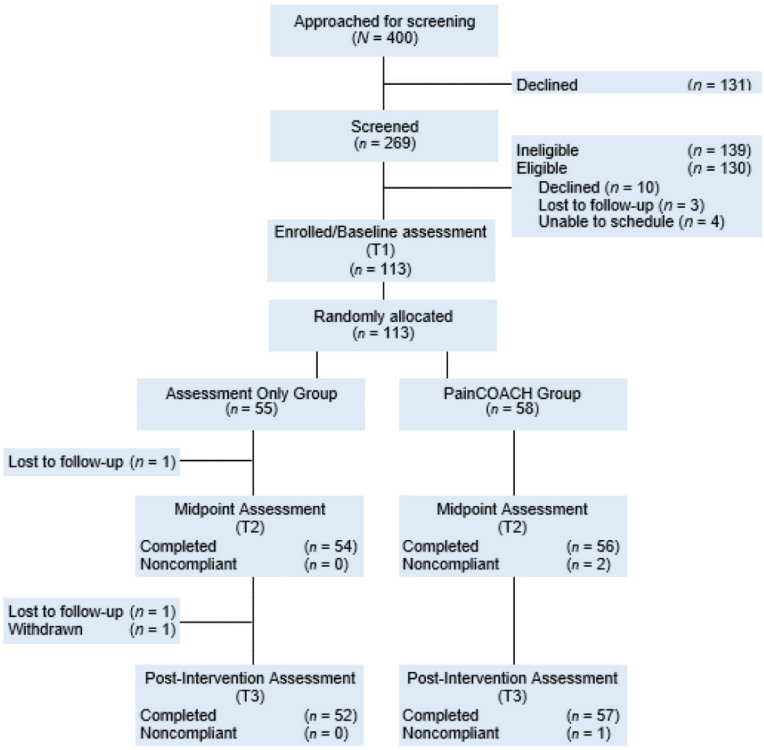

Fig. 1.
Flowchart of trial.

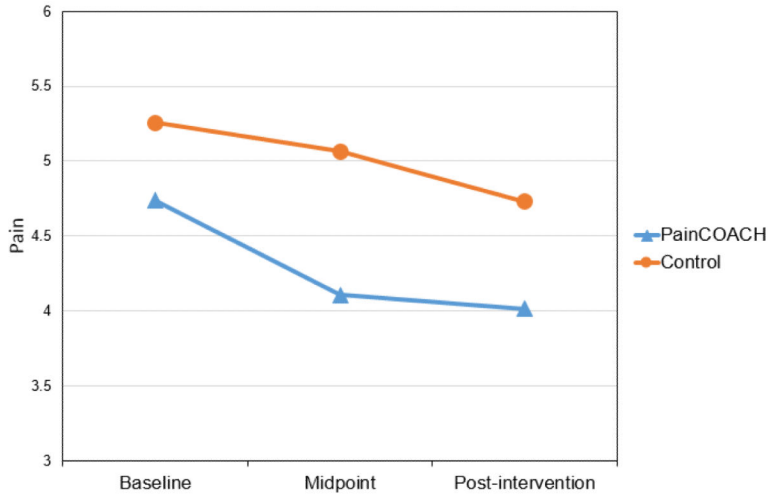

Fig. 2.

Pain scores at baseline, midpoint, and post-intervention by randomized study condition

Table 1

Summary of PainCOACH Modules

	Coping Skill	Content
1	Progressive muscle relaxation	• Introduce program and concept of pain coping skills • Therapeutic rationale (how thoughts, feelings, and actions affect pain through pain "gate") • Introduce progressive muscle relaxation • Exercise: Provide opportunity to practice progressive muscle relaxation • Help user identify positive aspects of experience to reinforce use of skill • Help user identify and address barriers to use of skill • Describe importance of regular practice and how to set up practice reminders • Set practice goal
2	Mini-practices	• Review progressive muscle relaxation and practices completed in prior week • Introduce "mini-practices" (brief relaxation) • Exercise: Provide an opportunity to do sitting and standing mini-practices • Help user identify positive aspects of experience to reinforce use of skill • Help user identify and address barriers to use of skill • Describe how to set up practice reminders and set practice goal
3	Activity/rest cycling	• Review mini-practice and practices completed in prior week • Introduce activity/rest cycling • Exercise: Identify activities user tends to overdo • Vicarious learning: Demonstrate how others have changed overdone activities • Exercise: Create personal plan to use skill that fits personal activities and goals • Discuss how other skills help with use of this one • Set practice goals for this skill and review practice goals for other skills
4	Pleasant activity scheduling, Negative automatic thoughts	• Review activity/rest cycling and practices completed in prior week • Introduce pleasant activity scheduling • Exercise demonstrating how to select and add pleasant activities to routine • Schedule 3 pleasant activities for week • Problem-solve barriers with interactive vicarious learning exercise • Introduce concept of negative automatic thoughts • Exercise demonstrating how to identify negative automatic thoughts • Set practice goals for week and review practice goals for other skills
5	Negative automatic thoughts, Coping thoughts	• Review pleasant activity scheduling and practices completed in prior week • Continue lesson on automatic thoughts, then introduce concept of coping thoughts • Exercise: Identifying negative thoughts and reactions to them • Exercise: Creating coping thoughts to address negative thoughts • Exercise: Identify and address circumstances that hinder use of skill • Set practice goals for week and review practice goals for other skills
6	Pleasant imagery and	• Review coping thoughts and practices completed in prior week

	Coping Skill	Content
	other distraction techniques	• Introduce pleasant imagery and other distraction techniques • Provide an opportunity to practice pleasant imagery and explore experience • Exercise on identifying negative thoughts and reactions to them • Set practice goals for week and review practice goals for other skills
7	Problem Solving	• Review pleasant imagery, distraction, and practices completed in prior week • Introduce concept of problem solving • Demonstrate problem solving, illustrated by stories told by other people • Exercise: Select skills for different situations, with personal plan for overcoming barriers • Set practice goals for week and review practice goals for other skills
8	Monitoring for maintenance	• Review content of all modules • Exercise: Evaluate skill use and helpfulness, including comparison with others' experiences • Exercise: Develop plan for maintaining use of skills • Present rationale to motivate continued practice and skill development • Review practice goals for skills

Table 2

Sociodemographic and clinical characteristics of sample

Variable	PainCOACH (*n*=58)	Assessment Only (*n*=55)	Total (*n*=113)
Age (years)			
Mean (*SD*)	68.52 (7.65)	66.67 (11.02)	67.62 (9.45)
Sex (*n*)			
Female	46 (79%)	45 (82%)	91 (81%)
Male	12 (21%)	10 (18%)	22 (19%)
Ethnicity (*n*)			
Not Hispanic/Latino	51 (88%)	50 (91%)	101 (89%)
Hispanic/Latino	7 (12%)	5 (9%)	12 (11%)
Race (*n*)			
White	38 (66%)	41 (75%)	79 (70%)
African American/Black	20 (35%)	13 (24%)	33 (29%)
Other race	0 (0%)	1 (2%)	1 (2%)
Marital status (*n*)			
Married/partnered	36 (62%)	34 (62%)	70 (62%)
Widowed	12 (21%)	11 (20%)	23 (20%)
Single/divorced/separated	10 (18%)	10 (19%)	20 (18%)
Work status (*n*)			
Retired	34 (59%)	34 (62%)	68 (60%)
Working full-/part-time	13 (22%)	11 (20%)	24 (21%)
Other	11 (19%)	10 (17%)	21 (19%)
Highest education level completed (*n*)			
Less than high school	4 (7%)	4 (7%)	8 (7%)
High school	13 (22%)	13 (24%)	26 (23%)
Partial college/trade school	17 (29%)	19 (35%)	36 (32%)
4-year college education	17 (29%)	13 (24%)	30 (27%)
Graduate/professional degree	7 (12%)	6 (11%)	13 (12%)
Annual household income (Median)	$30,000-$44,999	$30,000-$44,999	$30,000-$44,999
Medical comorbidities (number)			
Mean (*SD*)	1.34 (1.02)	1.31 (1.05)	1.33 (1.03)
Osteoarthritis (*n*)			
Knee	18 (33%)	22 (38%)	40 (35%)
Hip	9 (16%)	5 (9%)	14 (12%)
Both	28 (51%)	31 (53%)	59 (52%)

Note: Percentages for some variables do not sum to 100% due to rounding. Participants randomly assigned to the two study groups do not differ significantly on any listed variables.

Table 3

Descriptive statistics for primary and secondary outcomes by treatment condition over time

	PainCOACH			Assessment Only		
Variable	**Men (*n*=12) Mean (*SD*)**	**Women (*n*=46) Mean (*SD*)**	**Total (*n*=58) Mean (*SD*)**	**Men (*n*=10) Mean (*SD*)**	**Women (*n*=45) Mean (*SD*)**	**Total (*n*=55) Mean (*SD*)**
Pain						
Baseline	4.79 (1.71)	4.82 (1.75)	4.82 (1.73)	3.60 (1.26)	5.46 (1.74)	5.12 (1.81)
Midpoint	4.41 (1.92)	4.14 (1.63)	4.20 (1.68)	2.65 (1.20)	5.23 (1.92)	4.75 (2.07)
Post-intervention	4.13 (2.32)	4.06 (1.92)	4.07 (1.99)	3.50 (1.92)	4.85 (1.69)	4.62 (1.79)
Pain-related functioning						
Baseline	1.23 (.96)	1.82 (1.36)	1.70 (1.30)	1.69 (1.09)	1.94 (1.02)	1.89 (1.03)
Midpoint	1.78 (1.36)	1.73 (1.24)	1.74 (1.25)	1.26 (1.06)	1.94 (1.07)	1.82 (1.09)
Post-intervention	1.18 (.79)	1.73 (1.25)	1.62 (1.19)	1.28 (1.19)	1.85 (1.24)	1.75 (1.24)
Pain anxiety						
Baseline	19.00 (14.21)	28.83 (20.68)	26.79 (19.81)	32.70 (22.54)	29.36 (17.35)	29.97 (18.21)
Midpoint	25.27 (15.99)	28.33 (19.36)	27.73 (18.65)	27.30 (17.18)	31.20 (17.90)	30.48 (17.68)
Post-intervention	23.35 (20.23)	23.18 (16.67)	23.21 (17.29)	29.56 (16.09)	26.93 (17.41)	27.39 (17.06)
Negative affect						
Baseline	10.00 (6.12)	9.85 (6.55)	9.88 (6.41)	9.50 (5.78)	9.83 (7.20)	9.77 (6.92)
Midpoint	9.45 (5.28)	9.02 (6.67)	9.11 (6.38)	8.90 (6.24)	9.23 (8.87)	9.17 (8.39)
Post-intervention	8.92 (6.60)	8.00 (6.23)	8.20 (6.26)	9.44 (4.80)	8.79 (9.24)	8.90 (8.60)
Positive affect						
Baseline	37.42 (7.39)	35.18 (8.11)	35.64 (7.95)	32.40 (10.72)	36.05 (7.45)	35.39 (8.15)
Midpoint	34.27 (7.64)	36.61 (7.08)	36.15 (7.18)	31.10 (10.10)	33.79 (8.88)	33.29 (9.08)
Post-intervention	38.17 (8.60)	35.84 (8.70)	36.34 (8.65)	31.33 (9.76)	34.88 (10.26)	34.27 (10.17)
Self-efficacy						
Baseline	7.06 (1.64)	6.55 (1.85)	6.66 (1.81)	6.06 (2.10)	6.38 (2.09)	6.32 (2.08)
Midpoint	7.31 (1.24)	7.18 (1.94)	7.20 (1.81)	6.35 (2.06)	6.39 (1.98)	6.38 (1.97)
Post-intervention	7.66 (1.70)	7.53 (2.09)	7.56 (2.00)	7.31 (1.59)	6.53 (2.10)	6.67 (2.02)

Note: Table shows unadjusted means and standard deviations.