Exercise and Auricular Acupuncture for Chronic Low-back Pain

A Feasibility Randomized-controlled Trial

Ruth F. Hunter, PhD, Suzanne M. McDonough, PhD,* Ian Bradbury, PhD,† Sarah Dianne Liddle, PhD,* Deirdre M. Walsh, PhD,* Sue Dhamija, MD,* Philip Glasgow, PhD,‡ Gerard Gormley, MD,§ Siobhan M. McCann, PhD,‖ Jongbae Park, PhD,¶ Deirdre A. Hurley, PhD,# Anthony Delitto, PhD,** and George David Baxter, PhD††*

Objectives: To evaluate the feasibility of a randomized-controlled trial (RCT) investigating the effects of adding auricular acupuncture (AA) to exercise for participants with chronic low-back pain (CLBP).

Methods: Participants with CLBP were recruited from primary care and a university population and were randomly allocated (n = 51) to 1 of 2 groups: (1) "Exercise Alone (E)"—12-week program consisting of 6 weeks of supervised exercise followed by 6 weeks unsupervised exercise (n = 27); or (2) "Exercise and AA (EAA)"—12-week exercise program and AA (n = 24). Outcome measures were recorded at baseline, week 8, week 13, and 6 months. The primary outcome measure was the Oswestry Disability Questionnaire.

Results: Participants in the EAA group demonstrated a greater mean improvement of 10.7% points (95% confidence interval, –15.3, – 5.7) (effect size = 1.20) in the Oswestry Disability Questionnaire at 6 months compared with 6.7% points (95% confidence interval, – 11.4, – 1.9) in the E group (effect size = 0.58). There was also a trend towards a greater mean improvement in quality of life, LBP intensity and bothersomeness, and fear-avoidance beliefs in the EAA group. The dropout rate for this trial was lower than anticipated (15% at 6 mo), adherence with exercise was similar (72% E; 65% EAA). Adverse effects for AA ranged from 1% to 14% of participants.

Discussion: Findings of this study showed that a main RCT is feasible and that 56 participants per group would need to be recruited, using multiple recruitment approaches. AA was safe and demonstrated additional benefits when combined with exercise for people with CLBP, which requires confirmation in a fully powered RCT.

Received for publication November 1, 2010; revised March 20, 2011; accepted June 1, 2011.

From the *Health and Rehabilitation Sciences Research Institute and School of Health Sciences; ‖Psychology Research Institute, University of Ulster; ‡Sports Medicine, Sports Institute Northern Ireland; §Department of General Practice, Queen's University Belfast, Belfast, Northern Ireland; †Frontier Science Ltd, Inverness-shire, UK; ¶School of Public Health, Physiotherapy and Population Sciences, University College Dublin, Dublin, Ireland; #Department of Physical Medicine and Rehabilitation, University of North Carolina, Chapel Hill, NC; **Department of Physical Therapy, University of Pittsburgh, Pittsburgh, PA; and ††Centre for Physiotherapy Research, University of Otago, Otago, New Zealand.

Supported by the Research and Development Office, Northern Ireland, Strategic Priority Funding and Department for Employment and Learning, Northern Ireland. The authors declare no conflict of interest.

Ruth F. Hunter and Suzanne M. McDonough are joint first authors.

Reprints: Suzanne M. McDonough, PhD, Room 1F118, Health and Rehabilitation Sciences Research Institute, University of Ulster, Shore Road, Co. Antrim, Northern Ireland, BT37 0QB (e-mail: s.mcdonough@ulster.ac.uk).

Key Words: exercise, auricular acupuncture, chronic low-back pain, randomized-controlled trial, feasibility trial

(*Clin J Pain* 2012;28:259–267)

National and European guidelines advocate that activity is undertaken alongside adequate pain control to help promote active self-management strategies during recurrent exacerbations of chronic low-back pain (CLBP).[1,2] However, results from an European survey on chronic pain found that 79% of people experienced pain from activity and 64% described their medication as inadequate.[3] In addition, there is evidence that adherence to exercise-based treatment programs is often poor due to ongoing and exercise-induced exacerbations in pain.[4–7]

International evidence supports the use of acupuncture as an adjunct to usual care for people with CLBP[2,8–10] and it is 1 of 3 treatments (along with manual therapy and supervised exercise) recently recommended for CLBP in the UK National Institute for Health and Clinical Excellence guidelines.[2] Despite such recommendations, the effect of acupuncture when combined with the other treatments (eg, supervised exercise) is unclear.[2] A novel, potentially cost-effective way of combining acupuncture with supervised exercise is the use of auricular acupuncture (AA) which has certain advantages. It is relatively quick and easy to administer, and allows the patient to self-treat at home as the needles can remain in situ for more than 7 days.[11] AA in combination with usual care has previously been shown to significantly reduce pain and analgesic intake in post-operative hip and knee surgery, and in CLBP.[12–14]

Evidence supports the use of exercise-based treatment programs for CLBP,[2,6] in particular group-based programs.[15] However, to encourage adherence to such programs, there is a need for adequate pain control during exercise.[3–7] AA may be a useful adjunct to exercise in managing CLBP, as it provides pain relief while allowing people to continue with their daily activities. There is currently only limited evidence of the effects of AA for CLBP. Furthermore, to date, there have been no studies examining the adjuvant effect of AA when used alongside an evidence-based exercise program. Given the convenience of AA, coupled with a group-based exercise program, it may be possible that this adjuvant intervention could be a potential cost-effective treatment.

The aim of this study was to test the feasibility of a randomized-controlled trial (RCT) to investigate the

TABLE 1. Details of the Eligibility Criteria for the Study

Inclusion and Exclusion Criteria	
Inclusion Criteria	**Exclusion Criteria**
Participants with chronic ($\geq$ 3 mo) or recurrent ($\geq$ 3 episodes in previous 12 mo) LBP of mechanical origin with/without radiation to the buttocks and thighs (synonymous with mechanical LBP)	Currently or having received treatment for CLBP within the previous 3 mo
Male/female between 18 to 65 y	Red flags indicating serious spinal pathology, for example, cancer, cauda equina lesion
No spinal surgery within the previous 12 mo	Radicular pain indicative of nerve root compression*
Participants deemed suitable by their GP to carry out an exercise program	Participants diagnosed with severe spinal stenosis, spondylolisthesis, fibromyalgia
Participants deemed suitable by their GP to receive acupuncture treatment	History of systemic/inflammatory disease, for example, rheumatoid arthritis
Participants willing to attend for a 6-week treatment program of exercise and manual AA	Concomitant medical condition that contraindicates acupuncture
Fluency in English (verbal and written)	Participants with acute (< 6 wk) or subacute LBP (6-12 wk), provided that they have experienced < 3 LBP episodes during the previous 12 mo
Access to a telephone (for follow-up support)	Previously received auricular acupuncture
Participants categorized as "low" or "moderate" activity levels on the International Physical Activity Questionnaire	Participants with any confounding conditions such as a neurological disorder or currently receiving treatment for cancer
	Road traffic accident causing LBP
	History of psychological or psychiatric illness
	Participants having multiple body and/or ear piercings
	Fear of needles

*In accordance with the Clinical Standards Advisory Group[16] and the Royal College of General Practitioners Guidelines,[17,18] participants presenting with any or all of the following criteria indicative of radicular pain were excluded from the study:
unilateral pain usually worse than back pain;
pain generally radiating to the foot or toes;
numbness or paresthesia in the same distribution;
reduced straight leg raise that produces leg pain;
motor, sensory, or reflex change limited to 1 nerve root.
AA indicates auricular acupuncture; CLBP, chronic low-back pain; GP, general practitioner; LBP, low-back pain.

effectiveness of adding manual AA to an evidence-based group exercise program for people with CLBP compared with a group exercise program alone.

To determine the most effective design for a future fully powered RCT, our feasibility study had the following objectives:

(1) Identify the rate of participation and referrals from various recruitment routes;
(2) Determine recruitment and retention rate;
(3) Pilot methodological procedures;
(4) Identify participants' use of a free telephone advice and support service;
(5) Complete a qualitative exploration of trial procedures and design;
(6) Confirm training and monitoring requirements for a main trial;
(7) Determine the approximate effect size of each package.

MATERIALS AND METHODS

Ethical approval was obtained from the Northern Ireland Office for Research Ethics Committee (trial registration number 06/NIR02/68). Exercise classes were held in a purpose built gym at the Centre for Rehabilitation Research, University of Ulster, Northern Ireland.

Study Population

Individuals diagnosed with nonspecific CLBP who fulfilled the inclusion/exclusion criteria (Table 1) were recruited. As this was a feasibility trial, participants were recruited from primary care by a number of methods (retrospective General Practitioner (GP) referral, prospective GP referral, physiotherapy waiting list) and the university staff/student population (for further details see McDonough et al[19]). All participants were provided with a trial information sheet, and provided written informed consent.

Randomization

Consenting participants were randomized, by cohort, to 1 of 2 treatment groups (exercise alone or exercise and AA) using a computer-generated random allocation sequence. The trial statistician, who was not involved in the administration of treatment or collection of outcomes, generated the schedule for the random allocation sequence. The allocation sequence was held in a secure cabinet only accessible to the trial statistician. To investigate whether treatment preference had any influence on outcomes, each participant was asked which treatment he or she would prefer to receive before randomization. Due to the nature of the interventions, it was not possible to blind participants or treatment providers.

Physiotherapists

Treatment was provided by 2 chartered physiotherapists. The training that the physiotherapists undertook has been detailed previously.[19]

Interventions

Both groups received a 12-week intervention program consisting of 6 weeks supervised exercise followed by 6 weeks unsupervised exercise with telephone support. All participants were advised to continue their normal daily activities and medication but were requested to avoid all other forms of treatment during the study period.

Exercise Group

The exercise class, facilitated by chartered physiotherapists, followed a group-based format (maximum participants per cohort n = 10) similar to the "Back to Fitness" program,[20] which was also used in the UK Back Pain Exercise and Manipulation (BEAM) trial.[21] Participants attended a supervised group exercise session lasting for 1 hour a week for 6 weeks. The exercise program consisted of a 10-minute warm-up, a series of exercise stations involving core strengthening, flexibility and cardiovascular exercise, and a 10-minute cool down and period of relaxation. Each exercise station consisted of 3 levels: easy, moderate, and hard. Participants spent 1-minute at each exercise station for the first 2 weeks. This was then increased to 90 seconds per station for weeks 3 to 4, and 2 minutes per station for weeks 5 to 6. Participants were encouraged to exercise at a "somewhat hard" intensity as indicated on the Borg Rating Scale of Perceived Exertion, copies of which were displayed around the gym.[20]

The physiotherapist emphasized to participants that the supervised exercise classes were a stepping stone to self-directed activity and emphasized some of the key messages from The Back Book[22] on how to self manage their back pain; each participant received a copy of The Back Book. With the aid of the physiotherapist, each participant set short and long-term treatment goals. The aim of agreeing such goals was to gradually include activities or postures that the participant had been avoiding because of their LBP and increasing their general physical activity levels.

In addition, we reinforced this approach by using the Back Book[22] (also used in the BEAM trial), to reinforce the message to remain active despite pain, and develop positive coping strategies in the event of an exacerbation of symptoms. Messages from The Back Book[22] were placed on the walls in the gym and waiting area to reinforce key points.

The exercise class used in our study followed a group-based format based on the "Back to Fitness" program,[20] which was also used in the UK BEAM trial.[21] This exercise program is underpinned by cognitive-behavioral therapy (CBT) principles designed to change participants behavior by modifying their attitude to their LBP, that is "hurt" does not mean harm.[15,23] During the classes, the physiotherapists used these CBT principles to identify and combat illness behaviors, and to address fear-avoidance (of physical activity) behavior in particular. Each participant received a copy of The Back Book[22] (also used in the UK BEAM Trial[21]) to reinforce the message to remain active despite pain, and develop positive coping strategies in the event of an exacerbation of symptoms. Participants were encouraged to accept responsibility for determining and carrying out their weekly program of activity. Further details of the components of the exercise program were published previously.[19]

Exercise and AA Group

In addition to the procedures outlined above, participants in the EAA group also received manual AA for the first 6 weeks of the trial. Before each exercise class, participants received manual AA using conventional auricular stud needles were asked to leave the needles in for 48 hours. Stud needles consisted of a vertical shaft that inserts into the ear, and an external component that is a horizontal circular piece of metal that sits flat onto the surface of the ear; this flat circle is then covered with a small plaster (Seirin Pyonex ear needle; 1.80×0.26 mm; Seirin, Japan). For each participant receiving manual AA, a stud needle was inserted at 3 specific AA points (Shen Men, Lumbar Spine, and Cushion) (Fig. 1). The acupuncture points were chosen after a review of acupuncture textbooks and RCTs, and were tested for insertion time and safety in a pilot study (n = 5). A member of the research team monitored the acupuncture treatments on a regular basis throughout the trial to ensure correct technique and needle placement. Participants were asked to record how often they manually stimulated the stud needles and any reason for early removal (if applicable) during the 48-hour treatment period in a weekly diary during the 6-week intervention phase of the trial. In addition, participants were able to report any concerns to the physiotherapists during their weekly visit to the University.[12]

Telephone Support Helpline

After the 6-week supervised exercise program (± manual AA), participants were advised and encouraged to continue with daily self-directed physical activity, agreed with the physiotherapist. During this unsupervised exercise period, a free telephone support helpline was available for 6 weeks. This was accessible for those participants who felt they needed advice and support from the trial physiotherapists, or to answer any queries or concerns. Participants' use of the free telephone helpline was monitored to establish the value of such a service in a future RCT.

Outcome Measures

Outcome Measures Were Assessed by a Blinded Assessor

Outcome measures assessed the 5 core domains as recommended by Bombardier (2000)[24] and were collected at baseline, and by postal questionnaire at week 8, week 13, and at 6 months. The primary outcome measure was functional disability using the Oswestry Disability Questionnaire (ODQ). Other outcomes included quality of life (EuroQol 5D), low back/leg pain and bothersomeness (Visual Analogue Scale), physical activity (International Physical Activity Questionnaire, daily diary), fear-avoidance beliefs (Fear-Avoidance Beliefs Questionnaire), back beliefs (Back Beliefs Questionnaire), beliefs about Complementary and Alternative Medicine (Holistic Complementary and Alternative Health Questionnaire), self-efficacy (General Self-Efficacy Scale), and medication intake (daily diary). Self-exercise performed after the 6-week supervised exercise program was monitored by participants completing a weekly physical activity diary at week 13 and 6 months. In addition, participant expectation and satisfaction (Baseline and Exit Questionnaire) were assessed. Further details on the psychometric properties of these outcome measures are provided in the study protocol.[19]

Data Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 15.0 (SPSS Inc, Chicago, IL). Given that this was a feasibility study, significance tests

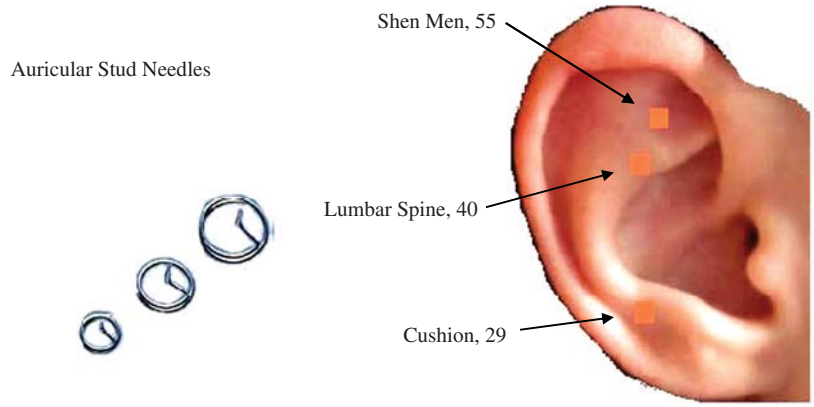

FIGURE 1. Auricular acupuncture needles and their placement on the outer ear. Image of auricular needles courtesy of Scarborough Acupuncture supplies, Somerset, United Kingdom.

were not performed or reported. Treatment effect with 95% confidence interval (CI) was estimated at each follow-up time point for the clinical outcomes.

RESULTS

Recruitment and Follow-up

Participant flow and retention are displayed in Figure 2. A total of 52 participants were recruited which included 6 cohorts, with an average of 8.5 participants per cohort. One participant was excluded from the main analyses as they did not attend baseline assessment or provide any data at the subsequent follow-up time points. Therefore, 51 participants were randomly assigned to 1 of 2 treatment groups: (1) "E Group" (n = 27); (2) "EAA Group" (n = 24). Follow-up data were obtained from 85% of participants at 6 months.

In total, 35 patients (from 10 GP practices) were referred to the trial by prospective GP referral, with 11 included (31% recruited). There was a mean of 3.5 participants identified per practice, with an average of 1.1 participants recruited and randomized per practice (practice recruitment rate = 0.01 per 1000 patients registered).

Baseline Characteristics

Table 2 shows the baseline characteristics of the 51 participants included in the main analyses. The mean age of participants was 42.8 ± 12.4 years (mean ± SD), and 63% were female. The mean duration of LBP was 9.9 ± 9 years (mean ± SD). The mean baseline score for the ODQ was 24.1 (95% CI, 21.2-27.1); this indicates a moderately functionally disabled CLBP population.

Treatment Effect

All participants (n = 51) received treatment as allocated. Table 3 presents the mean change scores (± 95% CI) from baseline for all outcome measures.

Participants in the EAA group demonstrated a mean improvement of 10.67% points (95% CI, −15.36, −5.97) in the ODQ at 6 months compared with 6.67% points (95% CI, −11.44, −1.90) in the E group. The number of participants achieving the minimal clinically important difference (MCID) (8% points) for the ODQ were similar in both groups (EAA group = 41.7%; E group = 40.7%). Participants in the EAA group demonstrated a mean improvement of 0.18 (95% CI, 0.12-0.25) in the EQ-5D (Weighted Health Index) at 6 months compared with 0.07 (95% CI, −0.02, 0.16) in the E group. This difference between groups was deemed clinically important (> 0.05 points).[25] Table 3 shows a similar trend in superior clinical benefits for the EAA group for LBP and bothersomeness, and fear-avoidance beliefs. However, there were no MCIDs observed between the groups for these clinical measures.

The majority of participants in both groups expected the exercise program to provide at least "some help" for their LBP (EAA group = 95.9%; E group = 88.9%). All participants in both groups expected the addition of AA to an exercise program to be of "great" or "some help" with a higher level of expectation expressed by those in the EAA group.

The majority of participants in both groups were "very satisfied" with the overall care they received during the course of the trial (EAA group = 89.5%; E group = 70.8%). The same trend was shown for level of satisfaction with the treatment received and the advice given during the trial. Over 90% of participants in both groups felt that the treatment they received was of at least "some benefit" for their LBP (EAA group = 94.7%; E group = 95.6%). A greater number of participants indicated a preference for the EAA group before randomization (EAA group = 54.2%; E group = 33.3%).

A greater number of participants in the E group (73.9%) thought that the treatment received had changed the number of pain relieving tablets they had taken compared with the EAA group (42.1%). The majority of participants in the E group had either reduced their tablet intake (35.3%) or stopped taking tablets altogether (52.9%) at 6 months.

Adherence

Participants attended a mean of 4 exercise classes (SD 2.11); overall attendance rate was 68.3%. Participants in the E group attended more classes (72.2% ± 36.1%) (mean ± SD) than the EAA group (64.6% ± 34.5%) (mean ± SD). Nonadherence was defined as those who failed to attend

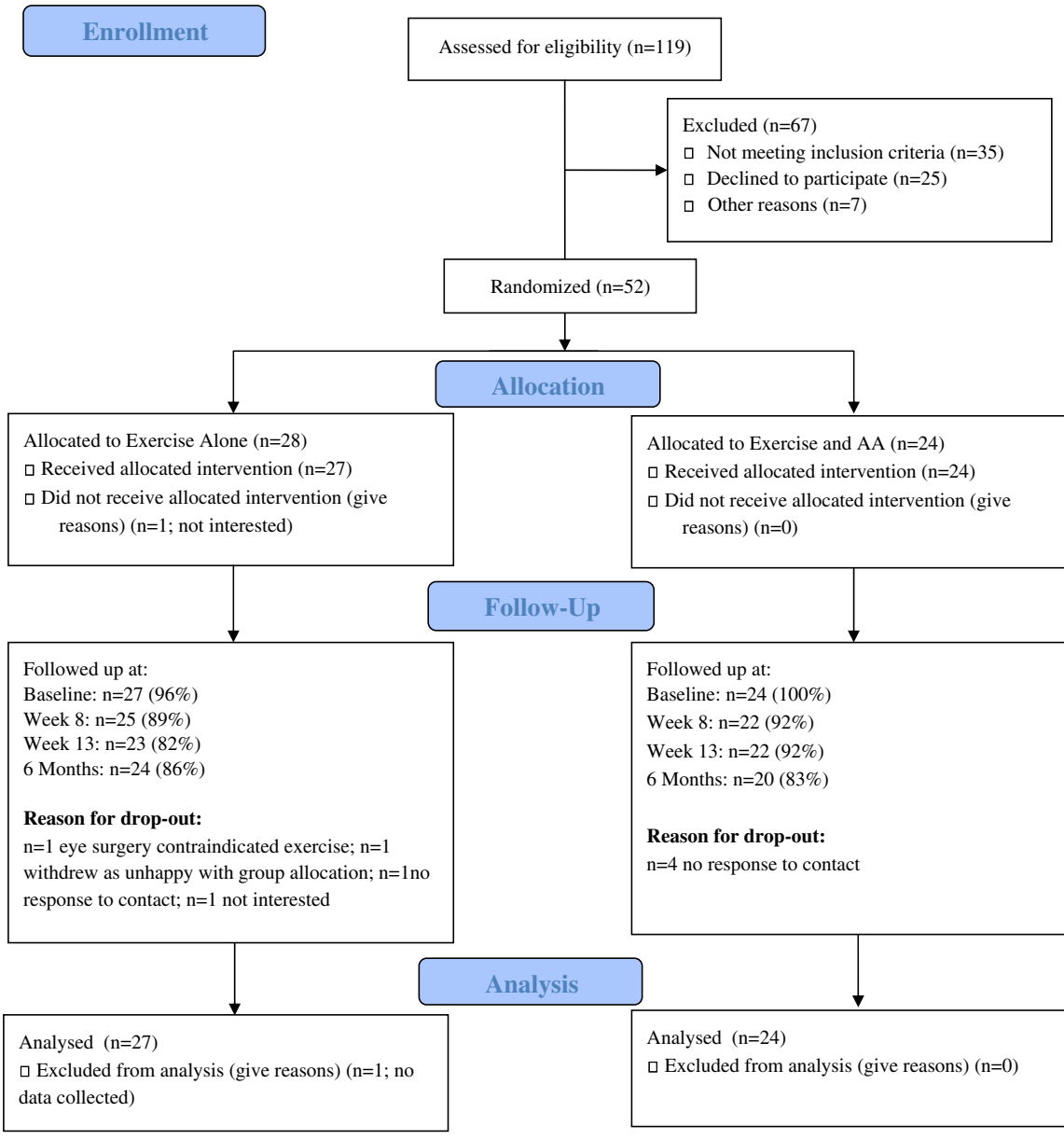

FIGURE 2. Consort flow diagram.

≥ 4 exercise classes as this was suggested as being the minimum number of classes required to show a positive outcome.[26] Those who met the criteria for nonadherence (n = 15) were younger, a smaller number of them were employed, they had a greater number of episodes of LBP in the past 6 months, and experienced pain on a greater number of days per week.

Adverse Effects

Participants recorded a number of adverse events with respect to AA that were expected, such as pain (14%), redness (2%), and minor bleeding (1%) at the site of insertion. In addition, there was n = 1 incidence of confirmed swelling around the needle insertion site, in a participant who did not disclose a history of rheumatoid arthritis (one of our exclusion criteria) during the initial screening. AA in this participant was discontinued and the swelling resolved.

Sample Size for a Main Trial

The effect size for the primary outcome measure (ODQ) for the EAA group was considerably larger than for the E group at 6 months (EAA group = 1.20; E group = 0.58). A sample size calculation using the proposed MCID of 8% points[23,27] between groups for the ODQ and the SD from this study (11.50), based on a 0.05 α level and 80% statistical power, demonstrated a sample size of 32 per group would be required for individual randomization.

TABLE 2. Baseline Demographic and Clinical Characteristics for the Study Population

Outcome Measure	E Group (n = 27)	EAA Group (n = 24)
Baseline demographics, mean (SD)		
Age (y)	43.2 (13.5)	42.4 (11.3)
Female (%)	59.25	66.67
Duration of LBP (y)	9.9 (9.0)	10.0 (9.3)
No. participants employed (%)	81	88
Episodes of LBP > 48 h in past 6 mo	4.26 (2.12)	4.33 (1.97)
Days of LBP in past week	4.04 (2.19)	4.08 (2.12)
Days sick leave	0.77 (2.16)	11.19 (35.28)
Days annual leave	1.05 (1.99)	0.29 (1.10)
Classes attended (%)	72.2 (36.1)	64.6 (34.5)
Stopped work as a direct result of LBP (%)	0	0
Government benefits (%)	3.7	0
Baseline clinical characteristics, mean (95% CIs)		
ODQ (0-100)	22.93 (18.22, 27.64)	25.51 (21.75, 29.27)
FABQ-PA (0-24)	14.26 (12.43, 16.09)	15.25 (13.19, 17.31)
BBQ (9-45)	24.74 (22.46, 27.02)	25.42 (22.95, 27.88)
VAS-LBP Intensity (0-10)	4.93 (3.98, 5.87)	4.23 (3.17, 5.29)
VAS-LBP Bothersomeness (0-10)	6.31 (5.27, 7.35)	6.25 (5.25, 7.25)
VAS-Leg Pain Intensity (0-10)	2.93 (1.68, 4.18)	1.78 (0.77, 2.80)
VAS-Leg Pain Bothersomeness (0-10)	3.47 (2.08, 4.86)	2.40 (1.09, 3.70)
EQ-5D Weighted Health Index (−0.59-1)	0.67 (0.57, 0.76)	0.68 (0.60, 0.76)
GSES (0-40)	32.00 (20.27, 33.73)	31.96 (30.37, 33.55)
HHQ-HH (5-25) subscale	9.89 (8.55, 11.23)	9.29 (8.07, 10.51)
HHQ-CAM (6-36) subscale	19.96 (18.44, 21.48)	18.79 (17.11, 20.48)
IPAQ-MET/min/wk	2933.26 (1241.42, 4625.10)	2931.10 (1289.96, 4572.25)

BBQ indicates Back Beliefs Questionnaire; CAM, Complementary and Alternative Medicine; CI, confidence interval; E, exercise alone; EAA, exercise and auricular acupuncture; FABQ-PA, Fear-Avoidance Beliefs Questionnaire-Physical Activity subscale; GSES, General Self-Efficacy Scale; HHQ-CAM, Holistic Complementary and Alternative Health Questionnaire-Complementary and Alternative Medicine; HHQ-HH, Holistic Complementary and Alternative Health Questionnaire-Holistic Health subscale; IPAQ-MET, International Physical Activity Questionnaire-MET/mins/week; LBP, low-back pain; ODQ, Oswestry Disability Questionnaire; VAS, visual analogue scale.

Using the variance inflation factor (intracluster correlation coefficient = 0.10; mean cluster size = 8.5), a sample size of 56 per group would be required for a fully powered RCT using cluster randomization.

DISCUSSION

The primary aim of this study was to test the feasibility of conducting a fully powered RCT to investigate the effects of adding AA to the "Back to Fitness" program[20] for people with CLBP. Results showed that participants in the E group maintained an improvement of 6.7% points for functional disability at 6 months follow-up, which is comparable with the findings reported in the "Back to Fitness" study.[15] In addition, results showed an increased functional benefit of 10.7% points for the EAA group at 6 months; however, this difference was not clinically important. The findings of a similar trend in clinical benefits for quality of life (which was clinically important), fear-avoidance beliefs, low back pain, and bothersomeness at 6 months for the EAA group are encouraging and support the need for further investigation of the additional benefits of AA combined with exercise for people with CLBP. Although current findings contribute to the growing body of evidence in the field of AA for musculoskeletal pain, these must be interpreted with caution given the lack of statistical power inherent in this study.

Factors to Consider When Recruiting for a Future Trial

Several investigators have highlighted problems with trial recruitment, and recommended potential strategies to overcome these.[28–30] This study piloted a number of recruitment methods to inform a future fully powered trial better. Recruiting by prospective GP referral alone was not sufficient in this feasibility trial to attain the required sample size. The use of retrospective GP referral increases the effectiveness of recruitment as it does not rely on recent patient presentation to their GP. To target GP practices for a future trial, the study should take into account those practices which have been identified as prepared and equipped to carry out research or part of a primary care research network. This would ensure that recruitment is maximized within available resources, for example, appropriately trained personnel, and office space.

Choosing an Appropriate Study Population

As previously highlighted, the study failed to demonstrate a clinically important difference between groups for the ODQ. For a future RCT, the use of a functional

TABLE 3. Mean Change Scores (95% CI) (From Baseline) for All Outcome Measures

Outcome Measure	Group	Week 8	Week 13	6 Months
ODQ	E Group	−4.80 (−7.76, −1.84)	−7.46 (−11.92, −3.00)	−6.67 (−11.44, −1.90)
	EAA Group	−6.30 (−9.61, −2.99)	−6.10 (−9.83, −2.36)	−10.67 (−15.36, −5.97)
FABQ-PA	E Group	−5.12 (−8.24, −2.00)	−6.21 (−9.63, −2.79)	−4.67 (−8.41, −0.93)
	EAA Group	−5.95 (−7.75, −4.15)	−5.71 (−7.76, −3.67)	−7.37 (−9.64, −5.10)
BBQ	E Group	−5.28 (−8.39, −2.17)	−5.71 (−9.53, −1.89)	−5.42 (−8.84, −2.00)
	EAA Group	−4.29 (−6.63, −1.95)	−4.00 (−7.42, −0.58)	−5.53 (−7.81, −3.24)
VAS-LBP intensity	E Group	−1.90 (−3.01, −0.79)	−2.12 (−3.23, −1.01)	−1.79 (−3.05, −0.53)
	EAA Group	−1.13 (−2.21, −0.06)	−0.93 (−1.98, 0.12)	−2.08 (−3.04, −1.13)
VAS-LBP bothersomeness	E Group	−2.42 (−3.66, −1.18)	−2.59 (−3.92, −1.26)	−2.08 (−3.37, −0.79)
	EAA Group	−2.16 (−3.60, −0.72)	−2.37 (−3.96, −0.79)	−3.08 (−4.79, −1.38)
VAS-Leg pain intensity	E Group	−1.83 (−3.08, −0.58)	−2.11 (−3.34, −0.88)	−1.18 (−2.35, 0.00)
	EAA Group	−0.33 (−0.85, 0.19)	−0.35 (−1.00, 0.29)	−0.02 (−1.07, 1.03)
VAS-leg pain bothersomeness	E Group	−2.05 (−3.43, −0.67)	−2.30 (−3.55, −1.04)	−1.45 (−2.71, −0.18)
	EAA Group	−0.75 (−1.22, −0.28)	−0.82 (−1.78, 0.14)	−0.31 (−1.60, 0.98)
EQ-5D weighted health index	E Group	0.06 (0.00, 0.11)	0.11 (0.04, 0.18)	0.07 (−0.02, 0.16)
	EAA Group	0.08 (0.03, 0.13)	0.05 (−0.02, 0.13)	0.18 (0.12, 0.25)
GSES	E Group	−0.44 (−1.74, 0.86)	−0.63 (−2.19, 0.94)	−0.75 (−1.83, 0.33)
	EAA Group	0.05 (−1.23, 1.32)	0.90 (−0.35, 2.16)	1.00 (−0.18, 2.18)
HHQ-HH subscale	E Group	—	—	−0.52 (−1.72, 0.68)
	EAA Group	—	—	−0.89 (−2.17, 0.38)
HHQ-CAM subscale	E Group	—	—	0.88 (−0.63, 2.39)
	EAA Group	—	—	1.05 (−0.92, 3.03)
IPAQ-MET/min/wk	E Group	−106.70 (−1405.40, 1192.00)	308.14 (−1623.90, 2240.18)	−692.13 (−2703.63, 1319.38)
	EAA Group	775.93 (−781.29, 2333.15)	−100.22 (−1270.60, 1070.16)	454.83 (−1843.18, 2752.84)

BBQ indicates Back Beliefs Questionnaire; CAM, Complementary and Alternative Medicine; CI, confidence interval; E, exercise alone; EAA, exercise and auricular acupuncture; FABQ-PA, Fear-Avoidance Beliefs Questionnaire-Physical Activity subscale; GSES, General Self-Efficacy Scale; HHQ-CAM, Holistic Complementary and Alternative Health Questionnaire-Complementary and Alternative Medicine; HHQ-HH, Holistic Complementary and Alternative Health Questionnaire-Holistic Health subscale; IPAQ-MET, International Physical Activity Questionnaire-MET/mins/week; LBP, low-back pain; ODQ, Oswestry Disability Questionnaire; VAS, visual analogue scale.

disability cutoff point at recruitment could be used to ensure that a more appropriate population (moderate-severely disabled) is recruited; this approach has been used successfully in previous RCTs [3 to 4 points on the Roland Morris Disability Questionnaire (RMDQ)[21,31,32]].

Exercise Classes

The recent National Institute for Health and Clinical Excellence guidelines[2] recommended that exercise programs for CLBP consist of a maximum of 8 sessions over a 12-week period with up to 10 people, and should incorporate aerobic activity, movement instruction, muscle strengthening, postural control, and stretching. In addition, to aid participants' adoption of a self-management approach, a "refresher class" could be offered a number of weeks postintervention.[21] This study was based on a 12-week intervention program comprising 6 weeks supervised exercise followed by 6 weeks unsupervised exercise with optional telephone support. In addition, telephone contact was made at week 13 to assess goal attainment and subsequently reset goals. The components of the exercise class incorporated findings from a previous review.[6]

Adherence

This study showed a mean attendance rate to the group exercise classes of 68%. In addition, the E group demonstrated an 8% greater attendance rate than the EAA group. This finding was not as anticipated, that is, that the addition of AA would provide adequate pain control therefore limiting exercise-induced exacerbations in pain and allowing the participant to be more adherent with exercise. One possible explanation is that the AA provided adequate pain control and the participants gained confidence and felt able to self-manage, therefore negating the need to attend the exercise classes. There is a dearth of evidence investigating adherence with exercise and advice in the CLBP population.[33] A number of strategies were used in this trial to encourage adherence with exercise including the use of Specific Measureable Achievable Realistic Timed principles to aid goal setting in conjunction with the physiotherapists, encouraging participants to monitor their own adherence with exercise, and reviewing goals at week 13.

Manual AA

As previously stated, there is a paucity of research on AA and musculoskeletal pain and further research is necessary to define adequate AA treatment parameters. In addition, the mechanism underpinning the effectiveness of AA is poorly understood and warrants further investigation. Although a small number of minor adverse effects were reported for AA during the course of the trial, these are considered minimal when compared with the reported side effects of alternative treatments such as nonsteroidal anti-inflammatories.[34] In addition, particular care needs to be taken to screen out people with rheumatoid arthritis and other inflammatory conditions due to the risk of adverse events in this group with AA.

Telephone Support Helpline

A telephone support helpline was available to participants for the 6 weeks after the completion of the supervised exercise classes; however, this helpline was not used. Qualitative exploration of this matter revealed that participants did not feel they needed it. Given the cost

implications for running such a service, its inclusion in a future trial needs to be carefully considered. However, the follow-up phone call that participants received at the end of week 13 regarding exercise adherence and goal reviews was useful and should be included in a future trial. In addition, consideration should be given to physiotherapists contacting participants by e-mail, text message, or phone call to act as a prompt for exercise.

Training and Monitoring

Physiotherapists in this study undertook 3.5 days of training in total for the exercise classes, AA and CBT principles supplemented by specially devised manuals. A future study, which would run over a longer time period should consider offering refresher training throughout the course of the trial. In addition, training DVDs for the physiotherapists and outcome assessors would aid standardization of treatment delivery. It is also worth considering monitoring approximately 10% of classes on an ad hoc basis at random time points to ensure standardized and accurate treatment delivery.

Outcome Measures

Choice of outcome measures and timing of assessment is of key importance in any trial. As this was a feasibility study, a number of outcome measures were piloted. It is important that the outcome measures chosen for the main RCT cover the 5 specific domain.[24]

The ODQ was the primary outcome measure for this feasibility study. The majority of CLBP research has used either a measure of functional disability[15,21] or quality of life[35] as the primary outcome measure. Two of the most commonly used back-specific measures are the RMDQ and the ODQ.[36] As indicated above, it has been suggested that the RMDQ is more sensitive to change in people with mild-moderate levels of functional disability due to their LBP, whereas the ODQ is more responsive to change in those who are severely disabled.[37] Therefore, the choice of primary outcome measure in the main trial requires careful consideration.

CONCLUSIONS

Activity alongside adequate pain control has been advocated to encourage self-management strategies for the treatment of recurrent exacerbations of CLBP.[1] The purpose of this study was to test the feasibility of adding AA to an evidence-based exercise program for people with CLBP. An essential requirement for the success of such a trial is a critical appraisal of the planned design and methods. This study highlighted a number of issues with regards to the choice of primary outcome measure, timing of follow-up, and eligibility criteria. In addition, given the common issue of failure to meet recruitment targets, careful consideration must be given to how GPs and participants will be recruited. Results demonstrated a trend toward increased benefit for clinical outcomes when AA is added to an evidence-based exercise program. This is encouraging and supports the further investigation of the additional benefits of exercise and AA for people with CLBP in a fully powered RCT.

ACKNOWLEDGMENTS

The authors thank the trial physiotherapists (Ms Caroline Esler, Ms Shona Pryde, Ms Susan McErlean), all the general practitioners, Whiteabbey Physiotherapy Department, the participants, and the administrative support from Mrs Glynis McBride and Mrs Jennifer Semple from Health and Rehabilitation Sciences Research Institute, School of Health Sciences, University of Ulster, Northern Ireland.

REFERENCES

1. Airaksinen O, Brox JI, Cedraschi C, et al. European guidelines for the management of chronic nonspecific low back pain. *Eur Spine J*. 2006;15(Suppl 2):s192–s300.
2. National Institute for Health and Clinical Excellence (NICE)-Low back pain: early management of persistent non-specific low back pain 2009. www.nice.org.uk/CG88.
3. Breivik H, Collett B, Ventafidda V, et al. Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. *Eur J Pain*. 2006;10:287–333.
4. Alexandre NM, Nordin M, Hiebert R, et al. Predictors of compliance with short-term treatment among patients with back pain. *Pan Am J Public Health*. 2002;12:86–94.
5. Hayden JA, van Tulder MW, Tomlinson G. Systematic review: strategies for using exercise therapy to improve outcomes in chronic low back pain. *Ann Intern Med*. 2005;142:776–785.
6. Liddle SD, Baxter GD, Gracey JH. Exercise and chronic low back pain: what works? *Pain*. 2004;107:176–190.
7. Maul I, Laubli T, Oliveri M, et al. Long-term effects of supervised physical training in secondary prevention of low back pain. *Eur Spine J*. 2005;14:599–611.
8. Furlan AD, van Tulder MW, Cherkin D, et al. Acupuncture and dry-needling for low back pain: an updated systematic review within the framework of the Cochrane Collaboration. *Cochrane Database Syst Rev*. 2005;1.
9. Manheimer E, White A, Berman B, et al. Meta-analysis: acupuncture for low back pain. *Ann Intern Med*. 2005;142: 651–663.
10. Yuan J, Purepong N, Kerr DP, et al. Effectiveness of acupuncture for chronic low back pain: a systematic review. *Spine*. 2008;33:887–900.
11. Leibing E, Leonhardt U, Koster G, et al. Acupuncture treatment of chronic low back pain—a randomised, blinded, placebo-controlled trial with 9-month follow-up. *Pain*. 2002; 96:189–196.
12. Sator-Katzenschlager SM, Scharbert G, Kozek-Langenecker SA, et al. The short- and long-term benefit in chronic low back pain through adjuvant electrical versus manual auricular acupuncture. *Anesth Analg*. 2004;98:1359–1364.
13. Usichenko TI, Dinse M, Hermsen M, et al. Auricular acupuncture for pain relief after total hip arthroplasty—a randomised controlled study. *Pain*. 2005;114:320–327.
14. Usichenko TI, Kuchling S, Witstruck T, et al. Auricular acupuncture for pain relief after ambulatory knee surgery—a randomised trial. *Can Med Ass J*. 2007;176:179–183.
15. Frost H, Klaber Moffett J, Moser JS, et al. Randomised controlled trial for evaluation of fitness programme for patients with chronic low back pain. *BMJ*. 1995;310:151–154.
16. Clinical Standards Advisory Group (CSAG). *Report on Back Pain*. London: HMSO; 1994.
17. Waddell G, McIntosh A, Hutchinson A, eds. *Low Back Pain Evidence Review*. London: Royal College of General Practitioners (RCGP); 1999.
18. Waddell G, eds. *The Back Pain Revolution*. London: Churchill Livingstone; 2004.
19. McDonough SM, Liddle SD, Hunter R, et al. Exercise and manual auricular acupuncture: a pilot assessor-blind randomised controlled trial. The acupuncture and personalized exercise programme (APEP) trial. *BMC Musculoskelet Disord*. 2008;9:31.
20. Moffett J, Frost H. Back to Fitness Programme. *Physiotherapy*. 2000;86:295–305.
21. United Kingdom BEAM Trial Team. United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: effectiveness of physical treatments for back pain in primary care. *BMJ*. 2004;329:1377–1384.

22. Roland M, Waddell G, Klaber Moffett J, et al, eds. *The Back Book: The Best Way to Deal With Back Pain—Get Back Active*. Norwich: The Stationery Office; 2004.
23. Frost H, Lamb S, Stewart-Brown S. Responsiveness of a patient specific outcome measure compared with the Oswestry Disability Index v2.1 and Roland and Morris Disability Questionnaire for patients with subacute and chronic low back pain. *Spine*. 2008;33:2450–2457.
24. Bombardier C. Outcome assessments in the evaluation of treatment of spinal disorders. *Spine*. 2000;25:3100–3103.
25. Kind P. Workshop "Measuring Health Outcomes in Today's NHS". Birmingham; 2000.
26. Klaber Moffett JA, Carr J, Howrath E. High fear-avoiders of physical activity benefit from an exercise programme for patients with back pain. *Spine*. 2004;29:1167–1173.
27. Ostelo RWJG, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine*. 2008;33:90–94.
28. Mapstone J, Elbourne D, Roberts IG. Strategies to improve recruitment to research studies. *Cochrane Database Syst Rev*. 2008;3.
29. McDonald AM, Knight RC, Campbell MK, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *BMC Trials*. 2006;7:9.
30. Watson JM, Torgerson DJ. Increasing recruitment to randomised trials: a review of randomised controlled trials. *BMC Med Res Methodol*. 2006;6:34.
31. Hurley DA, McDonough SM, Dempster M, et al. A randomised clinical trial of manipulative therapy and interferential therapy for acute low back pain. *Spine*. 2004;29:2207–2216.
32. Little P, Lewith G, Webley F, et al. Randomised controlled trial of Alexander technique lessons, exercise, and massage (ATEAM) for chronic and recurrent back pain. *BMJ*. 2008;337:884–891.
33. Middleton A. Chronic low back pain: patient compliance with physiotherapy advice and exercise, perceived barriers and motivation. *Phys Ther Rev*. 2004;9:153–160.
34. Bjordal JM, Ljunggren AE, Klovning A, et al. NSAIDs, including coxibs, probably do more harm than good, and Paracetamol is ineffective for hip OA. *Ann Rheum Dis*. 2005; 64:655–656.
35. Thomas KJ, MacPherson H, Ratcliffe J, et al. Longer term clinical effect and economic benefits of offering acupuncture care to patients with chronic low back pain. *Health Technol Assess*. 2005;9.
36. Grotle M, Vollestad N, Brox JI. Clinical course and impact of fear-avoidance beliefs in low back pain: prospective cohort study of acute and chronic low back pain: II. *Spine*. 2005;31:1038–1046.
37. Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. *Spine*. 2000;25:3115–3124.

