Challenges in Evaluating an Arthritis Self-management Program for People with Hip and Knee Osteoarthritis in Real-world Clinical Settings

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ABSTRACT. ***Objective.*** To evaluate the influence of a 6-week Arthritis Self-Management Program (ASMP) on health-related quality of life (HRQOL) and self-management skills in clinical settings.

Methods. Individuals with hip or knee osteoarthritis referred to orthopedic surgeons or rheumatologists at 6 hospitals in Victoria, Australia, were recruited. In a randomized controlled trial, participants received the Stanford ASMP and self-help book (intervention) or book only (control). Assessments included the Assessment of Quality of Life instrument (AQoL; range –0.04 to 1.00) and Health Education Impact Questionnaire (heiQ; range 1–6) at baseline and up to 12 months. The primary outcome was HRQOL at 12 months (assessed using the AQoL).

Results. Recruitment was concluded early due to persistent challenges including infrequent referrals and patient inability or disinterest in participating. Of 1125 individuals screened, only 120 were randomized (control, n = 62; intervention, n = 58). Seven ASMP were conducted while 18 scheduled ASMP were cancelled. Forty-four of 58 intervention group participants received the intervention as allocated (76%); all control group participants were sent the book (100%). Ninety-four participants (78%) completed 12-month assessments (control, 90%; intervention, 66%). There was no difference in HRQOL at 12 months (adjusted mean difference –0.02, 95% CI –0.09 to 0.05). At 6 weeks, the intervention group reported higher heiQ skill and technique acquisition scores (adjusted mean difference 0.29, 95% CI 0.04 to 0.55); however, this dissipated by 3 months.

Conclusion. Significant challenges hampered this evaluation of the ASMP. The observed lack of enthusiasm from potential referrers and patients raises doubts about the practicality of this intervention in real-world settings. (ANZCTR Clinical Trials Registry no. ACTRN12606000174583) (J Rheumatol First Release March 1 2012; doi:10.3899/jrheum.111358)

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Osteoarthritis (OA), the most prevalent form of arthritis, is increasingly prevalent and a leading cause of disability internationally[1]. OA also contributes to a substantial societal burden. In Australia, the condition accounts for over $A 1 billion annually in direct health expenditure alone[2]. The chronic nature of OA coupled with limited healthcare resources means that effective and ongoing self-management is essential.

Clinical guidelines for the management of hip and knee OA recommend self-management education programs[3,4], although evidence supporting their effectiveness is limited[5,6,7,8]. This contrasts with consistent findings of benefit following chronic disease self-management programs for hypertension, diabetes, and asthma[6,7]. More recently, a large study in the United Kingdom involving primary care patients with hip or knee OA (n = 812) reported only small improvements in anxiety and self-efficacy after a 6-week "Challenging Arthritis" self-management program[9]. Changes in pain, physical function or visits to general practitioners (GP) were not evident[9], and economic analyses showed the program was not cost-effective, with the intervention group reporting increased costs for hospital and community-based services at 12 months[10].

The overarching aim of arthritis self-management pro-

grams is to empower individuals to better manage their condition. A well-known program is the Stanford Arthritis Self-Management Program (ASMP), which is available in several formats[11,12,13]. In Australia, the ASMP is offered through arthritis consumer groups and community health centers. The program covers topics including pain management, healthy behaviors, communication with doctors, and disease-specific information[14]. Studies investigating the ASMP have had limited generalizability[15,16], often involving well-educated volunteers, and have used outcome measures that are not directly aligned with the program's goals. Therefore, the influence of the program on specific self-management skills (including appropriate self-monitoring, health-directed activities, and navigation of health services) and health-related quality of life (HRQOL) remains poorly understood. Additionally, uptake of self-management programs among people with arthritis is low[17,18,19], with limited referrals from health professionals, perhaps relating to their uncertainty regarding the clinical benefits[20,21,22]. Given the widespread availability of the ASMP, high-quality evidence is required to justify its inclusion in OA clinical guidelines and to garner clinician support. Our study aimed to evaluate the influence of the Stanford ASMP on HRQOL and self-management skills in people with hip or knee OA. As we were forced to terminate our study early, this report also describes the significant challenges and barriers faced in evaluating the ASMP in a real-world clinical setting.

MATERIALS AND METHODS

Study design. This study was a randomized controlled trial with 12-month followup (Australian New Zealand Clinical Trials Registry no. ACTRN12606000174583). The protocol has been described previously[15]. The intervention group received the standard 6-week Stanford ASMP and an arthritis self-help book, while the control group received the book only[14]. The primary outcome was HRQOL at 12 months. Participants and investigators were not blinded.

Participants. People referred to an orthopedic surgeon or rheumatologist for hip or knee OA were recruited through 4 public hospital outpatient clinics (Alfred Hospital, Austin Health, Barwon Health, and Northern Hospital) and private practices within 2 private hospital settings (Cabrini Hospital and Epworth Hospital) in Victoria, Australia. We specifically restricted recruitment to secondary or tertiary care to ensure that the study population would comprise participants who had a reasonable capacity to benefit from the intervention and be typical of the patient population that clinicians might refer to education and support programs. Patients with severe, endstage OA requiring joint replacement surgery were excluded, as described below.

Individuals were eligible to participate if they were aged 18 years or over, had a diagnosis of hip or knee OA (from radiology reports or able to be classified according to American College of Rheumatology criteria[23,24]), were referred to an orthopedic surgeon or rheumatologist, and had sufficient English language skills and vision to self-complete questionnaires and a reasonable expectation of attending the 6 sessions of the ASMP if randomized to the intervention group. Exclusion criteria included cognitive dysfunction, previous participation in an ASMP or similar education program, or placement on an orthopedic waiting list for joint replacement surgery or scheduled joint replacement surgery. After identification and preliminary screening, potentially eligible individuals were telephoned by research staff to provide detailed information about the study and complete the screening process. Eligible individuals who provided verbal consent were mailed a consent form and baseline questionnaire. Written informed consent was obtained from all participants.

Our study was approved by the Human Research Ethics Committees at each hospital and The University of Melbourne. All data collection for the study was undertaken between 2006 and 2009.

Randomization. After receipt of a completed consent form and baseline questionnaire, participants were randomized to either the control or intervention group, stratified by site. For each site, group allocation was assigned using a computer-generated random list in permuted blocks of 4 or 6. Group allocation was concealed using opaque sealed envelopes, with individual envelopes opened at the coordinating center (The University of Melbourne) by a research assistant not associated with the study and verified by an independent observer.

Intervention group. The intervention group received the 6-week Stanford ASMP, comprising one 2.5-hour education session each week. The program covers management of pain and fatigue, physical activity, managing emotions, health-related problem-solving, and communication with doctors[25]. We endeavored to build several enablers into our study design to facilitate attendance and minimize participant burden. ASMP were held in community-based and hospital locations at a range of times and reimbursement for parking/taxi/public transport expenses was offered, if required. One peer leader and 1 health professional leader led each course. To ensure optimal intervention, course leaders with appropriate training in the Stanford model were recruited. Course leaders were sent study newsletters and update e-mails to facilitate high retention rates. Participants allocated to the intervention group also received a copy of the arthritis self-help book at the ASMP[14].

Control group. The control group were mailed a copy of the arthritis self-help book[14]. No advice was given regarding use of the book. Previous research involving people with musculoskeletal conditions including OA reported no change in pain, self-efficacy, disability, or mental health following provision of this book[26].

Outcome measures. The primary outcome, HRQOL at 12 months, was chosen to identify the potential longer-term influence of the multifaceted ASMP[20]. We hypothesized that empowering individuals to better understand and manage their arthritis would improve HRQOL. HRQOL was measured using the Assessment of Quality of Life (AQoL) instrument, a generic utility tool responsive to change in people with arthritis[27]. Utility scores range from –0.04 (lowest HRQOL) to 1.00 (full HRQOL). An increase of 0.05 AQoL units was specified *a priori* as a minimally important improvement[28].

Secondary outcomes included the Health Education Impact Questionnaire (heiQ), Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index, Kessler Psychological Distress Scale (K10), and Hip and Knee Multi-Attribute Prioritisation Tool (MAPT). The heiQ was developed to provide information about specific self-management skills following chronic disease self-management programs. It is reliable and responsive[29,30] and covers 8 dimensions that score from 1 (strongly disagree) to 6 (strongly agree). The WOMAC Index is a disease-specific health status measure widely used in OA research; its validity, reliability, and responsiveness have been extensively demonstrated[31]. WOMAC pain, stiffness, and physical function scores are commonly transformed to a 0 (best health) to 100 (worst health) scale. The K10 is a measure of psychological distress[32] that produces a score ranging from 10 (lowest distress) to 50 (highest distress). The MAPT is a measure of arthritis disease severity and need for surgery that has demonstrated construct validity and test-retest reliability and responsiveness in a validation study involving over 900 people with arthritis[33]. It produces a score from 0 (least severity) to 100 (greatest severity).

Participants were mailed questionnaires at baseline, 6 weeks (heiQ and MAPT only to reduce participant burden), 3 months, and 12 months. The AQoL instrument was not included in the 6-week questionnaire as group differences in HRQOL were not expected in this period of time. Followup assessment dates were based on ASMP course starting dates (for the intervention group) or date of mailing the self-help book (control group). At each post-baseline assessment, participants were asked whether they attended an ASMP since entering the study (to detect potential contamination) and whether they had

undergone joint replacement surgery. Self-reported data on visits to health professionals during the previous month and use of community services were collected at each assessment. Reply-paid envelopes were provided to maximize response rates, and letters and/or telephone calls were used to followup nonreturned questionnaires and missing data where possible.

Sample size. Sample size calculations were as described[15]. A sample size of 600 (300 per group) was estimated to provide sufficient power ($1 - ß = 0.8$) to detect an additional 10% of intervention group participants reporting a minimal clinical improvement in HRQOL of 0.05 AQoL units. This was considered a conservative estimate of benefit.

Early termination of the study. Despite implementation of measures to maximize patient referrals, recruitment into the study was unexpectedly slow. To efficiently identify potentially eligible individuals at the public hospital sites, we used clinical staff (commonly physiotherapists) to regularly screen outpatient orthopedic and/or rheumatology outpatient records. Clinical staff were specifically funded to undertake this task. For the private hospital sites, detailed information about the study was provided to 25 orthopedic surgeons and rheumatologists, with direct and repeated followup by the study manager. Personalized referral packs were also provided to these medical specialists to minimize administrative burden. However, only 31 individuals were referred to the study by specialists at the private hospital sites (from 2 orthopedic surgeons and 1 rheumatologist) over the 22-month recruitment period.

During the recruitment period 3 further public hospital sites were added to augment recruitment, increasing the total number of sites to 6 (a seventh recruitment site was also planned). However, after almost 2 years of recruitment, our calculations indicated that the recruitment phase would need to be extended by 4 years in order to meet the target sample size. This was not considered to be feasible, as this study was publicly funded and only limited research support was available. After ethical approval, recruitment was consequently ceased in July 2008. This decision was made without knowledge of the study results and followup of randomized participants continued as planned.

Statistical analyses. Analyses were undertaken using SPSS Version 18.0. Between-group differences at 6 weeks, 3 months, and 12 months were evaluated using analysis of covariance, with adjustment for baseline score and hospital site. The planned repeated-measures analyses to evaluate the constancy of any effects of the ASMP over time were not undertaken[15]. Chi-square tests were used to determine between-group differences in the proportion of participants who reported improvement or deterioration in HRQOL (increase or decrease ≥ 0.05 AQoL units, respectively). Mann-Whitney tests were used to assess differences in visits to health professionals and use of community services between groups.

Statistical analysis was performed using all randomized participants who provided at least 1 postbaseline assessment[34]. Intervention group participants who did not receive the allocated intervention were not included in postbaseline analyses (n = 14; Figure 1), as 6-week, 3-month, and 12-month followup dates could not be calculated for these individuals.

RESULTS

Participants. Figure 1 illustrates the progress of participants from the screening phase through to the 12-month assessment. Of the 1125 individuals who were assessed for eligibility, 623 (55%) were found to be ineligible, 258 (23%) declined to participate, 118 (10%) could not be contacted, and 126 (11%) consented to take part. In total, 120 participants were randomized as part of the study: 62 to the control group and 58 to the intervention group.

While many people did not meet 1 or more of the eligibility criteria, the screening data presented in Figure 1 show that perceived difficulty in attending the 6-week ASMP was common. Overall, 216 individuals (27% of those who completed the screening process) stated they would be unable to attend 6 sessions of the ASMP.

Challenges associated with providing the intervention. In total, 7 ASMP were conducted between February 2007 and August 2008 as part of our study, while 18 scheduled courses had to be cancelled before commencement. Cancellations were commonly due to insufficient numbers resulting from slow recruitment or difficulty for participants attending a scheduled ASMP, despite these being offered at a range of venues close to where most patients lived and at a variety of times during the week.

Of the intervention group (n = 58), 44 participants (76%) received the intervention as allocated (Figure 1). Eleven participants were unable to attend an ASMP due to course cancellations or courses no longer being scheduled after cessation of recruitment. One participant did not attend any sessions of the ASMP, 1 participant was scheduled for joint replacement surgery soon after randomization, and 1 participant died before completing the ASMP (only 1 session was attended). Of those who did commence the ASMP, only 21 participants (47%) attended all 6 sessions. The median number of sessions attended was 5 [interquartile range (IQR) 4–6]. All 62 control group participants (100%) were mailed the self-help book.

Baseline characteristics. Baseline characteristics were similar for the control and intervention groups (Table 1).

Outcomes. Figure 1 shows that 12-month data were available for 94 of the 120 randomized participants [56/62 control (90%) and 38/58 intervention (66%), total 78%]. Excluding participants who did not receive the active intervention as planned (n = 14), 12-month data were available for 38/44 (86%) in the intervention group (total 94/106, 89%).

After adjustment for baseline score and hospital site, there was no between-group difference in the primary outcome of HRQOL at 12 months (Table 2). Mean AQoL score for the control group at 12 months was 0.61 (95% CI 0.55 to 0.67), compared to 0.59 (95% CI 0.51 to 0.68) for the intervention group (adjusted between-group mean difference –0.02, 95% CI –0.09 to 0.05). A similar proportion of participants in each group reported improvement in HRQOL (defined as an increase of 0.05 AQoL units) from baseline to 12 months (35% of the control group vs 32% of the intervention group; chi-square = 0.90, p = 0.64).

After adjustment for baseline score and hospital site, the intervention group reported significantly higher heiQ skill and technique acquisition dimension scores at 6 weeks (adjusted between-group mean difference 0.29, 95% CI 0.04 to 0.55); however, this was not evident at 3 or 12 months (Table 2). No between-group differences were observed for the other 7 heiQ dimensions at any timepoint, nor were there any differences between groups for HRQOL, pain, stiffness, physical function, or psychological distress at 3 or 12 months. There was no difference in arthritis disease severity at any timepoint.

Contamination. At the 6-week and 3-month assessments, none

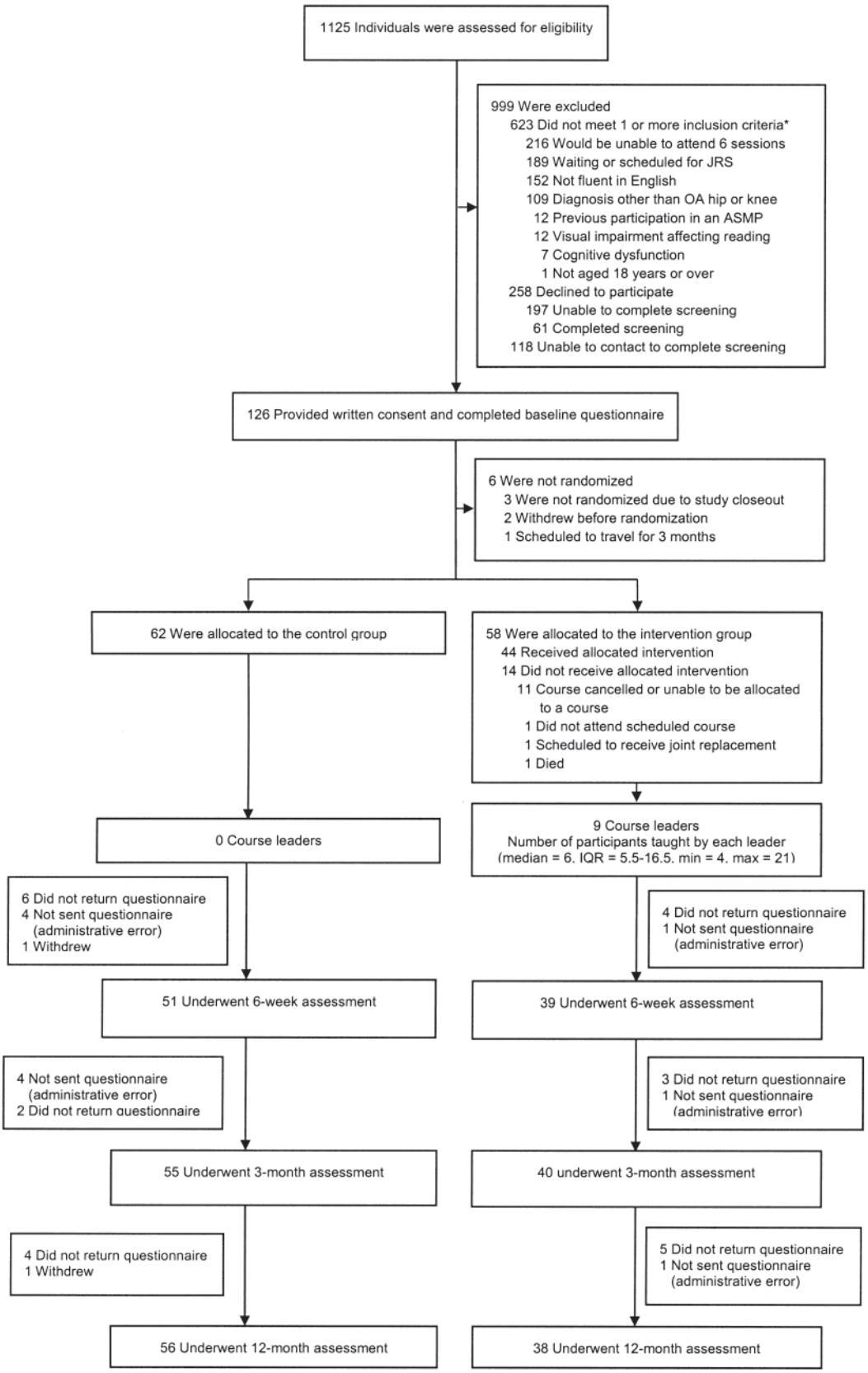

Figure 1. Flow of study participants. *Subcategories total more than 623 as some participants were excluded based on > 1 criterion. JRS: joint replacement surgery; ASMP: Arthritis Self-Management Program; IQR: interquartile range; OA: osteoarthritis.

Table 1. Baseline characteristics. Total numbers for each characteristic may not equal n = 62 or n = 58 due to missing responses.

Characteristic	Control, n = 62	Intervention, n = 58
Age, yrs, mean (SD)	66.6 (10.9)	63.5 (10.8)
Body mass index, kg/m^2, median (IQR)	29 (26–35)	30 (24–35)
Female, n (%)	36 (58)	36 (62)
Married or living with partner, n (%)	40 (65)	36 (62)
Education, n (%)		
Primary school or less	7 (12)	7 (12)
Year 7–10	27 (45)	27 (47)
Year 11–12	10 (17)	8 (14)
Trade/technical education	11 (18)	6 (11)
University	5 (8)	9 (16)
Australian-born, n (%)	42 (68)	40 (69)
Employment status, n (%)		
Paid employment	14 (23)	16 (29)
Retired	39 (65)	33 (59)
Not working due to OA or medical condition	6 (10)	4 (7)
Unemployed	1 (2)	3 (5)
Affected joint, n (%)		
Hip	16 (26)	21 (36)
Knee	42 (68)	33 (57)
Hip and knee	4 (6)	4 (7)
Visits to health professionals in previous month, median (IQR)		
General practitioner	1 (0–1)	1 (0–2)
Orthopedic surgeon	0 (0–0)	0 (0–0)
Rheumatologist	0 (0–0)	0 (0–0)
Physiotherapist	0 (0–0)	0 (0–0)
AQoL score, median (IQR), range –0.04 to 1.00	0.63 (0.47–0.78)	0.71 (0.45–0.83)
heiQ score, mean (SD), range 1.0 to 6.0		
Positive and active engagement	4.8 (0.8)	4.6 (1.0)
Health-directed activity	4.2 (0.9)	4.2 (1.0)
Skill and technique acquisition	4.4 (0.8)	4.2 (0.9)
Constructive attitudes and approaches	4.9 (0.7)	4.9 (0.9)
Self-monitoring and insight	4.8 (0.5)	4.8 (0.7)
Health service navigation	5.0 (0.6)	4.8 (0.7)
Social integration and support	4.6 (0.8)	4.7 (0.8)
Emotional distress	3.6 (1.0)	3.7 (1.0)
WOMAC score, mean (SD), range 0–100		
Pain	38.9 (20.0)	38.1 (22.2)
Stiffness	43.8 (20.5)	48.9 (23.3)
Physical function	41.4 (20.2)	40.7 (20.9)
K10 score, median (IQR), range 10–50	15 (13–19)	16 (13–21)
MAPT score, median (IQR), range 0–100	11 (3–28)	11 (3–39)

OA: osteoarthritis; IQR: interquartile range; AQoL: Assessment of Quality of Life; heiQ: Health Education Impact Questionnaire; WOMAC: Western Ontario and McMaster University Osteoarthritis Index; MAPT: Hip and Knee Multi-Attribute Prioritisation Tool; K10: Kessler Psychological Distress scale.

of the control group participants had attended an ASMP. At the 12-month assessment, 2 control group participants reported they had attended an ASMP; data from these participants were analyzed as part of the control group.

Use of health professional services. There was no difference between groups in the number of visits to GP, orthopedic surgeons, rheumatologists, or physiotherapists at 6 weeks or 3 months (Table 3). At 12 months, the intervention group reported more visits to orthopedic surgeons (total visits in previous month 13 vs 4; p = 0.02). Participants also reported seeing other health professionals (such as chiropractors and podiatrists) over the study period; however, few visits were reported for any one type of health professional, and between-group analyses were not performed.

Joint replacement surgery. At 6 weeks, 1 control group participant reported receiving knee replacement surgery since entering the study. At 3 months, 1 participant from each group had received hip replacement. At 12 months, a further 3 control group participants had received knee replacement and 4 intervention group participants had undergone joint replacement (2 received hip replacement and 2 received knee replacement). Data from these participants were analyzed according to allocated group.

Table 2. Changes from baseline according to group allocation. Values were calculated on the basis of 51 participants in the control group and 39 in the intervention group at 6 weeks; 55 and 40, respectively, at 3 months; and 56 and 38 at 12 months. Change data presented as unadjusted mean change scores, relative to baseline (SD); positive change scores represent improvement for the AQoL and heiQ instruments and negative change scores represent improvement for the WOMAC, K10, and MAPT.

Outcome Measure	6 Weeks*			3 Months			12 Months		
	Change in Control Group	Change in Intervention Group	Adjusted Between-group Mean Difference (95% CI)†	Change in Control Group	Change in Intervention Group	Adjusted Between-group Mean Difference (95% CI)†	Change in Control Group	Change in Intervention Group	Adjusted Between-group Mean Difference (95% CI)†
AQoL score, range, –0.04 to 1.00				0.03 (0.14)	–0.01 (0.14)	–0.04 (–0.10 to 0.01)	–0.03 (0.16)	–0.05 (0.19)	–0.02 (–0.09 to 0.05)
heiQ score, range 1–6									
Positive and active engagement	–0.11 (0.60)	–0.03 (0.89)	0.03 (–0.24 to 0.30)	–0.07 (0.65)	0.14 (0.75)	0.11 (–0.15 to 0.37)	–0.06 (0.71)	–0.15 (0.85)	–0.13 (–0.44 to 0.18)
Health-directed activity	0.05 (0.67)	0.22 (1.12)	0.20 (–0.10 to 0.51)	0.01 (0.62)	0.11 (0.78)	0.12 (–0.13 to 0.36)	0.00 (0.84)	–0.09 (1.06)	0.08 (–0.25 to 0.41)
Skill and technique acquisition	–0.02 (0.50)	0.41 (1.04)	0.29 (0.04 to 0.55)**	0.11 (0.55)	0.41 (0.72)	0.18 (–0.03 to 0.39)	0.16 (0.71)	0.41 (0.77)	0.07 (–0.18 to 0.32)
Constructive attitudes and approaches	–0.11 (0.59)	0.11 (0.81)	0.19 (–0.05 to 0.44)	0.00 (0.58)	–0.04 (0.67)	–0.08 (–0.32 to 0.15)	0.05 (0.55)	–0.14 (0.87)	–0.20 (–0.45 to 0.04)
Self-monitoring and insight	0.05 (0.48)	0.13 (0.59)	0.05 (–0.13 to 0.23)	0.09 (0.46)	0.12 (0.53)	–0.04 (–0.21 to 0.13)	0.05 (0.42)	0.14 (0.53)	0.04 (–0.13 to 0.21)
Health service navigation	–0.14 (0.66)	0.02 (0.76)	0.09 (–0.18 to 0.36)	–0.07 (0.69)	0.03 (0.75)	0.03 (–0.26 to 0.31)	–0.09 (0.64)	0.18 (0.55)	0.23 (–0.02 to 0.48)
Social integration and support	–0.02 (0.57)	0.00 (0.59)	0.02 (–0.19 to 0.24)	0.12 (0.68)	0.08 (0.73)	–0.07 (–0.33 to 0.20)	0.10 (0.63)	–0.11 (0.91)	–0.21 (–0.50 to 0.08)
Emotional distress	–0.12 (0.71)	–0.02 (0.83)	0.15 (–0.14 to 0.45)	0.11 (0.73)	0.10 (0.85)	0.00 (–0.30 to 0.30)	0.01 (0.77)	–0.01 (0.75)	0.00 (–0.31 to 0.31)
WOMAC score, range 0–100									
Pain				–2.66 (15.57)	0.14 (16.35)	–2.73 (–9.01 to 3.55)	–0.39 (18.97)	1.25 (20.40)	–1.48 (–9.37 to 6.40)
Stiffness				–2.95 (19.54)	–3.62 (17.41)	–0.49 (–7.90 to 6.92)	0.45 (20.26)	–0.34 (23.29)	–0.07 (–8.83 to 8.69)
Physical function				–3.01 (14.52)	–0.62 (12.90)	–2.38 (–7.94 to 3.19)	–0.66 (16.19)	0.04 (18.37)	–0.24 (–7.29 to 6.80)
K10 score, range 10–50				–0.21 (4.79)	–0.90 (4.32)	0.37 (–1.38 to 2.13)	0.35 (5.33)	1.84 (6.31)	–1.85 (–4.19 to 0.48)
MAPT score, range 0–100	–1.77 (20.82)	–3.10 (23.89)	1.30 (–7.43 to 10.02)	–2.70 (19.09)	3.86 (24.91)	–7.04 (–15.56 to 1.48)	–0.08 (25.70)	7.43 (23.12)	–6.79 (–16.45 to 2.86)

* 6-week assessment included in the heiQ and MAPT instruments only to minimize participant burden. ** $F[1,85] = 5.40$, $p = 0.02$. † Analysis of covariance adjusted for baseline score for each outcome measure and hospital site; positive values favor the intervention group. Definitions as given in Table 1.

Use of community services. Few community services (paid home help, unpaid home help, paid attendant carer, and Royal District Nursing Service) were used by either group at baseline, 6 weeks, 3 months, or 12 months (median hours per week 0, IQR 0–0 for each service). At each assessment, only 1 intervention group participant reported receiving Meals on Wheels. Use of paid home help did not differ at 6 weeks or 12 months (all analyses $p > 0.05$); however, the intervention group used more hours of home help at 3 months (total number of hours per week = 16.4 vs 3.8; $p = 0.03$). There was no difference in the use of unpaid home help, paid attendant carer, Royal District Nursing Service, or Meals on Wheels at any timepoint (all analyses $p > 0.05$).

DISCUSSION

Our study is the first Australian randomized, controlled trial of the Stanford ASMP for people with hip or knee OA. While we had planned a comprehensive evaluation of HRQOL and specific self-management skills after the program, after almost 2 years of recruitment it became clear that the target sample size could not be achieved within a realistic time frame and the study was closed. Our study thus provides limited information on the effectiveness of the 6-week ASMP, but provides new information on the pragmatics of applying the ASMP intervention across public and private healthcare settings in the real world.

Our data strongly indicate that the 6-week group-based for-

Table 3. Visits to health professionals according to group.

Characteristic	Control, n = 62 Total*	Control, n = 62 Median (range)	Intervention, n = 58 Total	Intervention, n = 58 Median (range)	p†
General practitioners					
Baseline	61	1 (0–3)	86	1 (0–20)	0.81
6 wks	53	1 (0–6)	39	1 (0–4)	0.92
3 mo	64	1 (0–10)	40	1 (0–4)	0.73
12 mo	64	1 (0–6)	53	1 (0–10)	0.40
Orthopedic surgeons					
Baseline	7	0 (0–1)	8	0 (0–1)	0.73
6 wks	8	0 (0–2)	7	0 (0–1)	0.47
3 mo	12	0 (0–2)	7	0 (0–1)	0.77
12 mo	4	0 (0–1)	13	0 (0–3)	0.02
Rheumatologists					
Baseline	1	0 (0–1)	1	0 (0–1)	0.98
6 wks	5	0 (0–4)	0	0 (0–0)	0.21
3 mo	2	0 (0–1)	0	0 (0–0)	0.23
12 mo	1	0 (0–1)	0	0 (0–0)	0.41
Physiotherapists					
Baseline	30	0 (0–8)	45	0 (0–30)	0.59
6 wks	15	0 (0–4)	24	0 (0–12)	0.72
3 mo	24	0 (0–3)	16	0 (0–6)	0.47
12 mo	21	0 (0–12)	24	0 (0–8)	0.27

* Summed number of visits per group to each type of health professional in the previous month. † Mann-Whitney test.

mat is either not desirable or not practical for many people with moderate or worse hip or knee OA. Although we anticipated likely barriers to participation and built enablers into the study design, our screening process identified that many people did not want or were not able to attend the program. In total, 216 individuals (27% of those screened) stated they would be unable to attend 6 sessions of the ASMP. A comprehensive analysis of qualitative data regarding barriers to attendance and patient preferences will be provided in a subsequent report; briefly, reasons included work and family commitments, difficulty in getting to courses, and poor health. Buszewicz, *et al*[9] also cited scheduling and accessibility issues in relation to poor attendance rates; almost 30% of participants randomized to receive a 6-week self-management program did not attend any sessions. Home-based interventions including telephone coaching or Web-based programs might be more accessible to people with OA who commonly have functional limitations and comorbidities.

Another challenge we encountered was limited and infrequent referrals from medical specialists, despite having senior local rheumatologists and orthopedic surgeons as chief investigators of the study and our use of health professionals as course coleaders. This is consistent with research from the United States reporting low referral rates by healthcare providers[21] and Australian qualitative research documenting barriers to referral by GP[22]. Slow recruitment combined with participant preferences to attend course venues close to home and at a limited range of times meant that organizing courses to run with a sufficient number of participants was a complex task. ASMP often had to be rescheduled after venues and course leaders had already been booked (due to insufficient numbers or participant commitments) and this also required considerable administrative support. This administrative time and associated costs should be considered carefully in light of the limited benefits of ASMP reported in the literature. Additionally, the substantial number of course cancellations over the study period (18 in total) had a negative effect on course leader and research team morale.

With respect to the primary outcome of HRQOL, no differences between groups were observed after the ASMP, although early but transient improvements in heiQ skill and technique acquisition were evident for the intervention group. The magnitude of the observed improvement in heiQ skill and technique acquisition scores is similar to that reported in a recent Australian study of multimodal self-management support for severe arthritis (effect size 0.38 at 6 months)[35]. While the studies are not directly comparable, they do provide some support for the notion that chronic disease education programs such as the ASMP can change self-management behaviors; this is critical for effective ongoing disease management. Interestingly, we found that the intervention group reported more visits to orthopedic surgeons at 12 months. This might relate to a trend toward increasing disease severity for the intervention group only (Table 2), although this difference remained after excluding participants who received joint replacement during the followup period. Another explanation may be that after attending an ASMP, participants became more confident in seeking out an orthopedic consultation for

their OA. This is supported by a trend toward increased heiQ health service navigation scores at 12 months for the intervention group only. No between-group differences in visits to GP or physiotherapists were seen after the program, similar to previous research in this field[10].

Earlier studies of the ASMP focused on physical outcomes including pain and disability[36], which would not necessarily be expected to change following the program, or psychological outcomes, for which only small improvements have been reported[8,9]. Our primary outcome of HRQOL at 12 months was chosen to identify the intended longer-term influence of the ASMP. We expected that a range of self-management capabilities would improve substantially as a result of the program and that this would lead to improvements in HRQOL[20]. Apart from the small gain in skills and technique acquisition, these immediate and intermediate outcomes were not observed. It is therefore not surprising that longer-term improvements in outcomes such as HRQOL were not seen. While our study was ultimately underpowered to detect small increases in HRQOL, both groups demonstrated an overall trend toward deterioration in HRQOL at 12 months. Many extraneous factors may negatively affect HRQOL including comorbidities and increasing OA severity over time. Although we could not control for all potential confounders, our completers analysis excluded people who underwent joint replacement surgery for severe OA during the study period and produced similar results with respect to HRQOL. A more highly powered study involving 812 participants in the United Kingdom found no significant improvement in quality of life (assessed using the SF-36 health status measure) up to 12 months after the "Challenging Arthritis" program, a 6-week program based on the ASMP[9].

A key strength of our research was the recruitment of patients from both the public and private health sectors to maximize generalizability. Average baseline heiQ scores were similar to those reported in an Australia-wide survey of 1341 people participating in chronic disease self-management programs[30], as was age and educational background, suggesting our sample is broadly representative of people attending self-management programs in Australia. However, the major limitation of the study was its premature termination of recruitment, limiting statistical power to draw conclusions about the effectiveness of the ASMP. While the risk of Type 2 error must be acknowledged, meaning that differences between groups may have been missed, the 95% CI suggest that any differences are unlikely to be clinically important in the context of OA. Another limitation of our trial was the lack of participant blinding, which was not considered feasible as the possibility of attending a 6-week program needed to be explained to potential participants. However, this would have biased the study in favor of the ASMP. It should also be acknowledged that the ASMP was not completed by all participants allocated to the intervention group, which could limit the generalizability of the results. Although the small subgroup sample size precludes meaningful analysis, as the majority of intervention group participants (76%) received the ASMP and attended an average of 5 out of 6 sessions, we do not expect this to have affected the findings significantly. Another potential source of bias was that control group participants may have sought additional information regarding arthritis self-management during the study period (either online or through other sources). Finally, although we had initially considered multilevel modeling to account for clustering within courses, the sample size precluded this and our planned cost-utility analysis[15] was not performed given there was no significant improvement in HRQOL.

Although transient short-term gains were evident for 1 component of the self-management skill set, we observed no other benefits of an ASMP over provision of a self-help book in this study. The real-world setting has elicited comprehensive information about barriers to attendance and implementation of the ASMP for people with hip and knee OA, and indicates that the practicality of the program in this setting is questionable.

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