

INTRODUCTION

Worldwide, musculoskeletal conditions are the fourth greatest burden on health, accounting for 6.7% of the total global disability-adjusted life years[1]. Further, they are the second largest contributor to years lived with disability—an index of morbidity[2]. They are the leading causes of persistent pain and physical disability[3] and are the most common causes for utilizing healthcare resources[4]. Given the high prevalence and significant health and economic burden of musculoskeletal conditions, effective management strategies for these conditions are required[5].

Exercise therapy, on land or in water, is an effective management strategy widely used in people with musculoskeletal conditions[6, 7]. It improves muscle strength and fitness; modulates responses to pain; and empowers patients to take an active role in the management of their condition[6]. In contrast to land-based exercise, the aquatic environment can allow higher-intensity exercises to be undertaken, with lower cardiovascular stress and joint impact than is possible on land[8]. Additionally, immersion in thermo-neutral water (32-36°C) decreases sympathetic nervous system activity, which in combination with compressive effects of hydrostatic pressure, can reduce swelling and decrease pain and stiffness of the musculoskeletal system[9, 10].

A number of randomized controlled trials (RCTs) have demonstrated the beneficial effects of aquatic exercise programs led by health professionals in people with musculoskeletal conditions, including rheumatoid arthritis[11, 12]; osteoarthritis[13-21]; fibromyalgia[22-24]; and low back pain[25, 26]. Benefits include decreases in pain, and improvements in physical function and health-related quality of life (HRQoL). The high cost of delivery of classes by health professionals raises questions about the long term sustainability of this model.

Exercising in a community group setting led by trained peer-leaders offers an appealing alternative. The ‘Waves’ program, developed by Arthritis and Osteoporosis Victoria provides peer-led exercises in warm water pools for people with musculoskeletal conditions. Arthritis and Osteoporosis Victoria is a peak not-for-profit organization that works with consumers and agencies across the sector to improve the lives of people with, or at risk of developing, a musculoskeletal health condition. The program was established in 1977 and there are now more than 120 trained volunteer leaders providing 45 classes in more than 20 locations across Victoria, Australia to over 450 participants.

Although RCTs are considered the ‘gold-standard’ of research designs to evaluate interventions, the majority of trials on aquatic exercise for musculoskeletal conditions have evaluated programs developed specifically for the research rather than programs delivered in existing community services. While the use of study-specific interventions in RCTs provide a good test of efficacy, they don’t provide a useful indication of what benefits could be expected in a real world setting[27]. Given the pre-established evidence for aquatic exercise, pragmatic evaluations of existing programs that are being delivered as part of community-based services would be beneficial to gain information on the translation of research evidence into practice. Further pragmatic studies, particularly pilot studies, are essential to informing the development of larger trials (e.g. sample size estimates) and larger-scale program evaluations.

A small number of studies have evaluated existing community-based aquatic exercise programs[12, 28-30]. These studies evaluated the Arthritis Foundation Aquatic Program (AFAP), a US aquatic exercise program provided by the Arthritis Foundation, and reported improvements in HRQoL and physical function[12, 28-30]. An evaluation of the Waves

program was completed in 2008-2009 and provided information on the characteristics of program participants and qualitative data on the perceived benefits of the program and potential areas for development and improvement[31]. The evaluation did not assess the impact of Waves on health outcomes. An impact evaluation is required to explore if the outcomes experienced by people participating in the peer-led community-based Waves classes are comparable to those reported in RCTs testing study-specific programs delivered by trained professionals.

The aim of this pilot study was to explore the effect of Waves on self-reported measures of pain, joint stiffness, physical function and HRQoL in people with musculoskeletal conditions to inform the design of a larger evaluation. We also aimed to explore participant perceptions of the value, impact and accessibility of Waves that could be used to guide service improvements.

MATERIALS AND METHODS

Study design

This study was a multi-center, quasi-experimental pilot study of aquatic exercise for adults with musculoskeletal conditions. Outcomes were compared across people participating in Waves (Waves participants), and a similar group of consumers not participating in Waves classes or other formal exercise programs (control participants). This study was part of a 3-stage evaluation of Waves, incorporating a systematic review of the evidence for aquatic exercise for adults with musculoskeletal conditions[7] (Stage 1), translation of that evidence into practice via delivery of workshops to Waves leaders (Stage 2), and this quasi-experimental pilot study to explore impacts (Stage 3). Ethical approval to conduct the study was obtained from Monash University Human Research Ethics Committee (CF13/610 – 2013000265).

Participants

This was a pilot randomized study designed to primarily provide data for a larger definitive efficacy trial; therefore a formal sample size calculation was not required or undertaken[32]. The sample size was a pragmatic decision based largely on study aims and resources. This study applied a pragmatic sample size where all new enrolments for Waves classes over a 10 month period between 1 April 2013 and 28 February 2014 were screened for eligibility (according to the criteria in Box 1) to participate in the study and those identified as eligible invited to participate. Control participants were invited to participate in the study via advertisements in the Arthritis and Osteoporosis Victoria newsletter, website and membership database. An equal number of control participants were sought and the same screening and recruitment processes applied as used for Waves participant recruitment except

that control participants were provided with a \$AU20 gift voucher as an incentive to participate in the study.

Box 1: Eligibility criteria for participation in the study

Inclusion criteria

1. Aged ≥ 18 years
2. Diagnosis of arthritis or other musculoskeletal condition confirmed by a health professional
3. Sufficient English language skills to complete self-report surveys

Exclusion criteria

1. Uncontrolled epilepsy or diabetes
2. Unstable heart condition(s) or severe cardiac failure
3. Unstable blood pressure—severe postural hypertension or uncontrolled hypertension
4. Open wounds or ulcers
5. Participation in Waves in the last six months
6. Currently participating in another form of formal exercise for more than one hour per week for eight or more consecutive weeks in the previous three months

The Waves program

Waves is an existing, standardized, community-based aquatic exercise program delivered in indoor pools with a water temperature between 32-36°C at aquatic centers across Melbourne. Classes run for 45 minutes and are delivered by a trained volunteer peer-leader and include a 5-10 minute warm-up (light aerobic and range of motion exercises); 15-25 minutes of strength (focusing on large muscle groups such as the biceps, quadriceps and gluteals) and

aerobic exercises (e.g. jogging and jumping); and a 10-15 minute cool-down (range of motion and stretching exercises) (Box 2). Classes include a maximum of 20 participants.

Box 2: Example Waves class plan

TYPE	ACTIVITY/EXERCISE	TIME (mins) or REPS	MODIFICATIONS (Easier/Harder)	EQUIPMENT / NOTES
WARM UP				
Introduction	Hokey pokey	2 mins		
Light aerobic	Walking across the pool	2 mins	Increase speed, change stride length and starting to swing arms	
Light aerobic	Walking across the pool sideways	2 mins	Increasing speed and starting to swing arms	
CORE				
REPEAT THIS SERIES TWICE		15 - 25 mins		
Strength - lower body	Lunges	10+10		
Aerobic	Punching	2mins		
Strength - lower body	Single leg Cycling	10 + 10 reps	10 times forward, then 10 reverse	
Aerobic	Star jumps (opposite arms / legs)	2 mins		
Strength - upper body	Rail/Wall push ups	10 reps		
Aerobic	Swimming strokes	2 mins	On the spot or walking around the pool	
ROM (range of motion)	Playing the accordion	1 min	Moving hands up and down	
REPEAT CORE SECTION TWICE OR THREE TIMES DEPENDING ON TIME				
COOL DOWN				
ROM - 'doing the domestics!	Washing machine (trunk rotations)		Can swing arms around the body	
ROM - 'doing the domestics!	Playing the piano		Can walk or move side to side as you play	
ROM - 'doing the domestics!	Doing the domestics		Stir the pot, tumble dryer with hands,	
ROM - 'doing the domestics!	Doing the domestics		Reaching high to brush away spiders	
Arthritis ROM	Hands & feet			
Spine ROM	Neck		Side stretch & head rotation	
CONCLUSION NOTES (Health and safety):				
REASONS FOR EXERCISES AND SEQUENCES:	The class core involves minimal equipment. Exercises alternate between strength exercise to Aerobic exercise. This is one of the different ways to structure a class core to maintain a moderate intensity and save time.			

Participants follow the same general exercises as demonstrated by the leader, but are encouraged to work at their own pace. Classes run in line with Victorian school terms, which are approximately of 10-11 weeks duration. Waves participants were able to attend one Waves class per week over the 10-11 week period. Control participants were asked to follow their usual pattern of activities (i.e. not participating in formal exercise programs) for the duration of the study.

Outcomes

Outcomes were assessed on entering the study (baseline) and at 12 weeks post-baseline. For Waves participants, baseline was defined as the time of enrolment to Waves. Primary

outcomes were pain, joint stiffness, physical function and HRQoL. Participant satisfaction with the Waves program was a secondary outcome.

Pain, joint stiffness and physical function

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC, Likert version)[33] was used to measure pain, joint stiffness and physical function. The WOMAC is a standardized self-report survey that has established reliability and validity for measuring these outcomes in people with a range musculoskeletal conditions[33]. The pain subscale includes five items (summed score range 0-20); the stiffness subscale includes two items (summed score range 0-8), and the physical function subscale comprises 17 items (summed score range 0-68). A total score for the WOMAC, that combines the scores for the pain, joint stiffness and physical function subscales, was generated yielding a total score between 0-96. Lower scores indicate less pain, joint stiffness, and physical impairment.

Health-related quality of life (HRQoL)

HRQoL was measured using the EuroQoL five dimensions survey (EQ-5D)[34]. The EQ-5D comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. An EQ-5D index utility score representing overall HRQoL was generated from the dimension scores. The utility score ranges from -1 to 1 where a higher score indicates better overall HRQoL. The EQ-5D also includes a question where the respondent scores their overall self-rated health status (EQ-5D overall health state) on a graduated scale from 0–100, with higher scores indicating better HRQoL.

Participant satisfaction

Participant satisfaction was measured by a customized satisfaction survey developed by the investigators. This survey included questions regarding the value, impact and accessibility of Waves. The survey was pilot tested with consumers before use in the study. Only Waves participants were required to complete this survey.

Statistical analysis

All statistical analyses were performed using STATA (version 12.1) statistical software. Descriptive statistics were calculated for demographic variables at baseline. Generalized linear mixed models were used to determine changes in WOMAC and EQ-5D outcomes with group allocation as the factor (predictor) variable. Age and baseline scores of the outcome measures were used as covariates. Therefore, any significant difference between groups at baseline was adjusted for and more precise estimates of effect determined. Due to the pilot design, results of between-group differences were intended to provide an indication of potential effectiveness rather than definitive estimates of effect. They also provide an indication of possible effect sizes from which sample size estimates for larger efficacy trials could be reliably determined. Statistical significance was set at $p < 0.05$.

RESULTS

Participants

Figure 1 outlines the people screened, recruited and included at each stage of the study analysis. Of the 146 people eligible to participate in the study, 109 (67 Waves participants and 42 control participants) consented to participate by returning baseline surveys. After the 12-week follow-up period, 24 Waves participants (36%) and 3 control participants (7%) did not complete the 12-week surveys. Overall, a total of 82 participants completed the protocol, 43 (64.2%) Waves participants and 39 (92.9%) control participants, and were included in the analysis. The sample was predominately female (n=89, 82%), and majority of participants had osteoarthritis (n=71, 65%). There were no significant differences between groups in demographic characteristics at baseline except for age, which was higher in the Waves group ($P < 0.05$). Demographic characteristics of participants at baseline are presented in Table 1.

Adherence

There were varying levels of attendance of Waves classes across participants. Of the 10-11 Waves classes offered during the study (dependent on term length), on average participants attended seven classes (minimum = 2, maximum = 10). During the study, 28 participants (65%) attended six or more classes, with only four participants attending at least 10 classes.

Pain, joint stiffness and physical function

There was no significant difference between groups at baseline for any WOMAC measures, with the exception of joint stiffness. While all WOMAC scores demonstrated an improvement from baseline to 12-weeks in the Waves group (Figure 2), there was no significant difference in 12-week scores between the two groups (Table 2).

Health-related quality of life

There was no significant difference between groups at baseline for any EQ-5D measures

There were no statistically significant differences in EQ-5D utility scores between groups at 12-week follow-up (Table 2, Figure 3). There was however a trend towards a statistically significant improvement in the overall health state change scores for the Waves group (mean difference=6.18; 95% CI: -1.01 to 13.35; p=0.091).

Participant satisfaction

In the Waves group, all participants that completed the follow-up surveys (n=43, 64% of total cohort) completed the participant satisfaction survey. Over 90% of participants found Waves classes enjoyable, and would recommend the classes to others. More than 90% of participants planned to continue attending the Waves program, and more than 90% of participants agreed that class format was suitable for their condition. Most participants (80%) agreed classes were beneficial for their condition(s) and enjoyed the social aspect of the classes (Figure 4).

DISCUSSION

The Waves program is one of the largest, formalized aquatic exercise programs in Australia. Whilst this uptake provides evidence of the positive impacts participants are likely to experience from the program, provision of empirical data to support health impacts is important in an environment of evidence-based best-practice and justification of health expenditure. In this study, people participating in Waves over the 12-week study period achieved non-significant improvements in musculoskeletal burden (pain, joint stiffness, physical function) and overall health. Importantly, participants that completed the satisfaction survey reported classes were enjoyable, acceptable and an effective strategy for managing their condition. This pragmatic evaluation of an existing community based-service extends the knowledge base provided by prior studies on the effectiveness of aquatic exercise for people with musculoskeletal conditions, and provides valuable information to inform the design of a larger evaluation.

The changes in outcomes in the Waves group did not reach statistical significance and were smaller than reported by prior RCTs evaluating health-professional delivered aquatic exercise in people with musculoskeletal conditions. However, participants of this study are likely to be more representative of the diverse population this program may be beneficial for. Majority of prior RCTs investigating the effects of aquatic exercise in people with musculoskeletal conditions used narrow inclusion criteria limiting the external validity and generalizability of their findings to the broader population of people accessing aquatic exercise programs in the community. In health services research, there is a trade-off between external validity and statistical significance with regards to sample size. As the diversity of the sample increases to optimize external validity the sample size required to determine statistically significant effects also increases. Indeed, the sample size required to determine statistically significant

effects of many service models is likely to be larger than available in an individual health service seeking to evaluate service impacts. It is likely that the small and diverse sample of people included in this study reduced the ability to detect statistically significant changes in the outcomes measured.

A factor that may have contributed to the smaller effects is that participants appeared to have high levels of self-reported HRQoL at baseline. The EQ-5D scores reported by participants was comparable to that reported for general population of the same age[35]. This suggests HRQoL may have already been optimized in Waves participants and therefore, there was little room for further improvements. Furthermore, HRQoL may require a longer follow-up period to detect changes. Long-term outcomes were not assessed in this study so it cannot be determined if greater improvements could be achieved with a longer follow-up period.

Another possible reason that may have contributed to the smaller than expected effects is that the dosage of exercise provided to participants was quite low. Results from the meta-analysis completed as part of stage 1 of this evaluation showed that programs were most effective if they included two 60-minute sessions a week and ran for at least 6 weeks[7]. Similarly, current physical activity guidelines recommend adults with arthritis should participate in moderate-intensity, low-impact physical activity (e.g. walking, cycling, aquatic exercise) 3 to 5 times per week for 30 to 60 minutes per session (approximately 150 minutes per week) to achieve health benefits including reduced pain, improved function, and a reduced risk of disability[36]. In comparison, Waves participants were only able to attend a maximum of one 45-minute class per week over the 12-week follow-up. This lower dosage of classes may have contributed to the smaller improvements in outcomes than those reported by prior studies[13]. In addition, there was no specific requirement that the repetitions or difficulty of

exercises increased from one session to the next. Therefore, the program may have required greater focus on exercise frequency progression to yield larger effects, as supported by the literature[37].

The effectiveness of an exercise intervention is also largely influenced by patient adherence[6]. Of the possible 10-11 Waves classes that were offered over the study, participants attended an average of seven classes suggesting only moderate adherence. However, individuals who have one or several chronic conditions may have difficulty attending an exercise program regularly due to illness or exacerbation of symptoms. Reasons for non-attendance were not formally explored as part of this study, but may include illness, vacations and family commitments.

An important finding of this study in the context of program evaluation was the high level of satisfaction Waves participants reported. There is a growing interest within the research literature of measuring customer satisfaction in recreational, sport and leisure services[38]. Waves participants strongly endorsed Waves classes as being enjoyable, safe and beneficial for managing their condition. Majority of participants (>90%) also agreed that Waves is a cost-effective management strategy and plan to continue attending classes. This is an important finding given the significant economic costs accompanying the management of musculoskeletal conditions[4].

Although most benefits observed in this study were small and did not reach statistical significance, the findings are meaningful from the perspective of evaluating an existing community-based program. Health service evaluations are particularly useful when an intervention is known to be efficacious in RCTs with strict eligibility criteria and intervention

protocols, but effectiveness within a more real world setting remains unknown[27]. They have a complementary role to undertaking RCTs. RCTs are generally explanatory—that is, they provide evidence of what can be achieved—however RCTs typically have low external validity—generalizability of results to the broader population and service delivery models[27]. As such, RCTs aren't sufficient by themselves to provide conclusive information about clinical interventions. This study was undertaken in a real world setting, with participants that were representative of people that would participate in community-based exercise programs. Therefore, the results of this study are reflective of benefits experienced in the community-dwelling population. The peer-led model adopted by Waves is also likely to have very good “return on investment”, a service model that has both a broad reach and is accessibility and feasible to deliver from a financial perspective. Further studies should include evaluation of economic cost-benefit.

Study Limitations

This study had several strengths including: the addition of a control group; the use of validated outcome assessment tools; and the use of a community-based program as the intervention being tested. Nevertheless, the absence of random allocation of participants to groups is a limitation. This may have resulted in selection bias that may have influenced study findings. Despite this, the only measured baseline differences between the groups were age and joint stiffness. However, factors such as medication use and other co-interventions were not collected from participants, which may have confounded our results. The small sample size didn't allow us to complete a sub-group analysis of intervention effectiveness according to specific musculoskeletal conditions. In addition, confidence intervals were wide, suggesting the sample was heterogeneous. As stated previously, the moderate attendance of Waves classes may have contributed to the smaller improvements in outcomes. Lastly, the

poor response rate to 12 week follow-up surveys in the Waves group may also have biased results. However, we suspect this is an artifact of offering a financial incentive (\$20 gift voucher) to the control but not Waves participants. In future studies, all participants should be offered an incentive to participate for future research. The mean age of the Waves group was higher than the control group which may have also contributed to the lower survey response rate in this group.

Accepted version

CONCLUSIONS

This pilot study provides an overview of the potential effectiveness of the community-based, peer-led Waves aquatic exercise program, and valuable information to inform the design of a larger evaluation. Overall, findings suggest that Waves classes may improve pain, joint stiffness, physical function and HRQoL in adults with musculoskeletal conditions. Based on these findings a large-scale trial is warranted to definitively test the Waves program. Such a study should aim to recruit a larger cohort of participants to be adequately powered to detect significant changes in pain, physical function, joint stiffness and HRQoL outcomes; incorporate physical activity guidelines in terms of frequency and dosage; and include a longer follow-up period to confirm long-term effects.

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FIGURE LEGEND

Figure 1: Flow of participants throughout study

Figure 2: Mean change in WOMAC scores from baseline to 12 weeks

Figure 3: Mean change in EQ-5D scores from baseline to 12 weeks

Figure 4: Satisfaction survey results

Accepted version

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