



Adaptive physical activity and back pain: a non-randomised community-based intervention trial

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Background. Back pain is a significant problem due to the high healthcare utilization, rising costs of care and low effectiveness of many current treatments.

Aim. Aim of this study was to determine the effects of a community-based Adapted Physical Activity (APA) program focused on chronic, non-specific back pain.

Design. Open-label intervention study.

Setting. Community.

Population. All patients admitted to Empoli Rehabilitation Department for non-specific back pain for at least three months, were considered for APA. Exclusion criteria were: "red flags", difficulty/disability in basic daily living activities, severe/acute medical conditions, acute pain, psychiatric disease or cognitive impairment, severe visuoauditory deficit. Overall, 650 persons were enrolled.

Methods. The APA program, including strength and flexibility training and exercises for improving posture was delivered for 12 months, with 1-hour group classes three times per week.

Results. Overall 261 (40.2%) subjects completed the 12-month APA program and were compared to the 310 (47.7%) who were screened but failed to initiate or complete the study. There were no significant differences in baseline demographic and clinical characteristics between groups. Patients who followed the APA program reported significantly improved health status and significant back pain improvement, compared with those who did not adhere to the program. In the logistic regression analysis adjusted for age and gender, a distance from home to gymnasium greater than the median for the study population (2.6 km)

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was the only baseline characteristic significantly associated with an increased risk of non-adherence (OR 1.44, 95%CI 1.01-2.13; P=0.04).

Conclusion. This study suggests that a community-based APA program can improve back pain and health status in persons with chronic, non-specific low back pain.

Clinical rehabilitation impact. These findings highlight the potential for new approaches to manage chronic disease and disability by facilitating a healthy lifestyle and promoting physical activity through implementation of community-based exercise programs.

KEY WORDS: Motor activity - Back pain - Exercise.

Back pain is a major public health problem leading to disability and increased use of health services.¹ It is a significant source of long-term absence from work and a substantial burden in industrialized countries.^{2, 3} Chronic back pain is a significant prob-

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lem due to the high healthcare utilization, rising costs of care and limitations of effectiveness of many current treatments.^{1, 2} Reviews of the literature report a lifetime prevalence of low back pain that ranges from 11% to 84%, with a point prevalence of 12% to 33%, and one-year prevalence from 22% to 65% in developed countries.⁴ Recent evidence shows that back pain is also one of the most frequent complaints in elderly patients, and an independent risk factor for limited mobility in older persons.⁵ The treatment for chronic, non-specific back pain is a major public health issue, as many clinical guidelines have widely reported throughout the years.^{6, 7} Systematic reviews have demonstrated that exercise for patients suffering from back pain is effective in decreasing pain and improving function,^{8, 9} as one of the most important risk factors for back pain is the sedentary lifestyle, while physical activity during the leisure-time has been consistently associated with a reduced incidence of back pain.³ Many exercise programs have been proposed, and quite different programs appear to have similar effects.⁹ However, most of these programs have been designed and performed using exercise prescription either in a therapeutic setting or as home exercise programs, whereas few studies considered the effects of community based exercise programs that are feasible for community dissemination among an elderly population suffering from chronic non-specific back pain.¹⁰

The Empoli Adaptive Physical Activity (APA) program provides physical activity adapted to specific chronic alterations of health status for tertiary prevention of disability.^{11, 12} By proposing exercises aimed at improving cardio-respiratory function, spinal flexibility, muscle strength, postural control, and providing an opportunity to increase social participation, the APA program offers a promising model for exercises that people with specific chronic alterations and/or disabilities can practice.^{13, 14} The APA protocols are specifically adapted to different chronic conditions.¹⁵ The Empoli APA program has proven to be extremely popular. There are now about 3 200 participants in 190 classes that are held in 61 gymnasiums distributed throughout the territory of the Empoli area (994 km², 229 787 residents, aged ≥ 65 years: 22%). The APA program is now being replicated throughout the Tuscany region.

Nevertheless, to the best of our knowledge, no data on the effectiveness of the APA program on back pain are available.

The purpose of this study was to describe the effects of the Empoli community-based APA program in a large sample of subjects with non-specific chronic back pain.

Materials and methods

Study population

All patients admitted to the Rehabilitation Department of Empoli, Italy from January to December 2006 with a medical diagnosis of non-specific chronic back pain, lasting at least for three months, were consecutively evaluated for eligibility. The diagnosis was made either by their general surgeon or by a physiatrist, who also ascertained the absence of exclusion criteria for the APA program:¹⁶ presence of "red flags",¹⁷ difficulty/disability in basic activities of daily living,¹ severe/acute medical conditions (such as heart/lung/renal failure, hemiplegia, etc.), pain in the acute or subacute phase, psychiatric disease or cognitive impairment, severe visual and/or auditory deficit, any other contraindication to weight bearing and low-moderate exercise. All patients provided spinal RX; all of them had received at least once physical therapy in the past for their back pain. All the subjects underwent a baseline evaluation at the time of admission to the department, performed by a physiotherapist, who verified the absence of red flags and other contraindications to the APA program, and included a physical examination with clinical measurements. All the patients gave their informed consent to participate to this study; the study complies with the Declaration of Helsinki and it was approved by the local ethics committee.

Clinical measurements

Body mass index (BMI) was measured by weight (kg)/height (m)². Low back pain symptoms were evaluated through the use of the visual analogue scale (VAS), a simple method for evaluating variations in pain intensity, already validated in the setting of chronic pain.¹⁸ Subjects were instructed to indicate the intensity of the pain by marking a 100-mm line anchored with terms describing the extremes of pain intensity. The amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain.

To measure physical performance we chose the

Short Physical Performance Battery (SPPB).¹⁹ The test consists of three components: standing balance, timed 4 meter-walk, and repeated chair stands. The standing balance test required participants to maintain a side-by-side, semitandem, and tandem stance for 10 seconds, with scores ranging from 0 to 4 (maximum score). The fastest time of two 4 meters usual-pace walk attempts was used.

Categorical scores (range 0-4) for the four meter-walk and chair stands were based on timed quartiles previously established in a large population.¹⁹ The sum of the three components comprised the total SPPB score with a possible range from 0 to 12 (12 indicating the highest degree of lower extremity functioning).

Intervention program

Based on task-oriented exercise and social learning models that facilitate exercise behaviours in adults, in agreement with the American College of Sports Medicine recommendations²⁰ we developed a structured APA program for patients suffering from back pain. The set of selected exercises to include in this program were discussed with physicians, physiotherapists and physical trainers in order to identify exercises focused on this specific clinical condition.

This APA research study ran for 12 months, with 1-hour classes three times per week. The protocol included low-impact exercises to reduce flexed posture, to increase muscle strength of the trunk and lower limbs, and to improve all major joints as well as spine flexibility. Low intensity, low impact aerobic exercise was included in the program, as well as exercises to promote balance and coordination. Task oriented exercises were also performed, e.g., raising from the floor, chair raising, climbing/descending stairs. The intensity and difficulty of the exercise would be adapted to the participant's capacity, and a detailed list of alternative type of exercises is proposed in the protocol for patients with specific problems (e.g., seated rather than standing position for persons with balance problems; simple walking rather than hip rotational movements for patients with total hip prosthesis etc.).²¹ The APA programs were held during the day, at "off hours" in the local gymnasiums. Physical therapists held a two-day course to the gymnasium trainers, who were all graduated in motor science, to train them in

delivering the APA protocol and regularly observed APA classes to ensure adherence to the protocol. Classes were conducted with an average ratio of one instructor to 17 participants and a maximum of 20 participants per trainer.

Follow-up

The occurrence of any serious event during classes was monitored all throughout the year. A serious adverse event was defined as an emergency room visit or a hospital admission.

At 12 months, all the enrolled subjects were contacted through a standardized telephone-interview for clinical information updates. A student to motor sciences' degree course performed the telephone interview. The content focused on obtaining information regarding health status and the severity of back pain, and adherence to the APA program. Adherence to the APA program was defined as an attendance rate of >75%.

Statistical analysis

Statistical analysis was performed by using the SPSS (Chicago, IL, USA) software for Windows (Version 13.0). Continuous variables were expressed as mean \pm standard deviation (SD) for normally distributed data and as median and range for non-normally distributed data. The parametric two-sided t test was used for comparison between single groups. Kruskal-Wallis two-sided test was used for comparison among different groups. Chi-square two-sided test was used to test for comparison between proportions. Logistic regression analysis was conducted in order to analyse the factors contributing to non-adherence to the APA program. Odds ratio (OR) and 95% confidence interval (CI) were reported. A P value <0.05 was considered to be statistically significant.

Results

The study population included 650 persons, with median age of 65 (range: 23-87) years with a higher prevalence of females respect to males (560 vs. 90). Mean body mass index for the study population was 26.5 ± 4.2 with a significantly higher value for older patients.

TABLE I.—Demographic and clinical characteristics of the study population according to age.

	< 65 years (N.=319)	>65 years (N.=331)	P value
Gender, M/F	38/281	52/279	0.2
BMI, kg/m ²	26.4±4.50	26.7±3.90	0.04
VAS			
Cervical pain	4.85±2.64	4.92±2.51	0.9
Dorsal pain	3.52±2.83	3.62±2.81	0.8
Lumbar pain	5.75±2.13	5.92±1.96	0.4
SPPB			
Standing balance	3.95±0.28	3.57±0.97	<0.0001
4 meter-walk	3.33±0.72	2.81±0.97	<0.0001
Repeated chair stand	2.60±1.16	2.11±1.12	<0.0001
Total	9.90±1.70	8.48±2.45	<0.0001

Data are presented as mean ± SD. BMI: Body Mass Index; VAS: Visual Analog Scale; SPPB: Short Physical Performance Battery.

VAS scales performed at baseline showed mean values of 4.88±2.57, 3.57±2.82, and 5.83±2.05 for cervical, dorsal, and lumbar pains, respectively, whereas SPPB mean value in the whole study population was 9.17±2.23. Baseline demographic and clinical characteristics according to the median age of the study population are depicted in Table I. As expected, patients older than 65 years reported lower values of SPPB than those younger than 65 years, while no significant age differences for intensity of pain were observed.

At a follow-up time of 12 months all subjects were contacted by telephone for assessment of adherence to the APA program and for evaluation of health status and back pain.

At the question: “Did you adhere to the APA program?” a total of 261 (40.2%) subjects answered that they adhered to the APA program, whereas 201 (30.9%) subjects said that they interrupted the program before the end, and 109 (16.8%) patients reported that they did not even start the program. Moreover, two patients died and 77 refused to participate to the study or were not found at the telephone interview.

In response to the question: “How is your health as compared to one year ago?” a total of 288 (50.4%) subjects answered “better”, 178 (31.2%) replied “the same”; the remaining 105 (18.4%) reported that their health status was considerably “worse” than one year ago. In response to the question, “How is

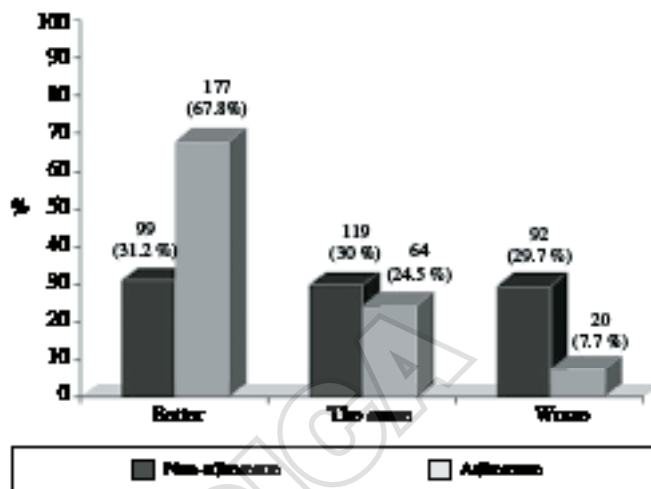


Figure 1.—Health status at follow-up according to the adherence to the APA program, P<0.0001 for all the comparisons between adherence and non-adherence.

your back pain as compared to one year ago?” 404 (70.8%) answered “considerably better”, 124 (21.7%) “the same”, while only 43 (7.5%) said “worse”.

To evaluate the main outcomes of the study, *i.e.*, the quality of health status and back pain, according to the adherence to the APA program, we divided our study population into a subset of patients that adhered to the whole program (N.=261) and a group of patients who either did not adhere or interrupted the program before the end (N.=310). The distance in kilometres from the home address to the nearest gymnasium was calculated by using Google Maps software. At a logistic regression analysis adjusted for age and gender the distance from home to gymnasium greater than 2.6 km, which is the median distance from home to gymnasium for the studied population, resulted to be the only baseline characteristic significantly associated with an increased risk of non-adherence (OR 1.44, 95%CI 1.01-2.13; P=0.04). There were no serious adverse events associated with the gymnasium classes for APA participants in the study.

Patients who followed the APA program reported significantly improved health status, as compared with those who did not follow the program (Figure 1), and, more importantly, those who adhered to the APA program reported significant amelioration of their back pain as compared with those who did not (Figure 2).

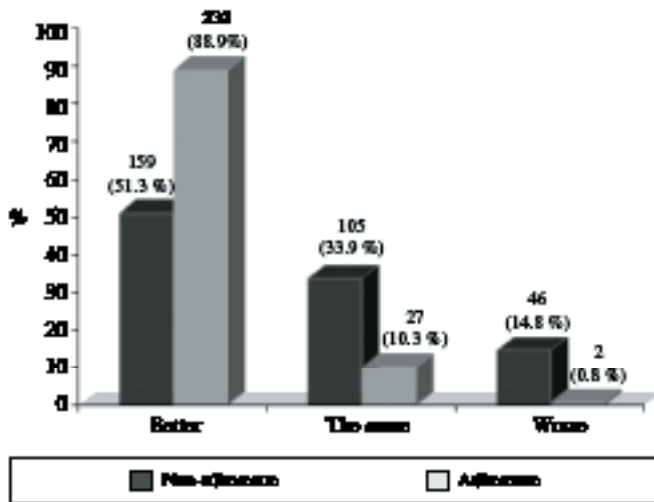


Figure 2.—Back pain at follow-up according to the adherence to the APA program. $P < 0.0001$ for all the comparisons between adherence and non-adherence.

Discussion

In a large sample of patients suffering from back pain, our study showed that a structured program of APA lasting for one year was associated with long-term pain relief and improvement of the self-perception of health status. Patients who completed the APA program at one year reported a better self-perception of health status and less back pain, in comparison to those who either interrupted or refused to initiate the program. The analysis of demographic, clinical and environmental characteristics showed that only the distance from home to gymnasium was significantly associated to the adherence to the APA program.

The treatment of chronic low back pain is a very controversial issue. Many interventions, including back school, education, and spinal manipulation showed evidence of effectiveness, but mostly in the short-term course; there is an universal consensus on the recommendation of regular exercise in chronic back pain, but the most effective and cost-effective exercise approach is still under discussion.^{22, 23} A recent review suggests that individually-designed, supervised exercise programs, including stretching or strengthening may provide more functional improvement and pain relief than home exercise in chronic non-specific low back pain,⁸ while the effectiveness of a community-based program of adap-

tive physical activity to this specific chronic condition has not previously been demonstrated. The APA program presented in this study has been developed for chronic patients and all of them have had previous experience of physical therapy without succeeding in solving their problems; indeed, physical therapy is generally delivered within a definite time frame, while its benefits seem to wear off with time in chronic pain, if the patient does not keep on exercising. Raising no issue as to the appropriateness of a physical therapy intervention in the acute/subacute phase of back pain, the APA program provides an alternative to the sanitary approach to chronicity that has nearly no public health costs, a very low cost to the patient and (differently from physical therapy programs) may provide continuous support to a long-lasting change of lifestyle. Previous research from our group found an APA community-based program designed for ischemic stroke to be feasible, safe, and efficacious,^{11, 12} but the present study was the first to evaluate the clinical effectiveness of a structured APA program designed for back pain.

The main finding of the present study is the amelioration of self-perceived health status and back pain among the study population that remained in the APA back pain program for the full length when compared to those who discontinued the program or failed to start. Another interesting finding is that the main barrier to participation in the APA program was the distance from home to gymnasium. Those who lived at a greater distance away from the gymnasiums showed a significantly lower adherence to the APA program and a significant risk of non-adherence, highlighting the importance of widespread geographic access and underscoring the challenge for community-based implementation of such exercise programs, especially in rural areas.

In light of the number of elderly participants in this study, the safety of the APA back pain program is noteworthy, as there were no serious adverse events, defined as an emergency room visit or a hospital admission, associated with the gymnasium classes for APA participants in the study.

Another feature of the APA program is that the exercise classes played a pivotal role in chronic disease management for the frail elderly. Not only classes provided exercise and social engagement for the participants; the gym instructors served also as an “early warning system” by reporting concerns re-

garding changes in health status, physical functioning, or attendance to the Rehabilitation Department. As to the cost, the Local Health Authority supported the program coordination and the physical trainers instruction and supervision, while the participants paid a fee of two euros per session for their attendance to classes. This special fee was agreed between Local Health Authority and the gymnasiums. The general practitioners were involved in the program and encouraged to promote patients adherence. For further discussion of how it used the community-based APA program, together with general practitioners and APA gym instructors, for chronic disease management.¹¹

Study limitations

This study has several limitations. The main drawback of our analysis is that we did not have a randomised control group. Indeed, we decided to compare those who attended the classes for 1 year to those who did not adhere or discontinued the program: although the groups were remarkably similar in baseline characteristics (except from the distance from home to the gymnasium), we must acknowledge that our results lack the strength of a randomised trial. Furthermore, we did not collect information on the reasons for non-adherence, and we may not exclude that the difference in our subjective outcomes, between the two groups, particularly for a multifactorial variable such as self-reported health, could be also due to unobserved factors. Another limitation of our study is that, since the study population was quite large and the district where the program was conducted covers a wide area with many villages participating, our 12-month follow-up was only based on telephone interviews, and the clinical examination and performance assessment were not repeated. On the other hand, the participation rate to the follow-up interview was high, including 88% of the persons enrolled in the study. Further, in the follow-up we did not collect information on additional treatments and drug intake that would have been relevant for our outcome. Finally, our study population was disproportionately female. Although this is consistent with the findings of previous studies conducted in US and Italy,^{9, 24} this data partially jeopardizes the generalizability of our findings also to the male group. Further research is needed to determine whether long-term participation in APA

reduces morbidity, modifies health services utilization, extends life expectancy, or improves quality of life for participants.

Conclusions

In conclusion, participation for a full year in the community-based APA program was associated with significant improvements in the self-perception of health status and back pain in a large group of Italian subjects. Even with a substantial percentage of participants over age 65, the APA back pain program appears safe and has been extended, expanded, and incorporated by the Local Health Authority into a chronic disease management system. Furthermore, other Local Health Authorities are currently replicating the program. These findings highlight the potential for new approaches to manage chronic disease and disability by facilitating a healthy lifestyle and promoting physical activity through implementation of community based exercise programs such as the Empoli APA back pain program.

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