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ORIGINAL ARTICLE

Adults with idiopathic scoliosis improve disability after motor and cognitive rehabilitation: results of a randomised controlled trial

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Abstract
Purpose To evaluate the effects of motor and cognitive rehabilitation on disability in adults with idiopathic scoliosis at lower risk of progression.
Methods 130 adults with idiopathic scoliosis (main curve <35°) were randomly assigned to a 20-week rehabilitation programme consisting of active self-correction, task-oriented exercises and cognitive–behavioural therapy (experimental group, 65 subjects, mean age of 51.6, females 48) or general physiotherapy consisting of active and passive mobilizations, stretching, and strengthening exercises of the spinal muscles (control group, 65 subjects, mean age of 51.7, females 46). Before, at the end, and 12 months after treatment, each participant completed the Oswestry disability index (ODI) (primary outcome), the Tampa scale for kinesiophobia, the pain catastrophizing scale, a pain numerical rating scale, and the Scoliosis Research Society-22 Patient Questionnaire. Radiological (Cobb angle) and clinical deformity (angle of trunk rotation) changes were also investigated. A linear mixed model for repeated measures was used for each outcome.
Results Significant effects of time, group, and time by group interaction were found for all outcome measures ($P < 0.001$). After training, the primary outcome showed a clinically significant between-group change (12 % points), which was preserved at follow-up. At follow-up, the radiological deformities showed a significant, although not clinically meaningful, between-group difference of 4° in favour of the experimental group.
Conclusion The experimental programme was superior to general physiotherapy in reducing disability of adults with idiopathic scoliosis. Motor and cognitive rehabilitation also led to improvements in dysfunctional thoughts, pain, and quality of life. Changes were maintained for at least 1 year.

Keywords Adult scoliosis · Self-correction · Task-oriented exercises · Cognitive–behavioural therapy · Randomised controlled trial

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Introduction

Adult scoliosis (AS) can be the evolution of an adolescent idiopathic scoliosis into adulthood or a consequence of disc and facet joint degeneration, pelvic obliquity secondary to hip pathologies or leg length discrepancies, and metabolic bone diseases [1]. The overall prevalence of AS has been reported to range from 1.4 to 20 % [2, 3]. Subjects with AS may variably present back pain, radicular pain, and neurological deficits; furthermore, spinal abilities may gradually decrease, leading to functional impairment and disability [1].

Growing attention being given to AS is principally due to the ever expanding elderly population, patients' awareness of natural history, and their willingness to face chronic pain as well as limitations in activities [1]. AS treatment is

challenging as clinicians are expected to successfully manage these criticisms despite the limited healing potential of the spine [4]; moreover, the presence of psychological factors such as catastrophizing, kinesiophobia, maladaptive coping strategies and mood disorders contribute to chronic symptoms and treatments including cognitive–behavioural therapy (CBT) are needed [2, 5].

Both surgical and non-surgical options exist, but previous studies have stated the superiority of operative over conservative treatments in AS, leading to better health-related quality of life (HRQoL), pain, walking abilities, and radiological findings [6–8]. However, surgical options should be reserved to subjects with chronic back pain unresponsive to conservative treatment, neurological signs and those with high risk of curve progression [1, 9, 10]; relevant costs and complications should also be considered when surgical decisions are being made [11, 12]. Attention should otherwise be directed towards conservative treatments when mild or moderate curves [13] are present, especially when subjects seek clinicians' help due to chronic symptoms and disability [14, 15].

Sparse evidence is available concerning AS conservative treatment as it is mostly based on case reports and case series, including injections, bracing, spinal exercises (both active and device assisted), chiropractic and osteopathic care, pilates, myofascial release, and cardio-respiratory training [16–27]. A systematic review on non-surgical treatments in AS concluded that evidence for conservative care was lacking and clinical research was suggested to define the target population (type of AS, curve magnitude, pain, etc.) and the most effective intervention (biomechanical rationale, characteristics, frequency, and duration) [28]. Based on this premise, the hypothesis underlying this study was that a multidisciplinary programme involving active self-correction, task-oriented exercises, and CBT would induce long-term improvements in disability, chronic back pain, kinesiophobia, catastrophizing, and HRQoL in adults with idiopathic scoliosis at lower risk of progression. The aim of this study was to evaluate the efficacy of such a programme in comparison with general physiotherapy in subjects with adult idiopathic scoliosis who sought clinicians' help due to back disability.

Methods

Design

This randomised, parallel-group superiority-controlled trial was conducted at the Operative Unit of Physical Medicine and Rehabilitation of a highly specialised centre that conservatively treats >300 subjects with idiopathic scoliosis every year. The staff involved has documented skills in AS management and attends annual theoretical and practical refresher courses on the management of this disease. The study was approved by the Institutional Review Board (number: 11; date of approval: 08/10/2010), and was conducted in conformity with ethical and human principles of research.

Immediately after the patients had given their written consent, a biostatistician randomised the subjects to one of the two treatment programmes using a list of blinded treatment codes previously generated and an automatic assignment system to assure the concealment of the allocation. The principal investigator (PI) obtaining and assessing the data and the biostatistician making the analyses were blinded to treatment allocation. The remaining health providers and the patients could not be blinded.

Participants

Subjects with a diagnosis of adult idiopathic scoliosis (i.e. a documented scoliosis since adolescence or childhood) not selected for surgical treatment but who sought clinicians' help due to back disability were selected for the study. Other inclusion criteria were a main curve magnitude of <35°, an adult age, and a good understanding of Italian. Radiological deformities were evaluated by long-standing full spine radiography. The curve magnitude was measured according to standard Cobb–Lippman's technique; ideal measuring conditions were pursued to assure an intra-observer measurement between 3° and 5° [29–31]. The curve type was defined according to the location of the apical vertebra of the main curve: thoracic (apex T2–T11–T12 disc), thoracolumbar (apex T12–L1) and lumbar (apex L1–L2 disc–L4) [32].

The exclusion criteria were any diagnosable cause of scoliosis, adult degenerative scoliosis, pelvis and lower limb deformities interfering with spinal posture, any specific causes of spinal diseases, cardiac and/or respiratory dysfunction, systemic illness, previous spinal surgery, and cognitive impairment.

Outpatients were consecutively recruited between January 2011 and December 2013 and evaluated by two physiatrists coordinated by the PI. Those satisfying the entry criteria were then asked to declare their willingness to comply with whichever treatment option they were randomly assigned to. To partially limit expectation bias and reduce crossover, patients were blinded to the study's hypothesis by telling them the trial was intended to compare two common approaches, whose efficacy had not yet been established.

Interventional programmes

These involved two physiatrists, a clinical psychologist, and two physiotherapists.

Experimental group

This programme firstly involved active self-correction, a rehabilitative technique consisting of selective vertebrae lateral deflection and preservation of the sagittal profile, both resulting in horizontal de-rotation [33]. Exercises for strengthening spinal deep muscles while maintaining self-correction and segmentary stretching involving limbs and back muscles were further introduced. Self-correction was progressively performed during task-oriented exercises (e.g. sit-to-stand, ascending/descending stairs) aimed at improving postural, proprioception, and neuromotor control of the spine and limbs. Additional exercises (e.g. turning, standing on unstable surfaces, and walking while changing speed and direction) were aimed at recovering coordination and balance.

During the intervention, by means of implementing cognitive–behavioural strategies under the supervision of the psychologist, patients were educated to view scoliosis as something that can be self-managed rather than as a disease that inevitably influences their life. The main situations avoided were identified on the basis of fear-avoidance beliefs emerging from questionnaires, habitual activities and the results of a presentation of images showing back-stressing activities. Patients were helped to increase their level of activity by graded exposure to exercises and to common activities of daily life and by communication aimed at sharing the goals to be reached.

Ergonomic advice to modify incorrect postural habits was provided by means of a booklet given to each patient during the first session.

Control group

General physiotherapy included exercises for spinal mobilisation (passive mobilisation to improve thoracic and lumbar range of motion), muscle segmentary stretching of upper/lower limb and back muscles, strengthening of abdominal and back muscles, and postural control (involving exercises aimed at developing motor control of the spine and pelvis).

Treatment administration

Under the supervision of a physiatrist, each physiotherapist was separately responsible for each programme, and was allowed to arrange one 60-min session of physical training per week for 20 weeks. In addition, the experimental group met with the psychologist twice a month for a 60-min session.

During and at the end of treatment, patients were asked to continue the taught exercises actively at home.

To ensure that there was no variability in treatment administration, a fidelity check based on a manual of exercises was conducted at the end of each session.

No other treatments (e.g. physical modalities, nerve blocks) were offered once the patients were accepted for the programme; participants were disallowed from taking major pharmacological agents (e.g. opioids, steroids, or anticonvulsants), whilst non-opioids and NSAIDs were permitted. Spouses and significant others were asked to support patients' compliance during the study and to inform the staff promptly of any difficulty if encountered, to strengthen treatment adhesion and minimise drop-out rates.

Outcome measures

Disability (primary outcome) was assessed using the Italian ODI, a self-administered 10-item questionnaire ranging from 0 (no disability) to 100 (maximum disability) and evaluating the intensity of pain and its disabling effect on daily activities [34].

Pain was assessed using an 11-point numerical rating scale (NRS) ranging from 0 (no pain) to 10 (the worst imaginable pain) [35].

Kinesiophobia was assessed using the Italian 13-item version of the self-report Tampa Scale for Kinesiophobia (TSK) [36], with the reversed items removed, ranging from 13 (no fear) to 52 (maximal fear).

Catastrophizing was evaluated by means of the 13-item Italian version of the self-reported Pain Catastrophizing Scale (PCS), ranging from 0 to 52, with higher scores representing greater catastrophizing [37].

Health-related quality of life (HRQL) was assessed using the Italian version of the region-specific Scoliosis Research Society-22 Patient Questionnaire (SRS-22) [38], which covers five domains: function, pain, mental health, self-perceived image, and satisfaction with management. Each domain is scored 1–5 (from worst to best).

Clinical deformity was evaluated by the angle of trunk rotation (ATR) of the hump on the main curve: ATR was measured with the patient bending forward using the Bunnell's scoliometer [39, 40].

Outcome measures were collected before treatment, 20 weeks later (post-training), and 12 months after the end of treatment (follow-up). The questionnaires were administered by secretarial staff who checked them and returned any uncompleted part(s) for completion. Clinical deformities were assessed by the PI. At follow-up, patients were also asked to perform a second radiography to assess possible changes in the main curve magnitude. The X-ray was evaluated by the same operator (PI) both at baseline and at follow-up, to assure ideal measuring conditions (28–30). The PI was blinded to the before–after radiographs.

Finally, during intervention, patients were asked to report any symptoms they experienced that required further treatment.

Statistics

The sample size was computed using the Italian ODI, for which it was estimated a minimum clinical important difference of 10 with a standard deviation of 16 [41]. To ensure 90 % statistical power, 110 patients were required, whilst 130 were actually recruited to allow for a 20 % drop-out rate. Baseline comparability was assessed using the Student's *t* test for independent samples for continuous data and proportions tests (Pearson's Chi-square) for ratios. Intention-to-treat analysis was conducted and linear mixed model analyses for repeated measures ($P < 0.05$) were made of each outcome measure to evaluate changes over time and between groups. This approach was selected since it is a valid method in case of missing data [42, 43].

The statistical analysis was performed using SPSS 22.0 software.

Results

Of the 152 patients screened, 130 who agreed to participate were randomised and included in the analysis. Nine subjects dropped out from the study before the intervention ended (experimental group: $n = 4$; control group: $n = 5$); a further nine were lost during follow-up ($n = 4$; $n = 5$), as shown in Fig. 1. No crossover problems arose as no patient asked to swap groups.

The two groups were comparable at baseline in terms of age, body mass index, and pain duration before treatment (Table 1), as well as outcome measures (Table 2). The sample was characterised by a main scoliotic curve with a mean magnitude of 28° and by a moderate level of disability (mean ODI score: 38/100) and pain (mean NRS score: 6.5/10).

A significant effect of time, group, and time by group interaction were found for all of the outcome measures ($P < 0.001$), except for the magnitude of the main curve which did not show a significant effect of group (Tables 3, 4).

A clinically significant between-group difference of 12 % was found after training on the primary outcome. This difference further increased at follow-up.

As for pain (NRS), the two groups showed a mean difference of three points at post-treatment assessment, which was preserved at follow-up.

As regards the psychological variables (TSK and PCS), a between-group difference of about ten points was achieved after training for both scales, and a further improvement was noticeable at follow-up.

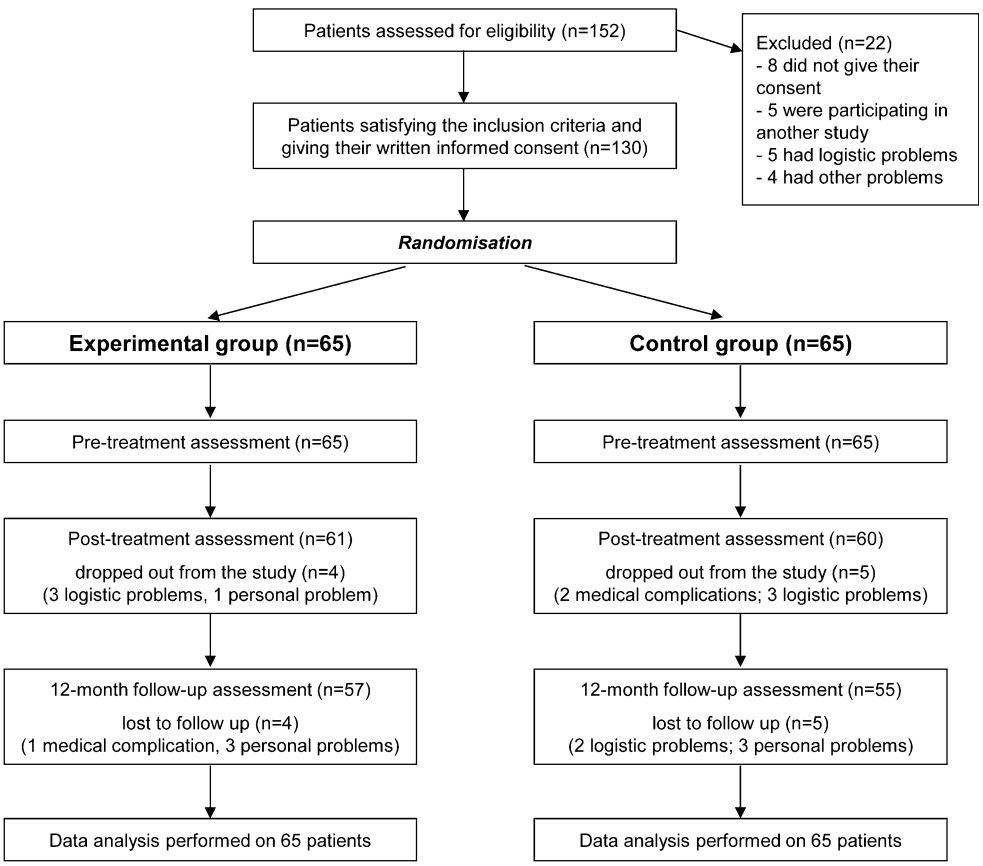

Fig. 1 Study flowchart

Table 1 Patients' baseline characteristics ($n = 130$)

	Experimental group ($n = 65$)	Control group ($n = 65$)	P value
Age (years)[a]	51.6 (8.1)	51.7 (8.5)	0.950*
Gender (male/female)[a]	17/48	19/46	0.695†
Body mass index (kg/m^2)[a]	21.8 (3.7)	22.0 (3.5)	0.655*
Pain duration (months)[a]	37.9 (20.5)	35.4 (19.9)	0.481*
Pain radiation to lower limbs (yes/no)	25/40	30/35	0.375†
Type of scoliosis			
Thoracic	15	14	0.940†
Lumbar	20	19	
Thoraco-lumbar	30	32	
Occupation			
Employed	28	27	0.865†
Self-employed	15	18	
Pensioner	13	10	
Housewife	9	10	
Education			
Primary school	4	5	0.447†
Middle school	17	25	
High school	30	24	
University	14	11	
Comorbidities (principal)			
Cardiac diseases	14	11	0.968†
Respiratory diseases	5	5	
Gastroenteric diseases	10	12	
Kidney diseases	2	1	
Endocrine diseases	9	7	
Other	2	2	
Type of drug used			
Antidepressant/anxiolytic	4	2	0.785†
Analgesic	22	20	
Muscle relaxant	8	10	
NSAIDs/corticosteroid	23	25	
Smokers (yes/no)	20/45	17/48	0.560†
Married (yes/no)	45/20	43/22	0.708†
General physical activity (yes/no)	20/45	25/40	0.357†

NSAIDs non-steroidal anti-inflammatory drugs

* Student's t test for independent samples

† Pearson's Chi-square for comparing proportions

[a] Mean values (standard deviation)

A more significant improvement was achieved by the experimental group in terms of HRQoL (Table 4), with all SRS-22 domains showing a significant effect of time, group and time-by-group interaction. The experimental group was also more satisfied with the intervention, as suggested by the Satisfaction with Management domain (between-group change of 1 point after training).

In terms of clinical deformity, mean changes of 2.5° and 4° were achieved for the ATR after training and at follow-up, respectively. However, both these differences were not clinically meaningful. Finally, one year after training, a between-group difference of 4° was observed in terms of Cobb angle, but this difference could not be considered clinically meaningful, as it was comparable with an intra-observer measurement error of 3–5°.

The physiotherapists systematically checked treatment diaries and compliance rates were satisfactory in both groups (100 %). Minor adverse effects of transient pain

Table 2 Patients' comparison at baseline ($n = 130$)

	Experimental group[b] ($n = 65$)	Control group[b] ($n = 65$)	P value[†]
Primary outcome			
Oswestry disability index (0–100)	38.0 (6.8)	37.8 (6.0)	0.880
Secondary outcomes			
Numerical rating scale (0–10)	6.5 (1.2)	6.6 (1.2)	0.557
Tampa scale for kinesiophobia (13–52)	31.5 (6.5)	30.2 (5.0)	0.228
Pain catastrophizing scale (0–52)	27.6 (3.9)	27.7 (3.0)	0.960
Main curve (Cobb angle) (°)	28.2 (4.9)	27.5 (5.0)	0.448
Angle of trunk rotation (°)	12.9 (3.3)	12.4 (3.4)	0.402
SRS-22[a]			
Function (0–5)	2.7 (0.5)	2.7 (0.5)	0.803
Pain (0–5)	2.8 (0.5)	2.8 (0.5)	0.663
Self-perceived image (0–5)	2.9 (0.4)	2.9 (0.4)	0.884
Mental health (0–5)	3.4 (0.4)	3.5 (0.4)	0.161

[†] Student's t test for independent samples

[a] Scoliosis Research Society-22 Patient Questionnaire

[b] Mean values (standard deviation)

worsening (experimental group: $n = 5$, control group: $n = 3$) and mood disorders ($n = 2$; $n = 4$) were easily managed by symptomatic drugs and brief periods of rest.

Discussion

Our findings show that a multidisciplinary rehabilitation programme involving active self-correction, task-oriented exercises, and CBT was superior to general physiotherapy in improving disability, pain, kinesiophobia, catastrophizing, and HRQoL in adult idiopathic scoliosis. The effects lasted for at least 1 year after the intervention ended.

A clinically significant between-group difference was found in favour of the experimental group [41]. Despite the spinal elasticity of an adolescent quite different from the one of an adult and the expectations of curve correction are lower, we found that self-correction was also applicable in more rigid curves. Moreover, when self-correction was implemented during task-oriented exercises it may have added value in enhancing functional outcomes and a faster return to usual activities, in contrast to general physiotherapy, mostly performed supine on a couch and in the absence of any functional input. Having explained to the patients how to modify their mistaken fears and encouraging them to adopt appropriate behaviours, they became more comfortable with their usual activities, exhibited a more positive attitude toward the exercises and increased their physical performance. Satisfactory levels were maintained until completion of follow-up, and the significant between-group difference in disability might be considered corresponding to the levels of catastrophizing and kinesiophobia, which also showed a significant between-group difference after training and at follow-up [44].

A significant between-group difference was also found in terms of pain perception both after training and at follow-up, suggesting the importance of functional exercises and CBT in modifying pain perception effectively in chronic populations [45].

The effect of the treatment on the SRS-22 domains confirmed the benefits of the experimental intervention. The improvement in the Mental Health domain suggested the synergistic effects of developing subjects' awareness of a disease which can be actively managed over time. Scores in Function and Pain domains increased as a result of approaches mainly targeted at improving functional abilities during usual activities. The Self-Image domain improved, supporting the educative and cognitive–behavioural component of the intervention proposed. The higher rates of satisfaction with management in the experimental group suggested that enhancing self-management skills was perceived as a more positive means of responding to concerns regarding AS. However, caution is required when interpreting these findings as the physiotherapists could not be blinded to the study hypothesis and, consequently, may have influenced patients' expectations.

Significant between-group differences in favour of the experimental group were also found in terms of radiological and surface deformities. It can be argued that exercise may have played a role in the recovery of the postural collapse present in

Table 3 Changes over time within and between groups ($n = 130$)

	Group	Pre-training[a]	Post-training[a]	Follow-up[a]	Difference at post-training[b]	Difference at follow-up[b]	Time effect[‡]	Group effect[‡]	Interaction effect[‡]
Primary outcome									
Oswestry disability index (0–100)	Experimental	38.0 (6.8)	19.7 (6.4)	17.6 (5.3)	−12.0 (−14.3; −9.8)	−14.8 (−17.1; −12.6)	<0.001	<0.001	<0.001
	Control	37.8 (6.0)	31.8 (6.1)	32.5 (6.5)					
Secondary outcomes									
Numerical rating scale (0–10)	Experimental	6.5 (1.2)	2.9 (1.2)	2.2 (1.2)	−3.2 (−3.7; −2.7)	−4.1 (−4.7;−3.6)	<0.001	<0.001	<0.001
	Control	6.6 (1.2)	6.1 (1.4)	6.3 (1.7)					
Tampa scale for kinesiophobia (13–52)	Experimental	31.5 (6.5)	21.0 (4.8)	18.8 (3.9)	−9.7 (−11.4; −8.0)	−12.0 (−13.6; −10.5)	<0.001	<0.001	<0.001
	Control	30.2 (5.0)	30.8 (4.9)	30.9 (4.5)					
Pain catastrophizing scale (0–52)	Experimental	27.6 (3.9)	17.2 (3.3)	15.9 (2.9)	−10.6 (−11.8; −9.3)	−12.4 (−13.6; −11.1)	<0.001	<0.001	<0.001
	Control	27.7 (3.0)	27.8 (3.7)	28.2 (3.6)					
Main curve (Cobb angle) (°)	Experimental	28.2 (4.9)	NA	25.3 (5.3)	NA	−4.3 (−6.4; −2.3)	<0.001	0.074	<0.001
	Control	27.5 (5.0)	NA	29.6 (5.7)					
Angle of trunk rotation (°)	Experimental	12.9 (3.3)	9.9 (2.8)	9.7 (3.2)	−2.5 (−3.6; −1.4)	−4.0 (−5.2; −2.7)	<0.001	<0.001	<0.001
	Control	12.4 (3.4)	12.3 (3.4)	13.7 (3.5)					

NA not available

‡ *P* value (linear mixed model)

[a] Mean values (standard deviation)

[b] Mean change (confidence interval)

Table 4 Changes over time within and between groups in terms of health-related quality of life ($n = 130$)

	Group	Pre-training[b]	Post-training[b]	Follow-up[b]	Difference at post-training[c]	Difference at follow-up[c]	Time effect[‡]	Group effect[‡]	Interaction effect[‡]
SRS-22[a]									
Function (0–5)	Experimental	2.7 (0.5)	3.7 (0.5)	4.2 (0.3)	0.7 (0.6; 0.9)	1.3 (1.2; 1.5)	<0.001	<0.001	<0.001
	Control	2.7 (0.5)	2.9 (0.3)	2.9 (0.4)					
Pain (0–5)	Experimental	2.8 (0.5)	3.8 (0.5)	4.2 (0.4)	0.9 (0.7; 1.0)	1.5 (1.3; 1.7)	<0.001	<0.001	<0.001
	Control	2.8 (0.5)	2.9 (0.4)	2.7 (0.5)					
Self-perceived image (0–5)	Experimental	2.9 (0.4)	3.5 (0.6)	3.8 (0.5)	0.5 (0.3; 0.7)	1.0 (0.9; 1.2)	<0.001	<0.001	<0.001
	Control	2.9 (0.4)	2.9 (0.4)	2.8 (0.4)					
Mental health (0–5)	Experimental	3.4 (0.4)	4.2 (0.4)	4.4 (0.3)	0.7 (0.5; 0.8)	0.9 (0.7; 1.0)	<0.001	<0.001	<0.001
	Control	3.5 (0.4)	3.5 (0.4)	3.5 (0.4)					
Satisfaction with management (0–5)	Experimental	NA	4.5 (0.2)	4.5 (0.2)	1.0 (0.9; 1.1)	1.5 (1.4; 1.6)	<0.001	<0.001	<0.001
	Control	NA	3.5 (0.3)	3.0 (0.5)					

NA not available

‡ *P* value (linear mixed model)

[a] Scoliosis Research Society-22 Patient Questionnaire

[b] Mean values (standard deviation)

[c] Mean change (confidence interval)

upright posture; however, differences in the Cobb angle and ATR cannot be considered as clinically significant [46, 47].

A case report investigated the effects of active self-correction on AS: a 25-year-old female scoliosis patient underwent individual sessions every 2 months at the Institute and continued the treatment by herself everyday at home [19]. Contrary to our results, the Authors showed a Cobb angle reduction of 18.5° after 1 year of exercises; however, this result was achieved on a single subject, younger than our population (mean age of 52 years), and after a longer period of training. Further comparisons cannot be made as they did not provide information regarding ATR, disability, pain, and HRQoL. Our programme developed self-correction also by means of task-oriented exercises, CBT, and by more frequent sessions of exercises to assure they were correctly carried out at home.

It is worth noting that the experimental programme has to be considered a low-cost intervention, as about 450 € are provided from the Italian healthcare system for the entire programme per patient; based on the positive findings described above, this intervention might be considered cost-effective by preventing limitations in usual life activities and days off work due to high levels of disability, kinesiophobia and catastrophizing.

This trial had a very significant level of internal validity as it was capable of distinguishing effects between groups, was adequately sized, involved concealed randomisation, blinded data collection, effective masking of assessors and analysts, and homogenous groups at baseline. The support of relatives and staff helped in creating a protected environment, limiting the drop-out rate and minimising adverse effects.

The sample was representative of the general population at low risk of curve progression undergoing rehabilitation for adult idiopathic scoliosis [28]; therefore, our findings cannot be generalised to other populations with greater risks of worsening. Furthermore, the described intervention cannot be carried out in every rehabilitation setting as it requires qualified staff specialised in chronic pain management and spinal deformities.

This study also poses some limitations. Firstly, contact-time differences between the treatment groups due to the psychological intervention may be raised. Secondly, treatment expectations were not addressed, and this confounding factor was only partially limited by telling the patients that the efficacy of both treatments had not yet been established. Thirdly, exercise compliance and adherence to treatment could not be fully guaranteed, although the patients' diaries were checked on a weekly basis.

Compliance with ethical standard

Conflicts of interest There are no conflicts of interest to declare.

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