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# Predictors of response to exercise therapy for chronic low back pain: result of a prospective study with one year follow-up

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***Background*. Low back pain (LBP) management is a critical public health issue in all developed countries. Most approaches show evidence of effects only in the short term.**
***Aim*. To identify predictors of functional outcome on discharge and at 1 year.**
***Design*. Prospective cohort study.**
***Setting*. Outpatient rehabilitation department.**
***Population*. Patients aged >18 addressed to exercise therapy for persisting LBP.**
***Methods*. The individually designed physiotherapy program provided 7 sessions (45'); patients were given advice to stay active and continue exercise program on discharge. Baseline (T0) assessment included: age, sex, time since onset, pain-related drug use, previous treatments, job, physical activity, pain (NRS) and Mental Health (SF36 sub-score); at follow-up (T2), we also enquired to on adherence to exercise prescription, physical activity, drugs. The primary outcome measure was the Roland and Morris Disability Questionnaire (RMDQ) patients scoring improvement >30% (minimal clinical important difference) were classified as respondent.**
***Results*. 211 completed follow-up (70% women; age 70.4±11.9). Average RMDQ score was reduced by 35% at T1 and by 31% at T2; NRS by 28% (T1) and 24% (T2); 125 patients (59%) were responders on discharge; 106 (50%) at follow-up. Only higher baseline NRS predicted poor response to treatment at T1 (OR=0.83, 95% CI: 0.71-0.95, P=0.012)). At T2, older age (OR=0.94, 95% CI: 0.91-0.98, P=0.003), drug use (OR=0.18, 95% CI: 0.08-4,69, P<0.001) and previous treatments (OR 0.33, 95% CI: 0.15 to 0.71, P=0.004) were significantly associated with poor response, while, baseline mental health (OR=1.1, 95% CI: 1.01-1.24, P=0.02) and adherence to exercises for LBP (OR=2.10, 95% CI: 1.03-4.42, P=0.04) predicted improved outcome.**
***Conclusions*. The individually designed exercise therapy program for chronic LBP was associated to clinically significant functional improvement both on discharge and at 1 year. Only severe pain intensity predicted poor treatment response on discharge. At one year, younger age and better mental health predicted improved outcome, while use of drugs and previous LBP treatments were associated with worse response. Adherence to the exercise program almost doubled the probability of a favorable outcome.**
***Clinical Rehabilitation Impact*. Adherence to an extensive individually designed exercise therapy program improves long term functional outcome of chronic low back pain.**

**KEY WORDS:** Low back pain - Exercise therapy - Treatment outcome.

Low back pain has a relevant impact on patients in terms of pain, activity limitations, participation restrictions, influence on career, use of sanitary resources and financial burdens.[1, 2] The chronic phase is characterized by constant, generally moderate pain, associated with relevant pain related disability. A very low rate of spontaneous resolution goes with a high rate of symptom exacerbation.[3]

The conservative approach is generally recommended for chronic non-specific low back pain: pa-

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tient education, tractions, lower-quarter nerve mobilization procedures have from moderate to weak evidence on treatment of chronic back pain, while manual therapy and treatments based on exercises have the stronger evidence, at least in the short term.[2, 4] Exercise therapy, defined as combination of trunk strengthening, stretching, coordination, and endurance exercises, is the most widespread conservative approach used in clinical practice and is recommended by most of the guidelines for acute or chronic low back pain.[3, 5, 6] Exercise therapy slightly decreases pain and improves physical function in adults with chronic low back pain, particularly in health care populations.[3] Exercise therapy programs can be classified as "individually designed", in which the therapist completes a clinical history and physical examination and delivers an exercise program specifically designed for the individual participant; "partially individually designed", in which the exercise program includes the same type of exercises but varied in intensity, duration, or both; or "standard design", in which a fixed exercise program is delivered to all participants. Systematic reviews report that the most effective strategy seems to be individually designed exercise programs delivered in a supervised format (for example, home exercises with regular therapist follow-up), however the gold standard for long term response to treatment is yet to be defined.[7]

Back pain management is a critical public health issue in all developed countries. In order to implement more effective health policies for outpatient rehabilitation services and resource allocation in 2005, the Tuscany Region Public Health Authority stated that patients with non-specific back pain and back pain related disability are entitled to an structured exercise-based physiotherapy program.[8] These programs are individually designed and integrated with personalized advice, including that of continuing specific exercise practice at home as well as of beginning or continuing low impact physical activity of choice. Similarly designed programs have already proven partially effective in the short-medium term,[5, 8] but, as non specific back pain covers very heterogeneous range of clinical conditions,[9] and not all patients respond to exercise treatment, the identification of possible predictors of response to treatment outcome among patient's baseline characteristic may help improving overall outcome.[10-12] At the same time, the long term outcome of such programs, especially for patient who complain of long lasting symptoms, has not yet been established, as well as if long term adherence to exercise prescription does indeed increase the likelihood of a better outcome in the long term.[13] This information may have relevant implications for clinical practice, both for selecting target populations for alternative treatment and for the therapist promoting behaviors that may be more protective in the long term. Thus, this prospective study describes the outcome of mechanical chronic low back pain (cLBP) treated in an outpatient rehabilitation department based on a structured exercise program designed according to the Tuscan Region regulation and aims to identify predictors of response to treatment on discharge and at one year follow-up.

## Materials and methods

### *Participants*

All patients presenting from January 2010 to March 2011 at the Don Gnocchi Foundation IRCCS Florence with a prescription of exercise treatment for persisting non-specific low back pain were considered eligible. The diagnosis and prescription came either from a specialist in physical medicine and rehabilitation or from the patient's family Physician. Further inclusion criteria were aged over 18 years and chronic low back pain, defined as pain persisting from very often to always for a t least 6 months. Exclusion criteria were neurological signs (irritation/deficit) and/or pain below the kneecap; severe osteoporosis; spondilolysis and spondilolysthesis; arthritis (rheumatoid arthritis, spondylitis, etc.); tumors; infections; previous spinal surgery; other debilitating and/or very painful musculoskeletal condition; recent trauma (<30 days); acute illness; anticoagulant therapy or phenobarbital or radio/chemotherapy; psychiatric illness; medical-legal disputes in progress; pregnancy. Eligible patients meeting the above criteria were invited to participate in the study, and were asked for their written consent. The Institutional Review Board of the Don Gnocchi Foundation approved the study protocol.

### *Intervention*

The exercise treatment protocol was formulated according to the national and international guide-

lines on the treatment of persistent low back pain with exercises [8, 14] and according to the Tuscany Region resolution. The program provided 6 sessions of 45 minutes each, delivered consecutively on working days (Monday-Friday). Therapist assessment was individually performed in an additional session, scheduled the day before initiating treatment, while the final assessment was delivered right after the end of the last session. Therapists with a University degree in Physiotherapy and at least 5 years experience were involved in assessment and delivery of the rehabilitation program. Each session was conducted by two physiotherapists, and included 4 patients at most. The exercise program was individually designed, including a set of 5-7 adapted and personalized exercises, selected on the basis of physiotherapy assessment and proposed to the patient. The purpose of each exercise was discussed with each patient and exercises were performed under the supervision of the physical therapist to correct execution. The overall goal of the rehabilitation program was to improve the competence of patient on their own disorder. Patient education was promoted by a booklet with evidence based, standardized educational information on basic back anatomy and biomechanics, optimal postures, ergonomics, and the advice to stay active, given to each participant and discussed with physicians or physiotherapists. Exercise was focused on stimulating awareness of the body scheme, balancing muscle function (de-contraction of the shortened muscles, strengthening of weakened muscles), stabilizing the spine and correcting any alteration of postural alignment. A the end of treatment, each patient received personalized practical advice based on ergonomics and an individually tailored short set of exercises to continue at home. On discharge the regular practice of low-impact physical activity of low to moderate intensity according to the clinical profile and preferences of patients was also generally recommended.

### *Measures*

Measures were taken at T0 (baseline), T1 (discharge, 6 working days form baseline), T2 (twelve months from discharge). Baseline assessment included general characteristics: age, sex, number of years or months suffering of low back pain, how often in the last 6 months, pain related use of drugs, previous treatments performed, job, number of days lost at work due to back pain, physical activity.

The primary outcome measure was low back pain-related functional disability, assessed by the Roland and Morris Disability Questionnaire (RMDQ).[15] The Roland Morris score range from 0 to 24 respectively represent from no to maximum low back pain-related disability. We regarded as "respondent" patients with a minimal clinically important difference (MCID) in scores at Roland Morris Disability Questionnaire (RMDQ), indicated by the literature as an improvement equal to or greater than 30% compared to baseline at both end of treatment and follow-up.[16] In addition, the Numeric Rating Scale (NRS) consisting in numbered line from 0 through 10 to represent pain severity levels from none to "most intense pain imaginable" [17] and the Mental Health subscore of the Short Form Healthy Survey (SF-36) [18] were assessed on baseline and follow-up.

Other potential predictors of response to treatment were identified from variables reported to be associated with chronic low back pain in the literature.[11, 19] Potential predictors included: age, sex, BMI, smoking, number of years suffering from back pain, frequency in the last 6 months, use of medications, previous treatments performed at baseline, type of work, number of days lost at work due to back pain, physical activity.

At one year (T2), the patients enrolled in the study were contacted for a follow-up interview, performed by an independent researcher, reassessing the RMDQ and NRS and enquiring about the any medication or other treatment for cLBP received, about the practice of any regular physical activity, any changes in activity or job in the past year and adherence to specific exercise program. This point were investigated by the question "have you been practicing your exercise program?" no, occasionally or regularly (at least twice a week). We considered as "adherent" those who reported to have regularly performed their specific exercise program at least twice a week.

### *Statistical analysis*

Statistical analysis was performed using the software STATA 7.0, from Stata Corporation (College Station, Texas, USA). Changes in disability scores and pain from baseline to follows-up, were analyzed using the Wilcoxon rank test, the Pearson chi-square

tests for dichotomous variables, and the Kruskal-Wallis test for ordinal variables.

Response to treatment, measured as improvement in the Roland Morris score >30% (MCID) was the outcome variable. The demographic, social and clinical variables of baseline were introduced into a stepwise logistic regression to predict the probability of response on discharge; the same set of variables, and those about reported pain related behavior and adherence to exercise prescription in the twelve months preceding T2 were used to model the probability of response at 1 year. The variables with p≥0.05 were excluded from the stepwise logistic regressions.

## Results

From January 2010 to March 2011, 278 patients diagnosed with persistent low back pain occurred at our facility for rehabilitation treatment and were assessed for eligibility. All met the inclusion criteria and received rehabilitation treatment, 44 patients were not recruited to the exclusion criteria, 9 eligible patients refused to participate in the study. Of the 225 patients recruited 10 had a discontinued treatment cycle and 4 do not complete the 1 year follow-up (Figure 1).

Data from the 211 patients who completed treatment were used this analysis: demographic and clinical characteristics were reported in Table I. The sample was mainly composed by women (70%), with mean age of 70.4±11.9; almost half of the sample (51%) referred to assume drugs currently for low back pain and 55 % recurred to previous treatments.

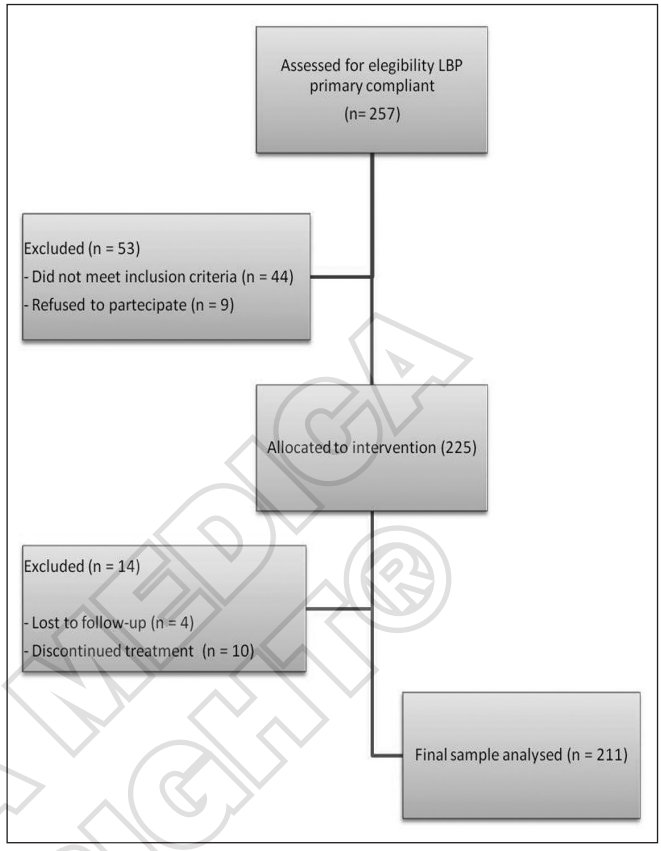


Figure 1.—Study flowchart. LBP: Low back pain.

Some parameters regarding job like absenteeism or change task were excluded from analysis because our sample included many housewives and retirees, in fact only the 33% of sample working.

TABLE I.—*Baseline general characteristics of the study sample (N.=211).*

| | |
|---|---|
| Age (years) (mean±SD) | 70.4±11.9 |
| Female sex (N., %) | 147 (70%) |
| Body mass Index (kg/m$^2$) | 26.1±3.7 |
| Working (N.,%) | 70 (33%) |
| Physical activity (N.,%) | 69 (33%) |
| Current smokers (N., %) | 22 (10%) |
| Mental health, [SF-36] (mean±SD) | 80.1±15.2 |
| Back pain related | |
| BP for how many years (mean±SD) | 14±14.7 |
| Use of drugs (N., %) | 107 (51%) |
| Previous BP treatments (N., %) | 115 (55%) |
| Roland Morris Disability Questionnaire (median, IQR) | 12 (8-16) |
| Numeric Rating Scale pain (median, IQR) | 7 (5-8) |

SF-36: Short Form Healthy Survey; IQR: interquartile range.

TABLE II.—*Primary and secondary outcome for efficacy of treatment.*

| | T0 | T1 | T2 |
|---|---|---|---|
| Primary outcome | | | |
| Roland Morris Disability Questionnaire (median, IQR) | 12 (8-16) | 8 (4-11)* | 8 (4-12)° |
| Secondary outcome | | | |
| Numeric Rating Scale pain (median, IQR) | 7 (5-8) | 5 (3-6)* | 5 (4-7)° |
| BP related use of drugs (%) | 51% | | 28%° |
| Body mass Index (kg/m$^2$) | 26.1±3.7 | | 26.1±3.6 |
| Physical activity (%) | 33% | | 42%° |
| Mental Health [SF-36] (mean±SD) | 80.1± 15.2 | | 87.4±7.8 |

* T0 *vs.* T1 P-value <0.001; °T0 *vs.* T2 P-value <0.001.

Both in the short-term (discharge) and in the long-term (1 year) our chronic LBP patients reported on average an improvement in the primary outcome (pain related disability) above the minimal clinically significant difference of 30%: in detail, disability score was reduced by 35% on discharge and by 31% at 1 year follow-up. Pain scores were also significantly reduced both in the short term (28%) and in the long term (24%) (Table II).

Considering as "respondent" patients who improved their RMDQ score by 30% or more,[15] 125 patients (59%) were classified as responders and 86 (41%) as non-responders on discharge. At follow-up (T2), responders were 105 (50%) and non-responders 106 (50%) (Figure 2).

The distribution of responders and non-responders at follow-up has the following pattern: responders at both T1 and T2 were 77 (36.5%), non-responders at both T1 and T2 are 58 (27.5%), 28 patients (13%) increase in T2 and 47 (22%) worse (Figure 2A, B).

Table III shows the data of the stepwise logistic regression model as probability of response after treatment. A less intense pain (NRS) at baseline was the only significant variable associated to a decrement at least of 30% of disability after treatment (OR 0.83, 95% CI: 0.71-0.95, P=0.012).

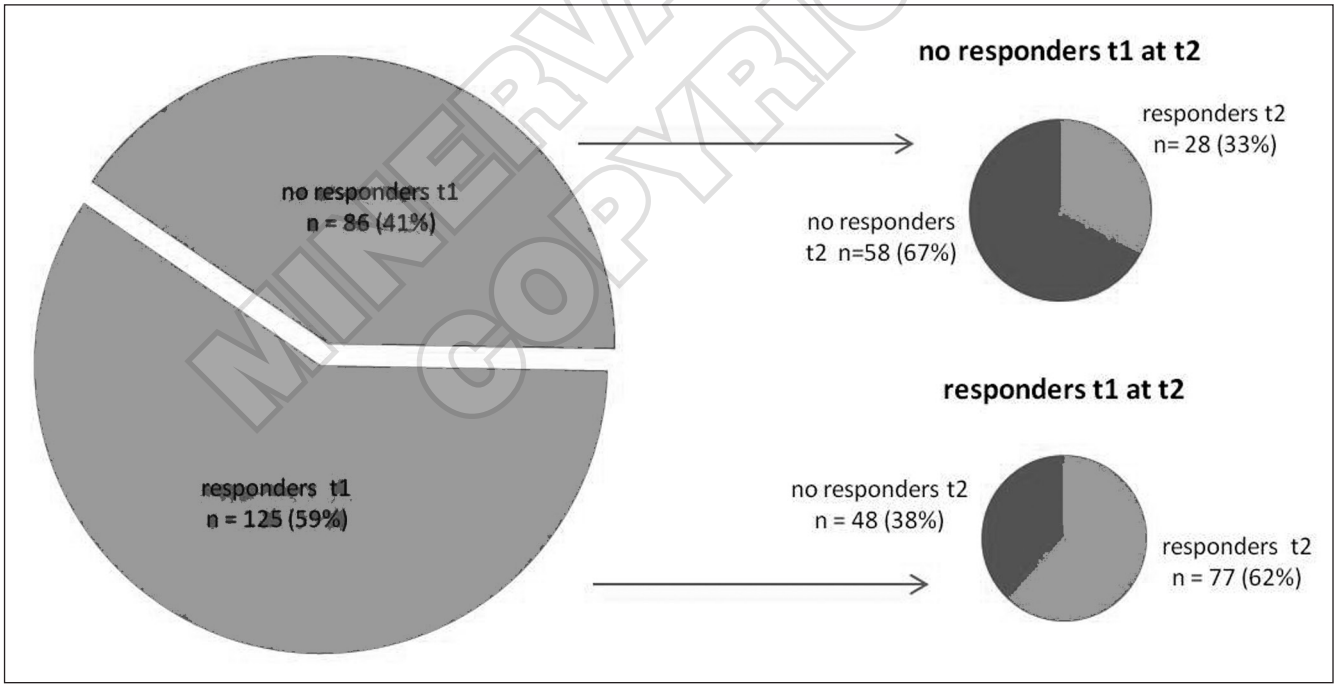


Figure 2.—Distribution of responders and no responders at discharge (t1) and follow-up (t2).

TABLE III.—*Independent predictors of response to treatment on discharge: stepwise logistic regression.*

| Final Model: Obs=211 LR $\chi^2$=6.95; Prob> $\chi^2$ <0.008; Pseudo R2=0.031 | | |
|---|---|---|
| Responders T1 | OR (95% CI) | P |
| NRS T0 | 0.83 (0.71 - 0.95) | 0.012 |

Removing from model: bmi (P=0.98), use of drugs before treatment (P=0.95), physical activity (P=0.61), previous treatment (P=0.54), sex (P=0.31), smoke habits (P=0.20), age (P=0.30), RMDQ at T0 (P=0.22), job (P=0.14), mental health (P=0.09)

TABLE IV.—*Independent predictors of response to treatment at 1-year form discharge: stepwise logistic regression.*

| Final model: Obs=211 LR $\chi^2$ =52.26; Prob >$\chi^2$<0.001; Pseudo R2=0.234 | | |
|---|---|---|
| RESPONDERS T2 | OR (95% CI) | P |
| Age | 0.94 (0.91-0.98) | 0.003 |
| Use of drugs in the 12 months to follow-up | 0.18 (0.08-4.69) | >0.001 |
| Previous treatments before study entry | 0.33 (0.15-0.71) | 0.004 |
| Mental health on baseline | 1.1 (1.01-1.24) | 0.02 |
| Adherence to home exercise program | 2.10 (1.03-4.42) | 0.04 |

removing from model: bmi (P=0.9), use of drugs before treatment (P=0.31), physical activity before treatment (P=0.76), physical activity in the twelve months to follow-up (P=0.11), treatments between T1 and T2 (P=0.10), sex (P=0.64), smoking (P=0.39), RMDQ at T0 (P=0.14), NRS at T0 (P=0.88), job (P=0.32).

In stepwise logistic regression model of the probability of response at one year after the treatment, the same baseline features were chosen as potential predictors of response to treatment; further, we also included reported behaviors in the twelve months preceding follow-up that may have influenced follow-up pain related disability: low-back pain related use of medications and adherence the advice to stay active, either to physical activity prescription and to specific home exercise prescription (Table IV).

Older age (OR 0.94, 95% CI: 091 to 0.98, P=0.003), and previous treatments (OR 0.33, 95% CI: 0.15 to 0.71, P=0.004) were significantly associated with lack of response to the treatment at follow-up, as well as the use of medication for back pain in the twelve months preceding follow up (OR 0.18, 95% CI: 0.08 to 4,69, P<0.001). Instead, baseline mental health (OR 1.1, 95% CI: 1.01 to 1.24, P=0.02) and adherence to exercises for low back pain prescribed on discharge and performed at home (OR 2.10, 95% CI 1.03 to 4.42, P=0.04), were significantly associated with higher rate of response at follow-up.

## Discussion

In a prospective cohort of chronic LBP patients, undergoing an individually designed exercise program the average improvement of pain and disability was above the minimal clinical important difference both in the short and long term. On basis of minimal clinically important difference, respectively. This is a prospective study, thus non conclusions may be driven as to the effectiveness of this exercise program. On the other hand, 59% on discharge and 50% of patients at one year improving their pain related disability score above the minimal clinically important difference suggest that overall treatment effects did positively influence the natural course of cLBP in our study sample. These results are in line with previous evidence supporting individually designed exercise treatment for cLBP. Considering the average scores of the RMDQ and NRS at the follow-up, that generally worsen over time compared to discharge, our results suggest also that repeating rehabilitation treatment within a few months, or the use of booster sessions throughout the year to increase the adherence to therapists' recommendations, may help to maintain improvements in function and pain over time.

The only predictive factor of functional outcome at discharge was less intense pain at baseline assessment. In the presence of very severe pain, treatment with exercises was not effective, at least in the short term: indeed other studies agree with this finding reporting that the low intensity of pain at baseline increases the probability to return to a normal and active life,[12] while the high intensity of pain is associated with unfavorable outcome of exercise treatment [11, 20] and is considered a strong prognostic indicator of disability at 12 months and 4 years.[20] In-

deed, when in severe pain, patients are more afraid that that movement may exacerbate pain and are also less compliant to treatment. Thus, these results support a clinical approach that addresses patients in severe pain first to other forms of treatment that have a more immediate effect on pain, such as analgesic therapy or spinal manipulation to optimize outcome, to approach exercise therapy as a second step of treatment.[4]

At follow-up, younger age, better mental health at baseline, no prior treatments to study entry and the lower use of drugs in the last year of the treatment predicted higher rates of response to treatment in the long term. Systematic reviews do not support the association between age and functional outcome in back pain exercise trials and, indeed, as our results show, age did not influence the probability of responding to treatment in the short-term.[7, 11] The reason why younger age was a predictor of long-term response, could be because, in the younger person, functional reserves are greater and consequently the improvements related to treatment last longer, or also because modification in lifestyle were better accepted and carried on by younger participants.[21, 22]

However, despite our inclusion criteria were extended to all adult age, our sample was mostly composed by older persons, and analyses on stratified age groups were not possible. As expected, based on the well known association between psychological factors and back pain,[14] high scores in Mental Health highlighted at the baseline assessment was a predictor of success at one year after treatment. In line with this result a systemic review associate a lower score of mental health to an increase of long-term disability.[23]

Reports of previous treatments for back pain prior to participation to the study was found to predict poor response to treatment in the long term. In literature, this possible predictor has been little studied, however in one study, previous physiotherapy treatment was not a predictor of returning to work both at 3 months and at one year.[24] It is usual for patients with chronic low back pain to have recourse to various types of treatment not always recommended by the guidelines and therefore not very effective. The failure of certain treatments or the recurrence of chronic low back pain may identify clinically complex patients with low probability of response to usual treatments. On the other hand, the negative experience lived could feed a certain skepticism about the following treatments causing a low participation, adherence and constancy usually required by the protocols of any treatment.

The probability of response at follow-up was negatively associated with the use of medication for back pain in the last year of treatment. This result, poorly explored in the literature, is similar to that obtained from another study we conducted on patients with chronic neck pain.[25] We can reasonably assume that the use of pain drugs is associated with the increase of pain due to the recurrent nature of low back pain. Patients who respond to physiotherapy at follow-up, in addition to report an improvement in the functional disability score, have also a lower NRS pain score. These results lead us to hypothesize that some chronic patients are more likely to rely on drugs, for fear that exercise may exacerbate rather than alleviate the pain or even damage the painful joints,[26] indicating a reduced grip and expectations and therefore lower ability to respond to treatment with rehabilitation exercises.

The practice of exercises at home was the strongest independent predictor of response to treatment in the long term, doubling the likelihood of response at one year after treatment. The practice of exercises at home is almost always recommended at the end of physiotherapy treatment, but as far as we could assess in the literature, the importance of adherence to this recommendation was not thoroughly investigated.[27, 28] In our study, the adherence to the exercise program proved to be the most important correlate to reduced pain related disability,[2, 29] while the practice of regular physical activity, was not equally associated to long term specific functional improvement.

Thus, while the literature still supports the recommendation of practicing a regular low-impact physical activity to improve participants' fitness, psychological well-being, and health, in our cohort of cLBP patients, only adherence to the prescription of specific individualized exercises seemed to associate to specific pain related disability improvement. This is a prospective study and no direct comparison can be made between groups, thus our result encourage to verify this hypothesis by a randomized controlled trial comparing the two specific recommendations. Further limitations that reduce the generalizability of our study were the uneven distribution of the age and gender of the sample, which was mostly composed by elderly, non working women; also the adherence to home

exercise was self reported and not monitored during follow-up, and the non specific physical activity was not further specified (*eg*., cycling *vs*. walking *vs*. swimming etc.). Finally a further study limitation is that the Nagelkerke pseudo-$R^2$, of our logistic regressions, was rather low. This might be due to the restricted selection of potential predictors that we considered on baseline, that explain our outcome only partially. The selected set included factors known for influencing CBP outcome [7, 10] that could be rapidly and reliably collected in routine clinical practice. However, since recent literature identifies also other potential predictors of LBP outcome, such as receipt of compensation or litigation, pain pattern, muscle palpation, gait, posture, Waddell symptoms, depression and subject expectation of recovery,[30] it is likely that a wider range of variables may have added useful information to our analysis. So, if providing advice to practice a regular to moderate intensity physical activity save form specific contraindications, is mandatory for all clinicians based on the solid evidence of the positive effects on fitness and health for the generality of the adult and older population, our results encourage to integrate this recommendation for cLBP patients with a prescription of and individualized set of specifically designed exercises, to improve LBP related functional outcome in the long term.

## Conclusions

The individually designed exercise therapy program, delivered according to Tuscany Region resolution to patients with cLBP, was associated to clinically significant functional improvement, both on discharge and at 1 year follow-up. Among the clinical, socio-demographic and psychological potential predictors considered on baseline, only severe pain intensity predicted poorer treatment response on discharge. At one year from discharge, younger age and better mental health predicted a better functional outcome, while use of drugs and a history of previous LBP treatments were associated with worse response to treatment. In the long term, adherence to the exercise program almost doubled the probability of a favorable outcome, while the practice of a non specific physical activity was not independently related to functional improvement.

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