Communication Skills Training for Practitioners to Increase Patient Adherence to Home-based Rehabilitation for Chronic Low Back Pain: Results of a Cluster Randomized Controlled Trial

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Abstract

Objective. To assess the effect of an intervention designed to enhance physiotherapists' communication skills on chronic low back pain patients' adherence to home-based rehabilitation recommendations.

Design. Cluster randomized controlled trial.

Setting. Publicly funded physiotherapy clinics in Dublin, Ireland

Participants. Physiotherapists (N = 53) and patients with chronic low back pain (N = 255, 54% female, M age = 45.3 years).

Interventions. Patients received publicly funded individual physiotherapy care. In the control arm, care was delivered by a physiotherapist who had completed a 1-hour workshop on evidence-based chronic low back pain management. Patients in the experimental arm received care from physiotherapists who had also completed 8 hours of communications skills training.

Main Outcome Measure. Patient-reported adherence to their physiotherapist's recommendations regarding home-based rehabilitation, measured at 1, 4, 12, and 24 weeks after initial treatment session. Pain and pain-related function measured at baseline, 4, 12 and 24 weeks.

Results. Linear mixed model analysis showed the experimental arm patients' ratings of adherence were greater than controls (overall mean difference = .41 [95% CI = .10 to .72, d = .28, p = .01). Moderation analyses showed that men, regardless of intervention, showed improvements in pain-related function over time. Only women in the experimental condition showed functional improvements; female controls saw little change in function over time. The CONNECT intervention did not influence patients' pain, regardless of their sex.

Conclusions. Communication skills training for physiotherapists had short-term positive effects on patient adherence. This training may provide a motivational basis for behavior change and could be a useful component in complex interventions to promote adherence. Communication skills training may also improve some clinical outcomes for women, but not men. Trial registration: ISRCTN63723433.

Keywords. self-determination; autonomy; competence; motivation; compliance

Abbreviations.

CONNECT: Communication Style and Exercise Compliance in Physiotherapy

RCT: Randomized controlled trial

Patient adherence to interventions based on self-management principles is often poor [1]. For example, patients with chronic musculoskeletal conditions often do not complete their home-based exercise programs as recommended by their healthcare practitioners [2, 3]. Poor adherence to treatment recommendations is problematic for both clinicians and patients, as it can limit the potential for positive treatment outcomes [4, 5]. Despite acknowledgement that interventions targeting patient behavior should be grounded in relevant behavior change theory [6], there is limited evidence regarding the effect of theory-based interventions to promote adherence in chronic pain populations [7-9].

According to self-determination theory [10] people have psychological needs for autonomy (feeling free to engage in an activity), competence (feeling effective and capable), and relatedness (feeling connected to and cared for by others). When healthcare practitioners support their patients' psychological needs, patients are more likely to be autonomously motivated (i.e., empowered), which results in more enduring behavior change [11]. In contrast, a controlling healthcare climate involves disregarding patients' views, pressuring patients, and making decisions on patients' behalf without consultation, leading to more controlled motivation and poorer long-term adherence. Unfortunately, health care practitioners often adopt this latter model of patient care [12-14].

We designed a self-determination theory-based communication skills training intervention, entitled 'Communication Style and Exercise Compliance in Physiotherapy' (CONNECT), for physiotherapists working with people seeking treatment for chronic low back pain. Communication skills training can increase patient adherence across a range of conditions [15], but there is limited evidence regarding its effect on adherence to chronic pain self-management [14] or clinical outcomes [16].

Aims

The aim of this cluster randomized controlled trial (RCT) was to assess the effect of an intervention designed to increase physiotherapists' needs-supportive communication skills on chronic low back pain patients' adherence to home-based rehabilitation recommendations. We also

sought to examine effects on hypothesized determinants (e.g., motivation) and clinical outcomes (e.g., pain) of increased adherence. Finally, in response to increasing calls for a gendered approach to health research [17-19], we explored the possibility that CONNECT may have differential effects on pain and function for male and female patients.

Hypotheses

Compared with the wait-list control arm, patients in the experimental arm will show:

1. greater self-rated adherence to physiotherapists' recommendations regarding home-based rehabilitation, greater increases in physical activity, and greater adherence during physiotherapy sessions.

2. greater decreases in pain, along with greater increases in function, well-being and perceived global improvement after treatment.

3. greater increases in perceived competence and autonomous motivation, as well as greater decreases in fear-avoidance beliefs, controlled motivation and amotivation (i.e., lack of motivation).

We did not formulate a priori hypotheses for our exploratory sex moderation analyses.

Methods

Design

This study was a patient and assessor-blinded cluster RCT (ISRCTN63723433). A methodological description has been published previously [20].

Participant recruitment, consent, and allocation

Centers. Managers at 13 publicly funded outpatient clinics providing general physiotherapy services in Dublin, Ireland were invited to participate. These clinics included all nine community care clinics and four of the six outpatient hospital clinics in the region. These four hospitals were purposively sampled to provide a cross-section of socio-economic levels and geographical locations. Research ethics committees responsible for each site granted approval and the study conformed to the Helsinki Declaration's requirements. Centers were assigned to the experimental or control arm (1:1) after their physiotherapists agreed to participate in the study. A person blinded to

the purposes of the study used a computerized random number generator algorithm to assign centers.

Patients. As randomization was by center, all participants in a given center belonged to the experimental arm or the control arm. We contacted each patient referred by a medical practitioner for physiotherapy for chronic low back pain to one of the 12 centers. Patients who met the inclusion criteria (Table 1) and provided informed consent were invited to complete baseline assessment.

Interventions

Training for physiotherapists. In both arms, physiotherapists participated in a one-hour refresher workshop on evidence-based physiotherapy care for chronic low back pain [21, 22]. In addition, physiotherapists in the experimental arm completed eight hours of communication skills training – details published previously [20, 23].

Treatment for patients. Patients in both trial arms received publicly funded physiotherapy care. We placed no restrictions on the number of sessions each patient could receive or the type of treatment the physiotherapist administered. As such, all patients received usual care, but in the experimental arm this care was delivered by a physiotherapist who had completed CONNECT training.

Outcomes

We conducted participant assessments at baseline, 1 week, 4 weeks, 12 weeks, and 24 weeks after each participant's first physiotherapy appointment. Patients' self-reported their overall adherence to their physiotherapists' recommendations using 7-point rating scales (e.g., 1 = completed none, 5 = completed all) [24]. They also reported the proportion of specific rehabilitation exercise they completed during the previous week (i.e., sessions completed/sessions prescribed) [3] and their leisure-time physical activity [25] (i.e., sessions completed/sessions prescribed). Physiotherapists rated patients' in-clinic adherence using 5-point rating scales [26]. A complete list of outcomes can be viewed in Table 2.

Statistical methods.

Using SPSS (version 23), we analyzed participants' data according to their assigned trial arm (i.e., intention-to-treat principle). We tested for baseline demographic and outcome differences across the trial arms using MANOVA for continuous variables and chi-square tests for categorical variables.

We tested the main study hypotheses using linear-mixed modelling with measurement occasions, patients, physiotherapists, and clinics as levels of analysis. In our main analyses, we tested differences in the rates of change in the outcome variables. As sensitivity analyses, we tested for differences in mean levels. The primary endpoint for the analysis was data collected at Week 24, except for in-clinic adherence which was only measured up to 12 weeks – few patients were provided treatment after this point.

In the sex moderation analyses, we studied cross-level interactions to determine the interrelationships between experimental conditions and sex with time (control arm coded as -1 and experimental arm coded as +1). Time-invariant predictors were mean-centered.

Sample size calculations

The sample size for the study was calculated based on an anticipated effect size of d = .4 for adherence [7, 36]. With an estimated ICC of .03, we required 254 participants to achieve 80% power.

Intervention fidelity

A convenience subsample of 24 physiotherapists (12 in each arm) audio recorded one of their initial (Week 1) treatment sessions with a participant. Blinded, expert raters assessed the support provided using the Health Care Climate Questionnaire [37]. As we previously reported [23], CONNECT had a large positive effect (d =2.27) on physiotherapists' support.

Deviations from protocol

We decided to discontinue our planned use of sealed pedometers to monitor physical activity [20]. Many participants in the initial month of the trial found the monitor burdensome.

Results

Data were collected between March 2011 and December 2012. Figure 1 shows the participant flow throughout the trial. Physiotherapists at 12 clinics (four hospitals, eight community clinics) agreed to participate. The six experimental clinic clusters ranged in size from 5 to 34 participants (mean = 20.67, SD = 6.86). The control arm clinic clusters ranged in size from 10 to 28 participants (mean = 21.83, SD = 10.51). In total, 255 participants entered the study (45% recruitment rate) and 207 (81%) provided follow-up data at Week 24. No adverse effects were reported.

Table 3 contains mean values for participants' characteristics, baseline outcomes, and physiotherapists' characteristics. There were no differences in demographics or clinical characteristics between the two arms at baseline (Wilks' $\lambda = .98$, $F = .93$, $p = .43$ and all χ^2 tests $p > .05$). There were no overall differences in outcome variables between the experimental and control arms at baseline (Wilks' $\lambda = .85$, $F = .52$, $p = .94$). There were no differences in physiotherapists' age ($t = 2.35$, $p = .81$), sex ($\chi^2 = .51$, $p = .48$), or baseline motivational orientations (Wilks' $\lambda = .78$, $F = 2.09$, $p = .07$).

Fifty-three physiotherapists were recruited and 50 delivered treatment to study participants. There was no significant difference ($t = .47$, $p = .64$) in the number of treatment sessions attended by participants in the experimental arm (mean = 3.08 sessions, SD = 1.88 sessions) and the control arm (mean = 3.20 sessions, SD = 1.45 sessions). The mean length of time between the first treatment session and the final treatment session was 7.45 ± 7.96 weeks across both arms. All except 19 patients had completed all their clinic-based treatment before Week 12. As shown in Supplementary File 1, the content of advice that physiotherapists provided to patients was largely similar across arms, except experimental arm physiotherapists provided more advice than controls regarding specific back exercises and advice directed at reducing fear-avoidance.

Intervention effects on outcomes

Unadjusted mean values are detailed in Supplementary File 2. The results of analyses related to the effects of the CONNECT intervention on outcomes are provided in Table 4.

Overall, CONNECT training for physiotherapists had a weak positive effect on patients' self-reported home-based adherence ($p = .01$, $d = .28$), with significant effects found at Week 1 ($p < .01$, $d = .32$), Week 4 ($p < .01$, $d = .30$), and Week 12 ($p = .03$, $d = .27$). These differences were not maintained at Week 24 ($p = .14$, $d = .25$), but the size of the effects at Week 12 and Week 24 were not statistically different ($p > .05$).

The CONNECT intervention had no significant effect on physiotherapists' ratings of in-clinic adherence or on the proportion of specific back exercises that participants reported completing at home. There were also no significant effects on physical activity.

CONNECT did not have a significant effect on any of the clinical outcomes (e.g., pain, function, satisfaction with treatment) or quality of life.

CONNECT training had a moderate significant positive influence on patients' perceptions of competence to follow their physiotherapists' recommendations ($p < .01$, $d = .66$). This effect was not observed immediately post-treatment ($p = .16$, $d = .36$), but was found at Week 4, Week 12, and Week 24 ($p < .01$, $d = .56$ to $d = .97$).

The CONNECT intervention also had a significant overall positive impact on patients' amotivation ($p = .01$, $d = -.42$). Once again, this effect was not observed immediately post-treatment ($p = .19$, $d = -.25$), but was found at Week 4, Week 12, and Week 24 ($p < .01$, $d = -.37$ to $d = -.59$).

CONNECT intervention effects on autonomous motivation were not observed, perhaps because of ceiling effects (i.e., patients reported high scores at baseline on this 7-point scale, experimental $M = 6.64 \pm .58$, control $M = 6.60 \pm .54$). CONNECT training for physiotherapists also did not influence controlled motivation ($p = .71$) or fear avoidance beliefs ($p = .36$). Similarly, patient ratings of their physiotherapists' needs supportive behavior were not influenced by the CONNECT intervention, as both arms had scores that were near the scale maximum of 7 immediately following their first treatment session (experimental $M = 6.70 \pm .68$, control $M = 6.55 \pm .77$).

Supplementary File 3 contains results of sensitivity analyses examining CONNECT intervention effects on mean levels. Results were similar to those examining rates of change.

Sex moderation

There was a significant effect of time ($p < .01$) for all three pain variables (pain intensity, bothersomeness, and satisfaction) indicating a decrease in pain for men and women in both arms, but no differential sex effects. In contrast, sex moderated CONNECT intervention effects on all three pain-related function variables: Roland Morris Disability Questionnaire ($p < .01$), Patient Specific Function Scale ($p < .05$) and interference with work ($p = .06$). As shown in Supplementary File 4, higher-order interactions (arm x time x sex) indicated a differential trajectory for men and women across time and between experimental conditions for these three variables. Men, regardless of intervention, showed improvements in pain-related function over time. In contrast, only women in the experimental condition showed improvements that were similar to men, whereas female controls saw little change in function over time. There was no significant interaction of arm x time x sex for any of the hypothesized mediators ($p > .05$).

Discussion

The trial provided mixed support for our hypotheses. When considering overall self-rated adherence to their physiotherapist's recommendations, patient adherence showed a general decrease over time, but communication skills training designed to increase support for patients appeared to slow this rate of decline. This generally positive conclusion should be tempered by the non-significant intervention effects on adherence to specific exercises and levels of physical activity. Thus, it appears that CONNECT had a positive effect on home-based adherence, but it is not clear which specific aspects of the physiotherapists' advice patients followed.

Previous interventions have sought to increase adherence to home-based rehabilitation for musculoskeletal conditions by adding components to usual care treatment (e.g., motivational counselling in addition to exercise prescription [39]). In contrast, the CONNECT intervention was designed to change the way treatment is provided, rather than add extra interventions. Helping

physiotherapists to learn skills that will improve their patients' adherence is a model that might be scaled-up more readily than models requiring additional personnel.

Future research is required to determine methods that can increase the impact of CONNECT on adherence. Indeed, training had a large positive effect on physiotherapists' communication skills [23], but independent observers still rated experimental physiotherapists' support well below ideal (mean rating = 4.57 on a 7-point scale). Efforts to increase the impact of CONNECT training could include individualized audit and feedback techniques are effective in promoting higher quality clinical practice [40]. We recently implemented this type of training for physiotherapists who had completed CONNECT training and found it was a feasible addition [41]. Research is required to determine the effect of this extra training on their patient adherence. Additional implementation strategies could include more extended continuing professional development provided via an online platform [42], implementation and self-reflection prompts from a mobile phone [43], and continued support from mentors [44, 45].

Contrary to our hypotheses, intervention effects on clinical outcomes were not significant. Sex, however, appeared to moderate the CONNECT intervention's effect on function, but not pain. Overall, men improved their function regardless of whether or not their physiotherapist had completed the CONNECT training. In contrast, only women in the experimental condition showed improvements that were similar to men, whereas female controls saw little change in function over time. At Week 24, women in the experimental arm had scores that were 4.94 points lower than controls on the RMDQ and 1.43 points higher than controls on the PSFS. These effects exceed the minimum clinically important difference of 3.5 for the RMDQ [46] and 1.3 for the PSFS [47], suggesting a meaningful effect of CONNECT training on function, but only for women. These findings raise a number of questions, including why do women appear to require physiotherapy delivered using supportive communication but men do not? None of the proposed mechanisms (e.g., fear avoidance differences) showed a significant arm x time x sex interaction and, therefore,

248 do not explain differences in function between men and women in our sample. It is also unknown
249 why sex differences appeared for function but not for pain.

250 In line with our hypotheses, CONNECT training had a moderate positive effect on selected
251 motivational variables, including an increase in patients' perceived competence to follow their
252 physiotherapists' advice (d = .66) and a decrease in their levels of amotivation (d = -.42). Previous
253 studies have shown that this type of training has positive motivational effects for people enrolled in
254 interventions designed to promote weight loss, physical activity, smoking cessation and oral
255 hygiene [11]. Our study suggests these motivational benefits can also be achieved in populations
256 with chronic musculoskeletal conditions.

257 **Future research**

258 CONNECT appeared to provide patients with a motivational basis that is likely necessary, but
259 not sufficient for long-term adherence. Interventions could also directly target patients' ability to
260 regulate the behaviours for which communication skills training has provided a motivational
261 foundation [5]. These methods could include more extensive prompting (e.g., text messages) and
262 self-monitoring strategies than were included in the CONNECT intervention [48]. Interventions
263 could also target social agents other than physiotherapists (e.g., family members) who influence
264 patients' motivation and adherence towards home-based rehabilitation [49]. Finally, complex
265 interventions that target patient motivation could be combined with those targeting patients'
266 perceptions of and reactions to pain (e.g., cognitive behavioural therapy [50] and mindfulness-based
267 stress reduction [51]. Changing patients' thoughts about pain and supporting their psychological
268 needs may have synergistic effects on their adherence to home-based rehabilitation.

269 **Study limitations**

270 There is limited evidence regarding the clinimetric properties of adherence measures relating
271 to musculoskeletal pain rehabilitation [52]. There is no reason to believe that scores in this trial
272 were biased in favor of patients in one arm over another, but future research is required to ensure

that adherence measures are based on a clear conceptual framework (e.g., what defines adherence?) and supported by strong validity evidence [53].

Additional limitations include the relatively small sample size, which was powered to detect moderate-sized effects. We observed small effects in relation to some clinical outcomes, suggesting CONNECT could be a useful component of complex interventions designed to improve clinical outcomes, but without a larger sample this suggestion is speculative.

Finally, our trial included multiple primary outcomes, (i.e., adherence, pain, pain-related function and quality of life) and, in keeping with Schulz and Grimes' recommendations [54], we did not make a statistical correction for this multiplicity. However, it could be argued that restricting our primary outcomes to measures of adherence, and specifying other outcomes as secondary, would have facilitated interpretation of our results.

Conclusions

CONNECT communication skills training for physiotherapists had a moderate effect on psychological mediators of behaviour change and a small effect on patients' adherence to home-based rehabilitation. This form of continuing professional development seems to provide a motivational basis for behaviour change and may be a useful component in complex interventions to promote adherence. Finally, this form of communication skills training for healthcare practitioners may improve some clinical outcomes for women, but not men.

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Figure Captions

Figure 1. CONSORT 2010 Flow Diagram.

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Interventions. Patients received publicly funded individual physiotherapy care. In the control arm, care was delivered by a physiotherapist who had completed a 1-hour workshop on evidence-based chronic low back pain management. Patients in the experimental arm received care from physiotherapists who had also completed 8 hours of communications skills training.

Main Outcome Measure. Patient-reported adherence to their physiotherapist's recommendations regarding home-based rehabilitation, measured at 1, 4, 12, and 24 weeks after initial treatment session. Pain and pain-related function measured at baseline, 4, 12 and 24 weeks.

Results. Linear mixed model analysis showed the experimental arm patients' ratings of adherence were greater than controls (overall mean difference = .41 [95% CI = .10 to .72, d = .28, p = .01). Moderation analyses showed that men, regardless of intervention, showed improvements in pain-related function over time. Only women in the experimental condition showed functional improvements; female controls saw little change in function over time. The CONNECT intervention did not influence patients' pain, regardless of their sex.

Conclusions. Communication skills training for physiotherapists had short-term positive effects on patient adherence. This training may provide a motivational basis for behavior change and could be a useful component in complex interventions to promote adherence. Communication skills training may also improve some clinical outcomes for women, but not men. Trial registration: ISRCTN63723433.

Keywords. self-determination; autonomy; competence; motivation; compliance

Abbreviations.

CONNECT: Communication Style and Exercise Compliance in Physiotherapy

RCT: Randomized controlled trial

Patient adherence to interventions based on self-management principles is often poor [1]. For example, patients with chronic musculoskeletal conditions often do not complete their home-based exercise programs as recommended by their healthcare practitioners [2, 3]. Poor adherence to treatment recommendations is problematic for both clinicians and patients, as it can limit the potential for positive treatment outcomes [4, 5]. Despite acknowledgement that interventions targeting patient behavior should be grounded in relevant behavior change theory [6], there is limited evidence regarding the effect of theory-based interventions to promote adherence in chronic pain populations [7-9].

According to self-determination theory [10] people have psychological needs for autonomy (feeling free to engage in an activity), competence (feeling effective and capable), and relatedness (feeling connected to and cared for by others). When healthcare practitioners support their patients' psychological needs, patients are more likely to be autonomously motivated (i.e., empowered), which results in more enduring behavior change [11]. In contrast, a controlling healthcare climate involves disregarding patients' views, pressuring patients, and making decisions on patients' behalf without consultation, leading to more controlled motivation and poorer long-term adherence. Unfortunately, health care practitioners often adopt this latter model of patient care [12-14].

We designed a self-determination theory-based communication skills training intervention, entitled 'Communication Style and Exercise Compliance in Physiotherapy' (CONNECT), for physiotherapists working with people seeking treatment for chronic low back pain. Communication skills training can increase patient adherence across a range of conditions [15], but there is limited evidence regarding its effect on adherence to chronic pain self-management [14] or clinical outcomes [16].

Aims

The aim of this cluster randomized controlled trial (RCT) was to assess the effect of an intervention designed to increase physiotherapists' needs-supportive communication skills on chronic low back pain patients' adherence to home-based rehabilitation recommendations. We also

sought to examine effects on hypothesized determinants (e.g., motivation) and clinical outcomes (e.g., pain) of increased adherence. Finally, in response to increasing calls for a gendered approach to health research [17-19], we explored the possibility that CONNECT may have differential effects on pain and function for male and female patients.

Hypotheses

Compared with the wait-list control arm, patients in the experimental arm will show:

1. greater self-rated adherence to physiotherapists' recommendations regarding home-based rehabilitation, greater increases in physical activity, and greater adherence during physiotherapy sessions.

2. greater decreases in pain, along with greater increases in function, well-being and perceived global improvement after treatment.

3. greater increases in perceived competence and autonomous motivation, as well as greater decreases in fear-avoidance beliefs, controlled motivation and amotivation (i.e., lack of motivation).

We did not formulate a priori hypotheses for our exploratory sex moderation analyses.

Methods

Design

This study was a patient and assessor-blinded cluster RCT (ISRCTN63723433). A methodological description has been published previously [20].

Participant recruitment, consent, and allocation

Centers. Managers at 13 publicly funded outpatient clinics providing general physiotherapy services in Dublin, Ireland were invited to participate. These clinics included all nine community care clinics and four of the six outpatient hospital clinics in the region. These four hospitals were purposively sampled to provide a cross-section of socio-economic levels and geographical locations. Research ethics committees responsible for each site granted approval and the study conformed to the Helsinki Declaration's requirements. Centers were assigned to the experimental or control arm (1:1) after their physiotherapists agreed to participate in the study. A person blinded to

the purposes of the study used a computerized random number generator algorithm to assign centers.

Patients. As randomization was by center, all participants in a given center belonged to the experimental arm or the control arm. We contacted each patient referred by a medical practitioner for physiotherapy for chronic low back pain to one of the 12 centers. Patients who met the inclusion criteria (Table 1) and provided informed consent were invited to complete baseline assessment.

Interventions

Training for physiotherapists. In both arms, physiotherapists participated in a one-hour refresher workshop on evidence-based physiotherapy care for chronic low back pain [21, 22]. In addition, physiotherapists in the experimental arm completed eight hours of communication skills training – details published previously [20, 23].

Treatment for patients. Patients in both trial arms received publicly funded physiotherapy care. We placed no restrictions on the number of sessions each patient could receive or the type of treatment the physiotherapist administered. As such, all patients received usual care, but in the experimental arm this care was delivered by a physiotherapist who had completed CONNECT training.

Outcomes

We conducted participant assessments at baseline, 1 week, 4 weeks, 12 weeks, and 24 weeks after each participant's first physiotherapy appointment. Patients' self-reported their overall adherence to their physiotherapists' recommendations using 7-point rating scales (e.g., 1 = completed none, 5 = completed all) [24]. They also reported the proportion of specific rehabilitation exercise they completed during the previous week (i.e., sessions completed/sessions prescribed) [3] and their leisure-time physical activity [25] (i.e., sessions completed/sessions prescribed). Physiotherapists rated patients' in-clinic adherence using 5-point rating scales [26]. A complete list of outcomes can be viewed in Table 2.

Statistical methods.

Using SPSS (version 23), we analyzed participants' data according to their assigned trial arm (i.e., intention-to-treat principle). We tested for baseline demographic and outcome differences across the trial arms using MANOVA for continuous variables and chi-square tests for categorical variables.

We tested the main study hypotheses using linear-mixed modelling with measurement occasions, patients, physiotherapists, and clinics as levels of analysis. In our main analyses, we tested differences in the rates of change in the outcome variables. As sensitivity analyses, we tested for differences in mean levels. The primary endpoint for the analysis was data collected at Week 24, except for in-clinic adherence which was only measured up to 12 weeks – few patients were provided treatment after this point.

In the sex moderation analyses, we studied cross-level interactions to determine the interrelationships between experimental conditions and sex with time (control arm coded as -1 and experimental arm coded as +1). Time-invariant predictors were mean-centered.

Sample size calculations

The sample size for the study was calculated based on an anticipated effect size of d = .4 for adherence [7, 36]. With an estimated ICC of .03, we required 254 participants to achieve 80% power.

Intervention fidelity

A convenience subsample of 24 physiotherapists (12 in each arm) audio recorded one of their initial (Week 1) treatment sessions with a participant. Blinded, expert raters assessed the support provided using the Health Care Climate Questionnaire [37]. As we previously reported [23], CONNECT had a large positive effect (d =2.27) on physiotherapists' support.

Deviations from protocol

We decided to discontinue our planned use of sealed pedometers to monitor physical activity [20]. Many participants in the initial month of the trial found the monitor burdensome.

Results

Data were collected between March 2011 and December 2012. Figure 1 shows the participant flow throughout the trial. Physiotherapists at 12 clinics (four hospitals, eight community clinics) agreed to participate. The six experimental clinic clusters ranged in size from 5 to 34 participants (mean = 20.67, SD = 6.86). The control arm clinic clusters ranged in size from 10 to 28 participants (mean = 21.83, SD = 10.51). In total, 255 participants entered the study (45% recruitment rate) and 207 (81%) provided follow-up data at Week 24. No adverse effects were reported.

Table 3 contains mean values for participants' characteristics, baseline outcomes, and physiotherapists' characteristics. There were no differences in demographics or clinical characteristics between the two arms at baseline (Wilks' $\lambda = .98$, $F = .93$, $p = .43$ and all χ^2 tests $p > .05$). There were no overall differences in outcome variables between the experimental and control arms at baseline (Wilks' $\lambda = .85$, $F = .52$, $p = .94$). There were no differences in physiotherapists' age ($t = 2.35$, $p = .81$), sex ($\chi^2 = .51$, $p = .48$), or baseline motivational orientations (Wilks' $\lambda = .78$, $F = 2.09$, $p = .07$).

Fifty-three physiotherapists were recruited and 50 delivered treatment to study participants. There was no significant difference ($t = .47$, $p = .64$) in the number of treatment sessions attended by participants in the experimental arm (mean = 3.08 sessions, SD = 1.88 sessions) and the control arm (mean = 3.20 sessions, SD = 1.45 sessions). The mean length of time between the first treatment session and the final treatment session was 7.45 ± 7.96 weeks across both arms. All except 19 patients had completed all their clinic-based treatment before Week 12. As shown in Supplementary File 1, the content of advice that physiotherapists provided to patients was largely similar across arms, except experimental arm physiotherapists provided more advice than controls regarding specific back exercises and advice directed at reducing fear-avoidance.

Intervention effects on outcomes

Unadjusted mean values are detailed in Supplementary File 2. The results of analyses related to the effects of the CONNECT intervention on outcomes are provided in Table 4.

Overall, CONNECT training for physiotherapists had a weak positive effect on patients' self-reported home-based adherence (p = .01, d = .28), with significant effects found at Week 1 (p < .01, d = .32), Week 4 (p < .01, d = .30), and Week 12 (p = .03, d = .27). These differences were not maintained at Week 24 (p = .14, d = .25), but the size of the effects at Week 12 and Week 24 were not statistically different (p > .05).

The CONNECT intervention had no significant effect on physiotherapists' ratings of in-clinic adherence or on the proportion of specific back exercises that participants reported completing at home. There were also no significant effects on physical activity.

CONNECT did not have a significant effect on any of the clinical outcomes (e.g., pain, function, satisfaction with treatment) or quality of life.

CONNECT training had a moderate significant positive influence on patients' perceptions of competence to follow their physiotherapists' recommendations (p < .01, d = .66). This effect was not observed immediately post-treatment (p = .16, d = .36), but was found at Week 4, Week 12, and Week 24 (p < .01, d = .56 to d = .97).

The CONNECT intervention also had a significant overall positive impact on patients' amotivation (p = .01, d = -.42). Once again, this effect was not observed immediately post-treatment (p = .19, d = -.25), but was found at Week 4, Week 12, and Week 24 (p < .01, d = -.37 to d = -.59).

CONNECT intervention effects on autonomous motivation were not observed, perhaps because of ceiling effects (i.e., patients reported high scores at baseline on this 7-point scale, experimental M = 6.64 ± .58, control M = 6.60 ± .54). CONNECT training for physiotherapists also did not influence controlled motivation (p = .71) or fear avoidance beliefs (p = .36). Similarly, patient ratings of their physiotherapists' needs supportive behavior were not influenced by the CONNECT intervention, as both arms had scores that were near the scale maximum of 7 immediately following their first treatment session (experimental M = 6.70 ± .68, control M = 6.55 ± .77).

Supplementary File 3 contains results of sensitivity analyses examining CONNECT intervention effects on mean levels. Results were similar to those examining rates of change.

Sex moderation

There was a significant effect of time ($p < .01$) for all three pain variables (pain intensity, bothersomeness, and satisfaction) indicating a decrease in pain for men and women in both arms, but no differential sex effects. In contrast, sex moderated CONNECT intervention effects on all three pain-related function variables: Roland Morris Disability Questionnaire ($p < .01$), Patient Specific Function Scale ($p < .05$) and interference with work ($p = .06$). As shown in Supplementary File 4, higher-order interactions (arm x time x sex) indicated a differential trajectory for men and women across time and between experimental conditions for these three variables. Men, regardless of intervention, showed improvements in pain-related function over time. In contrast, only women in the experimental condition showed improvements that were similar to men, whereas female controls saw little change in function over time. There was no significant interaction of arm x time x sex for any of the hypothesized mediators ($p > .05$).

Discussion

The trial provided mixed support for our hypotheses. When considering overall self-rated adherence to their physiotherapist's recommendations, patient adherence showed a general decrease over time, but communication skills training designed to increase support for patients appeared to slow this rate of decline. This generally positive conclusion should be tempered by the non-significant intervention effects on adherence to specific exercises and levels of physical activity. Thus, it appears that CONNECT had a positive effect on home-based adherence, but it is not clear which specific aspects of the physiotherapists' advice patients followed.

Previous interventions have sought to increase adherence to home-based rehabilitation for musculoskeletal conditions by adding components to usual care treatment (e.g., motivational counselling in addition to exercise prescription [39]). In contrast, the CONNECT intervention was designed to change the way treatment is provided, rather than add extra interventions. Helping

physiotherapists to learn skills that will improve their patients' adherence is a model that might be scaled-up more readily than models requiring additional personnel.

Future research is required to determine methods that can increase the impact of CONNECT on adherence. Indeed, training had a large positive effect on physiotherapists' communication skills [23], but independent observers still rated experimental physiotherapists' support well below ideal (mean rating = 4.57 on a 7-point scale). Efforts to increase the impact of CONNECT training could include individualized audit and feedback techniques are effective in promoting higher quality clinical practice [40]. We recently implemented this type of training for physiotherapists who had completed CONNECT training and found it was a feasible addition [41]. Research is required to determine the effect of this extra training on their patient adherence. Additional implementation strategies could include more extended continuing professional development provided via an online platform [42], implementation and self-reflection prompts from a mobile phone [43], and continued support from mentors [44, 45].

Contrary to our hypotheses, intervention effects on clinical outcomes were not significant. Sex, however, appeared to moderate the CONNECT intervention's effect on function, but not pain. Overall, men improved their function regardless of whether or not their physiotherapist had completed the CONNECT training. In contrast, only women in the experimental condition showed improvements that were similar to men, whereas female controls saw little change in function over time. At Week 24, women in the experimental arm had scores that were 4.94 points lower than controls on the RMDQ and 1.43 points higher than controls on the PSFS. These effects exceed the minimum clinically important difference of 3.5 for the RMDQ [46] and 1.3 for the PSFS [47], suggesting a meaningful effect of CONNECT training on function, but only for women. These findings raise a number of questions, including why do women appear to require physiotherapy delivered using supportive communication but men do not? None of the proposed mechanisms (e.g., fear avoidance differences) showed a significant arm x time x sex interaction and, therefore,

248 do not explain differences in function between men and women in our sample. It is also unknown
249 why sex differences appeared for function but not for pain.

250 In line with our hypotheses, CONNECT training had a moderate positive effect on selected
251 motivational variables, including an increase in patients' perceived competence to follow their
252 physiotherapists' advice (d = .66) and a decrease in their levels of amotivation (d = -.42). Previous
253 studies have shown that this type of training has positive motivational effects for people enrolled in
254 interventions designed to promote weight loss, physical activity, smoking cessation and oral
255 hygiene [11]. Our study suggests these motivational benefits can also be achieved in populations
256 with chronic musculoskeletal conditions.

257 **Future research**

258 CONNECT appeared to provide patients with a motivational basis that is likely necessary, but
259 not sufficient for long-term adherence. Interventions could also directly target patients' ability to
260 regulate the behaviours for which communication skills training has provided a motivational
261 foundation [5]. These methods could include more extensive prompting (e.g., text messages) and
262 self-monitoring strategies than were included in the CONNECT intervention [48]. Interventions
263 could also target social agents other than physiotherapists (e.g., family members) who influence
264 patients' motivation and adherence towards home-based rehabilitation [49]. Finally, complex
265 interventions that target patient motivation could be combined with those targeting patients'
266 perceptions of and reactions to pain (e.g., cognitive behavioural therapy [50] and mindfulness-based
267 stress reduction [51]. Changing patients' thoughts about pain and supporting their psychological
268 needs may have synergistic effects on their adherence to home-based rehabilitation.

269 **Study limitations**

270 There is limited evidence regarding the clinimetric properties of adherence measures relating
271 to musculoskeletal pain rehabilitation [52]. There is no reason to believe that scores in this trial
272 were biased in favor of patients in one arm over another, but future research is required to ensure

that adherence measures are based on a clear theoretical framework (e.g., what defines adherence?) and supported by strong validity evidence [53].

Additional limitations include the relatively small sample size, which was powered to detect moderate-sized effects. We observed small effects in relation to some clinical outcomes, suggesting CONNECT could be a useful component of complex interventions designed to improve clinical outcomes, but without a larger sample this suggestion is speculative.

Finally, our trial included multiple primary outcomes, (i.e., adherence, pain, pain-related function and quality of life) and, in keeping with Schulz and Grimes' recommendations [54], we did not make a statistical correction for this multiplicity. However, it could be argued that restricting our primary outcomes to measures of adherence, and specifying other outcomes as secondary, would have facilitated interpretation of our results.

Conclusions

CONNECT communication skills training for physiotherapists had a moderate effect on psychological mediators of behaviour change and a small effect on patients' adherence to home-based rehabilitation. This form of continuing professional development seems to provide a motivational basis for behaviour change and may be a useful component in complex interventions to promote adherence. Finally, this form of communication skills training for healthcare practitioners may improve some clinical outcomes for women, but not men.

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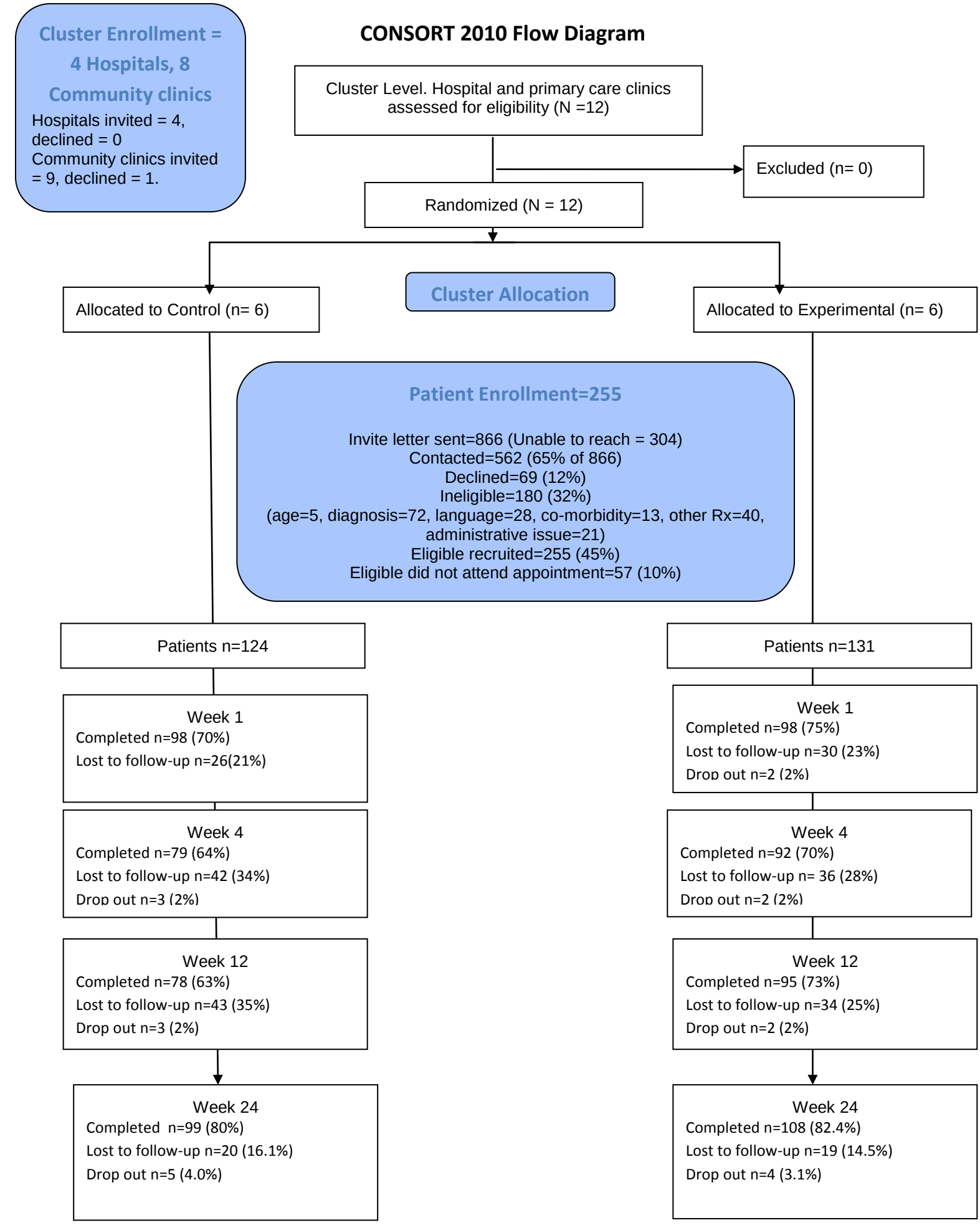
Figure Captions

Figure 1. CONSORT 2010 Flow Diagram.

Figure


CONSORT 2010 Flow Diagram
Cluster Enrollment = 4 Hospitals, 8 Community clinics
Hospitals invited = 4, declined = 0
Community clinics invited = 9, declined = 1.
Cluster Level. Hospital and primary care clinics assessed for eligibility (N =12)
Excluded (n= 0)
Randomized (N = 12)
Cluster Allocation
Allocated to Control (n= 6)
Allocated to Experimental (n= 6)
Patient Enrollment=255
Invite letter sent=866 (Unable to reach = 304)
Contacted=562 (65% of 866)
Declined=69 (12%)
Ineligible=180 (32%)
(age=5, diagnosis=72, language=28, co-morbidity=13, other Rx=40, administrative issue=21)
Eligible recruited=255 (45%)
Eligible did not attend appointment=57 (10%)
Patients n=124
Week 1
Completed n=98 (70%)
Lost to follow-up n=26(21%)
Week 4
Completed n=79 (64%)
Lost to follow-up n=42 (34%)
Drop out n=3 (2%)
Week 12
Completed n=78 (63%)
Lost to follow-up n=43 (35%)
Drop out n=3 (2%)
Week 24
Completed n=99 (80%)
Lost to follow-up n=20 (16.1%)
Drop out n=5 (4.0%)
Patients n=131
Week 1
Completed n=98 (75%)
Lost to follow-up n=30 (23%)
Drop out n=2 (2%)
Week 4
Completed n=92 (70%)
Lost to follow-up n= 36 (28%)
Drop out n=2 (2%)
Week 12
Completed n=95 (73%)
Lost to follow-up n=34 (25%)
Drop out n=2 (2%)
Week 24
Completed n=108 (82.4%)
Lost to follow-up n=19 (14.5%)
Drop out n=4 (3.1%)

Tables

Table 1. Patient Inclusion and Exclusion Criteria

Inclusion criteria	
Age	18 to 70 years
Diagnosis	LBP of mechanical origin with/ without radiation to the lower limb
Pain duration	chronic (≥ 3 months) or recurrent (≥ 3 episodes in previous year)
Language	English speaking and English literate
Contact status	Access to a telephone
Exclusion criteria	
Pathology	Suspected or confirmed serious spinal pathology (fracture, metastatic, inflammatory or infective diseases of the spine, cauda equina syndrome/widespread neurological disorder). Nerve root compromise (2 of strength, reflex or sensation affected for same nerve root)
Past medical history	Spinal surgery or History of systemic / inflammatory disease
Current medical status	Scheduled for major surgery during treatment
Treatment status	Currently or having received treatment for chronic low back pain within previous 3 months
Pregnancy	Suspected or confirmed pregnancy
Contraindications	Unstable angina / uncontrolled cardiac dysrhythmias / severe aortic stenosis / acute systemic infection accompanied by fever. No confounding conditions, such as a neurological disorder or an intellectual disorder

Table 2. Primary and Secondary Outcomes Measures

Outcome	Measure	Baseline	1st session	1	4	12	24
Primary Outcomes							
Home-based adherence	[24]			✔	✔	✔	✔
Clinic-based adherence	SIRAS [26]			✔	✔	✔	
Specific adherence to back exercises at home, patient report of % prescribed sessions completed/week	[3]			✔	✔	✔	✔
Physical activity (total METs)	IPAQ [25]	✔		✔	✔	✔	✔
Pain intensity	NRS [27]	✔			✔	✔	✔
Pain bothersomeness	[27]	✔			✔	✔	✔
Interference with work	[27]	✔			✔	✔	✔
Satisfaction with symptoms	[27]	✔			✔	✔	✔
Perception of recovery	[28]	✔			✔	✔	✔
Pain related function - disability	RMDQ [29, 30]	✔			✔	✔	✔
Pain related function – patient specific functional scale	PSFS [31]	✔			✔	✔	✔
Quality of life	EurQoL [32]	✔			✔	✔	✔
Secondary Outcomes							
Fear avoidance beliefs –physical activity subscale	FABQ [33]	✔			✔	✔	✔
Perceived competence to follow recommendations	[34]	✔	✔		✔	✔	✔
Autonomous motivation to follow recommendations	TSRQ [35]	✔	✔		✔	✔	✔
Controlled motivation to follow recommendations	TSRQ [35]	✔	✔		✔	✔	✔
Amotivation regarding recommendations	TSRQ [35]	✔	✔		✔	✔	✔

Note: 1st session = assessment conducted immediately following the first treatment session. MET = metabolic equivalent. SIRAS = Sports Injury Rehabilitation Adherence Scale. IPAQ = International Short Form Physical Activity Questionnaire. NRS = Numerical Rating Scale. RMDQ = Roland Morris Disability Questionnaire. PSFS = Patient Specific Functional Scale. EurQoL = European Quality of Life Questionnaire. FABQ = Fear Avoidance Beliefs Questionnaire. TSRQ = Treatment Self Regulation Questionnaire.

Table 3. Baseline characteristics

Participant characteristics	Control	Experimental
Age (years)	46.71 (13.48)	44.11 (12.96)
Female sex (%)	64/122 (52)	73/131 (56)
Irish birth (%)	80/93 (86)	87/101 (86)
Married or partner (%)	47/78 (60)	54/85 (64)
Weight (kg)	77.09 (15.48)	76.18 (17.47)
Height (cm)	167.52 (9.52)	167.73 (10.19)
Smoker (%)	27/87 (31)	25/102 (25)
Sick leave for low back pain (%)	50/91 (55)	41/97 (42)
Previous treatment (%)	38/93 (41)	46/100 (46)
Paid employment (%)	32/90 (36)	44/101 (44)
Participant Outcomes	**Control**	**Experimental**
Physical activity (total METs)	1849.06 (3525.31)	2356.84 (5650.21)
Pain intensity	5.84 (2.42)	5.53 (1.94)
Pain bothersomeness	3.31 (1.15)	3.28 (.99)
Interference	3.05 (1.14)	3.14 (1.15)
Satisfaction with symptoms	1.45 (.77)	1.63 (.95)
Perception of recovery	-.72 (2.17)	-.27 (2.20)
Pain related function (Roland-Morris Disability Questionnaire score)	12.44 (4.70)	11.51 (4.82)
Pain related function (Patient specific function)	3.85 (2.02)	4.03 (2.01)
Quality of life	.51 (.22)	.57 (.20)
Fear avoidance beliefs	16.95 (6.96)	17.39 (7.85)
Perceived competence to follow recommendations	6.67 (.57)	6.46 (.77)
Autonomous motivation to follow recommendations	6.64 (.54)	6.60 (.58)
Controlled motivation to follow recommendations	2.75 (1.29)	2.94 (1.45)
Amotivation	2.21 (.98)	2.27 (1.15)
Depression	9.07 (8.28)	7.32 (8.48)
Physiotherapist Characteristics	**Control**	**Experimental**
Female sex (%)	23/29 (79.31)	17/24 (70.83)
Age (years)	32.24 (5.26)	31.92 (4.70)
Clinical experience (years)	9.90 (5.16)	9.75 (4.33)
Autonomous orientation	100.10 (6.77)	94.05 (8.01)
Controlling orientation	57.21 (15.28)	58.61 (10.71)
Impersonal orientation	46.62 (9.03)	50.65 (12.03)

Note: MET = metabolic equivalent. Except where otherwise indicated, values represent group means with standard deviations listed in parentheses. Physiotherapist motivational orientation personality styles measured using the General Causality Orientations Scale [38].

Table 4. Effects of CONNECT intervention – between-arm differences in outcome variables over time

	Effects of intervention (Clinic cluster adjusted)				Effects of intervention (Therapist cluster adjusted)				Effects of intervention (not cluster adjusted)		
	Mean (95% CI)	*p*	ICC	*d*	Mean (95% CI)	*p*	ICC	*d*	Mean (95% CI)	*p*	*d*
Adherence Outcomes											
Home-based adherence											
Week 1	.46 (.15, .77)	.00		.32	.50 (.17, .82)	.00		.35	.46 (.16, .77)	.00	.32
Week 4	.43 (.14, .71)	.00		.30	.46 (.16, .76)	.00		.32	.43 (.15, .71)	.00	.30
Week 12	.39 (.04, .74)	.03		.27	.43 (.06, .81)	.02		.30	.39 (.04, .74)	.03	.27
Week 24	.35 (-.13, .83)	.15		.24	.40 (-.11, .91)	.12		.28	.36 (-.12, .83)	.14	.25
Overall	.41 (.10, .71)	.01	<.01	.28	.45 (.12, .78)	.01	<.01	.31	.41 (.10, .72)	.01	.28
Clinic-based adherence											
Week 1	.10 (-.14, .34)	.43		.15	.09 (-.16, .33)	.48		.13	.09 (-.16, .33)	.48	.13
Week 4	.09 (-.13, .31)	.44		.13	.08 (-.14, .30)	.48		.12	.08 (-.14, .30)	.48	.12
Week 12	.07 (-.19, .34)	.58		.10	.07 (-.19, .34)	.58		.10	.07 (-.19, .34)	.58	.10
Overall	.09 (-.13, .31)	.44	.08	.13	.08 (-.14, .30)	.48	.10	.12	.08 (-.14, .30)	.48	.12
Specific adherence to back exercises at home											
Week 1	4.44 (-1.72, 10.60)	.16		.03	4.71 (-1.39, 10.81)	.13		.04	4.47 (-1.70, 10.64)	10.64	.03
Week 4	3.82 (-1.02, 8.66)	.12		.04	4.54 (-.58, 9.66)	.08		.05	3.90 (-.95, 8.76)	8.76	.04
Week 12	3.20 (-2.77, 9.16)	.29		.05	4.37 (-2.09, 10.84)	.18		.07	3.34 (-2.64, 9.32)	9.32	.05
Week 24	2.57 (-6.05, 11.19)	.56		.06	4.20 (-4.96, 13.36)	.37		.08	2.77 (-5.87, 11.42)	11.42	.06
Overall	3.51 (-1.61, 8.62)	.18	<.01	.05	4.46 (-1.09, 10.00)	.11	<.01	.06	3.62 (-1.51, 8.75)	8.75	.05

	Effects of intervention (Clinic cluster adjusted)				Effects of intervention (Therapist cluster adjusted)				Effects of intervention (not cluster adjusted)		
	Mean (95% CI)	*p*	ICC	*d*	Mean (95% CI)	*p*	ICC	*d*	Mean (95% CI)	*p*	*d*
Physical activity (METS/total)											
Week 1	-711.67 (-2135.22, 711.88)	.33		-.20	-680.43 (-2187.02, 826.16)	.37		-.19	-735.22 (-2166.30, 695.85)	.31	-.21
Week 4	-709.64 (-2016.55, 597.28)	.29		-.20	-687.88 (-2070.55, 694.79)	.33		-.20	-729.57 (-2043.57, 584.42)	.28	-.21
Week 12	-707.60 (-1967.17, 551.98)	.27		-.20	-695.33 (-2029.48, 638.81)	.31		-.20	-723.93 (-1989.77, 541.91)	.26	-.21
Week 24	-705.56 (-1994.75, 583.63)	.28		-.20	-702.79 (-2071.85, 666.27)	.31		-.20	-718.28 (-2012.61, 576.05)	.28	-.20
Overall	-708.62 (-1982.45, 565.22)	.28	.02	-.20	-691.61 (-2039.79, 656.57)	.31	<.01	-.20	-726.75 (-2007.31, 553.80)	.27	-.21
Pain, Function, Quality of Life											
Pain intensity											
Week 4	-.38 (-1.16, .40)	.34		-.16	-.31 (-1.14, -.65)	.46		-.13	-.38 (-1.16, .40)	.34	-.16
Week 12	-.10 (-.71, .51)	.75		-.04	-.01 (-.65, .64)	.98		.00	-.10 (-.71, .51)	.75	-.04
Week 24	.18 (-.48, .83)	.60		.07	.30 (-.38, .98)	.38		.13	.18 (-.48, .83)	.60	.07
Overall	-.10 (-.71, .51)	.75	.03	-.04	-.01 (-.65, .64)	.98	<.01	.00	-.10 (-.71, .51)	.75	-.04
Pain bothersomeness											
Week 4	-.09 (-.48, .30)	.64		-.08	-.20 (-.61, .21)	.35		-.17	-.11 (-.50, .28)	.58	-.10
Week 12	-.07 (-.40, .24)	.65		-.06	-.16 (-.50, .19)	.37		-.14	-.09 (-.42, .23)	.58	-.08
Week 24	-.05 (-.39, .29)	.76		-.05	-.11 (-.47, .25)	.54		-.10	-.07 (-.41, .27)	.68	-.06
Overall	-.07 (-.40, .25)	.65	.01	-.06	-.16 (-.50, .19)	.37	.01	-.14	-.09 (-.42, .23)	.58	-.08
Interference with work											
Week 4	-.43 (-.83, -.04)	.03		-.38	-.45 (-.87, -.04)	.03		-.40	-.43 (-.83, -.04)	.03	-.38
Week 12	-.31 (-.65, .02)	.07		-.28	-.28 (-.63, .07)	.12		-.25	-.31 (-.65, .02)	.07	-.28
Week 24	-.19 (-.56, .18)	.30		-.17	-.11 (-.49, .27)	.58		-.10	-.19 (-.56, .18)	.30	-.17
Overall	-.31 (-.65, .02)	.07	.01	-.28	-.28 (-.63, .07)	.12	.02	-.25	-.31 (-.65, .02)	.07	-.28

	Effects of intervention (Clinic cluster adjusted)				Effects of intervention (Therapist cluster adjusted)				Effects of intervention (not cluster adjusted)		
	Mean (95% CI)	*p*	ICC	*d*	Mean (95% CI)	*p*	ICC	*d*	Mean (95% CI)	*p*	*d*
Satisfaction with current symptoms											
Week 4	-.18 (-.62, .26)	.41		-.56	-.07 (-.53, .39)	.76		-.09	-.17 (-.61, .27)	.46	-.22
Week 12	-.12 (-.44, .20)	.48		-.41	-.05 (-.38, .29)	.79		-.06	-.10 (-.42, .22)	.55	-.13
Week 24	-.05 (-.38, .28)	.77		-.25	-.02 (-.37, .33)	.91		-.03	-.03 (-.37, .31)	.87	-.04
Overall	-.12 (-.44, .20)	.48	<.01	-.41	-.05 (-.38, .29)	.79	.01	-.06	-.10 (-.42, .22)	.55	-.13
Treatment satisfaction											
Week 4	.10 (-.18, .39)	.47		-.22	.18 (-.13, .49)	.25		.22	.10 (-.20, .41)	.51	.12
Week 12	.05 (-.15, .26)	.62		-.14	.13 (-.10, .36)	.26		.15	.05 (-.17, .28)	.65	.06
Week 24	.00 (-.24, .24)	1.00		-.06	.08 (-.18, .33)	.55		.09	.00 (-.25, .25)	1.00	.00
Overall	.05 (-.15, .26)	.62	.002	-.14	.13 (-.10, .36)	.26	.01	.15	.05 (-.17, .28)	.65	.06
Perception of recovery											
Week 4	.58 (-.03, 1.20)	.06		.27	.50 (-.14, 1.13)	.13		.23	.60 (-.02, 1.21)	.06	.27
Week 12	.51 (-.01, 1.02)	.05		.23	.44 (-.10, .98)	.11		.20	.52 (.01, 1.04)	.05	.24
Week 24	.44 (-.19, 1.07)	.17		.20	.38 (-.27, 1.03)	.25		.17	.45 (-.18, 1.08)	.16	.21
Overall	.51 (-.01, 1.02)	.05	.03	.23	.44 (-.10, .98)	.11	.03	.20	.52 (.01, 1.04)	.05	.24
Pain related function (Roland-Morris Disability Questionnaire score)											
Week 4	-.80 (-1.38, .77)	.32		-.17	-.82 (-2.48, .85)	.34		-.17	-.94 (-2.53, .65)	.25	-.20
Week 12	-.36 (-1.68, .96)	.60		-.08	-.50 (-1.90, .90)	.48		-.11	-.49 (-1.83, .85)	.47	-.11
Week 24	.09 (-1.43, 1.60)	.91		.02	-.19 (-1.78, 1.41)	.82		-.04	-.05 (-1.58, 1.49)	.95	-.01
Overall	-.36 (-1.68, .96)	.60	.01	-.08	-.50 (-1.90, .90)	.48	.02	-.11	-.49 (-1.83, .85)	.47	-.11
Pain related function (Patient specific function)											
Week 4	.33 (-.28, .93)	.29		.16	.44 (-.21, 1.08)	.18		.22	.40 (-.22, 1.01)	.21	.20
Week 12	.38 (-.20, .95)	.20		.19	.44 (-.18, 1.06)	.16		.22	.45 (-.14, 1.04)	.14	.22
Week 24	.43 (-.34, 1.20)	.27		.21	.44 (-.37, 1.25)	.28		.22	.50 (-.28, 1.28)	.21	.25
Overall	.38 (-.20, .95)	.20	.07	.19	.44 (-.18, 1.06)	.16	.16	.22	.45 (-.14, 1.04)	.14	.22

	Effects of intervention (Clinic cluster adjusted)				Effects of intervention (Therapist cluster adjusted)				Effects of intervention (not cluster adjusted)		
	Mean (95% CI)	*p*	ICC	*d*	Mean (95% CI)	*p*	ICC	*d*	Mean (95% CI)	*p*	*d*
Quality of life											
Week 4	-.05 (-.12, .01)	.09		-.25	-.06 (-.13, .01)	.08		-.27	-.05 (-.12, .01)	.12	-.25
Week 12	-.04 (-.10, .01)	.13		-.19	-.04 (-.10, .02)	.19		-.17	-.04 (-.10, .01)	.13	-.19
Week 24	-.03 (-.09, .03)	.35		-.14	-.02 (-.08, .05)	.65		-.07	-.03 (-.09, .03)	.32	-.14
Overall	-.04 (-.10, .01)	.13	<.01	-.19	-.04 (-.10, .02)	.19	<.01	-.17	-.04 (-.10, 1.52)	.13	-.19
Motivational Outcomes											
Fear avoidance											
Week 4	-.99 (-3.40, 1.42)	.42		-.14	-.86 (-3.31, 1.60)	.50		-.12	-1.09 (-3.50, 1.32)	.38	-.16
Week 12	-.90 (-3.07, 1.28)	.42		-.13	-.77 (-3.04, 1.50)	.51		-.11	-1.01 (-3.20, 1.17)	.36	-.15
Week 24	-.81 (-3.73, 2.12)	.59		-.12	-.68 (-3.82, 2.46)	.67		-.10	-.94 (-3.87, 2.00)	.53	-.13
Overall	-.90 (-3.07, 1.28)	.42	<.01	-.13	-.77 (-3.04, 1.50)	.51	.01	-.11	-1.01 (-3.20, 1.17)	.36	-.15
Perceived competence to follow recommendations											
Immediately post-initial treatment	.21 (-.08, .50)	.15		.37	.27 (-.04, .57)	.08		.47	.21 (-.08, .49)	.16	.36
Week 4	.33 (.09, .56)	.01		.57	.38 (.13, .64)	.00		.67	.32 (.09, .56)	.01	.56
Week 12	.44 (.19, .69)	.00		.78	.50 (.23, .77)	.00		.87	.44 (.19, .69)	.00	.77
Week 24	.56 (.24, .88)	.00		.99	.61 (.28, .95)	.00		1.08	.55 (.23, .87)	.00	.97
Overall	.39 (.15, .62)	.00	<.01	.68	.44 (.19, .69)	.00	<.01	.77	.38 (.14, .61)	.00	.66
Autonomous motivation to follow recommendations											
Immediately post-initial treatment	.18 (-.04, .41)	.11		.34	.21 (-.02, .45)	.08		.39	.19 (-.04, .42)	.10	.35
Week 4	.09 (-.08, .26)	.28		.17	.12 (-.06, .30)	.18		.22	.10 (-.07, .27)	.26	.18
Week 12	.00 (-.13, .14)	.96		.01	.03 (-.11, .17)	.67		.06	.01 (-.13, .14)	.93	.01
Week 24	-.09 (-.23, .05)	.23		-.16	-.06 (-.21, .09)	.44		-.11	-.08 (-.23, .06)	.24	-.16
Overall	.05 (-.10, .20)	.53	<.01	.09	.08 (-.08, .23)	.34	<.01	.14	.05 (-.10, .20)	.50	.10

	Effects of intervention (Clinic cluster adjusted)				Effects of intervention (Therapist cluster adjusted)				Effects of intervention (not cluster adjusted)		
	Mean (95% CI)	*p*	ICC	*d*	Mean (95% CI)		ICC	*d*	Mean (95% CI)	*p*	*d*
Controlled motivation to follow recommendations											
Immediately post-initial treatment	-.10 (-.41, .21)	.53		-.08	-.19 (-.51, .13)	.24		-.15	-.10 (-.41, .21)	.52	-.08
Week 4	-.08 (-.38, .22)	.61		-.06	-.14 (-.46, .18)	.40		-.11	-.08 (-.39, .22)	.60	-.06
Week 12	-.06 (-.43, .31)	.76		-.05	-.08 (-.47, .31)	.68		-.06	-.06 (-.44, .31)	.73	-.05
Week 24	-.04 (-.52, .45)	.88		-.03	-.03 (-.54, .48)	.92		-.02	-.05 (-.53, .44)	.85	-.04
Overall	-.07 (-.40, .26)	.68	<.01	-.05	-.11 (-.46, .24)	.54	<.01	-.08	-.07 (-.40, .26)	.67	-.06
Amotivation											
Immediately post-initial treatment	-.25 (-.62, .12)	.19		-.25	-.23 (-.62, .16)	.25		-.23	-.25 (-.62, .12)	.19	-.25
Week 4	-.36 (-.67, -.05)	.02		-.37	-.34 (-.66, -.01)	.04		-.34	-.36 (-.67, -.05)	.02	-.37
Week 12	-.47 (-.81, -.12)	.01		-.48	-.44 (-.80, -.09)	.02		-.45	-.47 (-.81, -.12)	.01	-.48
Week 24	-.58 (-1.02, -.13)	.01		-.59	-.55 (-1.02, -1.02)	.02		-.56	-.58 (-1.02, -.13)	.01	-.59
Overall	-.41 (-.73, -.10)	.01	<.01	-.42	-.39 (-.72, -.06)	.02	.01	-.40	-.41 (-.73, -.10)	.01	-.42

Note: A positive value indicates that the experimental arm was higher on the outcome variable, compared with the controls. Standardized mean difference effect sizes (*d*) were calculated using baseline SD from control arm participants. Where baseline measures were not relevant (e.g., adherence variables), the control arm's SD at each time point was employed to calculate *d*.

Supplementary Material 1

Supplementary File 1. Proportion of patients in each arm who received advice from their physiotherapist

Advice provided	Experimental	Control
Remain active rather than resting	93%	91%
Posture	90%	84%
General exercise	92%	93%
Restoring functionally relevant activities into daily life	68%	63%
Specific rehabilitation exercises	90%*	75%
Decreasing fear-avoidance and illness behaviour	69%*	51%

Note: * indicates between-arm difference in χ^2 ($p > .05$).

Supplementary File 2. Mean Values for Outcomes

	Unadjusted Outcome Measures	
	Control	Experimental
Adherence Outcomes		
Home-based adherence, ARS	mean (SD)	mean (SD)
Week 1	5.61 (1.44)	6.09 (1.02)
Week 4	5.85 (1.27)	6.03 (1.13)
Week 12	5.10 (1.79)	5.59 (1.29)
Week 24	4.86 (1.92)	4.95 (1.98)
Clinic-based adherence, SIRAS	mean (SD)	mean (SD)
Week 1	4.30 (.68)	4.49 (.58)
Week 4	4.50 (.61)	4.50 (.70)
Week 12	4.49 (.60)	4.65 (.67)
Week 24	N/A	N/A
Specific adherence to back exercises, HECA	Mean (SD)	Mean (SD)
Week 1	80.20 (22.15)	84.63 (21.44)
Week 4	78.30 (27.46)	82.63 (21.08)
Week 12	71.40 (24.10)	78.42 (27.10)
Week 24	71.27 (26.32)	70.31 (30.03)
Physical activity (METS/week), IPAQ	Change scores (SD)	Change scores (SD)
Week 1	-554.89 (-554.89)	-811.17 (5936.86)
Week 4	330.87 (4634.43)	-682.03 (7251.97)
Week 12	1156.63 (4992.22)	-871.39 (6659.47)
Week 24	-221.11 (3171.80)	-917.82 (7313.01)
Clinical Outcomes & Quality of Life		
Pain intensity	Change scores (SD)	Change scores (SD)
Week 4	-.88 (2.26)	-.78 (2.37)
Week 12	-1.31 (2.36)	-1.53 (2.71)
Week 24	-1.18 (3.19)	-1.53 (2.78)
Pain bothersomeness	Change scores (SD)	Change scores (SD)
Week 4	-.18 (1.21)	-.37 (1.22)
Week 12	-.43 (1.49)	-.57 (1.28)
Week 24	-.66 (1.54)	-.80 (1.45)
Pain interference	Change scores (SD)	Change scores (SD)
Week 4	-.25 (1.26)	-.42 (1.35)
Week 12	-.47 (1.41)	-.75 (1.29)
Week 24	-.45 (1.54)	-.86 (1.46)
Satisfaction with current symptoms	Change scores (SD)	Change scores (SD)
Week 4	.47 (1.14)	.54 (1.17)
Week 12	1.13 (1.60)	.93 (1.53)
Week 24	1.26 (1.56)	1.19 (1.68)
Treatment satisfaction	Mean (SD)	Mean (SD)
Week 4	4.47 (.84)	4.51 (.80)
Week 12	4.33 (1.01)	4.52 (.92)
Week 24	4.40 (1.08)	4.21 (1.22)
Perception of recovery	Mean (SD)	Mean (SD)
Week 4	1.50 (2.78)	1.69 (2.58)
Week 12	2.30 (2.71)	2.46 (2.60)
Week 24	2.58 (3.07)	2.46 (2.63)
Pain related function (Disability, RMDQ)	Change scores (SD)	Change scores (SD)

Week 4	-2.11 (4.90)	-2.23 (5.82)
Week 12	-2.82 (5.77)	-3.48 (5.72)
Week 24	-4.09 (5.95)	-4.87 (5.86)
Pain related function (Patient specific function, PSFS)	Change scores (SD)	Change scores (SD)
Week 4	.81 (2.02)	1.25 (2.21)
Week 12	1.44 (2.32)	2.00 (2.47)
Week 24	1.76 (2.74)	2.39 (2.99)
Quality of life, EuroQol weighted health index	Change scores (SD)	Change scores (SD)
Week 4	.24 (.29)	.18 (.28)
Week 12	.25 (.28)	.21 (.27)
Week 24	.24 (.27)	.21 (.24)
Motivational Outcomes		
Fear avoidance	Change scores (SD)	Change scores (SD)
Week 4	-1.72 (7.82)	-3.29 (7.70)
Week 12	-2.21 (9.47)	-4.00 (8.79)
Week 24	-4.41 (9.88)	-4.63 (9.93)
Perceived competence to follow recommendations	Change scores (SD)	Change scores (SD)
Immediately post-initial treatment	.11 (.59)	.33(.74)
Week 4	-.37 (.86)	-.08 (.93)
Week 12	-.57 (1.43)	-.07 (1.11)
Week 24	-.92 (1.51)	-.50 (1.52)
Autonomous motivation to follow recommendations	Change scores (SD)	Change scores (SD)
Immediately post-initial treatment	.22 (.51)	.15 (.50)
Week 4	-.21 (.80)	-.05 (.59)
Week 12	-.17 (.92)	-.06 (.68)
Week 24	.00 (.76)	-.15 (.68)
Controlled motivation to follow recommendations	Change scores (SD)	Change scores (SD)
Immediately post-initial treatment	-.11 (1.02)	-.21 (1.13)
Week 4	-.16 (1.35)	-.14 (1.55)
Week 12	-.34 (1.37)	-.31 (1.27)
Week 24	-.51 (1.42)	-.58 (1.43)
Amotivation	Change scores (SD)	Change scores (SD)
Immediately post-initial treatment	.19 (.92)	-.09 (.93)
Week 4	.35 (1.59)	.04 (1.63)
Week 12	.41 (1.61)	-.20 (1.45)
Week 24	.62 (1.19)	.14 (1.69)

Note: N/A = not applicable as no participants were receiving physiotherapy treatment at 24 weeks. Where baseline measures were not relevant (e.g., adherence variables) mean scores, rather than change scores, are presented.

Supplementary Material 3

Supplementary File 3. Effects of CONNECT intervention on Mean Levels of Outcomes Measures – Results from Linear Mixed Models Examining Mean Levels

	Effects of treatment (Site cluster adjusted)				Effects of treatment (Therapist cluster adjusted)				Effects of treatment (not cluster adjusted)		
	Mean (95% CI)	*P*	ICC	*d*	Mean (95% CI)	*P*	ICC	*d*	Mean (95% CI)	*P*	*d*
Adherence Outcomes											
Home-based adherence											
Week 1	0.46 (.02, .90)	.04		.32	0.47 (-.01, .94)	.04		.33	0.46 (.02, .90)	-0.32	.32
Week 4	0.28 (-.19, .76)	.24		.19	0.38 (-.12, .89)	.24		.26	0.28 (-19, .75)	-0.19	.22
Week 12	0.59 (-.13, 1.06)	.01		.41	0.62 (.13, 1.11)	.01		.43	0.59 (.13, 1.06)	-0.41	.33
Week 24	0.17 (-.26, .60)	.44		.12	0.18 (-.27, .64)	.45		.13	0.17 (-.26, .60)	-0.12	.09
Overall	0.38 (.07, .69)	.03	<.001	.26	0.41 (.08, .75)	.03	<.01	.28	0.38 (.07, .69)	0.26	.23
Clinic-based adherence											
Week 1	0.14 (-.42, .70)	.58		.21	0.04 (-.28, .37)	.79		.06	0.14 (-.12, .40)	.29	.21
Week 4	-0.03 (-.59, 0.54)	.91		-.04	-0.12 (-.46, .22)	.48		-.18	-0.03 (-.31, .25)	.83	-.04
Week 12	0.14 (-.44, .72)	.61		.21	0.06 (-.31, .42)	.76		.09	0.16 (-.14, .46)	.28	.24
Overall	0.09 (-.47, .64)	.73	.08	.13	0.01 (-.30, .32)	.96	.10	.01	0.09 (-.32, .14)	.44	.13
Specific adherence to back exercises											
Week 1	4.45 (-3.74, 12.63)	.27		.07	3.94 (-4.25, 12.13)	.34		.06	4.20 (-2.65, 11.04)	.23	.06
Week 4	2.93 (-6.08, 11.94)	.51		.04	4.55 (-3.90, 12.99)	.29		.07	2.90 (-4.93, 10.74)	.47	.04
Week 12	7.26 (-3.07, 17.60)	.16		.11	7.80 (-1.53, 17.12)	. 10		.12	7.19 (-2.24, 16.61)	.13	.11
Week 24	0.38 (-10.90, 11.67)	. 95		.01	0.77 (-8.77, 10.31)	.87		.01	0.25 (-10.13, 10.64)	.96	.00
Overall	3.76 (-3.46. 10.97)	. 28	<.001	0.06	4.26 (-1. 35, 9.88)	.13	<.01	.07	3.63 (-1.55, 8.82)	.17	.06
Physical activity (METS/total)											
Week 1	-1282.37 (-5005.31, 2440.56)	.40		-.36	-498.27 (-2207.44, 1210.90)	.56		-.14	-541.04 (-2021.61, 939.53)	.47	-.15
Week 4	-1977.20 (-5659.39, -1704.99)	.22		-.56	-1143.23 (-2988.43, 701.96)	.22		-.32	-1240.26 (-2894.15, 413.63)	.14	-.35
Week 12	-1375.84 (-5071. 38, 2319.70)	.37		-.39	-749.03 (-2559.00, 1060.94)	.41		-.21	-653.06 (-2232.77, 926.65)	.42	-.19
Week 24	-1346.10	.37		-.38	-600.37	.45		-.17	-621.62	.36	-.18

Overall	(-5130. 70, 2438.49) -1495.38 (-5305.88, 2315.12)	.33	.02	-.42	(-2184.05, 983.30) -747.73 (-2282.62, 787.16)	.33	.004	-.21	(-1964.93, 721.70) -764 (-2057.92, 529.93)	.25	-.22
Pain, Function, Quality of Life											
Pain intensity											
Week 4	-.37 (-1.28, .53)	.40		-.15	-.35 (-1.37, .68)	.50		-.14	-.36 (-1.16, .45)	.39	-.15
Week 12	-.17 (-1.05, .71)	.69		-.07	-.19 (-1.15, .78)	.70		-.08	-.15 (-.92, .62)	.70	-.06
Week 24	.17 (-.65, .98)	.67		.07	.27 (-.62, 1.16)	.54		.11	.19 (-.49, .86)	.59	.08
Overall	-.13 (-.91, .66)	.73	.03	-.05	-.09 (-0.95, 0.77)	.84	.002	-.04	-.11 (-0.72, 0.51)	.74	-.05
Pain Bothersomeness											
Week 4	-.13 (-.68, .42)	.62		-.11	-.17 (-.63, .29)	.46		-.15	-.13 (-.53, .27)	.53	-.11
Week 12	-.04 (-.59, .51)	.87		-.03	-.10 (-.56, .35)	.66		-.09	-.03 (-.44, .38)	.87	-.03
Week 24	-.08 (-.61, .45)	.73		-.07	-.08 (-.49, .33)	.69		-.07	-.09 (-.44, .26)	.62	-.08
Overall	-.08 (-.60, .43)	.72	.01	-.07	-.12 (-.51,.27)	.55	.01	-.10	-.08 (-.41 .25)	.62	-.07
Interference											
Week 4	-.35 (-.99, .29)	.26		-.31	-.36 (-.88, .17)	.18		-.32	-.42 (-.82, -.01)	.05	-.37
Week 12	-.29 (-.93, .35)	.35		-.25	-.24 (-.74, .26)	.34		-.21	-.35 (-.75, .06)	.09	-.31
Week 24	-.11 (-.74, .51)	.70		-.10	-.00 (-.49, .48)	.99		-.00	-.18 (-.56, .20)	.34	-.16
Overall	-.25 (-.86, .36)	.38	.01	-.22	-.20 (-.66, 26)	.38	.02	-.18	-.32 (-.65, -.02)	.07	-.28
Symptoms											
Week 4	-.11 (-.63, .42)	.68		-.14	-.07 (-.58, .45)	.80		-.09	-.12 (-.58, .33)	.60	-.16
Week 12	-.25 (-.79, .28)	.34		-.32	-.22 (-.75, .29)	.39		-.29	-.27 (-.74, .21)	.27	-.35
Week 24	-.01 (-.45, .46)	.98		-.01	-.04 (-.44, .36)	.83		-.05	-.00 (-.35, .34)	.98	-.00
Overall	-.12 (-.57, .33)	.57	.003	-.16	-.11 (-.50, .28)	.57	.01	-.14	-.13 (-.46, .20)	.44	-.17
Treatment Satisfaction											
Week 4	.16 (-.18, .49)	.34		.19	.20 (-.13, .54)	.24		.24	.16 (-.14, .45)	.29	.19
Week 12	-.17 (-.52, .19)	.39		-.20	-.17 (-.54, .20)	.37		-.20	-.17 (-.49, .15)	.31	-.20
Week 24	.06 (-.24, .35)	.69		.07	.11 (-.18, .40)	.47		.13	.06 (-.19, .30)	.65	.07
Overall	.02 (-.26,.29)	.90	.002	.02	.05 (-.22, .31)	.72	.01	.06	.02 (-.19, .23)	.89	.02
Global perception of recovery											
Week 4	.58 (-.26, 1.43)	.16		.27	.42 (-.28, 1.12)	.23		.19	.52 (-.11, 1.16)	.11	.24
Week 12	.81 (-.05, 1.68)	.06		.37	.68 (-.04, 1.41)	.06		.31	.75 (.08, 1.42)	.03	.35
Week 24	.43 (-.42, 1.29)	.29		.20	.28 (-.45, 1.00)	.45		.13	.37 (-.28, 1.02)	.27	.17

Overall	.61 (-.19, 1.41)	.12	.03	.28	.46 (-0.14, 1.06)	.13	.03	.21	.55 (.03, 1.07)	.04	.25
Disability, RMDQ score											
Week 4	-.78 (-3.29, 1.72)	.51		-.17	-.71 (-2.65, 1.23)	.47		-.15	-.90 (-2.52, .74)	.28	-.19
Week 12	-.56 (-3.09, 1.96)	.64		-.12	-.62 (-2.57, 1.33)	.53		-.13	-.65 (-2.30, 1.00)	.44	-.14
Week 24	.10 (-2.37, 2.57)	.93		.02	.06 (-1.94, 1.82)	.95		.01	.02 (-1.57, 1.54)	.98	.00
Overall	-.42 (-2.82, 1.99)	.71	0.01	-.09	-.46 (-2.18, 1.26)	.59	.02	-.10	-.52 (-1.88, .84)	.45	-.11
Patient specific function											
Week 4	.48 (-.55, 1.50)	.32		.24	.39 (-.43, 1.21)	.34		.19	.41 (-.23, 1.05)	.20	.20
Week 12	.49 (-.55, 1.53)	.32		.24	.45 (-.41, 1.31)	.30		.22	.42 (-.27, 1.11)	.23	.21
Week 24	.57 (-.51, 1.66)	.28		.28	.42 (-.54, 1.38)	.38		.21	.50 (-.29, 1.29)	.21	.25
Overall	.51 (-.49, 1.52)	.27	.07	.25	.42 (-.37, 1.21)	.29	.16	.21	.44 (-.15, 1.04)	.14	.22
Quality of life											
Week 4	-.06 (-.13, .02)	.14		-.27	-.06 (-.13, .01)	.10		-.27	-.06 (-.13, .01)	.12	-.27
Week 12	-.04 (-.11, .04)	.30		-.18	-.04 (-.11, .04)	.32		-.18	-.04 (-.11, .03)	.28	-.18
Week 24	-.03 (-.10, .04)	.33		-.14	-.02 (-.08, .05)	.63		-.09	-.03 (-.10, .03)	.31	-.14
Overall	-.04 (-.11, .02)	.18	.002	-.18	-.04 (-.10, .02)	.20	<.01	-.18	-.04 (-.10, .01)	.13	-.18
Motivational Outcomes											
Fear avoidance											
Week 4	-1.09 (-4.08, 1.91)	.45		-.16	-.60 (-3.31, 2.11)	.66		-.09	-1.03 (-3.49, 1.44)	.41	-.15
Week 12	-1.33 (-4.55, 1.88)	.40		-.19	-1.16 (-4.22, 1.89)	.45		-.17	-1.29 (-4.10, 1.52)	.37	-.19
Week 24	-0.80 (-4.23, 2.64)	.64		-.11	-.19 (-3.69, 3.32)	.92		-.03	-0.75 (-3.84, 2.34)	.63	-.11
Overall	-1.07 (-3.93, 1.78)	.42	.002	-.15	-.65 (-3.19, 1.89)	.61	.01	-.09	-1.02 (-3.23, 1.19)	.36	-.15
Perceived competence to follow recommendations											
Immediately post-initial treatment	.19 (-.04, .43)	.10		.33	.19 (-.14, .51)	.27		.33	.21 (.02, .40)	.03	.37
Week 4	.39 (.06, .72)	.02		.68	.39 (-.01, .76)	.04		.68	.41 (.10, .71)	.01	.72
Week 12	.39 (-.03, .82)	.07		.68	.42 (.04, .79)	.03		.74	.41 (-.01, .82)	.05	.72
Week 24	.60 (-.08, 1.12)	.02		1.05	.54 (.15, .92)	.01		.95	.61 (.10, 1.12)	.02	1.07
Overall	.40 (0.11, 0.68)	.01	<.001	.70	.38 (.12, .64)	.01	<.001	.67	.41 (.15, .67)	.002	.72
Autonomous motivation to follow recommendations											
Immediately post-initial treatment	0.16 (-.14, .46)	.29		.30	.22 (-.03, .47)	.09		.41	.19 (-.04, .43)	.11	.35
Week 4	0.03 (-.30, 0.35)	.87		.06	.07 (-.21, .36)	.89		.13	.06 (-.21, .33)	.65	.11

Week 12	-.10 (-.42, .22)	.53		-.19	-.02 (-.30, .26)	.89		-.04	-.05 (-.32, .21)	.68	-.09
Week 24	-.10 (-.35, .16)	.41		-.19	-.04 (-.21, .13)	.67		-.07	-.07 (-.22, .08)	.35	-.13
Overall	.00 (-0.26, 0.25)	.98	.007	.00	.06 (-0.12, 0.24)	.52	.003	.11	.03 (-0.13, 0.20)	.71	.06
Controlled motivation to follow recommendations											
Immediately post-initial treatment	-.10 (-.49, .29)	.57		-.08	-.21 (-.53, .12)	.21		-.16	-.11 (-.42, .21)	.51	-.09
Week 4	-.08 (-.58, .43)	.76		-.06	-.03 (-.53, .47)	.91		-.02	-.08 (-.56, .39)	.73	-.06
Week 12	.09 (-.39, .58)	.69		.07	.13 (-.34, .61)	.58		.10	.09 (-.37, .54)	.71	.07
Week 24	-.15 (-.69, .38)	.57		-.12	-.19 (-.73, .36)	.50		-.15	-.16 (-.68, .35)	.53	-.12
Overall	-.06 (-.35, .46)	.76	.001	-.05	-.07 (-.45, .30)	.70	<.001	-.05	-.07 (-.42, .29)	.71	-.05
Amotivation											
Immediately post-initial treatment	-.26 (-.70, .17)	.22		-.27	-.27 (-.60, .06)	.10		-.28	-.27 (-.55, .00)	.05	-.28
Week 4	-.26 (-.75, .23)	.29		-.27	-.17 (-.75, .41)	.56		-.17	-.25 (-.80, .31)	.38	-.26
Week 12	-.60 (-1.10, -.10)	.02		-.61	-.55 (-1.11, .02)	.06		-.56	-.58 (-1.11, .04)	.04	-.59
Week 24	-.50 (-1.03, .04)	.07		-.51	-.49 (-1.12, .14)	.13		-.50	-.48 (-1.05, .09)	.10	-.49
Overall	-0.40 (-.80, .01)	.05	.001	-.41	-.37 (-.75, .01)	.06	.005	-.38	-0.31 (-.58, .05)	.02	-.32

Note: Standardized mean difference effect sizes (*d*) were calculated using baseline SD from control arm participants. Where baseline measures were not relevant (adherence variables), the control arm's SD at each time point was employed to calculate *d*.

Supplementary File 4: Sex Moderation Results

Table 1: Linear Mixed Model Estimates of Fixed Effects

Parameter	Estimate	*SE*	df	t	*p*	95% CI
RMDQ – Intercept	13.31	0.36	242.60	36.62	0.00	12.60, 14.03
arm	-0.28	0.36	242.68	-0.77	0.44	-1.00, 0.44
sex	0.62	0.37	242.64	1.70	0.09	-0.10, 1.34
time	-1.43	0.13	213.00	-11.31	0.00	-1.67, -1.18
arm * time	-0.18	0.13	213.11	-1.45	0.15	-0.43, 0.07
time * sex	-0.33	0.13	213.11	-2.58	0.01	-0.58, -0.08
arm * time * sex	0.31	0.10	211.36	3.16	0.00	0.12, 0.50
PSFS – Intercept	3.59	0.23	7.40	15.80	0.00	3.06, 4.12
arm	0.02	0.16	226.59	0.15	0.88	-0.29, 0.34
sex	-0.07	0.16	237.07	-0.44	0.66	-0.39, 0.25
time	0.69	0.06	220.56	10.90	0.00	0.57, 0.82
arm * time	0.08	0.06	220.49	1.20	0.23	-0.05, 0.20
time * sex	0.12	0.06	220.24	1.83	0.07	-0.01, 0.24
arm * time * sex	-0.09	0.05	212.96	-1.98	0.05	-0.19, 0.00
Interference – Intercept	3.25	0.09	239.96	36.42	0.00	3.07, 3.43
arm	0.11	0.09	239.90	1.20	0.23	-0.07, 0.28
sex	-0.06	0.09	240.51	-0.62	0.53	-0.23, 0.12
time	-0.22	0.03	221.15	-6.90	0.00	-0.28, -0.15
arm * time	-0.08	0.03	220.98	-2.45	0.02	-0.14, -0.02
time * sex	0.01	0.03	221.51	0.46	0.65	-0.05, 0.08
arm * time * sex	0.04	0.02	222.51	1.89	0.06	0.00, 0.08

Note: All *p* values are two-tailed. RMDQ = Roland Morris Disability Questionnaire, PSFS = Patient Specific Function Scale, Interference = interference with work. Pairwise comparisons identified an effect sizes for the mean difference between treated women and controls at Week 24: RMDQ d = .92, PSFS = .55, interference = .89.

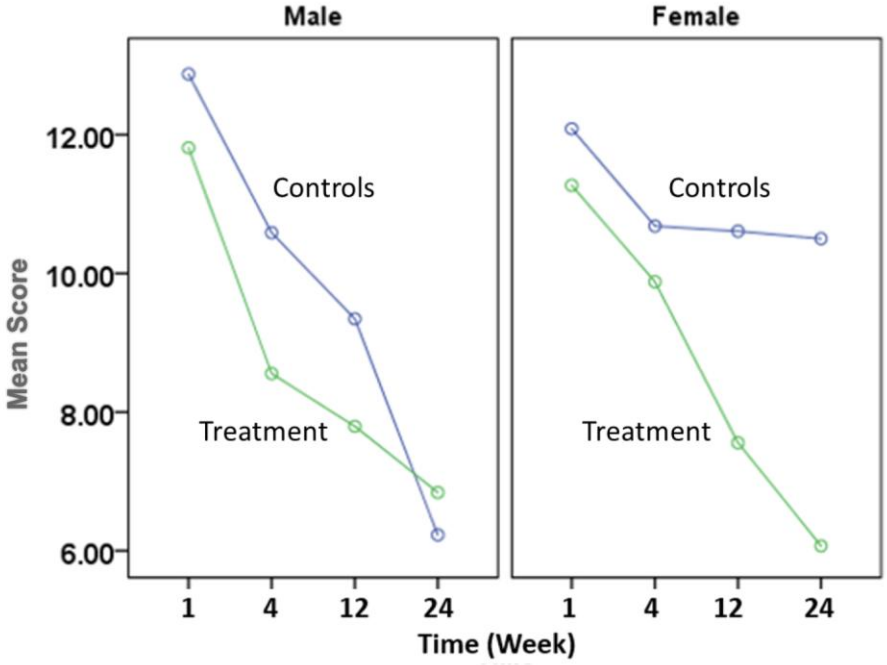


Figure 1

Roland Morris Disability Questionnaire mean scores at four measurement points in time for men and women in the experimental and control groups

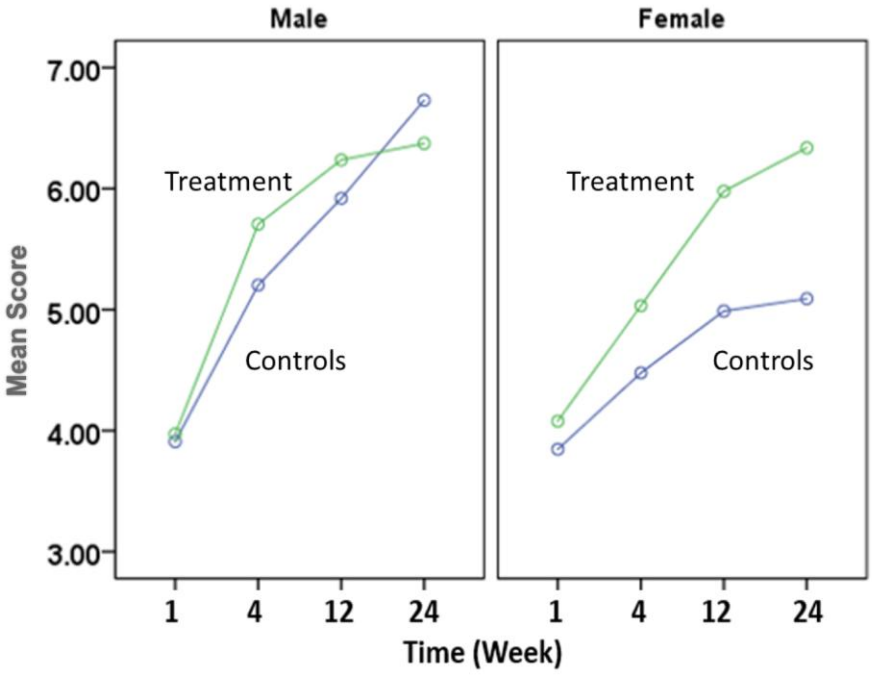


Figure 2

Patient Specific Functional Scale mean scores at four measurement points in time for men and women in the experimental and control groups

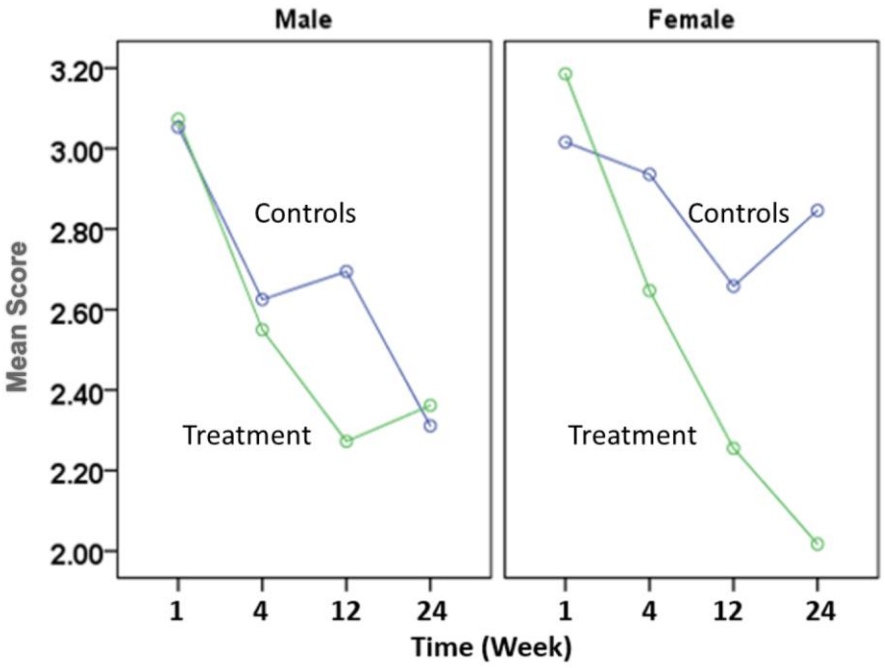


Figure 3

Interference with work mean scores at four measurement points in time for men and women in the experimental and control groups. ("During the past week, how much did pain interfere with your normal work (inside/outside home)", 1-5 scale)