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A six-participant pilot single-subject study of an individualized pain management program for people with spinal cord injury

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STUDY DESIGN: Single-subject repeated measures design.
OBJECTIVES: To explore the impacts of a novel individualized interdisciplinary pain self-management program for persons living with spinal cord injury pain.
SETTING: A large rehabilitation institute for adults with physical disabilities in Quebec city (Quebec, Canada).
METHODS: Six persons having sustained a spinal cord injury and experiencing chronic pain participated. Following a five-week pre-intervention phase (baseline repeated measures) and a clinical evaluation, individualized intervention objectives were developed in collaboration with each participant. Then, participants completed a ten-week intensive intervention and a six-month consolidation phase. The program included cognitive behavioral therapy, and physical and pharmacological interventions, which were group- and individual-based. Outcome measures were the Canadian Occupational Performance Measure (COPM), the French-Canadian Chronic Pain Self-efficacy Scale (FC-CPSES), the Brief Pain Inventory (BPI), and the Hospital Anxiety and Depression Scale (HADS).
RESULTS: For five out of the six participants, a majority of outcomes improved during either of the intervention phases or both. Improvements in occupational performance were clinically significant for three participants. Pain interference and anxiety improved significantly in five participants, while pain self-efficacy and depressive symptoms improved in four participants.
CONCLUSIONS: The results suggest that the pain self-management program was effective to reduce the impact of spinal cord injury pain. Further research is needed to replicate these results in a larger study and comprehend the factors favoring or undermining improvements with such programs, as well as their persistence over time.

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INTRODUCTION

Among the sequelae which can occur in people living with a SCI, pain is one of the most common, with a prevalence around 60% [1]. Over half of persons having sustained SCI will develop chronic pain [2]. SCI pain is associated with negative psychosocial consequences, notably on emotional functions (e.g., stress, depression, anxiety and diminished self-efficacy and wellbeing), as well as economic self-sufficiency [3].

Because SCI pain is often refractory to curative treatment [2], a few programs targeting *pain management* for persons living with a SCI have been developed [4–11]. Such pain management programs aim to improve persons' function and help them learn to live with pain [12]. Programs' contents include interventions such as education about pain mechanisms, cognitive and behavioral therapy (CBT) targeting self-management, exercise and relaxation. While their format varies, most programs offer multidisciplinary group interventions, based on cognitive-behavioral approaches, that extend over several weeks.

Studies have shown positive results for these programs on outcomes including pain intensity and interference with daily life, catastrophizing, self-efficacy, anxiety, depression, function, social participation and life satisfaction [4, 6–9, 11]. Maintenance of improvements over time has however shown to be inconsistent across outcomes and studies. Further focussing on relapse prevention and provision of booster sessions has been suggested for this purpose [4, 7, 8]. The core characteristics of these pain management programs are in line with the needs expressed by persons living with SCI neuropathic pain in a qualitative study [13]. However, while persons living with SCI related pain need to meet with peers, this study also revealed that it is important for them to be involved in the treatment plan and that the treatment also be individualized [13].

Thus, the main objective of this pilot study was to assess the impact of a novel pain self-management program (PSMP) for persons living with chronic SCI pain, inspired by previously conducted programs, but with a specific focus on individualization, and weaning intervention more gradually in order to help maintain gains over time. The PSMP was tailored to the needs of each participant by involving participants in the determination of intervention objectives meaningful to them, providing individual

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Table 1. Sequence of data collection points.

	Pre-intervention (phase A)					Pain self-management program																
						Clinical evaluation		Intervention – intensive (phase B_1)										Intervention – consolidation (phase B_2)				
	Weeks	-8	-7	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6	7	8	9	10	[…]	16	[…]	24	[…]	36
Measures	COPM				X														X						X
	BPI	X		X		X				X			X			X			X		X		X		X
	FC-CPSES	X		X		X				X			X			X			X		X		X		X
	HADS	X		X		X				X			X			X			X		X		X		X
	NRS	X		X		X				X			X			X			X		X		X		X

COPM Canadian Occupational Performance Measure, *BPI* Brief Pain Inventory, *FC-CPSES* French-Canadian Chronic Pain Self-efficacy Scale, *HADS* Hospital Anxiety and Depression Scale, *NRS* Numerical rating scale used to measure pain intensity, *X* Measurement point.

Table 2. Sequence of the interventions provided during the intensive intervention phase.

Week	Group or individual	Contents
1	Group	Pain neurophysiology
		Types of pain associated with spinal cord injuries and awareness of symptoms indicating damage to integrity of body systems
		Positioning
		Ergonomics
		Biopsychosocial conceptualization of chronic pain
		Cognitive behavioral therapy
		Determination of functional objectives
		Exercise sessions
		Relaxation sessions
2	Individual	Psychoeducative activities of reconceptualization of chronic pain
		Physical training
3	Individual	Follow-up about medication use
		Physical training
4	Group	Medication use
		Cognitive management strategies
		Communication and affirmation abilities training
		Exercise sessions
		Relaxation sessions
5	Individual	Follow-up about cognitive management strategies
		Communication and affirmation abilities training
		Physical training
6	Individual	Development and training of self-management abilities
7	Group	Problem solving strategies
		Gradual resumption of roles and dosage of daily life activities
		Gradual exposition to feared activities
		Theme of participants' choice
		Exercise sessions
		Relaxation sessions
8–9	Individual	Development and training of self-management abilities
		Physical training
10	Group	Training for pain crisis management and relapse prevention
	Individual	Medication adjustments

sessions alternating with group sessions to work on their own objectives over an extended period of time, and by using a client-centered primary outcome measure.

METHODS

Study design

A single-subject (A – B) design [14] was used for this pilot study, comprising a five-week pre-intervention phase (A) and a 36-week intervention phase (B). The intervention phase was further divided into a 10-week intensive phase (B_1), followed by a 26-week consolidation phase (B_2). Three baseline

measurement points took place during phase A, and seven measurement points during phase B. The detailed sequence of data collection points is presented in Table 1.

Study setting and participants

The study took place at the *Institut de réadaptation en déficience physique de Québec* (*IRDPQ*) of the *Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale*, in Quebec, Canada. Participants recruited for the study were the first six patients to participate in this program, as part of its pilot implementation. The target clientele for the PSMP consisted of 1) adults with traumatic or non-traumatic SCI; 2) living in the community in the territory of Eastern Quebec; and 3) presenting persistent or recurrent pain having an important impact on the accomplishment of life habits or fulfillment of roles that had been refractory to other treatment approaches for more than six months. The study was approved by the Research Ethics Committee of the *IRDPQ* (IRB #2014–397). Each participant provided written informed consent.

Intervention

The general aim of the PSMP was to make accomplishment of life roles and habits possible in spite of pain. Program acceptability and feasibility were assessed prior to its implementation by conducting focus groups and interviews with chronic pain experts and potential users [15]. The team providing the pilot program included a physiatrist, a physical therapist, a physical educator, an occupational therapist, a psychologist and a clinical coordinator.

Following phase A, the PSMP began with a three-week interdisciplinary clinical evaluation carried out for each participant as part of the program. The results of all the measures and evaluations carried out were used by the clinicians to determine individualized intervention objectives in collaboration with each participant. Ten weeks of intensive interventions (Phase B_1) followed. Two four-hour group-based intervention sessions were provided during weeks 1, 4, 7, and 10. During weeks 2, 3, 5, 6, 8, and 9, interventions were one-on-one and tailored to the specific needs of each participant. The consolidation phase (B_2) consisted of follow-up group-based intervention sessions provided at weeks 16, 24, and 36. During the six-month duration of this phase, the participants could request an appointment with either of the health professionals of the team on a one-on-one basis.

The interventions included CBT, and physical and pharmacological interventions. The CBT sessions were made up of psychoeducation, self-management skills development and training, training for the management of pain peaks and relapse prevention. Participants were allowed to choose topics beyond the pre-established content. Adapted exercise and relaxation sessions were provided. Participants also met the physiatrist to adjust their medication. Every week, personal objectives were set by each of the participants along with the health professionals, and they were given homework linked with their objectives. The detailed content and sequence of the interventions provided during phase B_1 is presented in Table 2.

Table 3. Characteristics of participants[a] ($n = 6$).

Characteristics	*n* (%)
Gender	
Women	4 (67)
Men	2 (33)
Age	
16–30	1 (17)
31–45	0 (0)
46–60	3 (50)
61–75	2 (33)
Time since injury	
1–5 years	1 (17)
6–10 years	1 (17)
11–15 years	3 (50)
16–20 years	1 (17)
Severity of injury	
C1–4 AIS A	1 (17)
C5–8 AIS C	1 (17)
T1-S5 AIS C	1 (17)
AIS D at any injury level	3 (50)
Type of pain	
Neuropathic only	1 (17)
Mixed neuropathic and nociceptive	5 (83)
Location of pain[b]	
Head and neck region	2 (33)
Dorsolumbar region	4 (67)
Either or both of upper limbs	4 (67)
Either or both of lower limbs	5 (83)

[a]Characteristics are not detailed for each participant to ensure confidentiality.
[b]All participants had pain in more than one region (three [50%] in two regions and the three others [50%] in three regions).

Data collection

Participants' demographics and clinical data were drawn from clinical records. As the general aim of the PSMP was to improve the accomplishment of life roles and habits of persons living with SCI pain, the primary outcome in this study was occupational performance, based on self-identification of functional goals. Pain self-efficacy, pain interference, pain intensity, as well as anxiety and depression symptoms were secondary outcomes. All these outcomes fall within the most important measurement domains identified for the evaluation of chronic pain self-management programs by Taylor et al. [16]. Occupational performance was assessed through semi-structured interviews conducted by phone by the same evaluator on three occasions: at baseline and at the end of phases B_1 and B_2. Secondary outcomes were measured with a single composite questionnaire self-administered online or in paper format, at each of the ten measurement points (see Table 1).

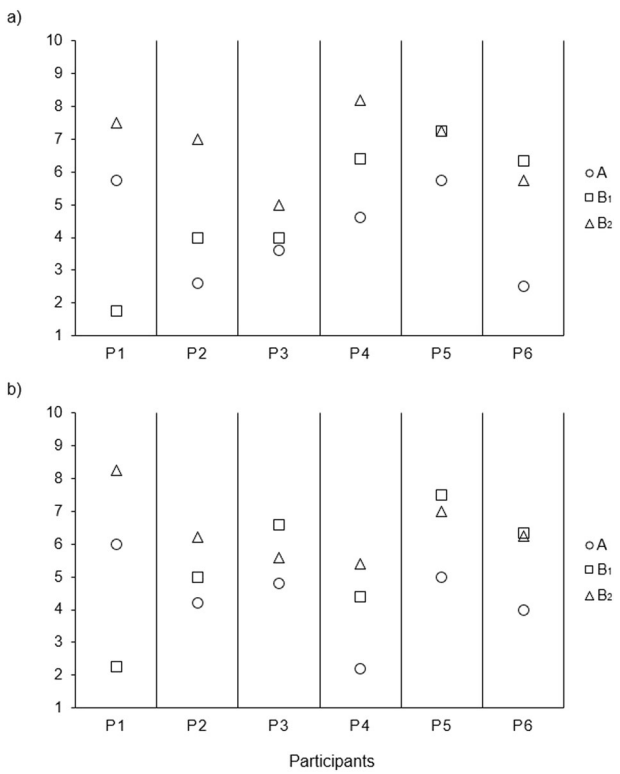

Fig. 1 Scores on the two subscales of the Canadian Occupational Performance Measure (COPM). Scores at baseline [A] and at the end of both intervention phases (intensive [B_1] and consolidation [B_2]) for the six participants (P1 to P6). **a** Occupational performance, **b** Satisfaction with performance.

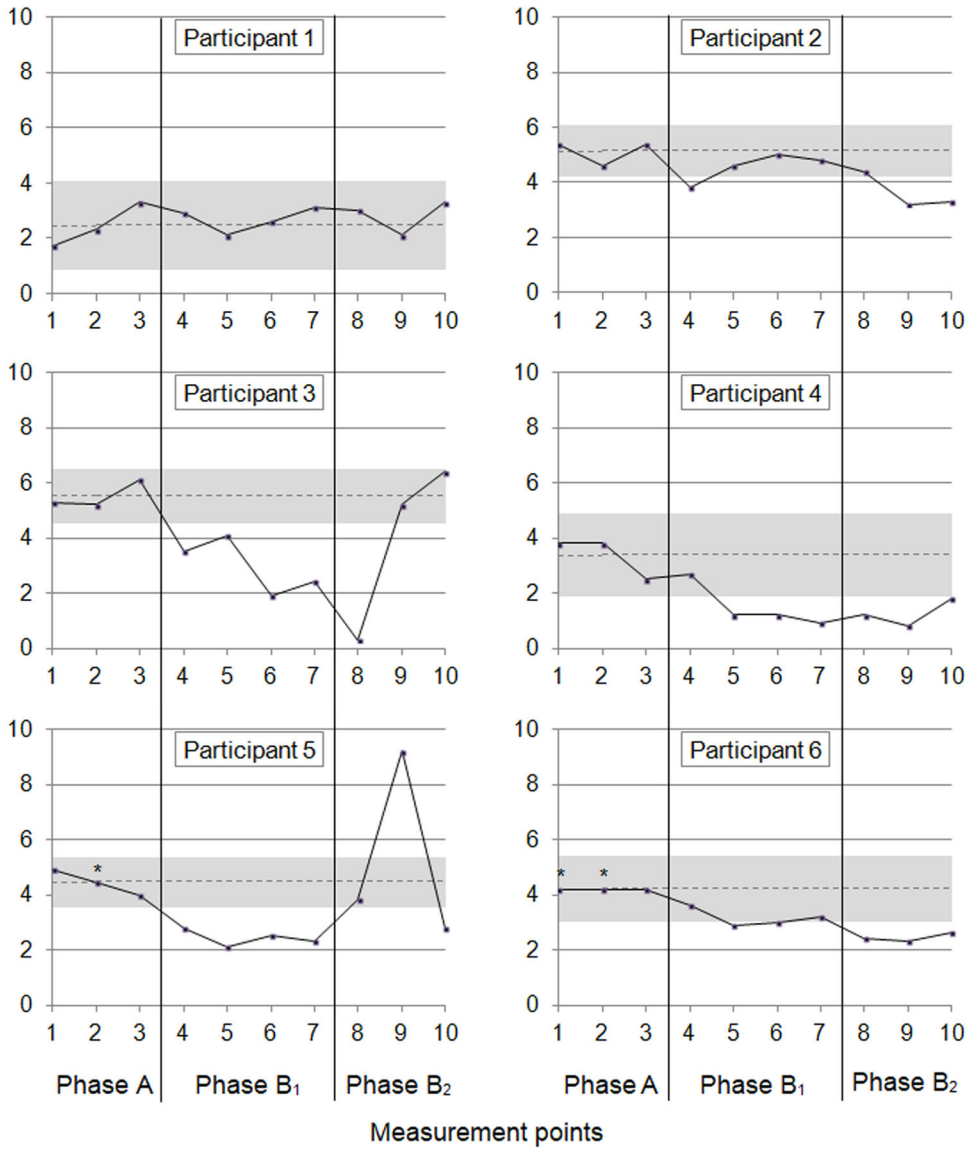

Fig. 2 Scores on the Pain interference subscale of the Brief Pain Inventory (BPI-I10). Scores over the three phases of the study (pre-intervention [A], intervention – intensive [B_1], and intervention – consolidation [B_2]). The dashed horizontal line represents the baseline mean score, and the grey band around this line indicates two standard deviations below and above the mean. * Missing data: Participant 5: replaced by the mean of T1 and T3 data points; Participant 6: replaced by the value of T3 data point.

Study instruments

Canadian Occupational Performance Measure (COPM). Occupational performance was assessed using the French version of the COPM [17]. This outcome measure asks participants to identify five problems important for them to address in regards to occupational performance, and rate their perceived performance level and satisfaction with performance in each of these problem areas, on a scale from 1 (*poor*) to 10 (*very good*). The COPM demonstrated good concurrent criterion validity and sensitivity to change, as well as good acceptability for participants in another study evaluating a chronic pain management program [18]. A 2-point difference in COPM scores is considered a clinically important change [17].

Brief Pain Inventory (BPI). A French translation of the pain interference subscale of the BPI adapted for persons with disabilities, the BPI-I10, was used to measure pain interference [19]. Participants rated the extent to which their pain interfere with ten activities over the previous seven days on a scale ranging from 0 (*does not interfere*) to 10 (*interferes completely*). The English version of the BPI-I10 was validated in the SCI population and demonstrated good reliability and convergent validity with other pain-related measures [19, 20]. Likewise, the French version of the original BPI interference subscale (BPI-I7) showed good internal consistency as well as convergent validity in other populations [21, 22].

French-Canadian Chronic Pain Self-efficacy Scale (FC-CPSES). Pain self-efficacy was measured using the FC-CPSES, six-item version. This instrument is an adaptation of the Chronic Disease Self-Efficacy Scale, which measures perceived self-efficacy to perform self-management behaviors, manage chronic disease in general and achieve outcomes [23]. Participants rated their level of confidence to perform six self-management activities for pain and related symptoms on a scale from 1 (*not at all*) to 10 (*fully*). The six-item version of the FC-CPSES has been validated in chronic pain patients, demonstrating high internal consistency, good convergent validity with measures of mental health-related quality of life and pain catastrophizing, as well as good sensitivity to change [23].

Hospital Anxiety and Depression Scale (HADS). Anxiety and depression symptoms were measured using a French-Canadian version of the HADS [24]. Participants rated the frequency of anxiety-related symptoms (7 items), and depression-related symptoms (7 items), over the last week on a four-level Likert scale. The HADS has been validated in persons with

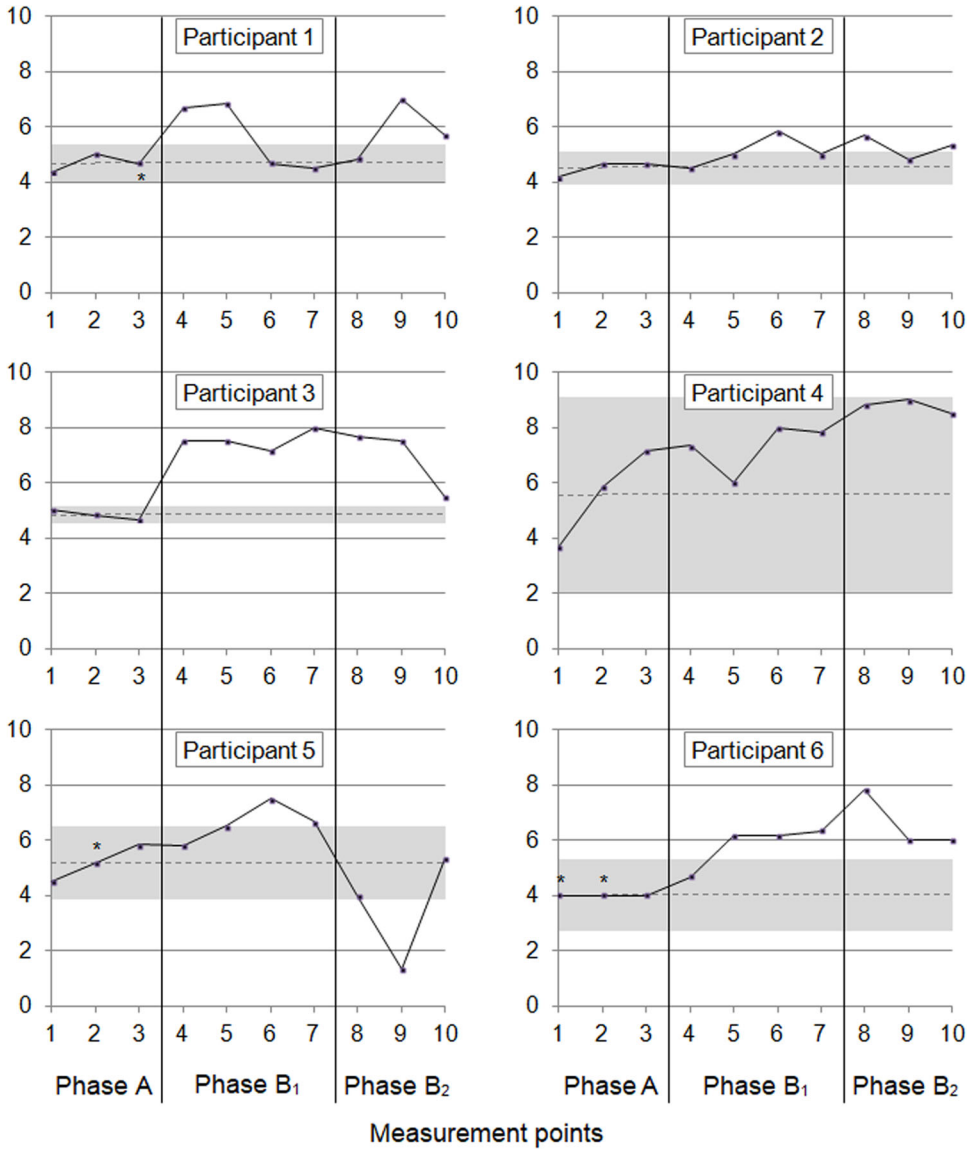

Fig. 3 Scores on the French-Canadian Chronic Pain Self-efficacy Scale (FC-CPSES). Scores over the three phases of the study (pre-intervention [A], intervention – intensive [B_1], and intervention – consolidation [B_2]). The dashed horizontal line represents the baseline mean score, and the grey band around this line indicates two standard deviations below and above the mean. * Missing data: Participant 1: replaced by the mean of T1 and T2 data points; Participant 5: replaced by the mean of T1 and T3 data points; Participant 6: replaced by the value of T3 data point.

SCI and both subscales demonstrate good reliability, as well as good preliminary construct validity [25, 26].

Numerical rating scale to measure pain intensity. A French numerical rating scale, "*average pain experienced over the last seven days*", was used to measure pain intensity. Participants rated the intensity of their pain on a scale from 0 (*no pain*) to 10 (*worst possible pain*). Numerical rating scales for measuring pain intensity demonstrate good validity and sensitivity to change among different populations and are recommended for use in studies of pain after SCI [19].

Data analysis

Participants' characteristics were synthesized using descriptive statistics. For all outcomes, data were analysed graphically for each participant at each measurement point. For all secondary outcomes, means and standard deviations were computed for scores measured at baseline for each participant. Scores obtained during phases B_1 and B_2 were then compared visually to the baseline mean. Two consecutive scores needed to be two standard deviations above or below the baseline mean for change to be considered significant [14]. In some cases, the standard deviation for baseline scores was zero, because of missing data or because of consistency in scores between measurement points. In such cases, the zero standard deviation was replaced by that of the other participant whose baseline mean for the same outcome was closest to the single measured value for that participant.

RESULTS

The six persons who took part in the pilot PSMP agreed to participate in the study. Characteristics of the participants are presented in Table 3.

Occupational performance

Occupational performance and satisfaction with performance scores improved for five participants (P2, P3, P4, P5, and P6) at the end of phase B_1 compared to baseline. These improvements were clinically significant in one participant for performance (P6),

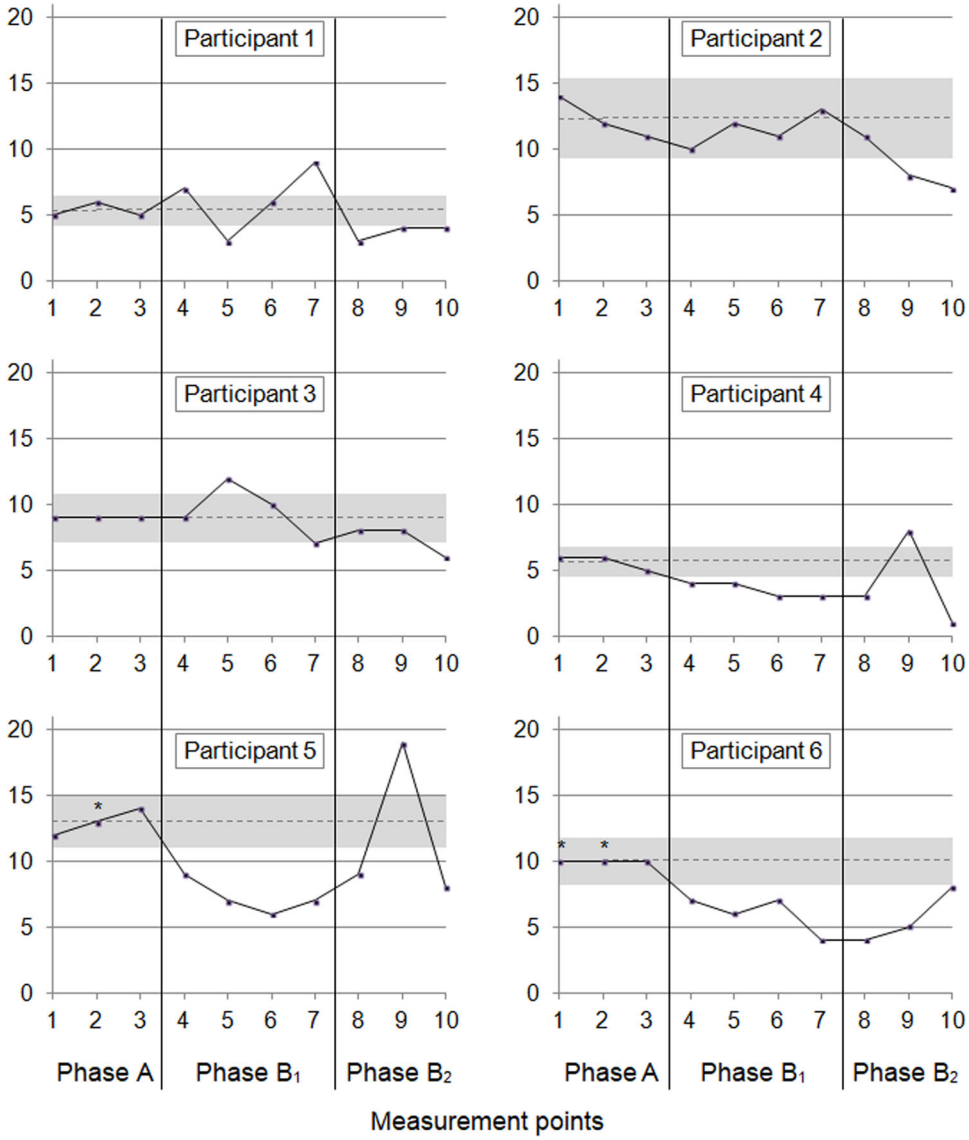

Fig. 4 Scores on the Anxiety subscale of the Hospital Anxiety and Depression Scale (HADS). Scores over the three phases of the study (pre-intervention [A], intervention – intensive [B_1], and intervention – consolidation [B_2]). The dashed horizontal line represents the baseline mean score, and the grey band around this line indicates two standard deviations below and above the mean. * Missing data: Participant 5: replaced by the mean of T1 and T3 data points; Participant 6: replaced by the value of T3 data point.

and in three participants for satisfaction (P4, P5, and P6). At the end of phase B_2, both occupational performance and satisfaction with performance were improved in all participants. These improvements were clinically significant in three participants for performance (P2, P4, and P6), and in five participants for satisfaction (P1, P2, P4, P5, and P6). These results are displayed in Fig. 1.

Pain interference

There was a significant decrease in pain interference with intervention for five participants (P2, P3, P4, P5, and P6) (see Fig. 2). For three of them (P3, P4, and P5), the decrease occurred during phase B_1, and it was maintained over phase B_2 for participant 4. For participants 2 and 6, the significant decrease occurred only during phase B_2. For participant 1, pain interference remained relatively stable over the three phases of the study.

Pain self-efficacy

Significant improvements in pain self-efficacy occurred during phase B_1 in four participants (P1, P3, P5, and P6) (see Fig. 3). For two of them (P3 and P6), the improvement was maintained over phase B_2. For the other two participants (P1 and P5), the level of pain self-efficacy fluctuated over the two phases of the intervention. For participants 2 and 4, there was a trend towards an increase in pain self-efficacy, but the improvement was not significant.

Anxiety and depression symptoms

The results for anxiety and depression symptoms are displayed in Figs. 4, 5, respectively. Anxiety decreased significantly with intervention in five participants (P1, P2, P4, P5, and P6). The decrease occurred during phase B_1 in three of them (P4, P5, and P6) and was maintained over phase B_2 in participant 6. Depressive symptoms decreased significantly with intervention in four participants (P2, P3, P5, and P6). For participant 6, the decrease occurred during phase B_1 and was maintained over phase B_2. Depression scores followed quite variable patterns over phases B_1 and B_2 in the other three participants (P2, P3, and P5). For participant 4, there was a trend towards a decrease in

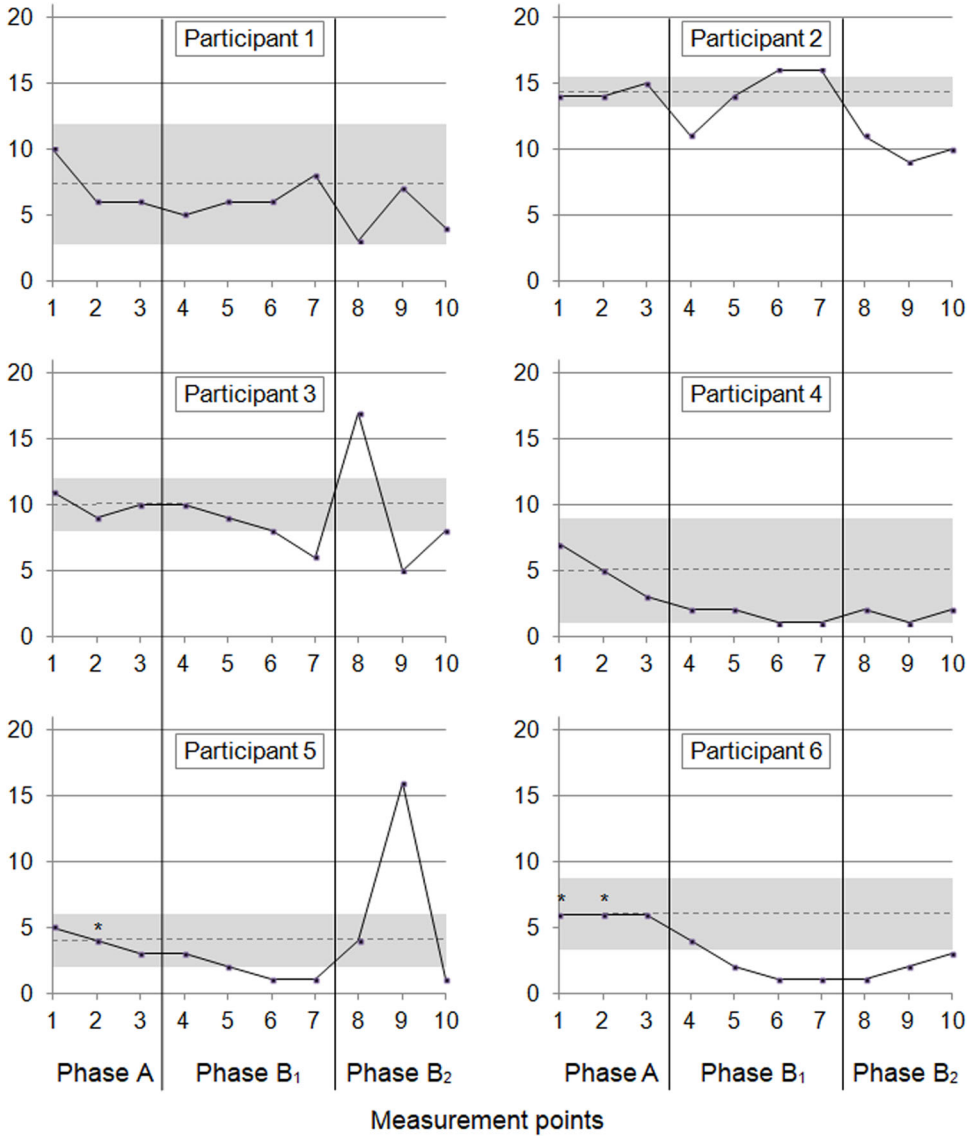

Fig. 5 Scores on the Depression subscale of the Hospital Anxiety and Depression Scale (HADS). Scores over the three phases of the study (pre-intervention [A], intervention – intensive [B_1], and intervention – consolidation [B_2]). The dashed horizontal line represents the baseline mean score, and the grey band around this line indicates two standard deviations below and above the mean. * Missing data: Participant 5: replaced by the mean of T1 and T3 data points; Participant 6: replaced by the value of T3 data point.

depression-related symptoms with intervention, but the improvement was not significant.

Pain intensity

The results for pain intensity are displayed in Fig. 6. There was a significant decrease in pain intensity with intervention in one participant (P4), which occurred during phase B_2. For the other five participants, there was either no significant change in pain intensity with intervention (P1, P2, and P6), or a significant increase (P3 and P5).

DISCUSSION

This pilot study used a single-subject design to assess the effects of an interdisciplinary PSMP for persons living with SCI and chronic pain. The PSMP was innovative in that it was tailored to the needs of participants, with individualized objectives for each of them.

Visual analysis of data revealed either significant improvement or a tendency towards improvement with intervention in all of the outcomes measured for a majority of participants, except pain intensity. For occupational performance, the scores improved during both intervention phases in a majority of participants. This may reflect the fact that the tool used to measure this outcome, the COPM, is tailored to the personal goals of the participants [17]. Participants were perhaps especially motivated to improve their performance in the areas they chose themselves. For satisfaction with occupational performance, pain interference, pain self-efficacy and anxiety and depression symptoms, scores did not follow such a clear trend over time across participants, but rather tended to return to baseline levels during the consolidation phase in some of them.

Visual analysis of each participant's data individually also reveals that the improvement or trend towards improvement across outcomes was more consistent in some participants. In some cases, for a given participant, scores fluctuated across outcomes during the course of the intervention, or even markedly worsened at some point. These variations may perhaps be explained by events in the life of the participants related to their SCI condition. Indeed, events such as urinary

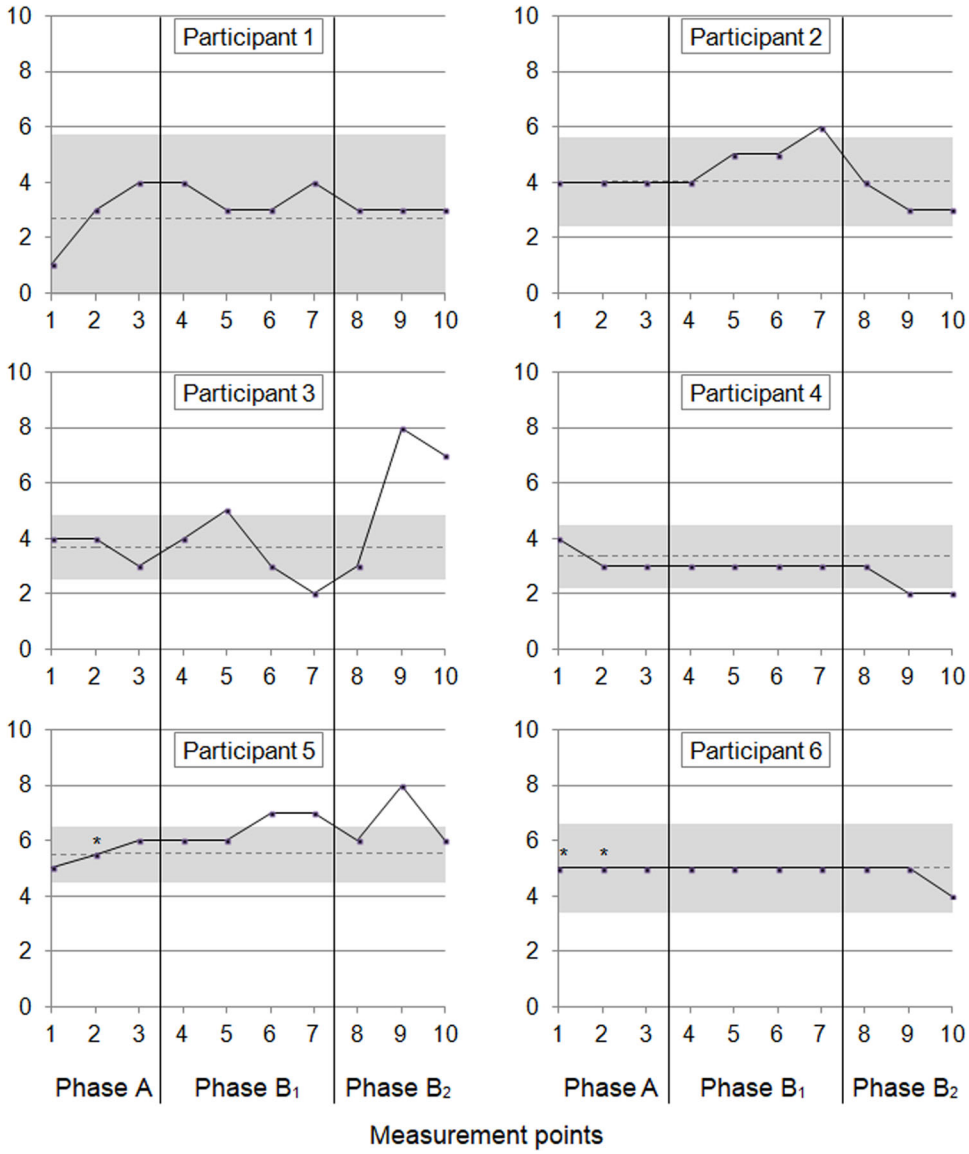

Fig. 6 Scores on the numerical rating scale "*average pain experienced over the last seven days*". Scores over the three phases of the study (pre-intervention [A], intervention – intensive [B_1], and intervention – consolidation [B_2]). The dashed horizontal line represents the baseline mean score, and the grey band around this line indicates two standard deviations below and above the mean. * Missing data: Participant 5: replaced by the mean of T1 and T3 data points; Participant 6: replaced by the value of T3 data point.

tract infections, pressure sores or upper limb joints overuse are secondary health conditions commonly reported in people living with SCI [27] that can impact on outcomes such as pain, distress or functioning.

To our knowledge, our study is the first to have assessed occupational performance, especially using a client-centered primary outcome measure. Previous studies found improvements in related outcomes such as pain-related disability [6, 7, 9] and participation in activities [6]. We also found improvements in pain interference, which is in line with other similar studies [4, 8]. Improvements were found as well in other studies on pain self-efficacy [8, 9], and anxiety [6, 8, 9, 11] and depressive symptoms [9, 11]. However, some studies found no significant change with intervention for this latter outcome [6–8]. In the present study, depressive symptoms are the outcome for which there was the greatest variability in scores across participants. Finally, for pain intensity, the absence of change we found was not surprising as pain reduction was not the primary objective of the PSMP. We nonetheless measured this outcome because it is important for people living with SCI and some studies on pain management programs in this population showed reductions in pain intensity reaching or approaching significance [6–9].

Long term effects of pain management programs are a crucial issue. In their study, Burns et al. [4] suggested to pursue interventions with a "periodic booster" after the end of the intensive program to help maintain improvements, because their outcomes tended to return to baseline levels after the end of the program. For the same reason, Nicholson Perry et al. [8] suggested to further insist on relapse prevention in such programs. Both booster interventions and relapse prevention were integrated within the PSMP. To our knowledge, our study is the first to have included a consolidation phase comprising periodic booster interventions provided over an extended period of time. The only study we have found which offered some intervention following its intensive phase provided a single comeback session three weeks after the end of a ten-week weekly intervention [5]. Our results indicate that the

progressive weaning of the intervention and the relapse prevention may have been effective, as outcomes continued to improve or at least were maintained during the consolidation phase in many cases.

This study had certain limitations. First, as we conducted a pilot study, our results are based on a small sample of individuals with SCI and pain who were their own controls. Although the study design does not allow making generalizations, it permitted to detect variability in results within and between participants. Second, additional measurement points prior to the beginning of the PSMP would have permitted to better characterize the baseline level and the normal degree of variability for each participant on each of the outcome measures. Moreover, some data at baseline were missing. Results in those cases should be interpreted with caution.

In conclusion, our results are in line with those of the few other existing studies that assessed the effects of a multidisciplinary pain self-management program for persons living with SCI. Findings suggest that the pain self-management program could be effective in improving pain interference in daily life, pain self-efficacy, as well as mood in people living with SCI and chronic pain. The fact that occupational performance, which was measured with a client-centered instrument, was the sole outcome that further improved during the consolidation phase in a majority of participants, suggests that tailoring the program to the individual needs of each participant is useful. Further research is needed to replicate these results in a larger study and comprehend the factors favoring or undermining improvements with such programs, as well as their persistence over time.

DATA AVAILABILITY

The datasets generated and analyzed during the current study could be made available from the corresponding author on reasonable request.

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AUTHOR CONTRIBUTIONS

MEL and RQ initiated and designed the study. The protocol was drafted by MEL, RQ, ID, KPe, and CM. Data were collected by RQ, ID and KPe. KPr and KPe analysed and interpreted the data. The manuscript was drafted by KPr and KPe. All authors critically revised the manuscript and they have accepted responsibility for its entire content and approved its submission.

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COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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