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THE USE OF WEARABLE TECHNOLOGY IN A COMPREHENSIVE CHRONIC PAIN MANAGEMENT PROGRAMME

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Abstract

Technology is increasingly being used to encourage physical activity and reduce sedentary lifestyles in the general population. While physical activity is critical to improving the quality of life of patients with chronic pain, opportunities to use technology to support physical activity in patients with chronic pain are still rare. At the same time, long-term goals for physical activity are largely dependent on the perception of pain, actual or expected exacerbation of pain, and lack of confidence when performing physical activity.

We aimed to determine whether wearable technology can improve management of chronic pain. Full protocol of this 8-week clinical trial is available in the Clinical Trials Registry (NCT 03837080). Patients with chronic pain enrolled in a 4-week interdisciplinary chronic pain management programme wore fitness bands during the 4-week programme (0-4 weeks) and follow-up (4-8 weeks). Fitness wristbands measured physical activity and sleep patterns. Additionally, anthropometric measurements and psychological condition of patients (by using Pain Catastrophizing Scale and Depression, Anxiety and Stress Scale – 21 Items questionnaires) was measured. The number of steps and average time of activity per day increased, as well as deep sleep time per day but without reaching statistical significance. Significant improvements in waist circumference and waist-to-hip ratio and waist-to-height ratio with longer deep sleep time were found. No significant correlation was found between physical activity, sleep quality and psychological characteristics or catastrophizing. By wearing fitness wristbands, patients feel actively involved in their chronic pain management. In a clinical/research setting, wristbands provide better, continuous oversight of patient's progress end enables tailoring of individualized strategies. However, the use of wristbands requires some level of IT knowledge, and sudden malfunctions of the wristband and/or the software can be expected. Additionally, some individual characteristics (i.e., demographics, psychosocial factors, lack of motivation) can also be obstacles to their use.

Keywords: *chronic pain, wearable technology, sleep, physical activity, anthropometry, psychological condition.*

Introduction

Chronic pain (CP) is typically defined as pain lasting longer than 3 months after an initial injury or underlying cause of the pain has been treated [*Surah A et al., 2014*]. Low back pain is the leading cause of job-related disability and a leading contributor to missed workdays affecting about 80% of adults at

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some point in a lifetime [*Amorim A et al., 2016*]. In comparison to healthy population, people with CP are less physically active, and physical activity (PA) seems to be an important factor influencing pain sensitivity [*Law L, Sluha K, 2017*]. However, pain perception is influenced by many other factors, such as sex, body mass index, depression and pain catastrophizing [*Law L, Sluha K, 2017*]. This multicomponent cycle of deterioration exaggerate back pain [*Gordon R, Bloxham S, 2017*]. Depression prevalence among chronic pain patients is between 40 and 60%, and according to some up to 85% [*Sheng J et al., 2017*]. Pain perception aggravates as body mass index increases [*Okifuji A, Hare B, 2015*] and pain severity directly correlates with pain catastrophizing [*Dong H et al., 2020*].

Physical activity and exercise behaviour is a very complex construct influenced by many factors. Several psychological factors play an important role in exercise behaviour, but motivation overpower all other. Motivation was found important for the initial adoption and adherence to PA and exercise [*Polman R et al., 2004*]. Wearable technology gained mush interest particularly in the aspect of motivating users to engage in PA [*Thorup C et al., 2016; Mercer K et al., 2016*]. Promoting self-awareness of one's health status, while providing individualized experience is considered useful trait of wearable technology, but the adoption rates of these devices has not reached expectations [*Puri A et al., 2017*].

Chronic pain patients benefit from PA on multiple levels; from reduced severity of the pain and disability [*Amorim A et al., 2016*], to improved overall physical and mental health [*Teh C et al., 2010; Geneen L et al., 2017*]. Yet, many psychological factors such as fear, anxiety, depression, a sense of helplessness, being overweight/obese represent barriers to engage in PA [*Chung E et al., 2013*; *Boutevillain L et al., 2017*]. Patient-centred approach is the current standard in chronic pain management [*Worley S, 2016*]. It was found to be effective in promoting PA in different clinical populations, including people with low back pain [*Amorim A et al., 2016*]. Tailored feedback has been shown to effectively encourage patient to adopt PA and be more active [*Mercer K et al., 2016*], which is exactly what wearable technology offers. From goal setting, self-control, social support, and feedback to rewards, these are all motivational methods implemented in wearable technologies to increase patient adherence and acceptance of PA as part of their chronic pain management [Kononova A et al., 2019].

The aim was to analyse whether wearable technology, i.e. fitness wristband had any impact on psychological condition, pain catastrophizing and anthropometry of chronic pain patients during and after the 4-week treatment.

Material and methods

Study design: Full protocol is available in the Clinical Trials Registry. The main aim of the trial is to assess the effectiveness of specifically tailored nutrition intervention on pain intensity in patients with chronic low back pain. Trial registration: ClinicalTrials.org, NCT03837080. Registered 11 February 2019.

Primary outcome measure of this randomized controlled trial is the change in pain intensity after the intervention and the 4-week follow-up. Measures of physical activity and sleep monitoring throughout the intervention and follow-up period tracked by a wearable wristband are among the other outcomes.

University Hospital Centre Osijek Ethics Committee approved this study (Number of approval R2-16 905/2018). All participants gave their written informed consent prior to enrolment in the study.

Study subjects: From February until August 2019, a total of 42 patients with chronic (non-cancer) low back pain were recruited. They were admitted into the 4-week multidisciplinary, patient - centred program for the treatment of chronic pain. Individuals of 18-80 years-old who were experiencing pain for over 6 months (with or without radiculopathy), confirmed symptoms with magnetic resonance imaging and/or electromyoneurography and a minimum pain score of 5 on a 0-10 visual analogue pain scale (PainDETECT) were eligible for the study.

To overcome it is possible, due to the uniting the knowledge and will of all doctors in the world

A minimum number of patients to be included in the study was calculated on the basis of study power of 90%, level of significance of 5%, and assumed drop-out rate of 10%, while expecting a significant drop in chronic pain intensity by 2 points on a 10-point visual – analogue scale of PainDETECT questionnaire.

Anthropometrics: Anthropometric measures obtained by Omron BF 500 Advanced Body Monitor (Japan) included weight (*kg*), body fat (%), skeletal muscle (%) and visceral fat index. Waist circumference (*cm*), upper arm (*cm*) and hip circumference (*cm*) were measured with non-elastic measuring tape. Height (*cm*) was measured by Seca GmbH & Co. measuring rod, model 220 (North America). All anthropometric measures were conducted at baseline, after the intervention and at a 4-week follow-up. Additionally, basic socioeconomic data was collected.

Questionnaires: At baseline (0 weeks), after the intervention (4 weeks) and at a 4-week follow-up (8 weeks since the recruitment) patients self-assessed their pain intensity (PainDETECT questionnaire), pain catastrophizing (pain catastrophizing scale questionnaire) and levels of depression, anxiety and stress (the depression, anxiety and stress scale (DASS) – 21 items questionnaire).

The Depression, Anxiety and Stress Scale is a self-assessment measure that examines the frequency and severity of negative emotional states of depression, anxiety and stress over the past seven days in both psychiatric patients and the healthy population. The scale consists of three relatively pure measures of associated negative affective states classified into three subscales. A higher score on each of them indicates higher levels of anxiety, depression and stress. Participants use a 4-point scale (from 0 = not at all referred to me, up to 3 = almost completely or most of the time referred to me) indicate how often they experienced the condition described in the claim [*Lovibond P, Lovibond S, 1995*]. Psychometric analyses confirmed high internal consistency, longitudinal stability, convergent validity, and satisfactory discriminant validity of the whole scale as well as all these subscales [*Brown T et al., 1997*].

The pain catastrophizing scale was developed as a measure of catastrophizing associated with the experience of pain and is the most widely used measure of catastrophizing today. The scale consists of 13 items and three subscales: rumination, magnification and helplessness. The task of the participants is to recall the last painful experience and to indicate on the Likert scale from 0 to 4 the extent of their agreement with each item [*Sullivan M, 2022*]. We used the Croatian translation of the questionnaire [*Marić A et al., 2011*].

Wearable technology: At baseline, patients were given Xiaomi Mi Fit Band 2® fitness wristbands (China) which they were instructed not to take off until the end of the follow-up (8 weeks since the recruitment). The wristbands collected the following data: number of days of the activity measured, average time of activity per day, average steps per day, average deep sleep time per day, average time spent awake per day, number of awakenings per day. Prior to the research commence, all Xiaomi Mi Fit Bands 2® (China) were paired with one single ARCHOS Access 70 3G tablet device (Igny, France) used to synchronize and download individual data for each study participant after the intervention (19 participants) and after the follow-up (23 participants).

Data analysis: Software tool Statistica 14.0 (StatSoft Tulsa, Oklahoma, USA) was used for the statistical analysis.

Normality of data distribution was tested by the non-parametric Kolmogorov-Smirnov test for the comparison of medians and arithmetic mean, and histograms plotting. Depending on normality, numerical data are presented as mean and standard deviations or median and interquartile range. Correlations were calculated by using Spearman and Pearson's test, while Wilcoxon matched pairs test or t-test for dependent samples were used to compare numerical data. The level of significance chosen was 0.05.

Results

Out of 42 CP patients who completed the programme, one CP patient was excluded due to compete absence of data from the wristband so the final analysis was conducted on 41 CP patients.

The level of PA indices and sleep quality improved over the 8-week period (Table 1), and patients who were more PA before entering the study were also more PA at follow-up (data not shown). However, these results need to be taken with cau-

Table 1

Physical activity indices and sleep pattern measured by fitness wristbands at baseline (0 week) and at follow-up (8 weeks)

Data retrieved from fitness wristbands	**n**	**Baseline** (0 week)	**Follow-up** (8 weeks)	**p**
Walking/day (*min*)	20	71.6 ± 19.4	75.2 ± 35.4	0.509
Average steps (*day*)	19	5262 ± 2092	5627 ± 2711	0.221
Deep sleep/day (*min*)	19	119.6 ± 47.2	121.7 ± 47.7	0.371
Awake (*day*)	17	9.1 ± 6.5	15.6 ± 8.1	*0.005**
Number of awakenings (*day*)	16	0.6 ± 0.4	0.8 ± 0.4	*0.030**

Notes: Statistically significant at p<0.05

tion due to a number of difficulties observed by either the patients or researchers. Out of 16 fitness wristbands used, sudden malfunction had 2/16 and/or problem with the software (also 2/16). During the intervention (4 weeks), three CP patients had no data on their wristbands, while during the 4-week follow-up, 19 CP patients had no data on the wristband to retrieve.

There were significant (p<0.05) baseline to follow-up changes in all levels of emotional distress and catastrophizing. The results show that in comparison to baseline, CP patients report significantly lower levels of anxiety (p=0.001), depression (p=0.002), and stress (p<0.001) (Table 2). Furthermore, lower levels of depression, anxiety and stress maintain during the follow-up (Table 2).

The same was found for all subscales of catastrophizing: rumination (p=0.047), magnification (p=0.030) and helplessness (p=0.002) (Table 3). Interestingly, in case of pain catastrophizing, except for rumination which continued to drop at follow-up (10.83±3.74 at baseline, 9.12±4.04 post-intervention, 8.48±4.84 at follow-up), helplessness and magnification started to rise (Table 3).

As such, scores on all DASS subscales ranged from normal to mild symptoms, while scores on PSC subscales ranged from average to slightly above average.

In comparison to baseline, there was no statistically significant correlation between psychological characteristics or catastrophizing, post intervention (4 weeks) or at follow-up (8 weeks), probably due to partial retrieval of data from the fitness wristbands.

At baseline, lower body fat percentage and hip circumference had CP patients who were more PA during day (Table 4). At follow-up sleep quality became important indicator of more favourable anthropometric indices; waist-to-height ratio (r=-0.610) and waist-to-hip ratio (r=-0.555) were lower with longer deep sleep (Table 4).

Table 2

Depression, anxiety and stress levels in chronic pain patients at baseline, post-intervention (4 weeks) and at follow-up (8 weeks) assessed with DASS-21 questionnaire

DASS scales	Baselin (0 week)	Post-Intervention (4 weeks)	p (0-4 weeks)	Follow-up (8 weeks)	p (0-8 weeks)	p (4-8 weeks)
Depression	9.67 ± 5.30	6.24 ± 4.75	*0.002**	6.13 ± 5.44	*0.013**	0.934
Anxiety	7.98 ± 5.71	4.40 ± 4.02	*0.001**	3.0 (0.0 – 9.0)§	0.117	0.407
Stress§	7.0 (2.0 – 11.0)	3.0 (1.0 – 6.0)	*<0.001**	3.0 (0.0 – 7.0)	0.077	0.986

Notes: *§Median (25-75%); * statistically significant at p<0.05*

Table 3

Pain catastrophizing dimensions in chronic pain patients at baseline, post-intervention (4 weeks) and at follow-up (8 weeks) assessed with PCS questionnaire

PCS scales	Baseline (0 week)	Post-Intervention (4 weeks)	p (0-4 weeks)	Follow-up (8 weeks)	p (0-8 weeks)	p (4-8 weeks)
Rumination	10.83 ± 3.74	9.12 ± 4.04	*0.047**	8.48 ± 4.84	*0.033**	0.571
Magnification	6.45 ± 3.08	5.00 ± 2.95	*0.030**	5.52 ± 3.64	0.279	0.533
Helplessness	13.00 ± 5.89	8.90 ± 5.68	*0.002**	10.52 ± 6.40	0.121	0.298

Note: ** statistically significant at p<0.05*

Table 4

Correlation coefficients between selected physical activity indices and sleep pattern and selected anthropometric measurements of chronic pain patients at baseline (0 week) and at follow-up (8 weeks)

	Baseline (0 week)			**Follow-up** (8 weeks)		
	Walking/day (*min*)	Average steps/day	Deep sleep/ day	Walking/day (*min*)	Average steps/day	Deep sleep/ day
BMI *(kg/m²)*	-0.213	-0.261	-0.092	-0.146	-0.195	-0.396
Waist-to-height ratio	-0.180	-0.242	-0.200	-0.058	-0.107	*-0.610**
Waist-to-hip ratio	0.143	0.095	-0.041	0.072	0.052	*-0.555**
Body muscle (%)	0.298	0.313	-0.169	0.165	0.203	0.365
Body fat (%)	*-0.397**	*-0.422**	0.008	-0.168	-0.212	-0.417
Visceral fat	-0.072	-0.118	-0.176	-0.367	-0.406	-0.299
Waist circumference (*cm*)	-0.104	-0.169	-0.278	-0.151	-0.207	*-0.526**
Hip circumference (*cm*)	*-0.386**	*-0.448**	-0.089	-0.313	-0.380	-0.225

Note: ** statistically significant at $p<0.05$*

Discussion

Personal and economic burden of CP is immense [*Phillips C, 2009*]. Psychological distress and sleep problems go hand in hand with CP [*Cohen S et al., 2021*]. Patients are expected to change their behaviour (including physical activity and diet) and find ways to cope with CP, strategies that should be learned through specially designed multimodal treatment programmes [*Gauntlett-Gilbert J, Brook P, 2018*]. These will help improve patient's everyday functioning and quality of life. Such approach was applied in the 4-week programme CP patents went through in this research. Besides psychotherapy, and physical therapy, patients were educated n how to change their diet and how to increase their physical activity level. The main intention behind using fitness wristbands was to reduce research burden on patients but also to give them the sense of being actively involved in their CP treatment. According to one recent meta-analysis [*Brickwood K et al., 2019*], consumer-based wearable activity trackers were found to significantly increase physical activity of study participants. The trackers were used alone or as part of a broader intervention, and as such, can be considered a valuable tool for health professionals, enabling monitoring and support for patients. Additionally, despite the effect on pain reduction is relatively small, benefits of their use are clinically important and sustained over time [*Ferguson T et al., 2022*].

Our results support literature findings on improved PA (Table 1). However, unexpected malfunctioning of the wristband and/or software were common, unveiling the need for a basic IT knowledge. This however can be challenging due to a number of obstacles [*Lewy H, 2015*; *Ferguson C et al., 2021*], including individual ones like older age, lower education level, etc. Difficulties with a device are very common; according to the study by Maher et al. [*Maher C et al., 2017*] 70% of activity track users experienced some functionality issues with their devices.

We found significant improvements in all psychological aspects (Table 2) post-intervention as well as at follow-up. Studies continuously report that depression and anxiety worsen CP, interfere with treatment and have a negative impact on the quality of life of people [*Surah A et al., 2014*; *Lerman F et al., 2015*; *Rayner L et al., 2016*]. Depression and CP have bidirectional relationship; one feeds the other. Both have additive adverse effects on patient outcomes, including poorer functioning and reduced response to treatment [*Rayner L et al., 2016*]. Any kind of depression treatment was found to improve patient's quality of life and mental health [*Frange C et al., 2019*].

Catastrophizing is prevalent among CP patients and it is found to be a major cognitive vulnerability factor for depression [*Lee E et al., 2008*]. Patients with CP and catastrophizing tend to ruminate about past painful experiences, exaggerate the pain and use learned helplessness when they cope with the pain. Additionally, catastrophizing correlates with higher levels of disability, along with more frequent use of the health care system, longer hospitalizations, reduced effectiveness of drug

therapy and longer rehabilitation times [*Lee E et al., 2008*]. We found that pain catastrophizing subscales dropped significantly post-intervention, but only rumination continued to drop at follow-up, while magnification and helplessness started to rise again (Table 3). Other variables, unknown to us, influenced catastrophizing and emotional distress among CP patients during follow-up. This points out the need for an extended support for CP patients, during at home care. This form of care is supported by a large systematic review on CP-relieving strategies used in home care residents [*Knopp-Sihota J et al., 2022*].

There is strong evidence that health coaching, which is based on behaviour change theory, can have a positive impact on health behaviours, including physical activity [*Amorim A et al., 2016*]. Studies show the importance of quality feedback and goal setting in motivation for physical activity. Basic devices, such as pedometers that can enable feedback about number of steps walked can help raise awareness about activity levels and increase the feeling of self-efficacy, which is a very strong motivator [*Naslund J et al., 2016*]. Similarly, systematic review of studies shows that monitoring daily step count using pedometers and setting personal activity goals contributed to increased physical activity and weight loss over time [*Bravata D et al., 2007*]. Our findings support improvements in anthropometric indices among CP patients who increased their PA (Table 4). However, having in mind that the study design focused on dietary intervention and not PA, we cannot speculate on the role of PA on improved anthropometrics. Yet, these findings are in line with a large cohort study on obese CP patients [*Dong H et al., 2021*].

Additionally, we confirmed the importance of sleep on anthropometrics (Table 4). Fragmented sleep is very common in CP [*Frange C et al., 2019*], and our CP patients improved sleep pattern over the course of the study (Table 2). Improved sleep patterns will not only improve weight but also reduce pain intensity [*Frange C et al., 2019*].

Conclusion

Our findings support the use of fitness wristbands as an effective method to reduce research burden on CP patients, improve their PA level, but also to provide them with a sense of control over their CP treatment. However, a number of malfunctions and obstacles were identified. Additional support may be needed to older CP patients, especially during their at-home care.

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