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Commentary
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A Drug-Free, Digital, Self-Management Tool for Chronic Pain Patients Powered by Artificial Intelligence – A Pilot Trial

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Abstract

We describe the design and clinical utility of a digital tool aimed to increase the quality of life for chronic pain patients. PainDrainer™ is a drug-free, self-management tool, powered by artificial intelligence that adapts to the self-reported activities of each individual patient, resulting in a truly patient-centric support. The tool was tested in an open label, one-arm pilot study performed in two phases, encompassing in total 15 patients. The change in quality of life, pre-and post-treatment by using PainDrainer™, was measured using a PROMIS® Pain Interference 6a validated questionnaire. The outcome showed a statistically significant improvement in pain interference, surpassed the minimal important difference between T-scores, and showed a reduction in pain intensity after six weeks' treatment. In conclusions the study showed both patient acceptance and improvement in quality of life for chronic pain patients.

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Commentary

Pain is one of the most common reasons patients see a physician [1], a leading reason for suffering and disability [2], and more than 100 million individuals only in the United States suffer from chronic pain [3]. This condition is considered as a major worldwide health problem and is associated with high personal and economic costs. Despite the high prevalence of chronic pain, most patients find even the most up to date treatments falling short due lack of efficacy or significant side effects. The current Opioid Crisis in the United States is a clear example of this problem [4]. Also, many patients have very limited access to highly specialized pain clinics due to both availability and/or cost [5]. An alternative option to increase accessibility, not only to chronic pain patients, but to a variety of health conditions are digital tools for self- management. Those tools have emerged over the past few years, one example being the recently developed PainDrainer™ [6] for chronic pain. PainDrainer™ was developed in collaboration with health care providers, pain specialists and experts in Artificial Intelligence (AI) and is utilizing the concept of the Acceptance and Commitment Therapy (ACT) [7], believed to constitute a core component in evidence-based treatment of chronic pain. ACT is considered a form of clinical behavior analysis and is based on functional contextualism leading to effective action and clinical interventions. Furthermore, ACT has a behavioral perspective of inner experience, for example pain, caused by environmental events which may influence the patient [7]. According to the American Psychological Association, ACT also recently achieved the status of "well established" for the treatment for chronic pain. If the relationship between daily activities and the experienced pain level of the patient could be understood and the balance be improved, it would allow the patients to do more, suffer less and improve their Quality of Life (QoL). In order for a patient to learn how their daily activities affect their pain, the different activities and pain levels need to be recorded, analyzed and presented back to the patient. Since the human brain can only process around four parameters at a given time [8], the relation between daily activities and pain is difficult to comprehend and interpret. Inaccurate conclusions can lead to problems, such as fear avoidance and catastrophizing. However, a digital device powered by artificial intelligence could better quantitative, clarify and decipher the relationship of daily activities and pain, which in turn could help patients maximize their desired activities. PainDrainer™ was

Figure 1: Display of the Daily log in the digital tool PainDrainer™.

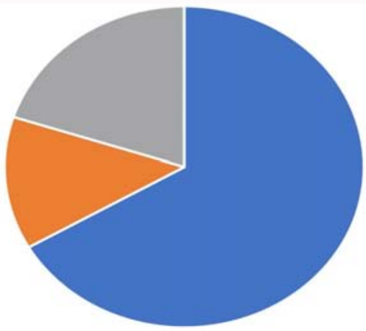

Figure 2: The relation between responding and non-responding patients, regarding improved Pain Interference, measured at 6 weeks posttreatment with the PROMIS 6a questionnaire. Patients (10/15) with improved QoL in blue, no change (3/15) in grey, and decreased (2/15) QoL in orange.

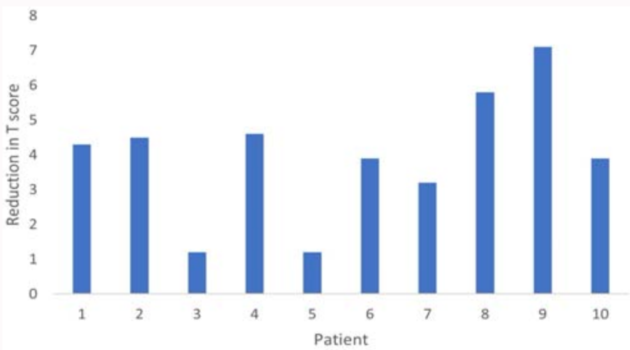

Figure 3: Change in Pain Interference, between week 0 and 6 for responding patients in study phase one (1 to 5) and phase two (6 to 10). The difference is represented as reduction in T-score units.

developed to takes advantage of the relation between environmental events, such as daily activities, and experienced pain to guide the chronic pain patient on how not to exceed a certain pain level. The patient simply records their daily activities and the resulting pain. The AI engine of PainDrainer™ is designed to adapt to each individual patient and the resulting advice is consequently truly patient-centric

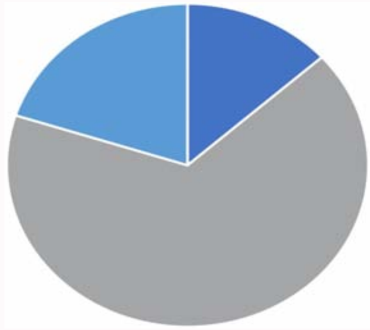

Figure 4: The relation between responding and non-responding patients regarding improved Pain Intensity, measured at 6 weeks post treatment with the PROMIS 6a questionnaire. Patients (10/15) with decreased Pain Intensity in grey, no change (3/15) in light blue, and increased (2/15) Pain Intensity in blue.

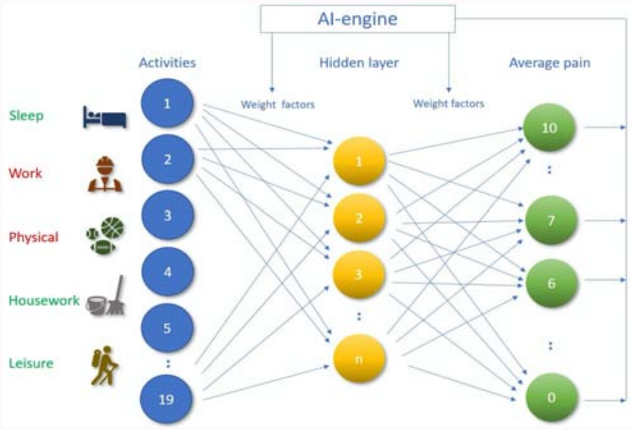

Figure 5: PainDrainer™ uses machine learning to teach an individual model associating activities with average pain. The model is based on artificial neural networks, specifically a multi-layer perceptron with a single hidden layer.

on how to best advise them to achieve their goals, using the information they provided. It is continually updated, allows review of prior activities and lets the patient set new goals each day. The display of PainDrainer™ is shown in Figure 1. The present clinical study design was a one-arm, open label pilot study performed at the Koman Family Outpatient Pavilion at UC San Diego Health (IRB 190759). The study tested the hypothesis that self-management, using a drug-free, digital tool powered by an AI engine could increase the QoL of chronic pain patients. The primary and secondary outcome of this pilot study was improvement in pain interference and pain intensity, respectively. Eligible patients (67% women), suffering from neck, shoulder, and/or lower back pain, who were undergoing standard medical care at a university based, chronic pain management clinic was included in the study after signing an informed consent. The first phase of the pilot study enrolled nine patients and was based on version 13 of PainDrainer™, while the second phase of the pilot study enrolled six patients and was based on version 14. The difference between versions was an improved user interface in the latter, including improved graphics, usability, helps texts, specific feedback and prognosis, all which provided an enhanced user experience. Importantly, both versions had the same functionality, including algorithms, AI engine and treatment options. Both study phases were evaluated, using the validated questionnaire PROMIS Pain Interference 6a to measure QoL [9]. From this questionnaire, the

T-scores were calculated and compared at the start of the study and post-treatment after around 6 weeks of using PainDrainer™. The T-score shows how many standard deviations the result is from the mean and a post-treatment reduction indicated a positive response. The positive response rate in the first phase was 56% (5/9), while 44% (4/9) of the patients showed no improvement. In the second phase, the positive response rate was 83% (5/6), while 17% (1/6) of the patients showed no improvement (Figure 2). The power in the response was then analyzed, using a one-tail, paired T-tests to calculate the statistical difference between T-scores, pre- and post-treatment. In phase one, the p-value between the T–scores obtained pre- and post-treatment was 0.0086 and in phase two the p-value was 0.0014. The Minimally Important Difference (MID) [10] was then analyzed for both study phases (Figure 3), where MID refers to the smallest meaningful difference in T-score that carries implications for the patient. For pain interference, MID estimates range from 2 to 3 T-score points [10]. In our first study phase the mean difference between T-scores was 3.0, while in the second study phase a mean of 4.8 was recorded. Consequently, after using PainDrainer™ for around six weeks the result surpassed a clinically relevant MID. This effect was also sustained in the majority of patients that continued to use PainDrainer™ for 12 weeks. The primary outcome was improvement in pain interference, indicated by a decrease in T-score, which the results supported. The secondary outcome was experienced pain intensity measured by the NRS scale. A reduction was recorded in 10/15 patients (Figure 4), with a mean reduction in pain intensity of 1.6 units (range 1-4 units). Three patients showed no change, while two patients showed an increased pain level with one unit. PainDrainer™ is powered by an AI engine and uses machine learning to teach an individual model associating activities with average pain. The model is based on artificial neural networks, specifically a multi-layer perceptron with a single hidden layer (Figure 5). During training (back-propagation) the weight factors are tuned such that a given activity record corresponds to the average pain as recorded by the patient. The training is carried out to ensure that model can generalize as good as possible to unseen activity settings. A trained model can be queried in a reverse fashion to find appropriate activities for a desired average pain level. To test the engine, we analyzed the convergence rate for each responding patient, using version 14. The AI engine showed convergence in all responding patients after their individual logging of activities. A converging AI engine demonstrates that the software adapts to the input data of each individual patients, illustrating the concept of patient-centricity. The effect of ACT has been investigated in a number of traditional clinical studies, where the outcome has varied from none to modest improvements in pain interference [11,12], while resulting in more significant improvements in depression, and anxiety [11,13]. Several trials with digitally delivered ACT have also been conducted [12,14,15], including smart phone applications, although these have not provided any theoretical rationale or have undergone clinical efficacy testing [16]. PainDrainer™ is, to the best of our knowledge, the first digital tool, powered by artificial intelligence to address an unlimited accessibility for chronic pain patients to a drug free, self-management tool with initial clinical evidence. In summary, we have designed a truly patient-centric digital tool to circumvent questions, such as what works for whom, how and under which circumstances? Consequently, we tested a digital, self-management tool powered by an AI engine, in a pilot study for chronic pain patients. The outcome of the study indicates that by utilizing PainDrainer™ the patients achieved an increased QoL, due to the fact that the AI engine allowed them to better manage the relation between their daily activities and their pain. The positive indications from the present pilot study will form the basis for further clinical investigations with larger sample size and an extended follow-up period.

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