The societal cost savings and health-related quality of life gains associated with a digital tool for self-management of chronic pain (PainDrainer™) – A feasibility study

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Please cite this report as:
Olofsson S, Rosén Klement M, Persson U. The societal cost savings and health-related quality of life gains associated with a digital tool for self-management of chronic pain (PainDrainer™) – A feasibility study. IHE REPORT 2023:8. IHE: Lund, Sweden.

This report was funded by Paindrainer AB. The responsibility for the analysis and conclusions in this report lies solely with the authors.

IHE REPORT 2023:8
e-ISSN: 1651-8187
ISSN: 1651-7628

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Foreword

Digital technologies are being implemented as treatment and monitoring alternatives in several different therapeutic areas. One of these is chronic pain, a common condition affecting around one fifth of the population in some parts of the world. This study estimates the gain from a societal perspective of introducing an AI-powered digital tool (Paindrainer™) in the management of chronic pain in the US.

This report was funded by Paindrainer AB. The responsibility for the analysis and conclusions in this report lies solely with the authors.

Lund, October 2023
Peter Lindgren
Managing Director, IHE

Summary

Chronic pain is pain that carries on for longer than 12 weeks despite medication or treatment. The condition is common, affecting around 1 in 5 people. The AI-powered digital tool PainDrainer™ allows for individualized coaching to manage and control chronic pain. The objective of this study is to estimate the societal gains, in terms of health gain, production gain and health care cost savings, associated with the use of PainDrainer™.

The health gain associated with PainDrainer™ was estimated using PROMIS® (Patient-Reported Outcomes Measurement Information System) data reported from the multicentre clinical trial, translated to preference-based quality-of-life weights, using two different available value sets. The productivity gain associated with PainDrainer™ was estimated using data on daily capacity to work reported in the clinical trial and values derived based on the human capital approach. The health care cost savings was estimated using published literature and assumptions, based on changes in treatment and medication reported in the clinical trial.

The total societal gain was estimated to around $8,700 per patient and year, consisting of a monetized health gain ($4,550 per patient and year), production gain ($3,370 per patient and year), and healthcare cost savings ($797 per patient and year). Future research, e.g., long-term follow-up, is needed to get a better understanding of the impact on healthcare resource use and production gain (including presenteeism).

1. Background

Chronic pain is pain that carries on for longer than 12 weeks despite medication or treatment (1). The condition is common, affecting around 1 in 5 people. Pain is individual, multi-faceted and impacted by psychological and cognitive factors. Cognitive behavioural therapy (CBT) and acceptance commitment therapy (ACT) are often utilized as part of pain management program. The effects do, however, decrease over time after the intervention (2).

The AI-powered digital tool PainDrainer™ is based on the principle of ACT and allows for individualized coaching to manage and control chronic pain. The patient records his or her daily activities and associated pain level and the neural network then generate recommendations for how to adjust daily activities in order to obtain control and reduce pain (2).

Digital technologies in the management of chronic pain have been found to enhance pain coping skills in patients (3) and a prospective, multicentre clinical trial found that PainDrainer™ resulted in significant reductions in pain interference, pain intensity and anxiety/depression and significant improvements in physical function, during a period of 12 weeks (2).

To provide payers and policymakers with relevant information it is important to demonstrate the value to society of PainDrainer™ in terms of reductions in health care use and sick-leave, as well as improvements in the quality of life of patients.

1.1 Objective

The objective of this study is to estimate the societal gain, in terms of health gain, production gain and health care cost savings, associated with the utilisation of PainDrainer™.

2. Methods

2.1 The clinical trial and patient characteristics

A single-arm, multicentre clinical trial was performed in a US setting (Mass General Brigham, Newton-Wellesley Hospital (NHW) in Newton, Massachusetts and New York-Presbyterian/Weill Cornell Medical Center Pain Management Division (WCMC) in New York City). Patients with chronic pain (at least 3 months with low back or neck pain rated with a score of at least 4 at the average daily numeric rating scale, NRS) started treatment with Paindrainer™ and were assessed at baseline and at 6 and 12 weeks of treatment. Respondent demographic, treatment, and medication data were only collected at the NHW site. The mean age was 48 years (SD: 15) and the BMI was 19 (SD: 5).

2.2 Health gain

The primary outcome in the clinical trial was pain interference measured using PROMIS® (Patient-Reported Outcomes Measurement Information System), a health profile measurement system developed by the National Institutes of Health (NIH) which includes item banks for several different domains (e.g., pain, physical function, sleep, social activity) (4). In addition to pain interference, PROMIS instruments were also used for the secondary outcomes, such as pain intensity, physical function, depression, and anxiety in the clinical trial (2).

In health economics, the health benefits are often estimated in terms of quality-adjusted life-years (QALYs). This is a measure combining the quality-of-life in a health state with a duration of the health states in terms of years. One QALY is one year in full health. The quality-of-life should be preference-based, meaning that individuals have made a hypothetical trade-off in order to reveal their preferences for the health state. To simplify the procedure, studies are performed to produce quality-of-life weights with a preference-based approach for a questionnaire (so called value set studies). This allows quality of life to be estimated indirectly by first having the patients respond to a questionnaire and then transform the result to preference-based weights, using an existing value set.

There are two value set studies for the PROMIS instruments. The first value set by Dewitt et al. 2018 (4) (the PROMIS-Preference (PROPr) scoring system) applied the standard gamble (SG) method and multiplicative multi-attribute utility (scoring) function to allow for quality-of-life weights to be generated for T-scores. T-score is a standardised score developed, using a representative sample of the population. It is centred around a score of 50, and 10 is equal to one standard deviation from the reference population (usually the US general population). The second value set by Craig et al. 2021 (5) applied the discrete choice experiment (DCE) approach to allow for quality-of-life weights to be generated for the PROMIS-29, a questionnaire generated for measurement of several domains.

The PROMIS results from the present clinical trial was translated using both value sets. The first value set (Dewitt et al. 2018) was applied to T-scores reported in the trial for pain interference, physical function, and depression (the value set did not include separate values for anxiety) (2). As the T-score for depression was only reported for respondents with depression at baseline (T-score ≥55), a quality-of-life weight was generated for respondents with and without depression. A weighted mean was then calculated using the share of respondents with and without depression. The second value set (Craig et al. 2021) was applied to individual-based data from the clinical trial for the PROMIS instruments that corresponded to items used in the PROMIS-29. Since items differed slightly, some assumptions

and simplifications were applied, see Table 1. Baseline quality-of-life was calculated by subtracting the loss in quality-of-life estimated at baseline from 1.

Table 1. Items in the PROMIS instruments used in the clinical trial and in the PROMIS-29 value set (grey rows = corresponding items used for translating clinical trial data to preference-based quality of life using Craig et al. (5))

Domain	Items in PROMIS used in the clinical trial	Items used in PROMIS-29 value set
Physical function	Vigorous activities	
	Walking – limit more than a mile	Walking – at least 15 minutes
	Stairs – limit in climbing one flight of stairs	Stairs – up and down, normal pace
	Lifting/Carrying groceries	Run errands and shop
	Bending, kneeling, stooping	
	Chores – vacuuming, yard work	Chores – vacuuming, yard work
	Dress yourself	
	Shampoo hair	
	Wash and dry body	
	Sit on and get up from toilet	
Pain interference	Day-to-day activities	Day-to-day activities
	Work around home	Work around the home
	Social activities	Social activities
	Household chores	
	Things do for fun	
	Enjoyment of social activities	Enjoyment of social activities
Depression	Worthless	Worthless
	Helpless	Helpless
	Depressed	Depressed
	Hopeless	Hopeless
Anxiety	Fearful	Fearful
	Focus	Focus
	Overwhelmed by worries	Overwhelmed by worries
	Uneasy	Uneasy

2.3 Production gain

The clinical trial reported the change in daily minutes of logged work at week 6 and week 12 compared to week 1. The level of productivity can be impacted by (i) sick-leave (absenteeism), (ii) choice to work part-time (and/or less overtime), and (iii) reduced productivity while at work (presenteeism). It is not clear from the trial data what the change in daily minutes of logged work represent. However, it is assumed that the time reported by the patients represent an increase in the productive time.

The human capital approach is the standard approach to value changes in productivity. It assumes that the value of production corresponds to what the employer pays for the employee, i.e., gross wage including payroll taxes. According to the Current Population Survey (CPS), the mean earnings per week in the first quartal of 2023 was $1,100 (6).

Assuming the typical work week is 40 hours, this would correspond to $27.5 per hour. Adding 15% of payroll taxes (7) results in a total value of $31 per hour.

The annual gain is estimated by multiplying the daily gain by the number of work days in a year. Subtracting weekends (104), bank holidays (10 (8)) and vacation days (11 (9)) from 365 days, result in 240 workdays for a year.

2.4 Health care savings

Health care cost savings was estimated using data from the literature and assumptions based on data from the clinical trial. First, a targeted search was performed to identify a baseline estimate of the healthcare cost for patients with chronic pain. The search was limited to studies performed in a US setting, published during the last 10 years, and reporting cost in terms of resource use multiplied by unit costs. Secondly, assumptions on change were based on analysis of the discontinuation of treatment and medication as reported by the clinical trial. This was also supported by a targeted search performed to identify studies that show the relationship between healthcare resource use and severity level for chronic pain. As these relationships were assumed to be relatively stable over time and space, no limitations were applied with respect to study setting (although a US setting was preferred if available) or publication date.

3. Results

3.1 Health gain

The mean baseline (i.e., level before start of treatment) quality-of-life was 0.426 when applying the value set of Craig et al (5) (Figure 1). The impact on physical function was the main reason for the reduction in quality of life followed by pain interference, anxiety and depression.

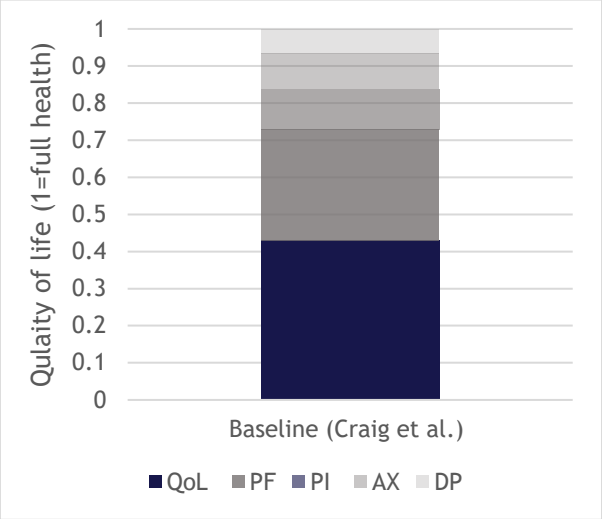

Figure 1. Baseline quality of life based on clinical trial data translated using value set from Craig et al. (PF=loss due to physical function, PI=loss due to pain interference, AX=loss due to anxiety, DP=loss due to depression)[1]

After 12 weeks of treatment, there was a mean gain of 0.054-0.068 in utility based on the dimensions physical function and pain interference (Figure 2, more detailed results are reported in Appendix). The largest part of the gain was seen in the dimension physical function (cannot be separated out using Dewitt et al. (4)).

[1] It is unclear if the separate reductions in anxiety and depression can be added. Excluding the reduction based on anxiety would increase baseline utility to 0.522.

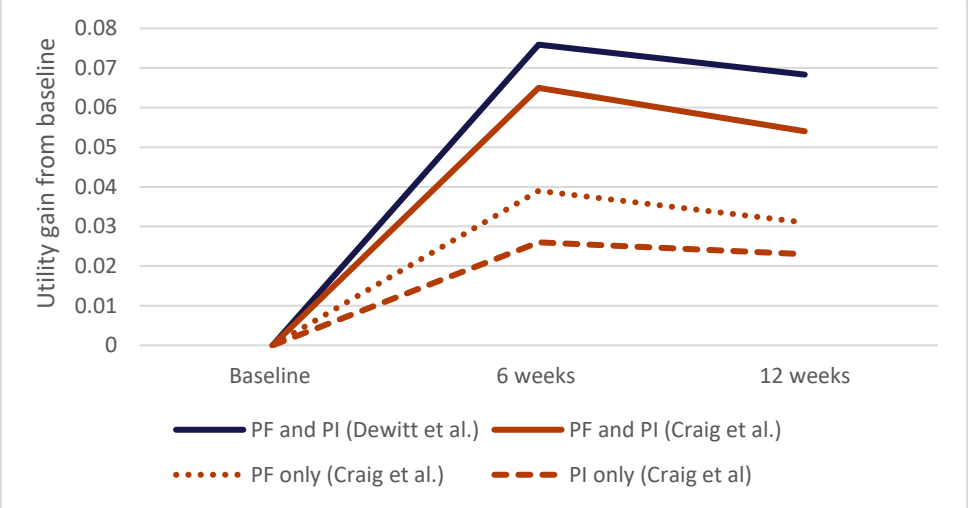

Figure 2. Utility gain in the dimensions physical function (PF) and pain interference (PI) based on value sets from Dewitt et al. (4) and Craig et al. (5)

After 12 weeks of treatment, there was also a mean gain of 0.022-0.037 in utility based on the dimension depression[2] (Figure 3). Based on the value set of Craig et al. (5), there was an additional gain of 0.038 based on the dimension anxiety (not included in the value set by Dewitt et al. (4)).

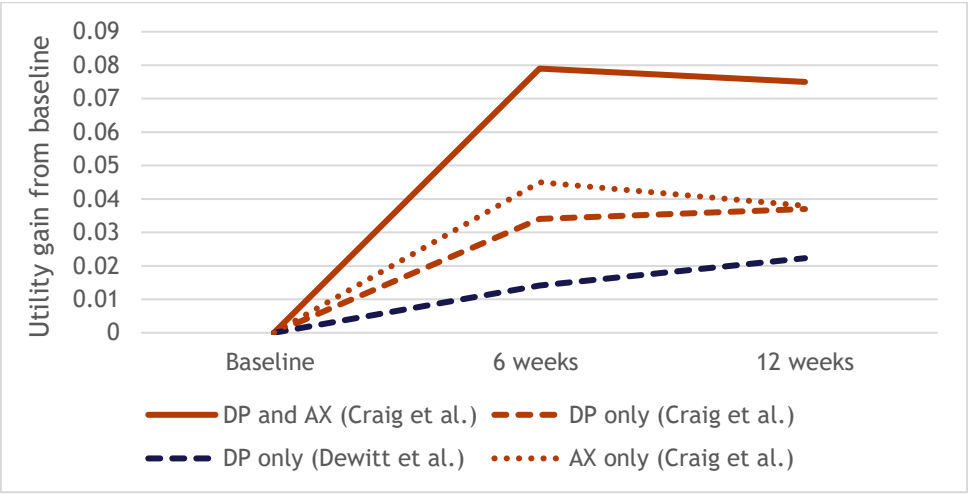

Figure 3. Utility gain in the dimensions depression (DP) and anxiety (AX) based on value sets from Dewitt et al. (no value set for anxiety) and Craig et al.

In total, there was a mean gain in utility of 0.091 based on the dimensions physical function, pain interference and depression (Figure 4). Adding the utility gain associated with the dimension anxiety would result in a total gain of 0.129.

[2] Only symptoms as asked in the questionnaire. Not a diagnosis.

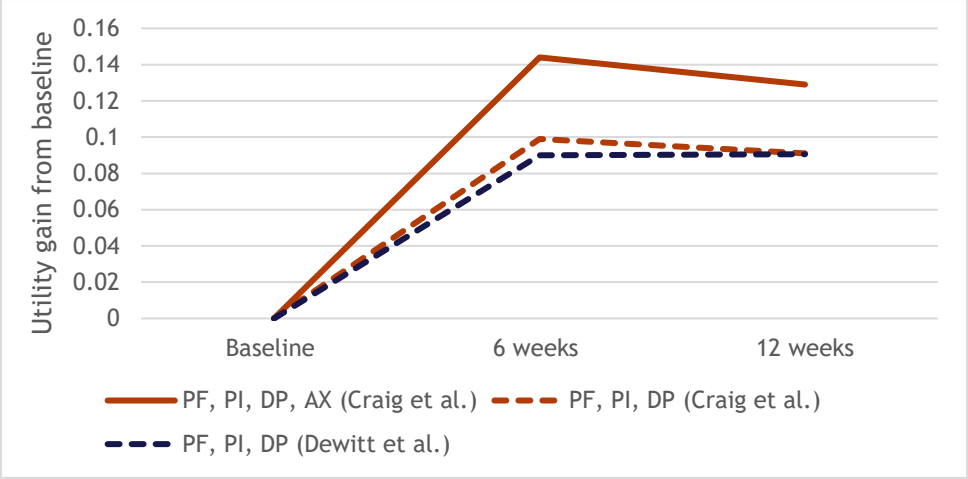

Figure 4. Utility gain in all dimensions measured (PF=physical function, PI=pain interference, DP=depression, AX=anxiety) based on value sets from Dewitt et al. (4) (no value set for anxiety) and Craig et al (5).

3.2 Production gain

The daily capacity to work was reported for 32 (78%) out of 41 patients enrolled in the clinical trial, assumed to correspond to the number of patients with employment. The mean daily capacity to work at baseline was 371 minutes (6.18 hours) per day (SD:149). The mean increase in daily capacity to work was 28.5 (SD:90, range -105 min to +237) minutes at 6 weeks and 34.1 (SD:104, range range -132 to + 322 minutes) minutes at 12 weeks (Figure 5). This corresponds to a daily gain of $15 and $18, with an hourly value of $31 (see methods, section 2.2). Provided that there are 240 workdays per year (see methods, section 2.2), this would translate to an annual gain of $4,320 based on the result at 12 weeks. Adjusting for the share who are employed (78%), the mean gain for all patients is $3,370.

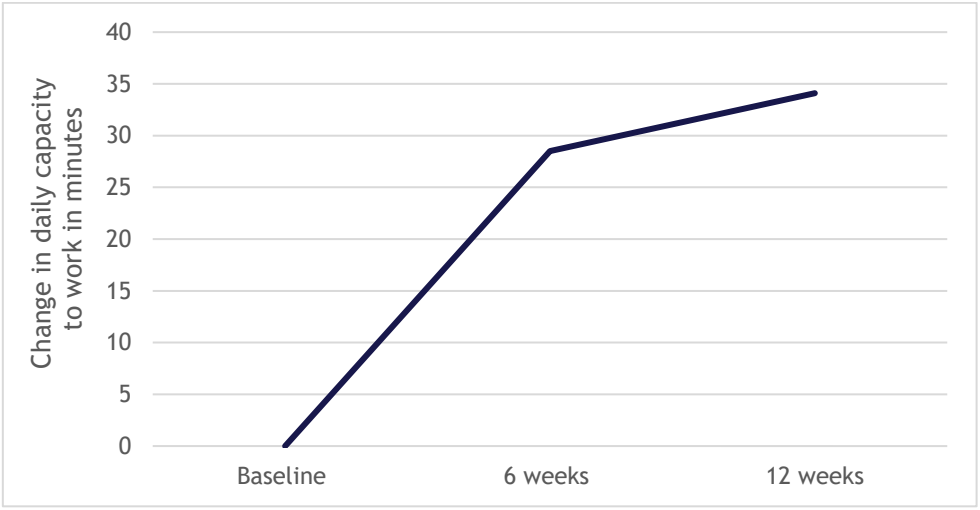

Figure 5. Change in mean daily capacity to work in minutes reported in the clinical trial.

3.3 Health care use

The baseline health care cost was assumed to correspond to the health care cost reported for a sample of patients (n=144) with chronic low back pain treated at the Brigham and Women's

Hospital between 2012 and 2014 (Figure 6) (10)[3]. The total mean cost per patient and year was $4,966. The main part of healthcare cost consists of cost related to medications (53%) and office visits (26%). Other studies report healthcare costs of a similar size for a sample of patients (n=31) with chronic low-back pain in the Netherlands (€4,129) (11) and a sample of the population with self-reported moderate, chronic pain (n=4,245) in the US ($3,957, 2010 years prices) (12).

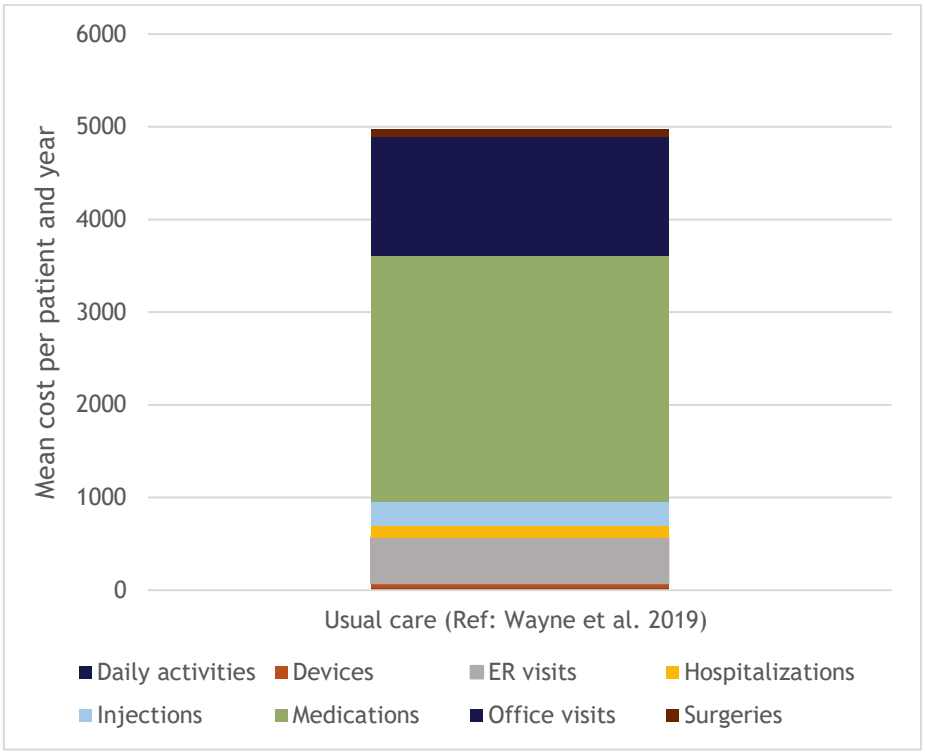

Figure 6. The mean cost per patient and year for a sample of patients (n=144) with chronic low back pain treated at the Brigham and Women's Hospital between 2012 and 2014 (10) (assumed baseline healthcare cost).

Study data from the NHW site in the Paindrainer™ trial show a reduction in the share with any treatment or medication at follow-up (Table 2 and 3). The share with any treatment was reduced from 81% at baseline to 58% at 12 weeks of follow-up. Most of the reduction was found in the use of physical therapy. The share with any medication was reduced from 84% at baseline to 74% at follow-up. In addition, there was a switch from NSAIDs to acetaminophen.

[3] This site is located in the same area as the sites included in the Paindrainer™ trial. However, the sample had one specified chronic pain diagnosis (chronic low back pain instead of chronic back or neck pain), a higher mean age (52 vs 48), a higher BMI (30 vs 19) and a higher utility (0.58 vs 0.43) compared to the sample in the Paindrainer™ clinical trial.

Table 2. Number of patients at the NHW site (n=31) receiving treatment during the last four weeks at baseline and at 6 and 12 weeks of follow-up

Treatment	Baseline	6 weeks	12 weeks
Physical therapy	17	13	8
Injection therapy	8	8	9
Cognitive behavioural therapy	4	3	2
Mindfulness meditation course	1	3	3
Regular home mindfulness/relaxation practice	9	8	8
Acupuncture	2	3	2
Chiropractor	5	4	2
Any treatment	**25**	**21**	**18**

Table 3. Number of patients at the NHW site (n=31) taking medication at baseline and at 6 and 12 weeks of follow-up

Medication	Baseline	6 weeks	12 weeks
Non-steroidal anti-inflammatory drugs (NSAIDs, e.g., ibuprofen/motrin, naproxen, celecoxib/celebrex etc.)	21	11	14
Acetaminophen (tylenol)	8	14	12
Nerve medications (e.g., gabapentin, pregabalin etc.	7	6	8
Antidepressants for pain (e.g., amitryptyline, nortriptyline, duloxetine, etc.)	2	2	1
Antidepressants for mood	4	6	5
Antianxiety medications on a regular basis (e.g., benzodiazepines such as lorazepam or clonazepam)	3	4	3
Muscle relaxants (e.g., cyclobenzaprine, Flexenil, tizanidine, etc.)	10	10	10
Any medication	**26**	**23**	**23**

Based on the trial data, we assume that medication cost ($2,656 at baseline) was reduced by 10%, resulting in a reduction of $266. Health care costs excluding medications ($2,310 at baseline) were assumed to be reduced by 23%, corresponding to a reduction of $531. In total, health care costs were reduced by around $800 ($266+$531) per person and year.

Other studies also indicate that health care use depend on the severity level of chronic pain. Based on data from the 2011 National Health Interview, Pitcher et al. 2019 (13) showed that the healthcare use of individuals with high-impact chronic pain (HICP)[4] was higher than the healthcare use of individuals with chronic pain without limitations (CPWL)[5] (Figure 7).

[4] Pain reported on most days or every day in the previous 3 months WITH ≥1 activity limitation/participation restriction (unable to do) from among 8 relevant questions (working, school, leisure, friends/family, household chores, transportation, religious activities, community gatherings) from the Adult Functioning and Disability Supplement (AFD).
[5] Pain reported on most days or every day in the previous 3 months WITHOUT activity limitation/participation restriction (able to do to some degree).

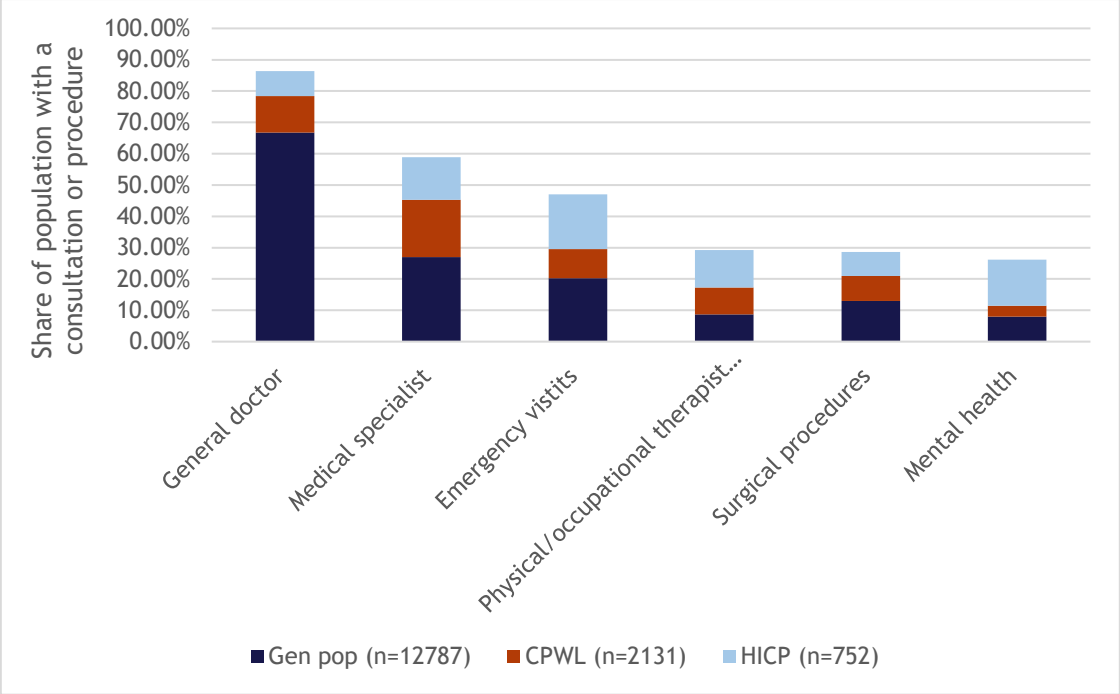

Figure 7. Share with a consultation or procedure during the previous 12 months among the general population, individuals with chronic pain without limitations (CPWL) and individuals with high-impact chronic pain based on Pitcher et al. 2019 (13).

Similarly, based on a telephone survey among a representative sample of the general population in Australia (n=2,092) in 1998, Blyth et al. 2003 (14) concluded that use of medication was associated with the chronic pain grade[6] (Figure 8).

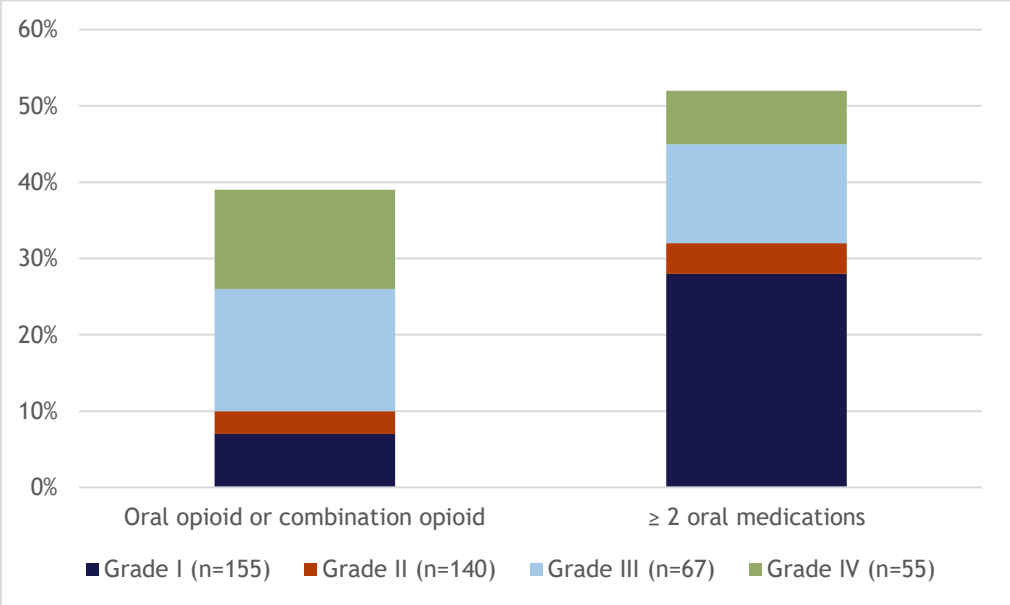

Figure 8. Share using medications by chronic pain grade based on Blyth et al. 2003 (14).

[6] Chronic pain grades: I = low disability-low intensity; II = low disability-high intensity; III = high disability-moderately limiting; and IV = high disability-severely limiting. Based on Chronic Pain Grade Scale (CPGS). https://www.physio-pedia.com/Chronic_Pain_Grade_Scale_(CPGS)

The classifications of chronic pain in the studies by Pitcher et al. 2019 and Blyth et al. 2003 were not used in the clinical trial. Both of these classifications were, however, based on the ability to perform daily activities, which was shown to increase in the clinical trial (Figure 9). See Appendix for more details on change across severity levels based on pain interference.

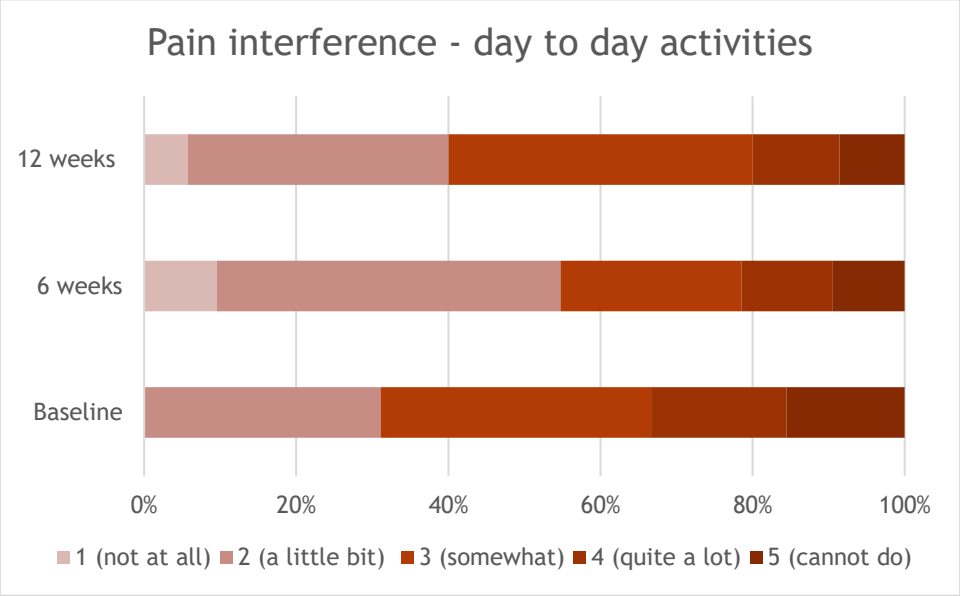

Figure 9. Level of pain interference among sample in clinical trial at baseline, and at 6 and 12 weeks of follow-up.

3.4 Total societal gain

The total societal gain is estimated to around $8,700 per patient and year (Figure 10). Around half of this gain is the monetized health gain, based on a value of a QALY of $50,000 (15) (0.091 x $50,000), around 39% is production gain, and the rest consist of healthcare savings.

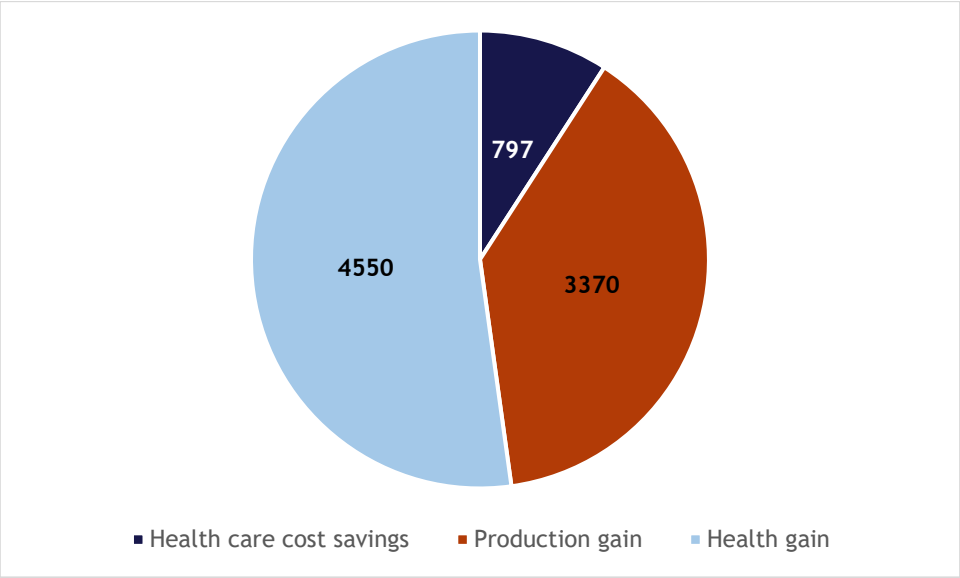

Figure 10. The total estimated societal gain per patient and year.

4. Discussion

This study has estimated the total societal gain of a digital tool for self-management of chronic pain (PainDrainer^{TM}). The total gain was estimated to $8,700 per patient and year, consisting of a monetized health gain ($4,550 per patient and year), production gain ($3,370 per patient and year), and healthcare cost savings ($797per patient and year).

Health gain was estimated in terms of the number of quality-adjusted life-years (QALYs) gained based on quality of life measured by PROMIS. Two different approaches were used to translate the data from the clinical trial to preference-based quality-of-life weights. Both approaches resulted in similar results. However, there remain uncertainty as to how quality of weights of different dimensions can be added without double counting. For example, it is unclear if the increase in quality of life for anxiety and depression reported by Dewitt et al. (4) can be added. Therefore, this study applied a conservative assumption, limiting the analysis to gains related to pain interference, physical function, and depression symptoms.

Production gain was estimated based on the daily capacity to work as reported by the patients enrolled in the clinical trial. This type of data is relatively unique and allows for an analysis on the real performance at work. However, it is not clear what the gain in daily capacity to work represent. Production gain can be a consequence of individuals being able to reduce their absence from work (absenteeism) or being able to work more while present at work (presenteeism). These components are valued differently. Studies of productivity among patients with chronic pain suggest that absenteeism, in terms of sick leave, is limited among patients with chronic pain ((10), (12), (16)). However, absenteeism, in terms of making a choice to work less hours (12), is more common as is presenteeism (16). Since it is reasonable to assume that individuals do not report hours for presenteeism, the daily capacity to work as reported in the clinical trial most likely represents the individual's own choice to work more hours e.g., an increased capacity to work. However, work was defined by the patients themselves and may include time spent on activities outside of paid labour (e.g. volunteer work). The estimated gain for productivity could be underestimated since the impact on presenteeism most likely is excluded.

The trial did only report the share of patients stopping treatment or medication. There may also be patients who reduce their number of visits or their medication dose. As this was not included in the calculations, they should be regarded as conservative. Moreover, there is often a delay in the reduction of health care costs as patients may be on a pre-set treatment schedule. A long-term follow-up study of both discontinuation and reduction of treatment and medication could provide more appropriate data for calculation of health care cost savings.

This study is based on data from a 12-week prospective, multicentre clinical trial (2). The clinical trial is a one-arm open trial, i.e., comparison of before and after intervention and not a randomized, controlled clinical trial. In the absence of a control group, this study applies the assumption that patients would have remained at baseline without the intervention. However, it's plausible that patients without the intervention might have received additional care, such as new medications or higher doses of existing medications, to manage their pain. If this were the case, the estimated improvements reported in this study would be conservative or underestimated. The estimations in this report are also based on the assumption that the treatment effect at 12 weeks would remain for a whole year. As the trial shows, not all patients will comply with or continue treatment and there may be a waning effect over time. If so, the estimated gains in this report would be overestimated. A future long-term study could help clarify the extent of under- or overestimation.

This study shows that chronic pain is associated with a significant burden including a very low quality-of-life, high healthcare costs and production loss, which implies that that there is an unmet need. The study also finds that there may be a substantial societal gain associated with a digital tool for self-management of chronic pain. Data from the clinical trial allowed for estimation of the three main parts of the societal gain, all pointing to a significant, positive impact associated with the new treatment. Future research is needed to get a better understanding of the long-term impact.

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Appendix

QALY results using Craig value set for PROMIS-29

Pain Interference

Measurement	N	Mean (SD)	Difference to baseline
Baseline	44	-0.110 (0.120)	NA
6 weeks	42	-0.084 (0.112)	+0.026
12 weeks	35	-0.087 (0.113)	+0.023

Physical function

Measurement	N	Mean (SD)	Difference to baseline
Baseline	45	-0.300 (0.404)	NA
6 weeks	42	-0.261 (0.112)	+0.039
12 weeks	35	-0.269 (0.113)	+0.031

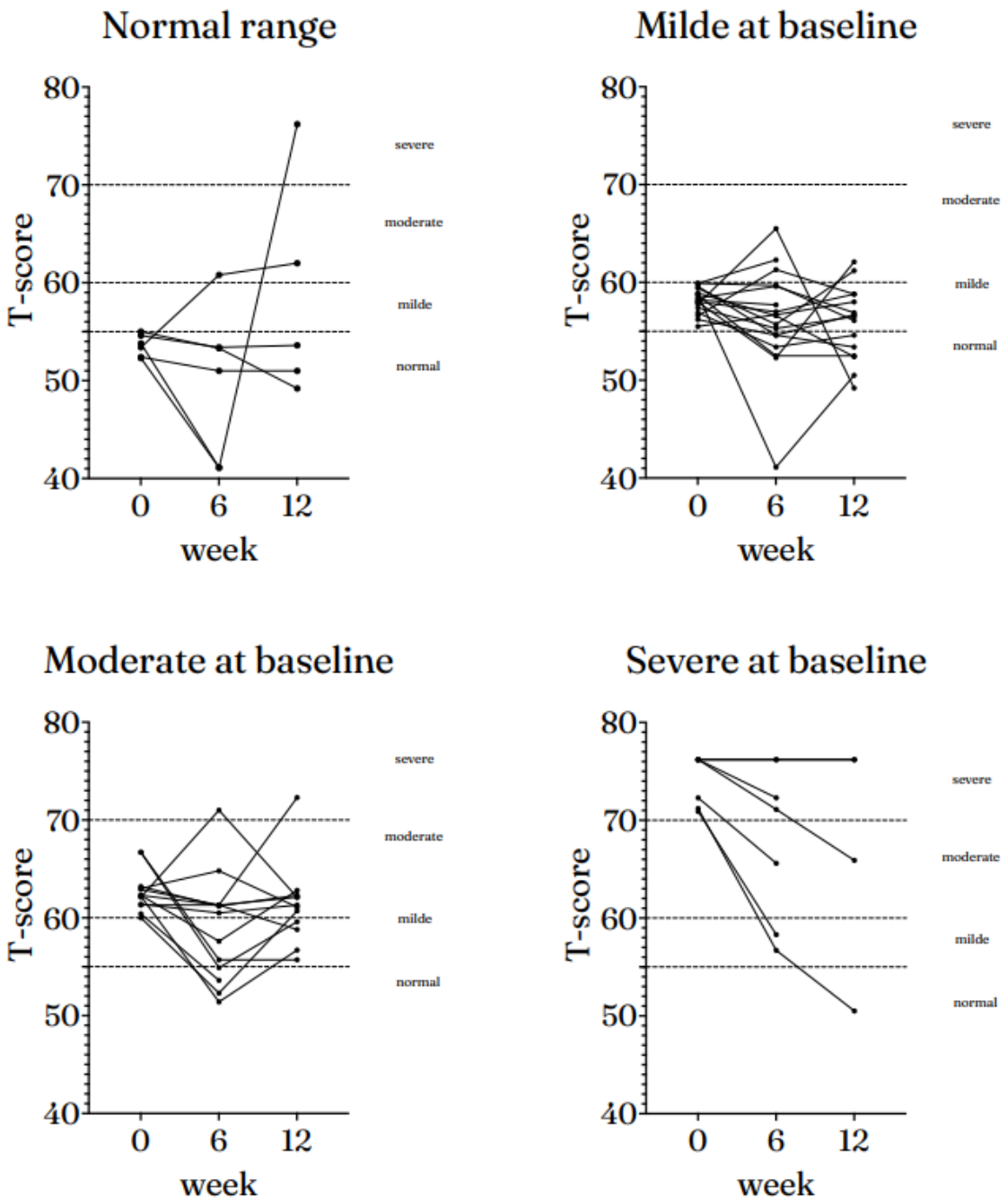
Depression

Measurement	N	Mean (SD)	Difference to baseline
Baseline	45	-0.065 (0.109)	NA
6 weeks	42	-0.031 (0.065)	+0.034
12 weeks	34	-0.028 (0.062)	+0.037

Anxiety

Measurement	N	Mean (SD)	Difference to baseline
Baseline	45	-0.096 (0.109)	NA
6 weeks	42	-0.051 (0.065)	+0.045
12 weeks	34	-0.058 (0.062)	+0.038

Individual change in pain interference by severity level at baseline



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IHE REPORT 2023:8
e-ISSN: 1651-8187
ISSN: 1651-7628

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