TRITECH
Sefydliad | Institute

Hywel Dda University Health Board

Evaluation report:
A real-world evaluation of Transcutaneous Electrical Nerve Stimulation (TENS) and osteoarthritis of the knee.

Report Produced on 22 November 2023

Report prepared by:

Billy Woods, Clinical Scientist, TriTech Institute and Innovation and Arya Chandran, Research Assistant, TriTech Institute and Innovation, Hywel Dda University Health Board.

With support from:

Dr Sean Jenkins, Research Director, Assistive Technologies and Innovation Centre (ATiC), Fatma Layas, Innovation Fellow, Assistive Technologies and Innovation Centre (ATiC), Ben Matthews, Physiotherapist, Hywel Dda University Health Board, Professor Keir Lewis, Consultant Respiratory Lead and TriTech Clinical Lead, Hywel Dda University Health Board.

Clinical Lead(s):

Professor Peter Cnudde, Consultant Orthopaedic Surgeon, Hywel Dda University Health Board.

Evaluation Lead:

Professor Chris Hopkins, Head of Tritech Institute & Innovation, Hywel Dda University Health Board.

Who We Are

In 2021 the Tritech Institute was launched. We are a team based in a bespoke facility within Hywel Dda University Health Board comprising of industry-leading engineers, scientists and clinicians.

Our Institute

Here at the TriTech Institute, we support the development of healthcare solutions on a local, national, and global level offering designers and manufacturers a single point of access to the NHS through a collaborative and agile approach.

What We Offer

The team's advanced skills in clinical and research design are combined with technical engineering expertise to manage the whole innovative pathway from early unmet need, through to concept design, prototyping, clinical investigations, and real-world service evaluations.

Our Services

We provide specific services and solutions for clinical engineering, research and innovation and Value-Based healthcare, and can also support with grant writing and submission.

Executive summary

Background

Osteoarthritis (OA) is characterised by damage to joints in the body causing them to become painful and stiff; this is progressive and gets worse over time. Pain from OA can be difficult to study because the magnitude of symptoms often fluctuates and changes. In the context of OA of the knee, replacement surgery is one of the most commonly undertaken and cost-effective musculoskeletal (MSK) surgical procedures (Price et al., 2018).

Current treatment of most OA relies primarily on a pharmacologic approach to pain management. Recently, it has been suggested that pharmacologic interventions in OA of the knee have limited benefit, causing a shift in strategy to nonpharmacologic methods (Sharma, 2021). Previous NICE guidelines have suggested transcutaneous electrical nerve stimulation (TENS) devices should be considered as an adjunct to standard care for pain relief of OA (NICE, 2014), however, the guidelines were updated in October 2022 and now state that TENS should not be used due to the lack of evidence (NICE, 2022).

Evaluation overview

To address the current lack of evidence around TENS use in OA of the knee a 'real world' evaluation was carried out within Prince Philip Hospital (PPH) orthopaedic department, Hywel Dda University Health Board (HDUHB) from 01/11/21 to 11/04/22. The evaluation assessed the potential benefits of a neuromodulation device for patients who had a diagnosis of OA in at least one knee, and who were also on the waiting list for total knee arthroplasty.

Evaluation aims:

1. To assess any potential benefits with regards to a patient's pain levels, knee function and quality of life whilst using the TENS device.
2. To collect data regarding patient feedback for the usability and acceptability of the TENS device.
3. To understand how clinical outcome data relates to user experience for the TENS device.
4. To evaluate staff feedback regarding the use of the TENS device for patients with osteoarthritis of the knee.

Methodology

30 patients were included within the evaluation and each issued with a TENS device for use at home over a 3-month period. Patient reported outcome measures (PROMs) were collected at baseline and every 4 weeks which included pain numeric rating scale (NRS), quality of life (EQ-5D-5L) and knee function (KOOS-PS). Patient feedback was collected during interviews with patients in clinic. Patient feedback was also collected by the assistive technologies innovation centre (ATiC), University of Wales Trinity Saint David (UWTSD) who conducted patient telephone interviews and feedback surveys relating to the user experience with the device. Feedback from key clinical staff involved in the treatment of the patients was collected through one to one interviews.

Results

Of the 30 patients recruited to the evaluation, 22 had complete PROMs data for baseline and month three (73% completion rate). Non-parametric statistical tests (Wilcoxon) were used on these 22 patients with completed PROMs to compare baseline to month three within groups. The results of this showed no significant change in pain (NRS) ($P>0.05$), a deteriorating quality of life (EQ-5D-5L) ($P<0.05$) and deteriorating knee function (KOOS-PS) ($P<0.05$) from baseline to month three.

In order to understand if usability factors affected these outcomes, the 22 patients were then divided into 'most' (n=11) device use and 'least' (n=11) device use groups (based upon the reported number of device usage over the three-month period).

The Wilcoxon test was then repeated for the 'most' and 'least' groups separately for their respective baseline and month three changes. For the 'least' use group, a worsening of knee function months (as assessed by the KOOS-PS) ($P<0.05$) was detected. Whereas the 'most' use group did not have any significant changes ($P>0.05$). The Wilcoxon test did not show a difference in baseline to month three changes in pain NRS or EQ-5D-5L for either 'most' or 'least' use groups when considered separately ($P>0.05$). The usability elements of the evaluation highlighted differences between these 'most' and 'least' use groups in terms of daily activities and attitudes towards this technology.

Patient

Patients who were part of the 'most' use group reported higher activity levels and reduced swelling with improved sleep. The user feedback also indicated that younger patients had more perceived benefits and were more likely to use the device. There were indications from the interviews and survey feedback that patients were concerned that their waiting times for surgery could be affected through being part of the evaluation, even though they were explicitly told this would not be the case.

Technology

Feedback from patients indicated the device was easy to setup and use. Most patients were pleasantly surprised how small the device was and how easy it was to access when they needed it. The device has no digital display to remind the patient which settings have been selected, and a loud beeping sound is emitted when cycling through the available modes and intensities. This meant some patients found it difficult to keep track of what settings they were using during a session.

Staff

Staff interviewed as part of the evaluation were positive about the device and its potential use with patients. More data regarding long term effectiveness would be required for clinical support and adoption of this device.

Infrastructure

Discussions with staff who work in orthopaedics and pain management services within HDUHB indicated that there are several areas where the device could be useful for patients. Physiotherapists reported that this device could support ongoing prehabilitation services for patients who are awaiting surgery. Pain management nurses reported that TENS devices are used for some in-patients on the wards and the portable nature of the device would be of benefit.

Conclusion

Based upon the Wilcoxon test, the pain NRS and EQ-5D-5L scores for the patients included in this study were unchanged between baseline and month three, when splitting them into 'most' and 'least' device use groups (11 in each). However, user experience data collected during the evaluation indicated a number of reported benefits for patients in the 'most' that were not reported by the 'least' use group. The benefits from the 'most' use group included increased confidence in daily activities, reduced knee swelling and improved sleep. The 'most' use group also did not have a significant reduction in knee function, whereas the 'least' use group did.

Long standing uncertainty regarding TENS use for pain management is confounded by a lack of understanding around responders and non-responders to the technology. The user experience aspects of this evaluation provided additional data which indicates activity levels and sleep quality may have been improved for some of those who used the device regularly. This user experience feedback may help steer future evaluations and research in this area.

Key recommendations

From the results of this evaluation, several recommendations have been suggested.

These recommendations have an order of priority with recommendation one suggested as the next evaluation or research step.

Recommendation 1: Exploration of TENS response factors

One of the key issues affecting TENS research is understanding those who respond and those who don't respond to the stimulation effects. Preliminary usability data suggested younger, more active individuals adopt the technology more readily, but a further evaluation to investigate the factors that affect response and non-response in more detail will aid in further study design.

Recommendation 2: Evaluating activity levels and sleep with TENS efficacy

Patients who used the device the most did not see a decline in KOOS-PS scores (Knee function score). The results of this evaluation indicated that activity levels, exercise and sleep were reported benefits from using the device in the patients who used it the most. These factors were not quantified during this evaluation. A further evaluation of the device whilst monitoring activity levels, sleep quality and confidence in activities is recommended.

Recommendation 3: Prescriptive research study

A clinical research study with a more prescriptive protocol, including the use of only certain modes or frequency characteristics and a specified number of uses per week would also address some of the uncertainty with TENS issues such as consistency in methodology. If this is undertaken whilst following recommendation two, the data collection could also include activity levels and sleep quality (provided the evidence supported this).

Recommendation 4: Development of an effective 'placebo TENS'

A lack of effective placebo TENS devices for randomisation and blinding of treatment interventions, is a limiting factor for research studies. The development and testing of an effective 'placebo TENS' would greatly benefit any larger scale randomised controlled trial (RCT).

Recommendation 5: Multi-site RCT with a 'run-in' phase

Another issue relating to the uncertainty with TENS use is the current lack of well-designed multi-centre RCTs. A recommendation from the literature is to have a 'run-in' phase for a multi-centre RCT where patients are identified as responders or non-responders for the recruitment in the early stages (Johnson, 2021). Completion of recommendation one could generate evidence to support this 'run-in' phase.

Table of Contents

Abbreviations

ATiC	Assistive technologies innovation centre
BMI	Body mass index
CMAT	Community musculoskeletal assessment team
CRC	Clinical research centre
EQ-5D-5L	EuroQol, 5 domain , 5 level
HDUHB	Hywel Dda University Health Board
ICHOM	International consortium for health outcomes measurement
IG	Information governance
KOOS-PS	Knee injury and osteoarthritis outcome score
ME	Myalgic encephalomyelitis
MRI	Magnetic resonance imaging
MSK	Musculo-skeletal
NHS	National health service
NICE	National institute for clinical excellence
NRS	Numeric rating scale
OA	Osteoarthritis
OKS	Oxford knee score
OTC	Over the counter
PIS	Patient information sheet
PPH	Prince Philip Hospital
PROM	Patient recorded outcome measure
QoL	Quality of life
RCT	Randomised control trial
TENS	Transcutaneous electrical nerve stimulation
THA	Total hip arthroplasty
TKA	Total knee arthroplasty
USB	Universal serial bus
UWTSD	University of Wales Trinity St.David
UX	User experience
VBHC	Value based healthcare
WTD	Worse than death

Acknowledgements

We would like to thank Professor Peter Cnudde as the clinical lead for this evaluation, Ben Matthews, physiotherapist, for supporting patient recruitment, Zohra Omar, research nurse, and the rest of the team at the clinical research facility in Prince Philip Hospital for providing a room in which to see the patients, and Professor Keir Lewis, TriTech clinical lead, for providing clinical guidance on patient safety and screening.

We would also like to thank Chantel Rhodes from the Value Based Health Care Team for assistance with selection and distribution of appropriate patient reported outcome measures.

We would also like to thank Dr Sean Jenkins, Research Director and Dr Fatma Layas, Innovation Fellow from the Assistive Technologies, and Innovation Centre (ATiC), for their continued support and collaboration with the whole project and for leading the user experience elements of the evaluation.

1. Background

1.1 Osteoarthritis of the knee

Osteoarthritis (OA) is characterised by damage to joints causing them to become painful and stiff. OA becomes progressively worse over time and can include reduced joint motion and muscle weakness (Sharma, 2021). Pain from OA of the knee is difficult to study because it fluctuates and changes. Episodic pain is predictable in the early stages of OA but becomes less predictable in later stages. The global prevalence of knee OA is estimated to be 16% in individuals over 15 and 22.9% in individuals aged 40 and over (Cui et a., 2020). Peat et al. (2001) reported that in a one-year period, 25% of people aged 55 and over from the UK experienced episodes of knee pain. About 10% of people aged 55 and over have disabling painful knee OA, a quarter of whom are severely disabled (Peat et al., 2001).

Treatment of knee OA is variable in its outcome, however, a reduction in pain and disability over time can be achieved. Clinical outcome data is sparse, but it has been shown that one third of cases will improve over time, one third do not change and the final third develop progressive symptomatic disease (condition gets worse) (NICE, 2014). In the third of patients whose symptoms get worse, prosthetic joint replacement is often the only recourse. Over 120,000 joint replacement surgeries are performed annually in the UK accounting for 1% of the total healthcare budget (NICE, 2014). Despite its cost effectiveness, knee replacement surgery still places a significant burden on patients and the health system across the UK.

The impact on quality of life for people suffering with knee OA has been shown to be significant. In one large cross-sectional study, 2168 patients undergoing total knee arthroplasty (TKA) completed the EuroQol five-dimension (EQ-5D), which is a widely used and validated to assess a patient's health related quality of life. On the EQ-5D an index score of < 0 defines a state 'worse than death' (WTD). The rate of WTD in TKA patients was 12% pre-operatively which dropped to 2% post-surgical procedure (Scott et al, 2019), which indicates the improved quality of life for patients after the knee has been replaced. This presents a significant issue, showing a large proportion of patients suffering poor quality of life whilst they are waiting for their joint replacement. This issue is increasing as patients waiting times for hip and knee replacement surgeries is increasing and was impacted in a detrimental way by the COVID-19 pandemic (Farrow et al., 2023).

A study exploring the quality of life of patients on the waiting lists for total hip arthroplasty (THA) or TKA indicated a significant negative impact caused by the COVID 19 pandemic. During the study period (August and September 2020), 843 patients from 10 UK centres reported their EQ-5D scores and completed waiting list questionnaires. Data from a retrospective cohort of non-Covid waiting list patients (January 2014 to September 2017) were used as a control group. It was found that the 2020 group of patients had significantly worse EQ-5D scores for both THA and TKA, over one-third of THA patients and nearly one-quarter of TKA patients were in a state WTD. Over 80% of the 2020 group felt their quality of life had deteriorated whilst waiting (Clement et al., 2021).

Recently there has been a shift in strategy for the treatment of the knee OA to non-pharmacologic methods due to the proven limited benefits of a primarily pharmacologic approach. Pharmacological solutions for managing pain often come with side effects associated with long term use such as addiction or organ damage leading to the need for non-pharmacologic solutions. The new approach relies on educating patients, providing skills, self-efficacity and the importance of a proactive approach to prevent functional decline (Sharma, 2021). In addition, another potential solution to reducing the dependence on pharmacological agents is the utilisation of technology for pain relief which could avoid many of the side effects (Johnson, 2021).

1.2 Technology solution

Transcutaneous Electrical Nerve Stimulation (TENS)

Transcutaneous Electrical Nerve Stimulation (TENS) is used clinically in a range of scenarios for the reduction or relief of pain. TENS is a non-invasive modality that is easy to apply with relatively few contraindications. The mechanism behind TENS is that a small electrical impulse is delivered through the skin of a user through conductive and adhesive electrodes. The sensation felt varies between user but most report a 'tingling' sensation as the nerves below the electrode sites are receiving the electrical impulses (Sluka & Walsh, 2003).

TENS is a technique-based intervention to activate selective peripheral nerve fibres to elicit physiological neuromodulation. The amplitude of the pulsed electrical currents used is a key characteristic to influence the axons which are stimulated. The frequency of the electrical pulses is limited by the absolute and relative refractory periods for the axon. TENS appears to modulate the nociceptive input at peripheral segmental and extrasegmental nerve sites, which may be able to extinguish 'incoming' orthodromic impulses conducted. This translates as an ability to 'block' pain signals in some individuals. By its very nature TENS offers a relatively temporary pain relief measure (Johnson, 2021).

TENS use for the reduction of pain has been documented in one form or another since the late 1700s. Although the technology has developed more sophisticated devices since its early uses, the mechanisms behind the pain relief reported by some patients is still poorly understood. Following three decades of systematic reviews and clinical trials for TENS use in pain management, the exact mechanisms for relief and its effectiveness is still unclear.

Uncertainty with clinical TENS use

There are a number of issues identified in a review by Johnson (2021) that relate to the uncertainty of the clinical efficacy of TENS as a pain relief tool. The evidence that exists currently can be conflicted and contradictory. Some of these key issues are:

1. Design and execution of trials relating to the consistency of dosage and selection of outcome assessments. More careful scrutiny of research methodology is required.

2. Sample size – The majority of randomised control trials (RCTs) investigating TENS use had fewer than 50 patients which compromises statistical power of the results.

3. Difficulty with placebo TENS – RCTs that have been conducted to date include randomisation, but the best methods for doing this with either a sham TENS or reduced settings is still unclear and could be contributing to the uncertainty in results.

4. Using pain as a primary outcome measure – Pain measures such as visual analogue scales and numerical rating scales are difficult to capture consistently and many studies do not report how these are collected.

5. Response to TENS – To date there is still uncertainty regarding the mechanisms behind those that respond to TENS like treatments and those that do not. More work is required in this area.

Ultra portable TENS device

The TENS device used for this evaluation was ultraportable, and consisted of two pads with an interconnected wire. This device was battery powered and is charged via USB cables, giving it an advantage of other TENS device that require standard UK power sockets to function. This TENS device had 6 different stimulation profiles, the intensity of which could be controlled using two simple buttons on the opposite side to the pads.

2. Service context

Location

Hywel Dda University Health Board (HDUHB) is one of seven local health boards in Wales. It provides primary and secondary care services for residents within its borders in the counties of Carmarthenshire, Pembrokeshire and Ceredigion. Prince Philip Hospital (PPH) has an onsite dedicated Clinical Research Centre (CRC) with facilities including a patient waiting area and a clinical consultation room.

The clinical lead for this evaluation was Professor Peter Cnudde, Consultant Orthopaedic Surgeon at Hywel Dda University Health Board. The project lead was a registered clinical scientist, with previous experience of interacting with NHS patients using neuromodulation devices. Appropriate training was carried out before any patient data systems were used. Hywel Dda University Health Board's (HDUHB) information governance (IG) team were contacted before the evaluation started to ensure that patient data was handled in line with health board policies.

Patient screening

Patients were identified from the clinical lead's total knee arthroplasty waiting list. Patients were initially pre-screened by the clinical lead and supporting physiotherapist, suitable participant names were sent securely via NHS email to the evaluation lead where patients were then fully screened with support from the TriTech clinical lead. If patients were deemed as suitable for the evaluation (see eligibility criteria below) the evaluation lead contacted the patients to ask further screening questions where case medical notes were not clear, after which patients were invited to the service if eligible. The patient pathway for this evaluation can be seen in appendix 1. Every patient screening call was documented, using the form seen in appendix 2. If patients agreed to take part in the evaluation, they were invited for an initial consultation.

Service eligibility criteria

The inclusion criteria can be seen below.

Inclusion criteria:

1. Be a patient within Hywel Dda University Health Board.
2. Have a diagnosis of OA of the knee, with diagnosis confirmed by imaging (Xray/ MRI) and surgical consultant.
3. Are on the waiting list for total knee arthroplasty.
4. Have an average knee pain intensity ≥ 5 on the Pain Numeric Rating Scale (NRS) at the time of enrolment.
5. Be willing and capable of giving written informed consent to participate in this service evaluation based on voluntary agreement after a thorough explanation of the subject's participation has been provided.
6. Be willing and capable of subjective evaluation, read and understand written questionnaires.
7. Be on a stable pain medication regimen, as determined by the investigator, for at least 14 days prior to enrolling in this service evaluation.
8. Be willing and able to comply with related assessments, device handling and visits.

Exclusion criteria:

1. Be less than 40 years of age.
2. Be more than 80 years of age.
3. Have inflammatory arthropathy.
4. Have a surgery or other major intervention planned which is in addition to the knee arthroplasty within the evaluation period.
5. Have severe comorbidities for chronic pain that require input from the pain team or rheumatology(review clinically).
6. Have contraindications to electrical stimulation (cardiac pacemaker, implantable defibrillator or any other implantable electrical device fitted, dermatological conditions (open wound on/ around knee, abnormal sensations in the knee).
7. Have a diagnosis of fibromyalgia.
8. Have a diagnosis of myalgic encephalomyelitis (ME).
9. Suspected or diagnosed epilepsy.

10. Have a pacemaker.
11. Have any open wounds.
12. Suspected or diagnosed cancers of any type(review clinically).
13. Pain symptoms that are undiagnosed(review clinically).
14. Diagnosed lack of skin sensation in the affected area.
16. Have open wounds on or around the affected knee.
17. Be concurrently participating in any other clinical evaluation or study.
18. Have pain in other area(s) and/or medical condition requiring the regular use of significant pain medications that could interfere with accurate pain reporting, and/or confound the evaluation of outcome measures, as determined by the Investigator(review clinically).
19. Have any other severe medical condition that in the opinion of the medical investigator would preclude them.

In the criteria above where the term 'review clinically' is seen, the severity of the condition was considered by a consultant orthopaedic surgeon or similarly qualified clinician before exclusion.

Initial consultation

The initial consultation was carried out in the Clinical Research Centre (CRC) at PPH (appendix 3). At the start of the initial consultation the patients were given a copy of the patient information sheet (PIS) (appendix 4) and given the opportunity to read through this. The PIS was also discussed with the patient and if they still wanted to proceed, both they and the evaluation lead signed the document.

The following points were also discussed with the patient during the initial consultation, and this was documented using the form in appendix 5:

- The aims and rationale of the evaluation.
- The voluntary nature of the evaluation.
- That the patient's standard care will not be affected if they decide to participate or not.
- The right to withdraw from the evaluation without giving a reason.
- What the patient's involvement in the evaluation will involve.
- The potential benefits and disadvantages of them taking part in the evaluation.
- The patient's privacy, data protection and confidentiality.
- The patients contact with primary care regarding their knee pain was discussed including GP visits, physiotherapy, or chiropractors.
- The patient's medication relating to their pain, including type and dosage where possible.
- How to use the device at home.

After the device was demonstrated to the patient and they had the opportunity to try it for themselves and ask questions, each patient was given an instruction leaflet on how to operate the device (appendix 6), and guidance on the various settings and modes as well as how to progress once they were comfortable (appendix 7). The patients were also provided with a user diary to complete at home and were asked to complete one page of feedback each week where possible. See appendix 8 for the user diary weekly pages

Using the device at home

After the initial consultation was completed, the responsibility was then with the patient to use the device as instructed at home. The device supplier had expert advice available in the form of phone calls or emails, that could have been utilised for the use of the device for these patients. This additional support was not utilised, in order to maintain a real service, where surgeons and physiotherapists would not discuss patient case details with an external company. This decision was taken to maintain the integrity of the evaluation in a real clinical pathway.

3. Evaluation introduction

TriTech was commissioned for this real-world evaluation on 27/10/2021. This evaluation was a collaboration between Tritech, HDUHB, and the Assistive Technologies, and Innovation Centre (ATiC). The aim of the evaluation was to explore the potential benefits of TENS technology for patients who are awaiting total knee arthroplasty surgery. At the time of commissioning, NICE guidelines (NICE, CG177, 2014) suggested that TENS should be considered as an option for patients with OA of the knee as an adjunct to their care. A 'real world' evaluation was carried out to investigate how effective these devices could be for these patients. NICE guidelines regarding TENS use in OA were updated in October 2022 (NG226).

3.1 Evaluation aims

1. To assess any potential benefits with regards to a patients pain levels, knee function and quality of life whilst using the TENS device.
2. Evaluate staff feedback regarding the use of the TENS device for knee OA patients.
3. To collect data regarding patient feedback for the usability and acceptability of the TENS device.
4. To understand how clinical outcome data relates to user experience for the TENS device.

3.2 Evaluation plan

A mixed-methods approach was utilised to meet the aims of the evaluation via the outcomes set out below. The evaluation was led by the TriTech Institute as part of HDUHB and in collaboration with ATiC. The patient facing component of the evaluation was handled by TriTech and HDUHB.

The service evaluation period was six months in total with the first appointment for the first patient carried out on the 12 November 2021, and the last appointment for the last patient carried out on the 13 April 2022. The data collection period was three months for each individual patient.

3.3 Evaluation outcomes

1. **Value based/clinical outcomes –** To assess any potential benefits with regards to a patients pain levels, knee function and quality of life whilst using the TENS device.
2. **Participant feedback –** To collect data regarding patient feedback for the usability and acceptability of the TENS device.
3. **Correlation between clinical outcomes and user experience –** To understand how clinical outcome data relates to user experience for the TENS device.
4. **Clinical workforce feedback –** Evaluate staff feedback regarding the use of the TENS device for knee OA patients.

4. Methodology

4.1 Value based/clinical outcomes

The Value-Based health care (VBHC) team within HDUHB were consulted during the early stages of this project, to explore potential areas of exploration that would show potential value for TENS use in this group of patients. The guidelines from the International Consortium for Health Outcomes Measurement (ICHOM) were followed for patients with OA of the knee.

The ICHOM recommended monitoring of pain scores, EQ-5D-5L and KOOS-PS for patient outcomes related to OA of the knee and hip. Differences in these measures were discussed with the VBHC team as the best starting point to quantify the value outcome for the patients in this evaluation.

Clinical outcomes were assessed using paper-based questionnaires that were administered during the initial consultation (baseline), then at one, two and three months after baseline. The questionnaires had three sections: pain numeric rating scale (NRS), the EQ-5D-5L and the KOOS-PS (appendices 9, 10 and 11 respectively). Patients filled out the first questionnaire during the initial consultation. For months one, two and three patients were sent home with these and pre-paid envelopes in which to post subsequent completed questionnaires back to the TriTech Institute office.

4.1.1 Pain NRS

Pain numeric rating scale (NRS) is a scale ranging from 0 (no pain at all) to 10 (worst pain imaginable). The pain NRS is a measure that can be used to record the overall pain level of an individual. When completing the pain NRS, the patients were asked to indicate their pain levels as an overall average of the past seven days.

For the pain score, no calculations were required for the analysis. The baseline pain scores were subtracted from the month three pain scores to indicate the overall change in pain score.

4.1.2 EQ-5D-5L

The EuroQol 5 domain 5 Level (EQ-5D-5L) validated questionnaire is a patient reported outcome measure (PROM) for quality of life across five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each domain is scored on a five-level severity ranking that ranges from "no problems" (1) to "extreme problems, unable to do" (5).

These five domains can be used to calculate an index score representing overall quality of life. The EQ-5D-5L also includes a 'self-score' measure of between 0 (worst) and 100 (best) for how an individual feels their health is on that day.

Since the introduction of the original EQ-5D in 1990, numerous country-specific value sets were produced to elicit preferences from members of the general public about how the domains impact overall quality of life. More recently EuroQol has developed new index value sets for the EQ-5D-5L. A value set does not currently exist for a Wales specific population but there is an English Devlin set that was used for calculations in this study (EuroQol, 2022). Please see appendix 12 for the EQ-5D-5L index table.

The equation for calculating the index score is as follows (using scores seen in appendix 12):
EQ-5D-5L Index=1-(Mobility+Selfcare+Activities+Pain+Anxiety)

4.1.3 KOOS-PS

The short form knee injury and OA outcome score (KOOS-PS) uses seven domains to measure the physical function of the knee. These measures are kneeling, twisting/pivoting, squatting, bending to the floor, rising from sitting, putting on socks/stockings and rising from bed. Each of these measures are scored between 0 (no difficulty at all) to 4 (extreme difficulty/unable to do). Similar to the EQ-5D-5L an overall score can be calculated to indicate overall knee function.

The short form KOOS-PS has responses to each of its seven domains as 0 to 4 for no problems and extreme difficulty/unable to do respectively. There are two ways to show an overall difficulty value with KOOS-PS, the version used for this evaluation ranged from no difficulty (0) to extreme overall difficulty (100). The score from each of the seven domains are summed (0 to 4 for each), then this total score is used on the look up table which can be found in appendix 13.

4.1.4 Statistical analysis

For the statistical analysis of changes between baseline and month three, the 'Related-Samples Wilcoxon Signed Rank Test' was used to determine if the median value of groups were significantly different. For the correlations between user feedback and clinical data, Pearson's correlation coefficient was used. SPSS was used to perform all statistical calculations.

4.2 Medication use

As part of the data collected through the user diaries and interviews, patients were able to indicate the types of medication they were using to help with pain associated with the knee. The categories used for this were as follows:

- **None –** No medications used at all.
- **Non-pharmacy OTC –** Over the counter medications that did not require pharmacy permissions (e.g. paracetamol, ibuprofen).
- **Pharmacy OTC –** Over the counter medications that could only be sold via a pharmacist (e.g. Co-codamol).
- **Prescription –** Medications that require a prescription from a doctor to be issued (e.g. Tramadol, codeine).
- **Monitored medications –** Medications that require prescription and are also monitored due to high chances of addiction or complications (e.g. Gabapentin, Oramorph).

4.3 Participant feedback

After three months had passed from the initial consultation, patients were invited for a final consultation appointment which took place either in the clinic room at CRC, PPH or as a virtual appointment conducted over the telephone. This final interview was a chance to gather any missing data and to ask the participant about their thoughts on the device and its potential use with patients who have OA of the knee. Please see appendix 14 for the questions asked of the patients during the final interview.

In addition to the above questions, patients were also asked for general feedback about their experience. Feedback was also provided by patients in the user diaries (for those that had completed them) which contained information about the device mode used, how they were placing the electrodes and general comments about use throughout the three-month period.

4.4 Usability evaluation (ATiC)

This service evaluation was a collaboration between HDUHB (TriTech) and the assistive technologies innovation centre (ATiC). For this collaboration HDUHB (TriTech) focussed on the patient and clinical aspects whilst ATiC carried out a user experience (UX) evaluation on the same patients. The patients that were taking part in the service evaluation were told about the UX elements during the initial consultation, if they were interested in taking part, they were asked to complete a separate questionnaire that they could send to ATiC so they could be contacted separately. Some of the data collected for the UX evaluation was captured using weekly diary pages that were issued to patients during the initial consultation (appendix 8).

The data captured using these weekly diary pages were:

- Pain numeric rating scale (NRS) (as an average pain score over the previous seven days).
- Number of uses per day/week.
- Device settings used.
- Placement of the device electrodes.
- Feedback for use in the UX evaluation.

4.4.1 Correlation of clinical and UX data

A number of user experience elements (UX) were collected by ATiC as part of their evaluation. These were correlated against the clinical measured outlined in previous sections and also against qualitative feedback collected during the final interviews with the patients involved. The UX elements included the early satisfaction score collected by ATiC during telephone interviews at around four weeks, the data collected during the final interviews and total device use data available in user diaries. Please see appendix 15 for the full list of correlation data types used.

4.5 Clinical workforce feedback

For the clinical workforce feedback, one-to-one interviews were conducted with key staff from the health board. These interviews were conducted with a consultant orthopaedic surgeon, a physiotherapist working in orthopaedics and specialist pain nurse. The interviews were all conducted over Microsoft Teams during clinical/working hours. The themes explored during the interview included thoughts on the device, how they thought the device would impact patients and typical knee arthroplasty patients. Please see appendix 16 for the full list of questions asked during these interviews.

5. Results

5.1 Value based/ clinical outcomes

30 patients were included in the evaluation, only 22 were included in the statistical analysis that follows. Eight patients were not included as four were non-responsive to follow ups and four had early unplanned/emergency knee surgery. These were excluded from the analysis as those non-responsive had incomplete data sets and those who had early surgeries would have introduced bias into the results.The availability of the data types can be seen in appendix 17. The data collected for Pain NRS, EQ-5D-5L and KOOS-PS had 22 patients with baseline and month three data available. This data was not normally distributed in nature so non-parametric tests were appropriate. The variances between baseline and month three were similar for the three clinical metrics (Pain, EQ-5D and KOOS-PS), and this data was 'paired' and the related samples Wilcoxon Signed Rank Test was used to compare medians. User feedback collected, indicated the total number of device uses over the three-month period, this data was used to order the patients in terms of the use statistics. The whole group (n=22) was split into a 'least' use group (n=11) and 'most' use group (n=11) from this ordered data.

For the statistical analysis, the null hypothesis that was tested as part of the VBHC/Clinical analysis, was: "the median differences between baseline and month 3 equals 0". This was undertaken for all three clinical measures (Pain NRS, EQ-5D-5L and KOOS-PS) for the group as a whole, 'least' group, and 'most' group. The summary results for these 9 tests are available in table 1 below. Statistical significance is highlighted in table 1.

5.1.1 EQ-5D-5L results for the whole group

It was possible to plot and look at the domains of the EQ-5D that changed during this time. Appendix 18 shows the changes in EQ-5D domains for the 22 patients who had baseline and month three data available. These values are the average (mean) of each domain for all 22 patients. These changes are for indication purposes only and do not represent statistical significance. Figure 1 shows a radar plot of these average (mean) changes in EQ-5D-5L domains for the 22 patients.

Group	N	Clinical measure	Significance (p)	Baseline median	Month 3 median	Result of Wilcoxon rank test
Whole	22	Pain	0.788	7	7	No change
Whole	22	EQ-5D-5L	0.044	0.6195	0.4425	Worse QoL
Whole	22	KOOS-PS	0.020	47.3	51.2	Worse knee scores
Least	11	Pain	0.083	6	8	No change
Least	11	EQ-5D-5L	0.110	0.691	0.479	No change
Least	11	KOOS-PS	0.013	44	51.2	Worse knee scores
Most	11	Pain	0.297	7	7	No change
Most	11	EQ-5D-5L	0.285	0.548	0.406	No change
Most	11	KOOS-PS	0.767	48.5	51.2	No change

Table 1 - Shows the hypothesis testing results for the differences between baseline and month three for the clinical measures (Pain, EQ-5D-5L, and KOOS-PS).

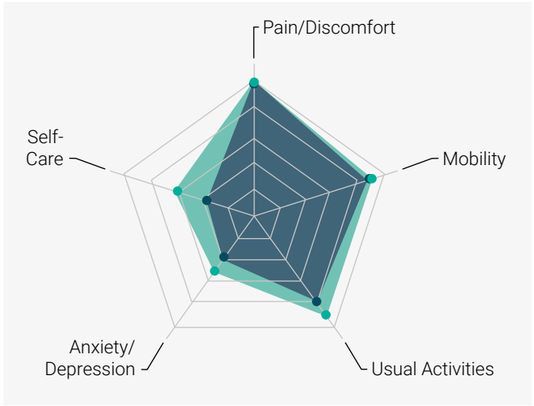


Figure 1 - Shows a radar plot of the changes in EQ-5D domains, dark blue is the baseline, light green indicates the month three data.

5.1.2 KOOS-PS results for the whole group

KOOS-PS difficulty scores increased during the three-month period across all 22 patients with complete data. It was possible to plot and look at the domains of the KOOS-PS that changed during this time. Appendix 19 shows the changes in KOOS-PS domains for the 22 patients who had baseline and month three data available. These values are the average (mean) of each domain for all 22 patients. These changes are for indication purposes only and do not represent statistical significance. A radar plot of these average changes can be seen in figure 2.

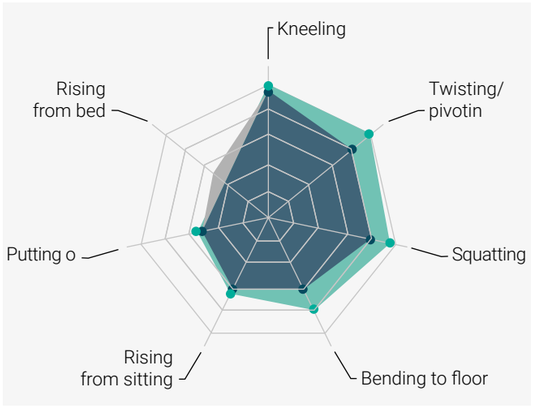


Figure 2 - Shows a radar plot of these changes in KOOS-PS domains, dark blue is the baseline. light green indicates the month three data.

5.2 Medication use

The summary results for pain medication use and whether or not the participant had changed their pain medication amount can be seen in appendix 20, in addition to the change in pain score from baseline to month three. When looking at the 22 patients who had baseline and month three data, eight (36.36%) were using non-pharmacy OTC such as paracetamol and ibuprofen, nine (40.9%) were using pharmacy OTC such as co-codamol, three (13.63%) were using no medication, one (4.54%) was using prescribed medication such as tramadol and one (4.54%) was using a monitored medication such as Gabapentin.

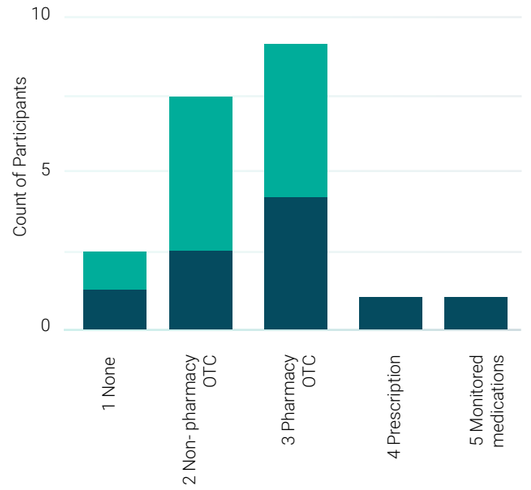


Figure 3 - Shows a stacked bar chart for strongest medication type separated into "least" (in dark blue) and "most" (in light green) groups.

The two patients who were on either prescription or monitored medications were both in the 'least' use group. Figure 3 shows the split of 'least' and 'most' groups across medication type. Note, that two patients in the 'least' group and three in the 'most' group had increased their dosage of pain medications between baseline and month three, none indicated an increase in medication type or strength. No patients indicated they had decreased their overall pain medication use from baseline to month three.

5.3 Participant feedback

The comments collected from patients during the final interviews can be seen in appendix 21, which also includes comments collected in the diary pages for those that completed them.

To summarise these responses, a number of themes were extracted with an indication of participant numbers (n) in each. These themes with a summary explanation are detailed below.

5.3.1 No feedback at all (3)
Some patients had no specific feedback, were unavailable for final comments and/or did not complete the user diaries.

5.3.2 Had difficulties with the device or its use (3)
One participant had additional pain whilst using the device. Others had issues with time commitments and were not able to use the device very often. This time consideration was not limited to this theme and others who felt benefits but had busy jobs also reported difficulties with finding time to use device.

5.3.3 Liked the device but it did not help with pain (6)
The feedback from these patients was positive towards the device, reporting ease of use, portability, and design as positive factors. But these patients did not report any benefit for the pain in their knees, or very little/temporary pain relief.

5.3.4 Device didn't help with the pain, but gave other benefits (3)
There were some examples of benefits to patients that did not include pain relief, such as reduced swelling around the joint, reduction in frequency of cramps leading to better sleep and increased range of motion.

5.3.5 Device helped with knee pain and other benefits (5)
A number of patients did report that the device helped with their pain in a meaningful way.

There were also comments from these patients about benefits with activity levels and the portability helping with use on vacations and use at work.

Appendix 22 shows the table of results for responses collected during the final interviews with patients. This includes device use, final satisfaction, final benefit, and Likert scale responses to questions regarding the device use with OA and the need for knee replacement surgery (as outlined in the methodology section). Appendix 23 also shows the graphs of the data presented in appendix 22. The key points from this data are as follows.

5.3.6 Device use frequency
The number of individual device uses was determined using data from the user diaries (where available) and from interview feedback. The total use ranged from 0 (for those that did not use the device at all) to the highest use case of 198 (for someone using several times a day for the entire 3 months).

5.3.7 Satisfaction score
The satisfaction score ranged from 0 (not satisfied at all) to 10 (very satisfied). Appendix 23, graph [1] shows the range of satisfaction scores from patients and this is separated into the 'least' and 'most' categories. There is a mixed response for satisfaction from both 'least' and 'most' groups. This may be due to the satisfaction score being related to their overall experience with the device and not just with the potential pain relief. Some of the 'least' group were scoring high on satisfaction even if they did not use it much or get any benefit because they liked the device. Similarly, some in the 'most' group scored lower in satisfaction as they had used the device regularly over an extended period of time without benefit.

5.3.8 Benefit score
The benefit score was a 0 to 10 value which the patients used to indicate if the device had a positive effect on their knee pain or not, with 10 being the highest benefit. Appendix 23, graph [2] shows the range of benefit scores and is separated into the 'least' and 'most' categories. The patients who felt no real pain relief score low on benefit even if they liked the device and were in the 'most' use category.

There is a correlation between the benefit score and satisfaction score, this is covered in more detail in the 'correlation of clinical and UX data' in the next section of this report.

5.3.9 Can TENS help with knee pain
This was a question asked of the patients during the final interviews, the full question was "Do you think this kind of technology (TENS) can be beneficial to patients who are suffering with knee pain associated with OA?". The responses were on a Likert scale ranging between 'strongly disagree' to 'strongly agree'. The 'least' group had a mixture of responses but many of them resulted in 'agree', the 'most' group who provided an answer all responded, 'strongly agree'. During the interviews the 'least' group patients who did not feel a benefit personally still agreed that this could help others, even if it did not help themselves. Appendix 23, graph [3] shows the Likert scale responses, 82% of 'most' group strongly agreed and 64% of 'least' group agreed/strongly agreed.

5.3.10 Is knee surgery the only solution
This was also a question asked during the final interviews that had a Likert scale response. The full question was "do you think that knee replacement is the only real solution to the pain associated with OA?". Both 'least' and 'most' groups had a majority of responses in the 'strongly agree' or 'agree' category. Even those that had a benefit from the device commented on pain relief being a temporary measure only. Some of the patients had also already had one of their knees replaced and commented on how much better it felt afterwards. One participant in the 'most' had a 'disagree' response and commented that they felt the surgery may not always be successful and other methods for pain relief need to be researched. Appendix 23, graph [3] shows the Likert scale responses, 64% of 'most' group agreed/strongly agreed and 64% of 'least' group agreed/strongly agreed.

5.3.11 Device mode usage
The device had six modes of use, the user diaries that were given to patients had space where they could indicate which mode had been used and where they were placing the electrodes for each use. The diary pages were completed each week and using this information it was possible to determine a 'most used mode' for each of the patients. Appendix 24 shows the satisfaction and benefit scores mapped to the mode most used by the patients. Modes one and four on the device were the 'Pain+' modes and have been coloured green in appendix 24 for indication purposes. The four patients that used 'Pain+' had the higher satisfaction and benefit scores than those that used other modes.

5.4 Correlation of clinical and UX data

The complete correlation data between clinical and user experience elements can be found in appendix 25. Table 2 shows a summary of the correlations between data types that were statistically significant.

The correlations which were not significant can be seen in appendix 19. A p value of < 0.05 is considered statistically significant, p values of < 0.01 are highly statistically significant which are highlighted below. Pearson's correlation coefficient was used for these calculations.

5.4.1 Satisfaction, benefit, and pain scores
The two correlations which had high statistical significance were 'early satisfaction and benefit score' and 'final satisfaction and benefit score'. These factors were all related to the user experience of the device. The early satisfaction score was captured by ATiC during telephone interviews with patients after approximately four weeks of use. The final satisfaction and benefit score correlation could be explained by from those patients who had better pain relief were also more satisfied overall with the device.

The early satisfaction score correlates significantly with both final benefit and change in pain NRS score, this may indicate that patients who were rating highly on the early satisfaction scores were also experiencing pain relief benefits in the early stages (within the first four weeks). This relationship needs further exploration as change in pain NRS was not correlated significantly with the final benefit or final satisfaction scores.

Correlation	Pearson's coefficient (r)	Significance (p)
Age & change in EQ-5D	-0.048	0.0229
Age & UX final satisfaction	-0.48	0.0446
Age & UX benefit score	-0.57	0.0131
UX early satisfaction & change in pain NRS	-0.6	0.0495
UX early satisfaction & UX benefit score	0.92	0.0001
Change in EQ-5D & UX final satisfaction	0.48	0.0429
Change in EQ-5D & UX benefit score	0.5	0.0348
Change in pain NRS & UX total uses	-0.46	0.033
UX total uses & UX benefit score	0.49	0.0395
UX final satisfaction & UX benefit score	0.71	0.0009

Table 2 - Shows the statistically significant correlations between clinical and user experience data.

5.4.2 Age of patients

The age of patients correlated significantly with final satisfaction and final benefit scores. These two correlations were inverse in nature which could mean that younger patients were more likely to feel a benefit and be satisfied at the end of the evaluation period than older patients.

5.4.3 EQ-5D-5L changes

Age, final satisfaction, and final benefit scores all correlate significantly with changes in EQ-5D-5L index scores. As a whole group (22 patients) the EQ-5D-5L index scores see a significant decrease (see value based/clinical results).

Age correlated negatively with EQ-5D-5L index scores which could indicate that older patients see a larger decrease in index scores than younger patients.

Looking at the average changes in EQ-5D-5L domains across the whole group with complete data (22 patients, see figure 1), the largest changes were in self-care, with smaller changes also seen in anxiety/depression and usual activities. The was little change in pain/discomfort (this is confirmed on the pain NRS results in the value based/clinical results section) or mobility. The correlation with change in EQ-5D-5L, satisfaction and benefit scores may indicate that those who rated the device, and its benefits higher may also have seen smaller decreases in the self-care and usual activity domains of the EQ-5D-5L.

5.4.4 Device use

Change in pain NRS and final benefit score both correlated with total number of device uses during the course of the evaluation. This indicates that more frequent device use has a relationship with the reduction in pain scores and overall benefits felt by the patients.

5.5 Clinical workforce feedback

The full feedback notes from the clinicians can be found in appendix 26. The summary findings for the questions asked during these interviews are below.

5.5.1 Dimensions, weight and appearance of the device

There was a consensus between all three clinicians that the device was well presented and they were pleased it was smaller and easier to manage than other TENS devices in clinical use.

5.5.2 Controlling the TENS

There were mixed responses regarding the control aspects of the device. There was a comment about the pain modes being unorganised (why are the pain+ modes not together?) and that having fewer modes might make this easier to use. Selecting the different modes was easy enough but this could become difficult if the device was placed out of sight. A digital display may prove beneficial for some clinical applications.

5.5.3 Charging, quality, length of cable and packaging of the device

Staff comments towards the charging, quality, length of cable and packaging of the device were overall positive. Some staff commented on the need for a longer cable between electrode sights for larger patients or for use in places other than the knee. Overall, staff were in agreement that the product was of a high quality.

5.5.4 Consumable electrodes

Only one comment was received on the ‘stickiness’ of the electrode and that some patients might need to shave prior to use.

5.5.5 Instructions for use

There were generally favourable responses regarding instructions for use. The clinicians preferred the larger more detailed guide that was produced between ATiC and TriTech over the small guide that comes within the box.

5.5.6 Method of operation

Staff agreed that the device was easy to use but the large number of modes and the many audible beeps heard when changing intensity might be difficult for some patients to follow and keep track of. The interviewees also commented on the order of the pain modes, and that this could be simplified.

5.5.7 Clinical potential and recommendations

Staff commented that the clinical potential would depend on the results seen in evaluations and future clinical trials, but were positive about the potential for the device to be used in a clinical setting. The benefits to patients might be more pronounced earlier in the patient pathway, when OA has been diagnosed but has not progressed to a stage where surgery is being offered. This opinion was echoed by the physiotherapist who was interviewed; he felt that the device could benefit patients who were on a prehabilitation programme that was launched in the health board last year.

Prehabilitation is defined as a process of improving the functional capability of a patient prior to a surgical procedure so the patient can withstand any postoperative inactivity and associated decline. The pain nurse also suggested this small wearable device could really help with inpatients on the ward as they use similar technologies already.

5.5.8 Typical patient journey for osteoarthritis of the knee

Patients with knee pain start with accessing physiotherapy or seeing their GP. A GP would refer to a physiotherapist for assistance (if not already doing so). The community musculoskeletal assessment team (CMAT) are involved in the early stages of assessment. An X-Ray is usually undertaken in the early stages to assess the condition of the bone. After an X-Ray has been undertaken a consultant is usually brought in to advise, at this stage the patient will be given tools and instructions on self-care in addition to their physiotherapy to keep the knee function as high as possible to slow the degeneration of the joint if OA has been confirmed.

Patients will be put onto the waiting list for total knee arthroplasty once all other avenues have been explored. At this stage, it usually means that a patients' OA has progressed to such a state that daily activities and quality of life are becoming severely affected.

Courses run by physiotherapists can help prepare patients for surgery. The speed at which patients progress through this pathway can vary widely, as the onset and progression of OA can differ between patients.

6. Conclusion

This project was designed and conducted as a 'real world' evaluation in a particular patient demographic. Patients were encouraged to explore its use and feedback as much as they possibly could through the user diary and interview sessions. This work has resulted in a large data set that has set the foundations for many follow-on projects that could either be evaluative or research. The paper written by Johnson (2021), described the long-Standing Uncertainty about the Clinical Efficacy of Transcutaneous Electrical Nerve Stimulation (TENS) to Relieve Pain. A different approach has been required for some time, to begin tackling some of these issues and this hybrid user experience together with the clinical evaluation may provide a new approach to the issues seen in this field for decades.

There are many factors which can be investigated following on from this 'real world' evaluation. Clear benefits have been suggested from our clinicians in relation to supporting OA patients earlier in their treatment pathway (such as primary care, early physio stages).

With the exception of KOOS-PS, the current PROMS recommended by ICHOM may not be the most suitable for quantifying the benefits of a TENS device but monitoring activity levels and other physiological outcomes might be. Understanding the reasoning behind early satisfaction and response to TENS will be important when designing future research and evaluation work.

A correlation between age of patients and perceived benefit of the device was detected, indicating that younger patients were more likely to report a positive impact and satisfaction when using the device regularly.

A full value-based analysis of a medical technology requires a very large amount of data collected over an extended period of time (100s of patients for 12 months or more), however this evaluation was still able to highlight areas that would benefit from further exploration that could lead to value-based benefits.

The pain and EQ-5D-5L scores were unchanged between baseline and month three for the patients included within this evaluation, when considered as whole group (n=22) or by 'least' (n=11) and 'most' use groups. The user experience data indicated that patients who used the device more regularly had increased confidence in daily activities and other secondary effects that might explain no reduction in their knee function. Some of the other secondary benefits seen in some patients included reduced knee swelling and improved sleep. TENS may not be effective for pain (Reichenbach et al., 2022), but this evaluation demonstrates that there may be other benefits that should be explored further.

Long standing uncertainty regarding TENS use for patient benefit is limited by a lack of understanding around responders and non-responders to the technology. Through the inclusion of user experience elements within this evaluation we generated additional data in relation to activity levels and sleep quality of those who used the device regularly. This data help steer future evaluations and research in this area.

Recommendations

From the results of this evaluation, several recommendations have been suggested.

These recommendations have an order of priority with recommendation one suggested as the next evaluation or research step.

Recommendation 1: Exploration of TENS response factors

One of the key issues affecting TENS research is understanding those who respond and those who don't respond to the stimulation effects. Preliminary usability data suggested younger, more active individuals adopt the technology more readily, but a further evaluation to investigate the factors that affect response and non-response in more detail will aid in further study design.

Recommendation 2: Evaluating activity levels and sleep with TENS efficacy

Patients who used the device the most did not see a decline in KOOS-PS scores (Knee function score). The results of this evaluation indicated that activity levels, exercise and sleep were reported benefits from using the device in the patients who used it the most. These factors were not quantified during this evaluation. A further evaluation of the device whilst monitoring activity levels, sleep quality and confidence in activities is recommended.

Recommendation 3: Prescriptive research study

A clinical research study with a more prescriptive protocol, including the use of only certain modes or frequency characteristics and a specified number of uses per week would also address some of the uncertainty with TENS issues such as consistency in methodology. If this is undertaken whilst following recommendation two, the data collection could also include activity levels and sleep quality (provided the evidence supported this).

Recommendation 4: Development of an effective 'placebo TENS'

A lack of effective placebo TENS devices for randomisation and blinding of treatment interventions, is a limiting factor for research studies. The development and testing of an effective 'placebo TENS' would greatly benefit any larger scale randomised controlled trial (RCT).

Recommendation 5: Multi-site RCT with a 'run-in' phase

Another issue relating to the uncertainty with TENS use is the current lack of well-designed multi-centre RCTs. A recommendation from the literature is to have a 'run-in' phase for a multi-centre RCT where patients are identified as responders or non-responders for the recruitment in the early stages (Johnson, 2021). Completion of recommendation 1 could generate evidence to support this 'run-in' phase.

References

1. Arthritis Research Campaign. Arthritis: The big picture. London. Arthritis Research Campaign, 2002. Available from: www.arc.org.uk.

2. Carroll, D.; Moore, R.A.; McQuay, H.J.; Fairman, F.; Tramer, M.; Leijon, G. Transcutaneous electrical nerve stimulation (TENS) for chronic pain. Cochrane Database Syst. Rev. 2001, CD003222.

3. Clement, N. D., Scott, C. E. H., Murray, J. R. D., Howie, C. R. & Deechan, D. J. (2021) The number of patients "worse than death" while waiting for a hip or knee arthroplasty has nearly doubled during the COVID-19 pandemic; The British Editorial Society of Bone & Joint Surgery doi:10.1302/0301-620X.103B.

4. Cui, A., Li, H., Wang, D., Zhong, J., Chen, Y. & Lu, H. (2020) Global, regional prevalence, incidence and risk factors of knee osteoarthritis in population-based studies; Published:November 26, 2020DOI: https://doi.org/10.1016/j.eclinm.2020.100587

5. Dailey DL, Vance CG, Rakel BA, Zimmerman MB, Embree J, Merriwether EN et al. A Randomized Controlled Trial of TENS for Movement-Evoked Pain in Women with Fibromyalgia. Arthritis & rheumatology (hoboken, NJ). 2019.

6. EuroQol (2022) EQ-5D Index set calculators; https://euroqol.org/support/analysis-tools/index-value-set-calculators/ (Last accessed: 10/02/2023).

7. Farrow, L., Gardner, W. T., Tang, C. C., Low, R., Forget, P. & Ashcroft, G. P. (2023) Impact of COVID-19 on opioid use in those awaiting hip and knee arthroplasty: a retrospective cohort study; http://dx.doi.org/10.1136/bmjqs-2021-013450

8. Johnson, I. M. (2021) Resolving Long-Standing Uncertainty about the Clinical Efficacy of Transcutaneous Electrical Nerve Stimulation (TENS) to Relieve Pain: A Comprehensive Review of Factors Influencing Outcome; Medicina 2021, 57, 378. https://doi.org/10.3390/medicina57040378

9. Jordan K, Jinks C, Croft P. A prospective study of the consulting behaviour of older people with knee pain. British Journal of General Practice. 2006; 56(525):269-276.

10. Jordan K, Clarke AM, Symmons DP, Fleming D, Porcheret M, Kadam UT et al. Measuring disease prevalence: a comparison of musculoskeletal disease using four general practice consultation databases. British Journal of General Practice. 2007; 57(534):7-14.

11. National Institute for Health and Care Excellence (NICE) (2014) Osteoarthritis Care and management in adults; Clinical guideline CG177 Methods, evidence and recommendations.

12. National Institute for Health and Care Excellence (NICE) (2022) Osteoarthritis Care and management in adults; Clinical guideline NG226 Methods, evidence and recommendations.

13. Murina F, Bianco, V., Radici, R., Felice R, Martino, M. Di. & Nicolini, U. (2008) Transcutaneous electrical nerve stimulation to treat vestibulodynia: a randomised controlled trial; BJOG: An International Journal of Obstetrics & Gynaecology Volume 115, Issue 9 p. 1165-1170.#

14. Peat, G., McCarney, R. & Croft, P. (2001) Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care; Ann Rheum Dis. 2001 Feb;60(2):91-7. doi: 10.1136/ard.60.2.91.

15. Price, A. J., Alvand, A., Troelsen, A., Katz, J. N., Hooper, G., Gray, A., Carr, A. & Beard, D. (2018) Knee Replacement; Lancet 2018; 392: 1672–82.

16. Public Health England (2021) Arthritis Research UK - Prevalence of osteoarthritis in England and local authorities: Birmingham.

17. Reichenbach, S., Jüni, P., Hincapié, C. A., Schneider, C., Meli, D. N., Schürch, Streit, S., Lucas, C., Mebes, C., Rutjes, A. W. S. & da Costa, B. R. (2022) Effect of transcutaneous electrical nerve stimulation (TENS) on knee pain and physical function in patients with symptomatic knee osteoarthritis: the ETRELKA randomized clinical trial; https://doi.org/10.1016/j.joca.2021.10.015

18. Scott, C. E. H., MacDonald, D. J. & Howie, C. R. (2019) 'Worse than death' and waiting for a joint arthroplasty; Bone Joint J 2019;101-B:941–950.

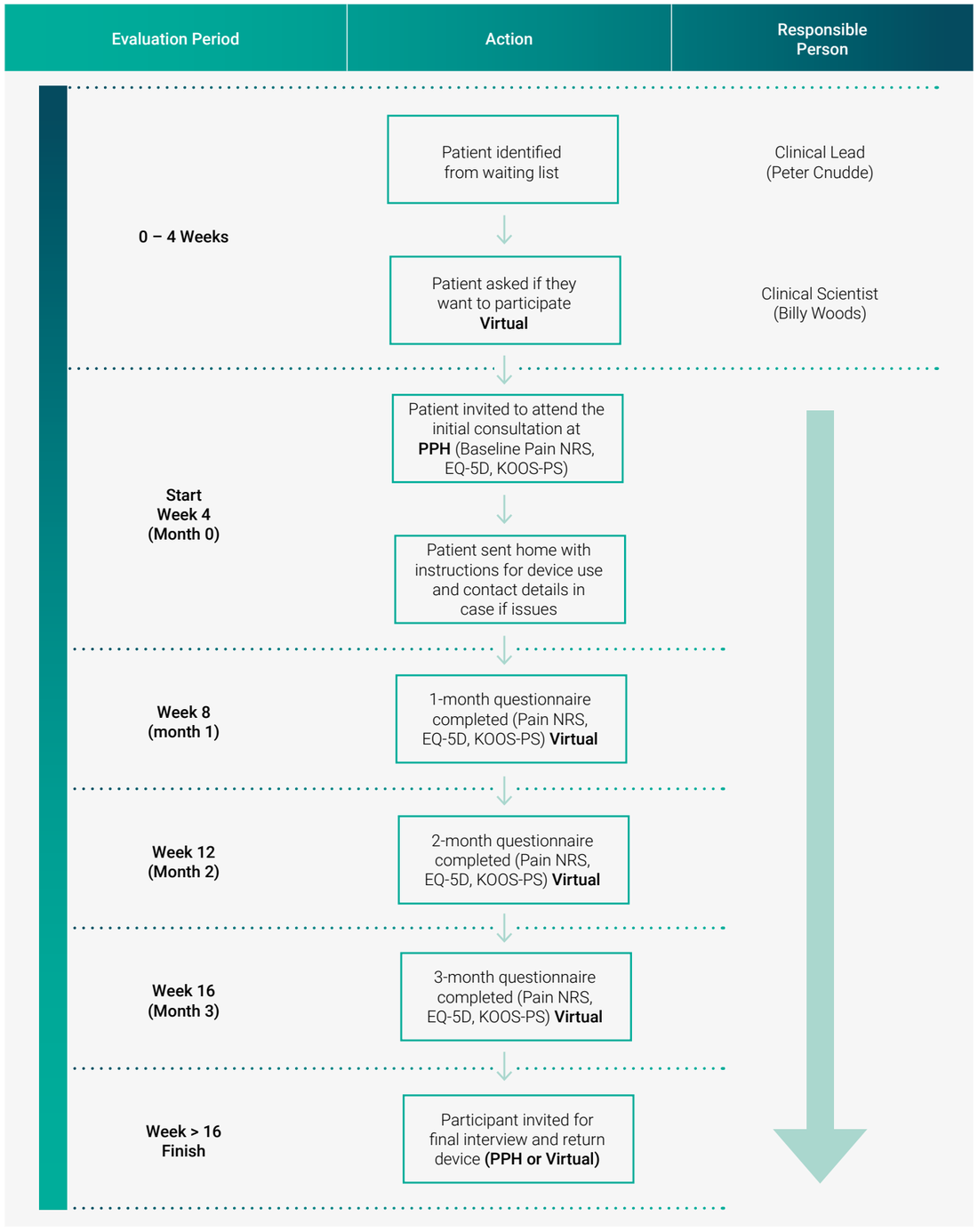
19. Sharma, L. (2021) Osteoarthritis of the Knee; N Engl J Med 2021; 384:51-59 DOI: 10.1056/NEJMcp1903768.

20. Sluka, K. A. & Walsh, D. (2003) Transcutaneous electrical nerve stimulation: Basic science mechanisms and clinical effectiveness; https://doi.org/10.1054/jpai.2003.434

21. Woolf AD, Pfleger B. Burden of major musculoskeletal conditions. Bulletin of the World Health Organisation. 2003; 81(9):646-656.

Appendices

Appendix 1 – Patient pathway



Appendix 2 – Patient screening notes

Osteoarthritis Evaluation: Patient Recruitment Summary Form (for patient medical notes)

A real-world service evaluation of a TENS device, for pain management in patients with osteoarthritis of the knee awaiting total knee replacement surgery

Hywel Dda UHB Site		Patient Study ID	
Principal Investigator		Date:	
Hospital Number			

I met _____ during their visit to **Dura Park / CRC**. I discussed the evaluation with them and gave them a Patient Information Sheet to read (version _____ dated_____).

The following was discussed with the patient;

- The aims and rationale of the evaluation.
- The voluntary nature of the evaluation.
- That the patient's standard care will not be affected if they decide to participate or not.
- The right to withdraw from the evaluation without giving a reason.
- What the patient's involvement in the evaluation will involve.
- The potential benefits & disadvantages of them taking part in the evaluation.
- The patient's privacy, data protection and confidentiality.
- The patients contact with primary care regarding their knee pain was discussed including; GP visits, physiotherapy or chiropractors.
- The patients medication relating to their pain, including type and dosage where possible
- The device and how it is used at home.
- The usability portion of the evaluation and they were also provided with a PIS for this to read (version _____ dated_____).

The patient was given an opportunity to consider the evaluation and ask questions that were answered to their satisfaction. The patient has given written and verbal consent on end of the PIS (Version___ dated_____) and they were given a copy of their consent by **post / email / in-person.** A copy has been filed in their medical notes & the signed original is retained in the Investigator Site File, along with the baseline data collected.

Additional comments:

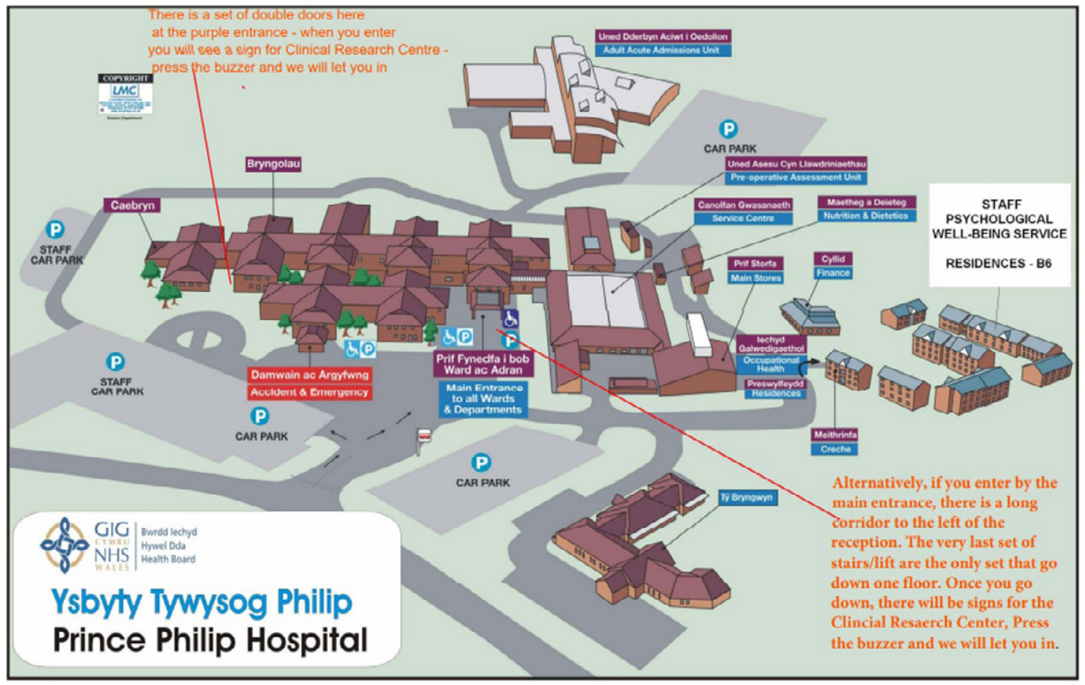
.....

.....

Name: Signed:

Title: Date:

Appendix 3 – CRC PPH map



Appendix 4 – Patient information sheet (PIS)

Hywel Dda University Health Board

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

OSTEOARTHRITIS KNEE PAIN MANAGEMENT EVALUATION PARTICIPANT INFORMATION SHEET

Version number: 09 **Date: 05-11-2021** **Site: PPH**

Evaluation Title: Evaluation of a TENS device as a complementary aid in the management of pain in osteoarthritis of the knee.

1. **Invitation and brief summary**

We are inviting you to take part in an evaluation of a TENS device used to help with pain treatment relating to osteoarthritis of the knee. This device is an approved medical device for the treatment of chronic pain and has been CE marked. Before you decide to take part in this evaluation, it is important that you understand why this evaluation is being conducted and what it would involve for you. You do not have to take part if you do not want to. Please read this information carefully and discuss it with friends, relatives, and your GP if you wish. Do not hesitate to ask us if there is anything that is not clear or if you would like additional information.

2. **What is the purpose of the evaluation?**

Transcutaneous nerve stimulation (TENS) devices have been shown to help with the management of pain, but more information is needed about how useful these devices are to patients who experience knee pain due to osteoarthritis.

This evaluation aims to assess the value of this device for use with patients who are suffering from pain caused by osteoarthritis of the knee. It will help to gain insights about how much this kind of device can help patients and may improve available services within the NHS.

This is a collaborative project between Hywel Dda University Health Board who are evaluating the use of these devices in a clinical service and the Assistive Technologies Innovation Centre (ATiC), who are investigating the ease of use and insights around these devices for patients and healthcare professionals alike.

3. **Why have I been chosen to take part?**

We have invited you to take part in this evaluation as you are a patient of Hywel Dda University Health Board on the waiting list for total knee arthroplasty. As someone who is receiving care whilst waiting for this procedure and who has pain in the knee due to osteoarthritis, you could help us to explore whether this type of device helps improve the service and patient experience.

4. **Do I have to participate in this evaluation?**

No. And if you do choose to participate you are free to withdraw at any time without giving a reason. Your care and treatment as a patient of Hywel Dda University Health Board will not be affected in any way if you choose to take part or not, or if you drop out part way through.

5. **What will happen to me if I agree to participate in the evaluation?**

If you choose to take part in the evaluation you will be invited for an initial consultation session with a clinical scientist from Hywel Dda University Health Board. This will take place at the clinical research centre at Prince Philip Hospital in Llanelli.

At this initial consultation the clinical scientist will explain the evaluation in more detail and ensure you understand what is involved. If you wish to continue you will then be shown the device and instructed on its safe use. You will also be provided with a diary where you can log your use of the device. The total duration of this evaluation is 12 weeks.

You will be provided with an instruction manual to take home to help you use the device. You will be asked to fill out questionnaires that we will provide to you during the initial consultation. The first questionnaire should be completed during or the same day as the initial consultation and the other questionnaires should be completed every 4 weeks until the evaluation is over. This is 4 questionnaires in total. A final consultation appointment will be planned for the 12-week point where you will be invited for a final consultation where the device will be handed back, at this point the evaluation will be complete.

6. How will I be kept safe from COVID-19?

The consultation space at both the CRC at Prince Philip Hospital for the initial consultation and the TriTech Institute office will be thoroughly cleaned between appointments, staff members will be wearing appropriate PPE and your contact with others within the buildings will be kept to a minimum. A waiting area with social distances measures in place will be available at both consultation locations will be available.

7. What will I have to do?

You will be guided through the manufacturer's guidance on the use of the device. The evaluation will involve using the device daily where possible, at home where you can comfortably sit or lie down for at least 20 minutes.

There are no restrictions on your lifestyle or usual activities if you take part in the evaluation, but you cannot use the device whilst in the shower or near water. Other than using the device daily if possible, we want you to continue your normal activities and all of your usual treatments and medications will be unchanged.

8. What are the possible benefits associated with me taking part in this evaluation?

We cannot promise the evaluation will help you immediately, but there is evidence of improvement in symptoms with the device. The information we get from this evaluation will help Hywel Dda University Health board to organise treatment options that are available to patients and to help ensure that medical devices are developed with ease of use and patient benefits in mind. Unfortunately, we cannot pay you for agreeing to take part in this evaluation.

9. What are the possible disadvantages and risks of participating in this evaluation?

This TENS device works by electrically stimulating the nerves that are close the surface of the skin. This is achieved by using two electrodes with a sticky surface that are applied to the surface of the skin. These electrodes will be positioned on/near the affected knee. It is possible that you may find the sensation of using this TENS therapy device uncomfortable, or you may find it difficult or time consuming to set up before use. If the sensation of the device in use is uncomfortable then you can try to reduce the intensity or to try one of the other settings.

These electrical stimulations have been shown to be very safe and present little risk of harm or injury, but some users may find the sensation uncomfortable. If you find the sensation uncomfortable you can stop using the device. Some users of TENS devices find that there is a slight discolouration of the skin after use, however this is harmless, and the skin will go back to normal colour after a short duration in time.

10. What will happen if something goes wrong?

If you have any concerns about this evaluation, we encourage you to raise your concerns as soon as possible.

This is an evaluation as part of your normal NHS care, participation will not change how you access any healthcare that you need. If you have a sudden and dramatic change in your pain levels or any other medical emergency, please call 999 as you normally would. For non-life-threatening symptoms please contact your GP as you normally would. Please do not make any changes to your prescribed medication unless you have been specifically instructed to do so by a qualified staff member within the NHS.

If you have any concerns about the device or its use, please stop using it immediately and contact one of the evaluation team as follows:

Email: Billy.wood@wales.nhs.uk
Phone: 07790 978507

Email: Peter.cnudde@wales.nhs.uk
Phone: 01554 783321 (Answer phone)

If you feel that you have any reason to complain about any aspect of the way you have been approached in the hospital or further treated during the course of the evaluation, the normal National Health Service complaints mechanisms are available to you.
www.wales.nhs.uk/ourservices/contactus/nhscomplaints

You can also contact the NHS concerns team:

Email: **hdhb.patientsupportservices@wales.nhs.uk**
Phone: **0300 0200 159**
Writing a letter to: FREEPOST FEEDBACK @ HYWEL DDA

11. Will my participation in this evaluation be kept confidential?

Yes, all the information collected about you during the course of the evaluation will be kept strictly confidential. Any information that leaves the hospital will be coded so you cannot be identified from it. In addition, we will not give any identifiable information to life insurance, private medical insurance companies or any other third parties.

12. What will happen with the results generated by this evaluation?

The results that are generated as part of this evaluation will be used by Hywel Dda University Health Board and ATiC to help develop better services and devices for patients and to give new insights into how patients currently manage their pain at home. The health board may wish to publish the evaluation findings. As stated previously you will not be identified in any written report unless you have given you express consent.

13. Who is organising and funding this evaluation?

This evaluation is being organised as a collaboration between Hywel Dda University Health Board and ATiC. The evaluation will follow standard care practices. The results will be analysed by the TriTech institute which is part of Hywel Dda University Health Board.

Contacts for further information:
For any advice about your knee care, please contact the joint replacement team at Prince Philip Hospital:

Email: Ben.Matthews@wales.nhs.uk (Preferably)
Phone: 01554 783321 (Answer phone)

For all other enquiries about the evaluation or you wish to know anything further about the device, please do not hesitate to contact the TriTech Institute:

Email: Billy.wood@wales.nhs.uk
Phone: 07790 978507

Email: Chris.tattersall@wales.nhs.uk
Phone: 01437 773813.

INFORMED CONSENT FORM - Version number 9 Date 05-11-2021

Evaluation Title: Evaluation of a TENS device as a complementary aid in the management of pain in osteoarthritis of the knee.

Participant Identification Number: **Site: Prince Philip Hospital**

Evaluation Team Leads: Peter Cnudde, Billy Woods

Contact Telephone Number: 07790 978507

Read carefully the following statements and, if you agree, please INITIAL (do not tick) the adjacent boxes.

		INITIAL BOX
1.	I confirm that I have read and understood the Participant Information Sheet – (Version number 9 05/11/2021) for the above evaluation. I have had the opportunity to ask questions, and I am happy with the answers given.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3.	If relevant, I understand that sections of any of my medical notes may be looked at by responsible individuals from the Evaluation Team or regulatory authorities where it is relevant to my taking part in this evaluation and the sponsor's representatives in Hywel Dda University Health Board for monitoring the conduct of the evaluation. I give permission for these individuals to have access to my records.	
4.	After the evaluation has finished, I agree that the device will be returned during the final consultation and that the use of the device is only intended for the duration of the evaluation.	
5.	I confirm that I understand that this device evaluation will not affect my waiting time for surgery or any other aspect of my care as a result of taking part.	
6.	I confirm that I have understood all the above-mentioned aspects and I agree to take part in this evaluation.	

Full Name of Participant (PRINT)	**Date:**	**Signature:**
Full Name of Person receiving consent (PRINT)	**Date:**	**Signature:**

Appendix 5 – Medical notes insert

Osteoarthritis Evaluation: Patient Recruitment Summary Form (for patient medical notes)

A real-world service evaluation of a TENS device, for pain management in patients with osteoarthritis of the knee awaiting total knee replacement surgery

Hywel Dda UHB Site		Patient Study ID	
Principal Investigator		Date:	
Hospital Number			

I met _____ during their visit to **Dura Park / CRC**. I discussed the evaluation with them and gave them a Patient Information Sheet to read (version _____ dated_____).

The following was discussed with the patient;

- The aims and rationale of the evaluation.
- The voluntary nature of the evaluation.
- That the patient's standard care will not be affected if they decide to participate or not.
- The right to withdraw from the evaluation without giving a reason.
- What the patient's involvement in the evaluation will involve.
- The potential benefits & disadvantages of them taking part in the evaluation.
- The patient's privacy, data protection and confidentiality.
- The patients contact with primary care regarding their knee pain was discussed including; GP visits, physiotherapy or chiropractors.
- The patients medication relating to their pain, including type and dosage where possible
- The device and how it is used at home.
- The usability portion of the evaluation and they were also provided with a PIS for this to read (version _____ dated_____).

The patient was given an opportunity to consider the evaluation and ask questions that were answered to their satisfaction. The patient has given written and verbal consent on end of the PIS (Version___ dated_____) and they were given a copy of their consent by **post / email / in-person.** A copy has been filed in their medical notes & the signed original is retained in the Investigator Site File, along with the baseline data collected.

Additional comments:

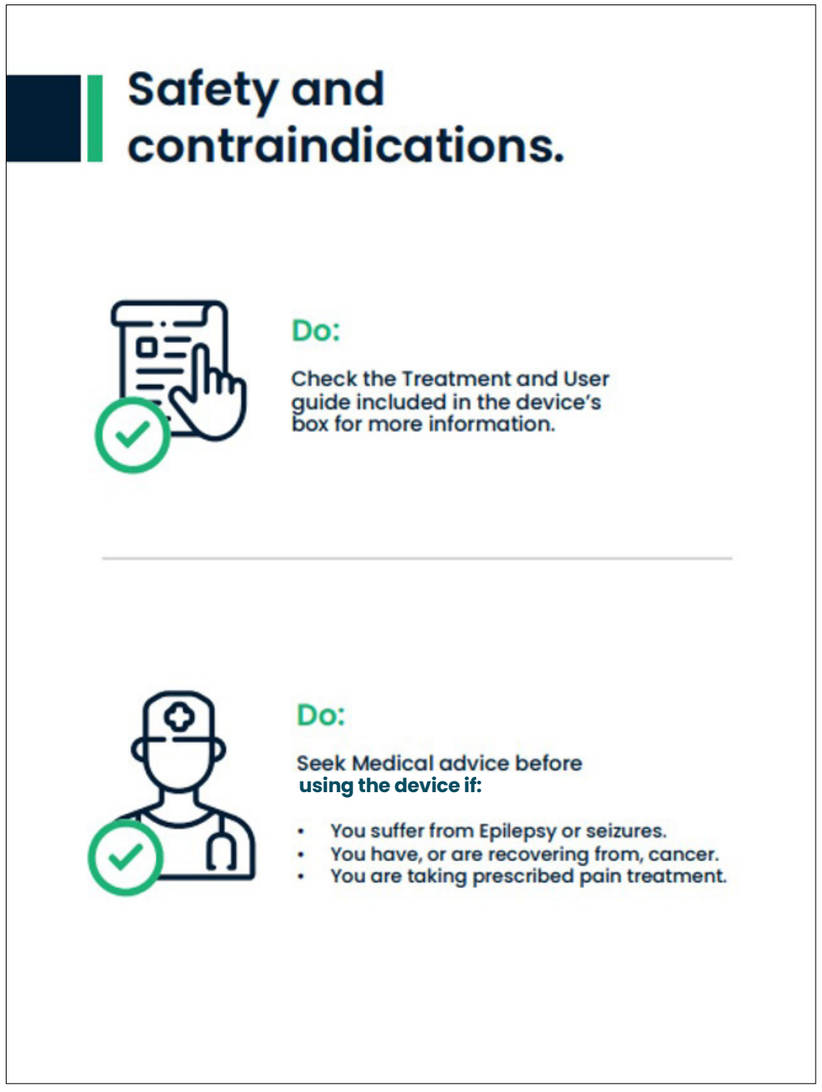
……

……

Name: Signed:

Title: Date:

Appendix 6 – Device use instructions



General User Instructions

Detailed guidance for your therapy with the device during the service evaluation

For best results, we ask you to explore the pain modes and experiment with what works best for you.

For this service evaluation we advise you to follow the below steps:

1. First 2 days start with the Pain+ program (1 or 4) and use it 1 to 2 times per day. Each session is automatically set for 20 minutes.
    a. Please try to adjust the intensity (+) or (-) button. You can increase the intensity but be careful, it should be a non-painful sensation. We recommend to select the highest intensity which is well tolerated by you.
2. If pain improves remain on this program.
3. If the pain does not improve, there are some options to try:
    a. Please try to use the Pain+ treatment modes more frequently. You can use it more than 2 times per day or can you increase the duration of your session from 20 minutes to for example 40 minutes.
    b. Please try the other Pain treatment modes. You can choose between 2, 5 and 6. Also, here you can try it more than 2 times per day or you can increase the duration of your session. Just like with the Pain+ treatment mode you can increase your intensity which can be tolerated well by you.
4. Treatment mode 3 can also be used but is not offering pain management

Appendix 8 – User diary weekly pages

Use Log
WEEK No:

When are you completing this week's use log?
Mon / Tue / Wed / Thu / Fri / Sat / Sun Date:_____

How has your knee pain been on average this week?
Please circle a number:

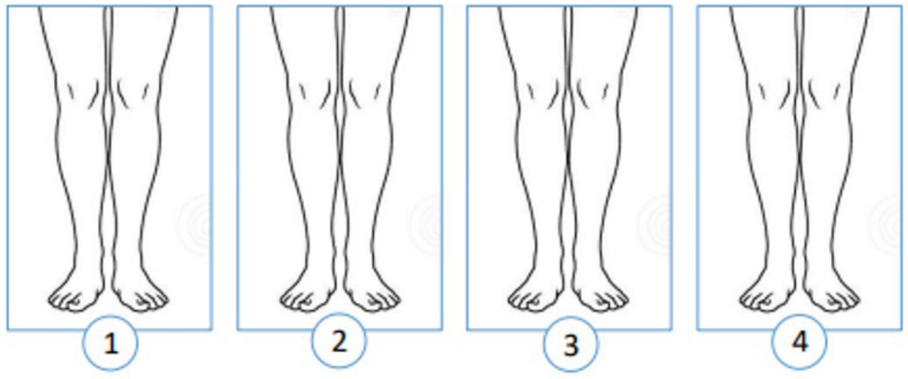
No pain at all 0__1__2__3__4__5__6__7__8__9__10 **Worst possible pain**

How many times have you used the device this week?

Day number:	1	2	3	4	5	6	7
Number of times used each day:	___	___	___	___	___	___	___
Which mode did you use the most: (Mode 1, 2, 3, 4, 5, or 6?)	___	___	___	___	___	___	___
Which intensity level did you use the most: (Intensity level 1 to 20?)	___	___	___	___	___	___	___

Have you tried placing the device on different locations on your knee this week ?

Add a + and − on the images to indicate the locations you have used this week



Which location did you find the most effective this week?
Please circle a number:

Location **1** Location **2** Location **3** Location **4**

Please turn over and complete the other side of this week's use log...

How was your experience using the device this week?
Please circle a number:

Very negative 0__1__2__3__4__5__6__7__8__9__10 **Very positive**

Tell us about your experience using the device this week, this may include positive and/or negative comments...

Negatives	**Positives**

How satisfied are you with the device this week?
Please circle a number:

Not satisfied 0__1__2__3__4__5__6__7__8__9__10 **Very satisfied**

Why was this?

Thank you for completing this week's use log. Don't forget to do the same again next week!

Appendix 9 – Questionnaire front sheet

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Hywel Dda
University Health Board

Participant

Date:

How has your knee pain been on average this week?
Please circle a number:

No pain at all 0__1__2__3__4__5__6__7__8__9__10 **Worst possible pain**

Has your pain medication use changed in the last 4 weeks?

- ☐ Using less pain medication
- ☐ No change
- ☐ Using more pain medication

If your pain medication has changed please give more details

Appendix 10 – Quality of life (EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY
- I have no problems in walking about ❑
- I have slight problems in walking about ❑
- I have moderate problems in walking about ❑
- I have severe problems in walking about ❑
- I am unable to walk about ❑

SELF-CARE
- I have no problems washing or dressing myself ❑
- I have slight problems washing or dressing myself ❑
- I have moderate problems washing or dressing myself ❑
- I have severe problems washing or dressing myself ❑
- I am unable to wash or dress myself ❑

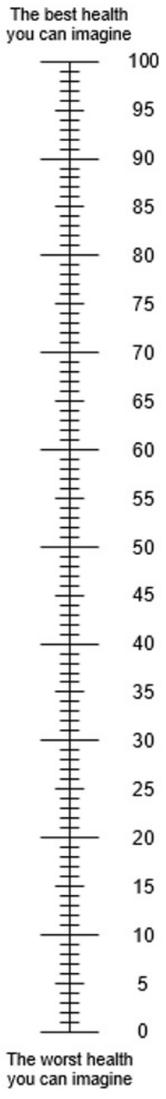
USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*
- I have no problems doing my usual activities ❑
- I have slight problems doing my usual activities ❑
- I have moderate problems doing my usual activities ❑
- I have severe problems doing my usual activities ❑
- I am unable to do my usual activities ❑

PAIN / DISCOMFORT
- I have no pain or discomfort ❑
- I have slight pain or discomfort ❑
- I have moderate pain or discomfort ❑
- I have severe pain or discomfort ❑
- I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION
- I am not anxious or depressed ❑
- I am slightly anxious or depressed ❑
- I am moderately anxious or depressed ❑
- I am severely anxious or depressed ❑
- I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Please mark an X on the scale to indicate how your health is TODAY.
- Now, write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Appendix 11 – Knee function score (KOOS-PS)

Knee injury and Osteoarthritis Outcome Score (KOOS) – Physical Function Shortform (KOOS-PS) English version

KOOS-Physical Function Shortform (KOOS-PS)

Today's date:_____/_____/_____ Date of birth: _____/_____/_____

Name: _____

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how well you are able to perform different activities.
Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can so that you answer all the questions.

The following questions concern your level of function in performing usual daily activities and higher level activities. For each of the following activities, please indicate the degree of difficulty you have experienced in the **last week** due to your knee problem.

1. Rising from bed

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

2. Putting on socks/stockings

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

4. Bending to floor

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

5. Twisting/pivoting on your injured knee

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

6. Kneeling

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

7. Squatting

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

Appendix 12 – EQ-5D-5L index score table

Score	Mobility	Self-care	Usual activities	Pain/ discomfort	Anxiety/ depression
1 (None)	0	0	0	0	0
2	0.058	0.05	0.05	0.063	0.078
3	0.076	0.08	0.063	0.084	0.104
4	0.207	0.164	0.162	0.276	0.285
5 (Extreme problems)	0.274	0.203	0.184	0.335	0.289

Index score reference table for the 5 domains of the EQ-5D-5L.

Appendix 13 – KOOS-PS lookup table

Raw summed score (0-28)	0 (no difficulty) to 100 (extreme difficulty)	Raw summed score (0-28)	0 (no difficulty) to 100 (extreme difficulty)
0	0.0	15	42.0
1	5.6	16	44.0
2	10.5	17	46.1
3	14.8	18	48.5
4	18.6	19	51.2
5	22.0	20	54.4
6	24.9	21	57.9
7	27.5	22	62.0
8	29.7	23	66.6
9	31.8	24	71.8
10	33.6	25	77.7
11	35.3	26	84.3
12	37.0	27	91.8
13	38.6	28	100.0
14	40.3		

Lookup table for KOOS-PS difficulty score.

Appendix 14 – Participant final interview questions

1. On a scale of 0-10 do you feel this device has been beneficial to you. (0 not at all, 10 very beneficial)

2. On a scale of 0-10 how satisfied are you overall with the device? (0 not satisfied at all, 10 very satisfied)

3. How often did you use the device?

4. Do you think electrical stimulation is a suitable interim solution for your pain whilst you wait for surgery?

5. Do you believe that the knee surgery is the only solution that will help with your knee pain?

Appendix 15 – Clinical and UX data types for correlation

- Age – Of participant at time of enrolment on to the study.
- UX First impression – was a score collected during the user experience questionnaire which was completed and sent to ATiC as the first part of the UX evaluation data collection.
- UX Early satisfaction – This was a score between 0 (not at all satisfied) and 10 (very satisfied) relating to how satisfied the patients felt overall with the device and its use around 4 weeks into the study. This data was collected during telephone interviews with ATiC.
- Change in EQ-5D – This was the change in EQ-5D index score from the first measurement (baseline) to the end of the study (month 3).
- Change in KOOS-PS - This was the change in KOOS-PS index score from the first measurement (baseline) to the end of the study (month 3).
- Change in Pain NRS - This was the change in pain score from the first measurement (baseline) to the end of the study (month 3).
- Change in self score (EQ-5D) – The EQ-5D questionnaire also includes a self-score, this was correlated separately to the EQ-5D index score.
- UX Total uses – Relates to the total number of uses as indicated by diary completions and final interview feedback.
- UX Final satisfaction score – Was the overall satisfaction score from the patients, 0 (not at all satisfied) and 10 (very satisfied). Collected during the final interview with patients at the end of month 3.
- UX Benefit score – This was the score given by patients to indicate how much the device helped them with their knee pain. Scored from 0 (no benefit at all), to 10 (greatly benefited knee pain).

Appendix 16 – Clinical workforce interview questions

1. **What do you think of the design of the device?**

    a. Any thoughts on;

    - The dimensions of the device
    - The weight of the device
    - The appearance of the device
    - The controls of the device
    - The charging of the device
    - The quality of the device
    - The length of cable
    - The packaging of the device
    - The consumable electrode pads

2. **What do you think of the instructions for use this device?**

    a. How does this compare with other devices you have given patients?

3. **What do you think of the method of operation of the device?**

    a. How does this compare with other devices you have given patients?

4. **Would this kind of device fit in to a real clinical service scenario?**

    a. If so how? If not, why?

5. **Would you recommend this kind of technology for knee osteoarthritis patients?**

    a. If so why? If not, why?

6. **Can you tell me about a typical patient journey up to the point they are added onto the waiting list for knee arthroplasty?**

Appendix 17 – Participant data availability

Note
Green – The data was available at the end of month three
Grey – The participant was excluded from the final analysis

Participant number	Baseline data collected in clinic	Usability Q returned	Month one clinical Q returned	Usability interview completed	Month two clinical Q returned	Month three clinical Q returned	Final interview completed	Notes
1								Had surgery, was put on the urgent list or went private
2								
3								
4								
5								Had surgery, was put on the urgent list or went private
6								
7								Had surgery, was put on the urgent list or went private
8								
9								No responsive to study/ not answering calls
10								
11								Still non responsive
12								No responsive to study/ not answering calls
13								
14								
15								
16								
17								
18								Had surgery, was put on the urgent list or went private
19								
20								No responsive to study/ not answering calls
21								
22								
23								
24								
25								
26								
27								
28								
29								
30								

Appendix 18 – EQ-5D-5L group average changes

EQ-5D domain	Baseline (mean)	Baseline (SD)	Month three (Mean)	Month three (SD)
Mobility	3.05	0.82	3.14	0.76
Self-care	1.27	0.54	2.14	1.10
Usual activities	2.68	0.55	3.09	1.16
Pain/discomfort	3.45	0.78	3.50	0.58
Anxiety/depression	1.41	0.72	1.73	0.86

Appendix 19 – KOOS-PS group average changes

KOOS-PS domain	Baseline (mean)	Baseline (SD)	Month three (Mean)	Month three (SD)
Kneeling	3.36	0.94	3.55	0.98
Twisting/pivoting	2.91	1.03	3.55	1.19
Squatting	2.86	0.89	3.36	0.97
Bending to the floor	2.23	1.04	2.77	1.20
Rising from sitting	2.18	0.67	2.32	0.58
Putting on socks	1.82	0.57	1.95	0.58
Rising from bed	1.82	0.81	1.59	0.88

Appendix 20 – Pain medication change summary

Participant number	Use group	Strongest medication type	Change in pain score	M3 change in meds
2	Least	Non-pharmacy OTC	2.00	No
3	Least	Pharmacy OTC	1.00	No
4	Most	Pharmacy OTC	1.00	No
6	Most	Non-pharmacy OTC	2.50	More
8	Least	Prescription	0.00	More
10	Most	Pharmacy OTC	1.00	More
13	Least	Pharmacy OTC	0.00	No
14	Most	Non-pharmacy OTC	-1.00	No
15	Most	Non-pharmacy OTC	-2.00	No
16	Least	Monitored medications	2.00	No
17	Least	Pharmacy OTC	-1.00	No
19	Most	Pharmacy OTC	-2.00	No
21	Most	Non-pharmacy OTC	-2.00	No
22	Most	Pharmacy OTC	-1.50	More
23	Most	Non-pharmacy OTC	1.00	No
24	None	None	1.00	No
25	None	None	2.00	No
26	Least	Pharmacy OTC	1.00	No
27	Least	Non-pharmacy OTC	-1.00	More
28	Most	None	-1.00	No
29	Least	Non-pharmacy OTC	0.00	No
30	Most	Pharmacy OTC	-1.00	No

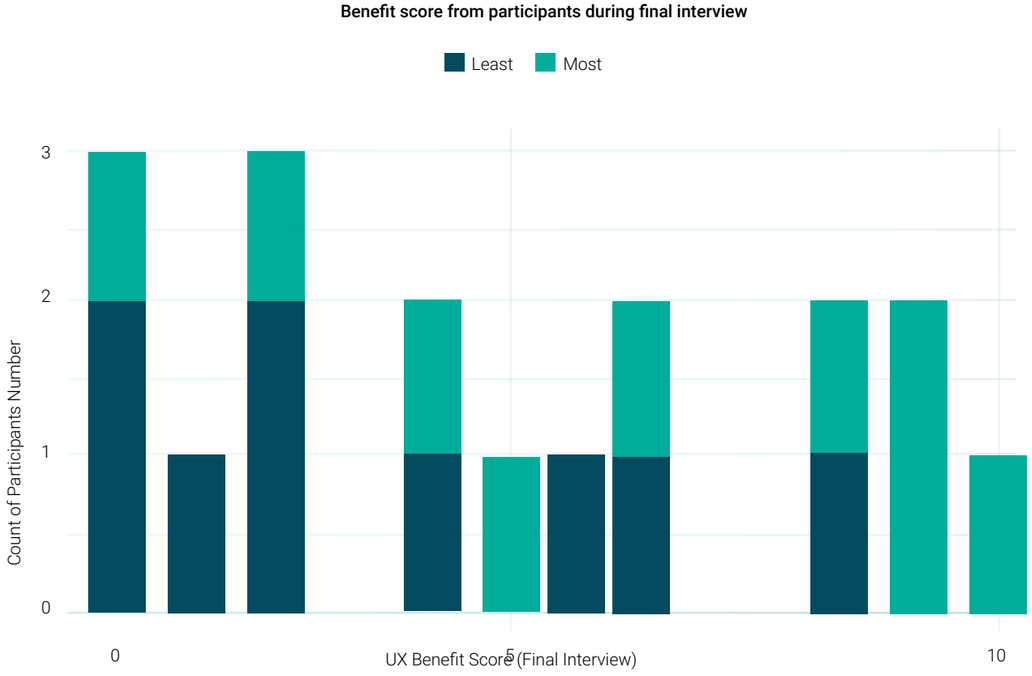
Appendix 21 – Participant comments

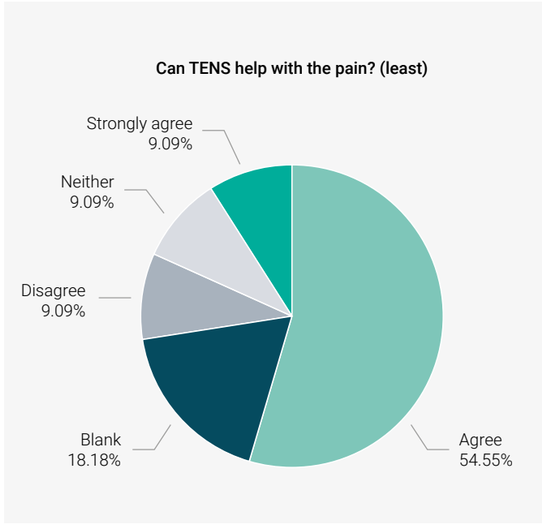
Participant number	Use category	Comments from final consultation	Comments from user diary
2	Least	Easy to use, but did not help much with the pain	None
3	Least	None	None
4	Most	Packaging and the device itself was good quality	No benefit to pain or quality of life experienced. Used for around 10 weeks consistently and it did not offer much in the way of relief
6	Most	Knee pain in general was getting much worse	Pain relief was subtle, but noticed some real benefits with regards to range of movement whilist walking. Helped ease the stiffness felt behinf the knee. Relaxing effect
8	Least	Had some difficulty using the device, and experience some painful sensations after it was used. They felt like this might be more beneficial to patients after the surgery as a rehab tool	None
10	Most	Initially found it fiddly to use, but after they had got used to it they took it everywhere. Very beneficial and enjoyed completing the user diary	Took this on holiday to Australia, really helped with the flight over. Become part of a routine and eased the additional pain felt taking long walks
13	Least	Pain relief was only temporary, but it did help with tenderness around the knee after long days at work	None
14	Most	Really pleased with the size of the device, but felt the double packaging was a bit much. The device was easy to use and provided a benefit to the pain.	Really helped ease the pain of walking, the pain relief was only temporary but was a great addition to medication. The biggest benefit reported was increased sleep quality
15	Most	Initially very impressed with the device, although it caused some extra pain after use. It didn't help a great deal with the pain, but was relaxing to use	Didn't help much with the pain, the knee was hetting worse throughout the evaluation period. Device was easy to use and set up
16	Least	Easy to operate, but did little for the pain	Nice to use, but no real benefit to the pain
17	Least	Easy to use and helped with the pain, but was very busy working in the ambulance service. Was beneficial for the first few weeks but the novelty wore off. Knee function was improving a bit, so ended up not using it	Found it easy to use and reaally healped with th epain at work, which is physically demanding. Didn't end up using it after the first 4 weeks or so as the knee was feeling a lot better
19	Most	No help with pain with swelling and cramps at night. Device was easy to use	Almost no benefit to pain associalted with the knee, but seems to have a beneficial impact on swelling, bruising and settles the joint down at night time. An increased quality of sleep was experienced with regular use of the device despite it not directly helping with
21	Most	Really helped with the pain, and was a great alternative when they couldn't take paracetamol. This would be great for travel. Exceeded all expectations	Found modes 1 and 4 the most beneficial, the device is easy to use. Really helped with the pain, this helped enough that some days pain medication was not needed. Has become part of a routine
22	Most	Time commitment for use of the device was a struggle, didn't feel much benefit. Brought more awareness of pain levels rather than relief. Very busy in general so dound it difficult to fit into routine use	No real benefit to pain seen
23	Most	None	Pain relief was only temporary, helped with muscle pain associated with walking and easy to use whilist at work
24	Least	Device was easy to use, didn't help much with the knee. Pain is worst whilist active	Didn't help at all with knee pain, but ended up using on lower back which was very beneficial
25	Least	Took a bit of time to get used to the device, didn't offer much benefit. but seemed to help with the pain a bit more when using for double sessions (40 min)	None
26	Least	Easy to use, but struggled to find time to use it. Was a busy farmer, on their feet for long periods throughout the day Didn't notice much of an effect for the pain, but didn't use it very much	Had some issues with the device, not a lot of benefit for the knee pain
27	Least	None	Device was relaxing to use, but not a lot of benefits to the pain
28	Most	None	Really noticed the effects when using regularly. Was part of a routine and could feel it when they were away from the home and had not used for a few days. The device was easy to use
29	Least	None	None
30	Most	None	None

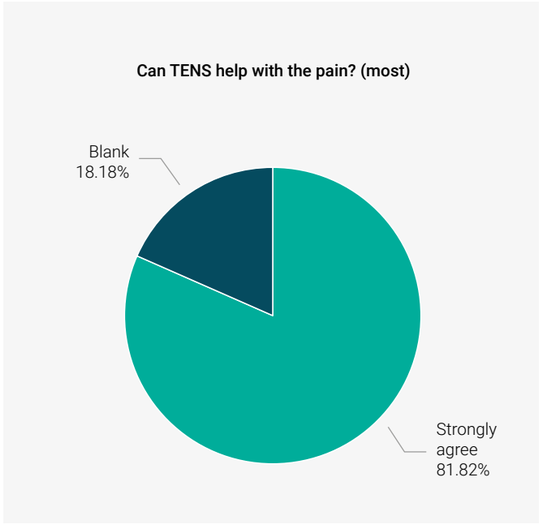
Appendix 22 – Participant feedback table

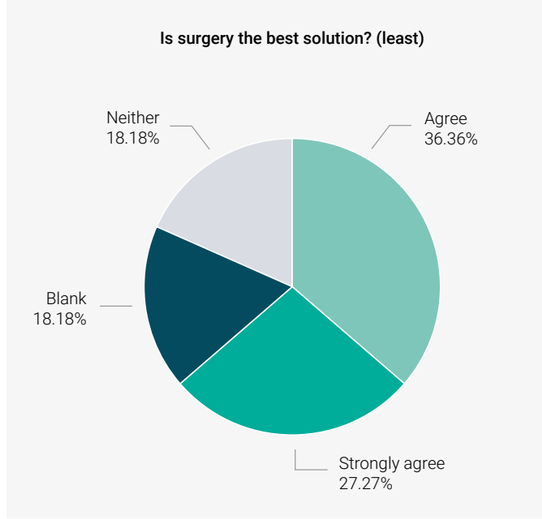
Participant number	Use group	Device uses (total)	Satisfaction score (final)	Benefit score (final)	Can tens help with knee pain?	Is surgery the only option?
8	Least	0	3	0	Strongly agree	Neither
13	Least	0	6.5	5.5	Agree	Strongly agree
29	Least	0	5.5	2	Agree	Strongly agree
3	Least	3	Blank	Blank	Blank	Blank
24	Least	10	8	0	Agree	Agree
25	Least	20	7	4	Agree	Strongly agree
26	Least	23	7	6	Agree	Neither
27	Least	24	Blank	Blank	Blank	Blank
2	Least	28	6	2	Disagree	Agree
17	Least	28	9	8	Agree	Agree
16	Least	33	5	1	Neither	Agree
23	Most	44	Blank	Blank	Blank	Blank
30	Most	63	9	8	Strongly agree	Agree
4	Most	83	5	0	Strongly agree	Strongly agree
19	Most	86	5	5	Strongly agree	Strongly agree
6	Most	90	5.5	4	Strongly agree	Disagree
22	Most	91	6	6	Strongly agree	Agree
10	Most	126	9	9	Strongly agree	Agree
28	Most	126	Blank	Blank	Blank	Blank
21	Most	143	9	10	Strongly agree	Neither
15	Most	159	8	2	Strongly agree	Strongly agree
14	Most	198	9	9	Strongly agree	Strongly agree

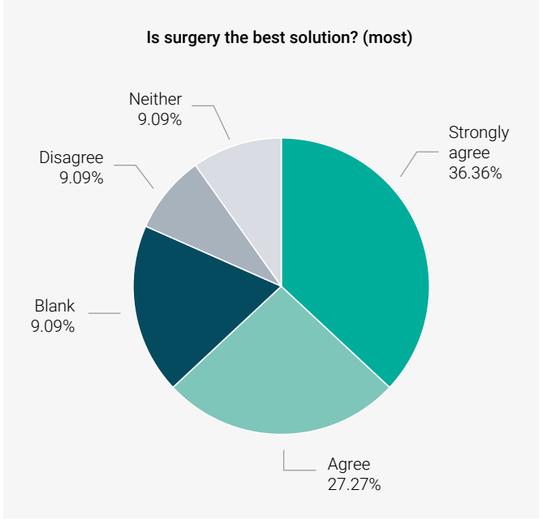
Appendix 23 – Participant feedback graphs



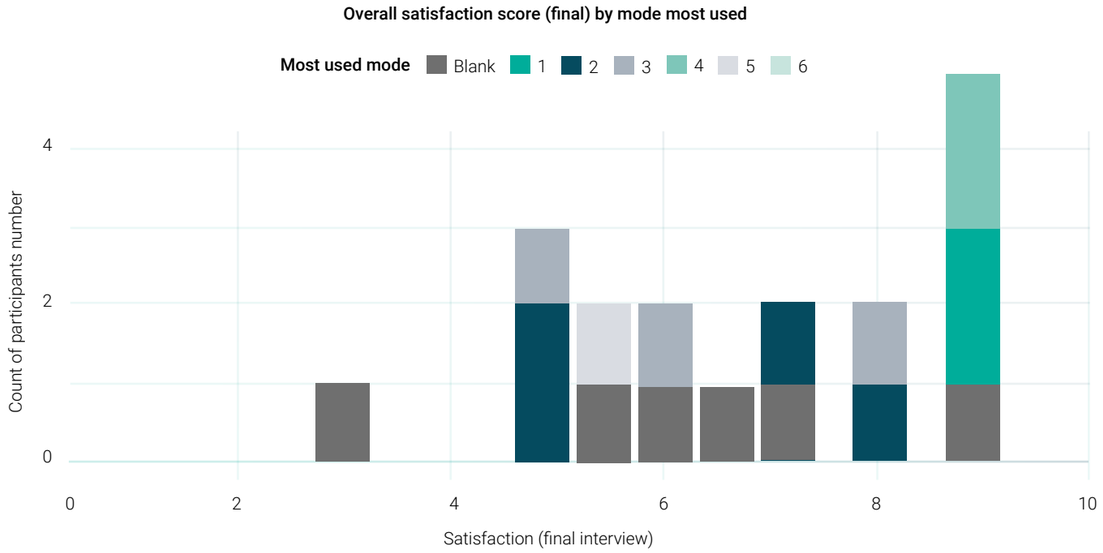


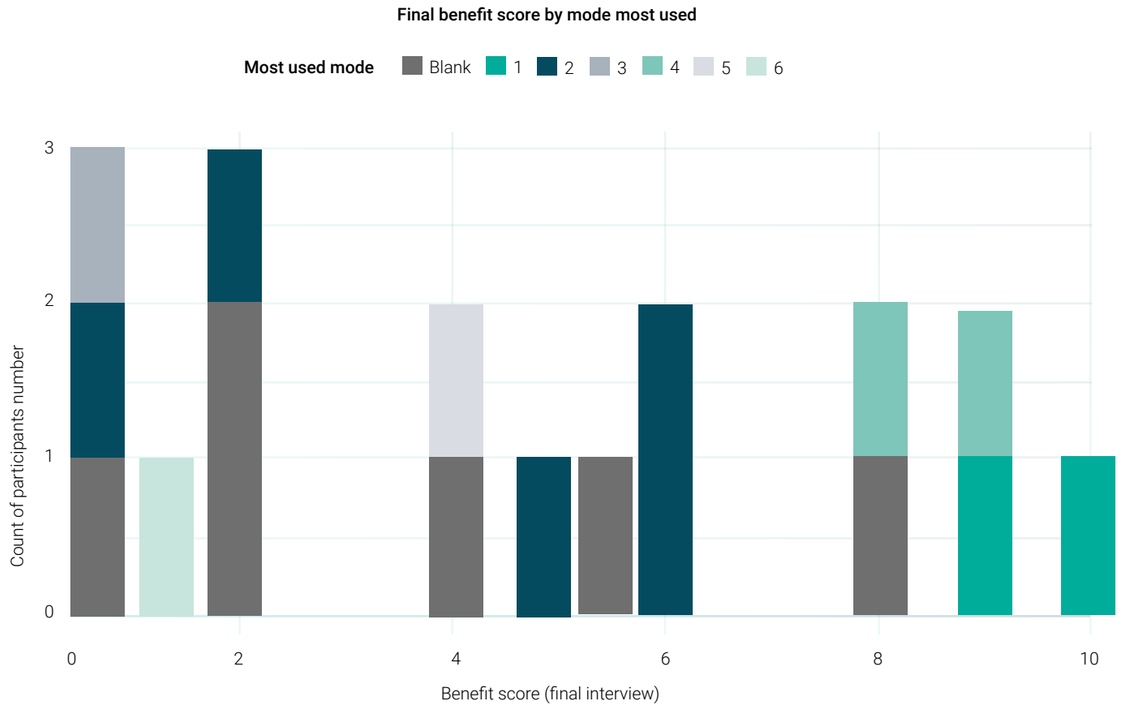






Appendix 24 – Device mode and satisfaction/benefit scores





Appendix 25 – Correlation table of clinical and UX data

Pearson's correlation coefficients (most and least, 22)

Calculations done in R, presented using Excel

This table shows the Pearson's correlation coefficients calculated for the UX and clinical change data collected for the 22 participants with valid data. The highest correlation was between the early satisfaction score capture during telephone interviews about 1 month into the study against the final benefit score relating to the befefits with pain. Interestingly the self score (0-100 metric overall health) had no correlation to the EQ-5D index score despite being from the same questionnaire.

(n)* denotes significance of p < 0.05 (statistically significant)

(n) denotes significance of p < 0.001 (highly statistically significant)**

Correlation	Pearson's Coefficient (r)	Significance (p)
Age & Change in EQ-5D	0.048	0.0229
Age & UX Final Satisfaction	-0.48	0.0446
Age & UX Final Score	-0.57	0.0131
UX Early Satisfaction & Change in Pain VAS	-0.6	0.0495
UX Early Satisfaction & UX Benefit Score	0.92	0.0001
Change in EQ-5D & UX Final Satisfaction	0.48	0.0429
Change in EQ-5D & UX Benefit Score	0.5	0.0348
Change in Pain VAS & UX Total Uses	-0.46	0.033
UX Total Uses & Benefit Score	0.49	0.0395
UX Final Satisfaction & UX Benefit Score	0.71	0.0009

High Correlation

Low Correlation

Category	Age	UX first impression	UX early satisfaction	Change EQ-5D	Change KOOS-PS	Change pain VAS	Change self score (EQ-5D)	UX total uses	UX final satisfaction	UX benefit score
UX first impression	1.00									
UX early satisfaction	-0.18	1.00								
Change EQ-5D	-0.59	0.49	1.00							
Change self score (EQ-5D)	(-0.048)*	-0.41	0.45	1.00						
Change KOOS-PS	0.05	-0.02	0.08	-0.40	1.00					
Change pain VAS	0.36	-0.30	(-0.6)*	-0.20	0.27	1.00				
Change self score (EQ-5D)	-0.08	0.48	0.08	0.08	-0.33	-0.30	1.00			
UX total uses	0.04	-0.06	0.40	-0.01	-0.41	(-0.46)*	0.13	1.00		
UX final satisfaction	(-0.48)*	-0.16	0.60	(0.48)*	-0.32	-0.32	-0.10	0.46	1.00	
UX benefit score	(-0.57)*	-0.08	(0.92)**	(0.5)*	-0.20	-0.44	0.15	(0.49)*	(0.71)**	1.00

Appendix 26 – Clinician feedback

Question	Orthopaedic surgeon	Physiotherapist	Specialist pain nurse
What do you think of the design of the device	As below	As below	As below
Dimensions?	Good, liked that it was so small	Good, didn't expect it to be this small, was expecting a screen though	Nice and small, easier to manage than other TENS devices
Weight?	Good weight, small	Liked how lightweight it was	Nice and light
Appearance?	Good	Packaging was really nice and the box it came in was great and the colour scheme was great	No comments
Controls?	Not sure about the beeps, digital display of some kind could be better, was a little confusing at first when changing the modes and intensities. Why are the pain modes so chaotic? (Pain+ is 1 and 4). Might be easier to follow to have less treatment modes or have them in order. The user manual was unclear about the theraputic differences between modes, a clinicial might want more details about the modes and their differences	Easy to use, was pleasently surprised about how simple it was to get on and get going. Commented on the fact that ensuring the patients know what mode they are selecting is important, without a screen it might be difficult for some of them to keep track. Appreciate this is a more affordable option but extra features such as a screen or being able to connect to an app would be great clinically	Had an issue with not being able to see the buttons when it is out of reach. But this was more of a general statement for using the device in other areas such as the back. Would be hard to use it anywhere other than where you could see it (not a problem with the knee). Had some issue around not knowing what mode and intensity was selected
Charging?	No issues	No problems	No problems
Quality?	Looks strong and sturdy, good quality	Good quality	Good quality
Length cable?	No issues with the length of the cable	Could the cable be longer or have a longer version? For bigger patients or use in other areas	Cable would need to be longer to use in other places on the body
Packaging?	Had a bit of trouble getting it out of the box initially, nicely wrapped though	Packaging was good	No comments
Consumable electrode pads	No comments	Was concerned about how sticky the pads were, do patients need to be advised to shave the area?	No comments
What do you think of the instructions for use of this device?	No issues with the instructions, the order of the modes was a bit all over the place (see above comments). Could the modes be simplified? One deep, one superficial, one massage, for example he mode order	Clear instructions, nice and easy to follow. Pictures and layout was good for the guide. Easy to pick up and understand.	Easy enough to understand, the guides that were put together for the project were a bit easier to follow

Question	Orthopaedic surgeon	Physiotherapist	Specialist pain nurse
What do you think of the method of peration of the device?	Good to operate, easy to put on, only issue is the mode order	Will require the patient to pay attention to how many times they have pushed the buttons so that they don't forgot which settings they are on	Easy to use, but harder for neck, back and spine (without assistance). Patients would need to be reminded that this will only help with the pain whilst the device is switched on and in use
Would this kind of device fit into a real clinical service scenario?	If the results are positive then this could be considered. Ideally this should be in the pathway for patients before they are added onto a surgery waiting list. Further research or evaluation could be done with primary care	Yes, this could fit well into the new prehab group for keeping patients fit for upcoming surgeries. This prehab group already uses telehealth technologies and the patients have been quite engaged and use devices like smart watches and weighing scales so that clinicians can monitor changes. This kind of device could compliment this new service	Would definitely work in a clinical scenario, on the wards would be best for them. TENS devices are used on the wards in acute scenarions, so this could be a good area to look at next. (Usability might be a bit harder to capture in an acute scenario but we could look into this)
Would you recommend this kind of technology for knee OA patients?	Apprenhensive at this stage, would like to see more data	There is a place for this kind of technology for OA, but it really depends on the patient group. Some patients are very closed off to what might help them and are only interested in the surgery. However other patients are very responsive to extra steps would respond well to this kind of device	These would be great for these kinds of patients.
Can you tell me about a typical patient journey up to the point they added onto the waiting list for knee arthroplasty?	Patients are encouraged to help themselves in the early stages of knee pain and subsequent diagnosis. Early interventions such as crutches for support and physio for rehab would happen before the OA is progressed enough for the patients to need surgery. If none of these early interventions is proving successful then the patients will eventually end up on the surgery waiting list. There is a lot of variation in the patients, some have fast onset of OA, others have a very gradually degredation	They start by accessing physio or seeing a GP about knee pain, The GP would then refer to a physio (if not already under the care of an NHS one). Community musculoskeletal assessment team (CMAT) are involved in the early stages to assess. An X-ray is normally done early in the physio process, if required a consultant will be brought in to advise. Podiatry will help with pain, exercise classes will be used to help with pain and managing the patients. 8 week courses can be used to prep a patient before surgery. Physios can be in a good position to identify patients that will adopt this kind of technology as they see how they respond during appointments	The GP that the patient first sees would refer them to a physio, when necessary a consultant would become involved. X-Ray is normal OA diagnosis method

TRITECH

Sefydliad | Institute

Hywel Dda University Health Board

TriTech Institute
Unit 2 Dura Park
Bynea
SA14 9TD

0300-303-6115
Tritech.HDD@wales.nhs.uk

tritech.nhs.wales @tritech_hd Tritech Institute