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Hywel Dda University Health Board

Evaluation report
Repetitive transcranial magnetic stimulation for drug resistant depression

Report Produced on 15/06/2022

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Who We Are

In 2021 the TriTech Institute was launched. We are a team based in a bespoke facility within the 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 testing, 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

A repetitive transcranial magnetic stimulation (rTMS) service was assessed over a three-month period at the adult mental health service within Glangwili hospital (GGH), Hywel Dda University Health Board (HDUHB). For the duration of the assessment, Magstim® provided their rTMs device to HDUHB to explore the potential for a national roll out of rTMS technology in Wales. rTMS technology has previously shown to be beneficial for patients who have drug resistant depression. As part of the evaluation 10 patients with drug resistant depression were invited to receive 30 treatments of rTMS, each lasting 37 minutes each over a course of 6 weeks.

All patients completed the required rTMS treatments, 9 out of 10 of the patients provided feedback via questionnaire after the 20th treatment session. The clinical team collected relevant patient reported outcome measures (PROMS). Clinical outcomes were measured using BDI II, PHQ-9, MADRS and CGI validated tools. Staff feedback was also collected through 1-on-1 interviews.

The rTMS service was found to be acceptable to both patients and staff with clinical benefits demonstrated in some patients. However, the cost effectiveness, impact on staff and service time as well as the longer-term clinical benefits need further analysis before rTMS is moved into routine clinical care within Hywel Dda.

This report presents the findings of the evaluation which covers the period of 10/01/2022 to 31/04/2022.

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Abbreviations

BDI	Becks depression inventory
CGI	Clinical global impression
CPD	Continuing professional development
CRHT	Crisis resolution and home treatment team
CVA	Cerebrovascular accident
DLPFC	Dorsolateral prefrontal cortex
ECT	Electroconvulsive therapy
EMG	Electromyography
FDA	Food and drug administration
HDUHB	Hywel Dda University Health Board
HCRW	Health care research Wales
HTW	Health technology Wales
ILS	Immediate life support
LSHW	Life sciences hub Wales
MADRS	Montgomery-Asberg depression rating scale
MEP	Motor evoked potential
MRI	Magnetic resonance imaging
MT	Motor threshold
NHS	National health service
NICE	National institute of clinical excellence
PROM	Patient reported outcome measures
PHQ9	Patient health questionnaire
PIS	Patient information sheet
R&D	Research and development
RAID	Risks, actions, issues, and dependences
RCPsych	Royal college of psychiatrists
rTMS	Repetitive transcranial magnetic stimulation
SE	Service evaluation
VBHC	Value based health care

Acknowledgements

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We would like to thank all of the patients who agreed to participate in the evaluation for their time and contribution.

We would also like to thank Robin Davies and all of the team at Magstim® for the loan of the device and all of the training and support they have provided throughout the project to date. We are very grateful to Life Sciences Hub Wales (LSHW) for supporting this project.

Situation

Technology Background

Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-invasive, non-convulsive form of neuromodulation used for treatment of psychiatric illnesses. It is based on the principle of electromagnetic induction. Magnetic fields are generated by passing rapidly alternating electrical currents through a coil with a ferromagnetic core. The magnetic field generated by the TMS device varies from 1.5 to 3 Tesla comparable to that of an MRI machine. The magnetic pulse is applied to a small, focused area of the brain to result in cortical stimulation. The common area of stimulation is the left dorso-lateral pre-frontal cortex (LDLPFC). The pulses can be delivered in a rapid (1-20Hz) repetitive fashion, increasing the cortical activity or in a slow (<1Hz) repetitive fashion, inhibiting cortical activity.

rTMS has been shown to be a well-tolerated procedure with minimal side effects. rTMS is an effective treatment option for patients with depression who have not benefitted from antidepressant treatment. It received food and drug administration (FDA) approval in 2008 and since then has been used widely in the USA.

The national institute for health and care excellence (NICE) renewed its guidance for use of rTMS recommending its use as treatment for depression in 2015. rTMS treatments are being used in England NHS trusts but currently not in Wales.

The strongest evidence base available is in the treatment of depression but there is an emerging evidence base for its use in other psychiatric disorders such as anorexia nervosa and post-traumatic stress disorder (PTSD) (NICE, 2015).

In a systematic review of 63 studies including 3236 patients treated by rTMS (n=2330), sham stimulation (n=806) or electroconvulsive therapy (ECT) (n=100), percentage changes in Hamilton depression rating scale (HDRS) scores (lower scores indicate less depression) were pooled and converted to Clinical Global Impression – Improvement scale (CGI-I) scores. CGI-I scores range from 1 to 7: scores of less than 4 indicate improvements in depression and scores of more than 4 indicate worsening depression.

For patients with any type of depression, the mean percentage reduction in HDRS scores was 37% (CGI-I equivalent 2.8) following rTMS compared with 22% (CGI-I equivalent 3.4) in the sham stimulation group ($p<0.05$). For patients with treatment-resistant depression, the mean percentage reduction in HDRS scores was 48% (CGI-I equivalent 2.4) in the rTMS group and 23% (CGI-I equivalent 3.4) in the sham stimulation group ($p<0.05$) (Lepping et al., 2014). However, with any type of depression, the mean percentage reduction in HDRS scores was 34% (CGI-I equivalent not reported) following rTMS versus 46% (CGI-I equivalent 2.45) in the ECT group ($p<0.05$) (Lepping et al., 2014) suggesting ECT had a better effect.

Whilst the technology has shown to be safe and effective in NHS England, further work is needed around the feasibility, cost effectiveness and scalability of rTMS in NHS Wales.

NICE guidelines recommendations

The following recommendations are from the national institute of clinical excellence (NICE) guidelines' publication regarding rTMS treatments (NICE, 2015):

1.1. "The evidence on repetitive transcranial magnetic stimulation for depression shows no major safety concerns. The evidence on its efficacy in the short-term is adequate, although the clinical response is variable. Repetitive transcranial magnetic stimulation for depression may be used with normal arrangements for clinical governance and audit."

1.2. "During the consent process, clinicians should, in particular, inform patients about the other treatment options available, and make sure that patients understand the possibility the procedure may not give them benefit."

1.3. "NICE encourages publication of further evidence on patient selection, details of the precise type and regime of stimulation used, the use of maintenance treatment and long-term outcomes."

Service context

Hywel Dda University Health Board (HDUHB) is one of seven acute Health Boards / Trusts in Wales. It provides primary and secondary care services for residents within its borders in the counties of Carmarthenshire, Pembrokeshire, and Ceredigion. Glangwili General Hospital (GGH) is the biggest of the Health Board's four acute hospitals and is approximately 2 miles from the centre of Carmarthen. GGH has approximately 320 beds to provide inpatient services for patients across the region.

The HDUHB rTMS Service was run from Glangwili General Hospital as a service evaluation overseen by the consultant nurse of mental health and learning Disabilities (MHLD). The Team's oversight meant no treatment was withheld or started inappropriately and safety and Good Clinical Practice was followed throughout.

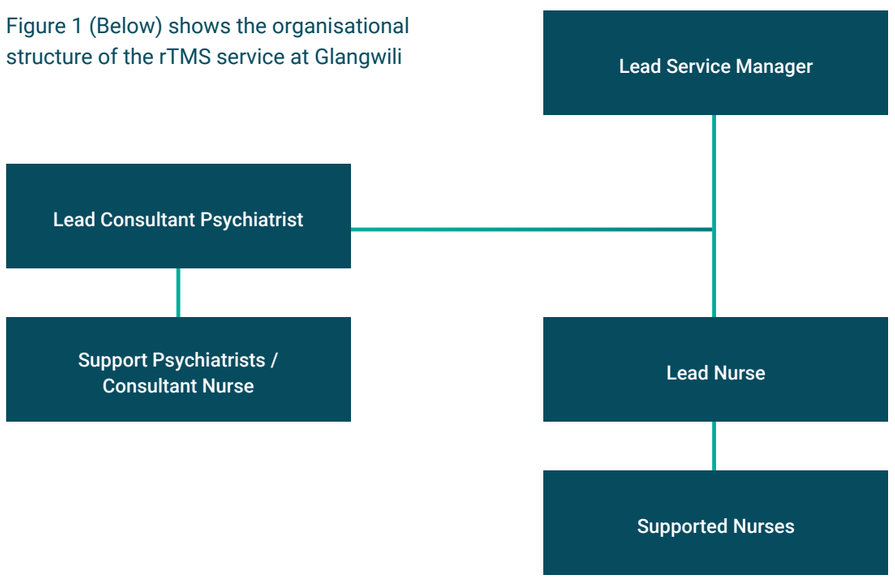
- The service was available 5 days a week, the treatment sessions took place on a Monday and ran consecutively Monday to Friday.
- Sessions were scheduled 5 days a week for approximately 4 to 6 weeks, however, the provision for rTMS was limited during bank holidays.
- The clinic used the Magstim® Rapid Plus machine.

Any potential patient completed an rTMS safety screening questionnaire. Presence of capacity to consent was recorded and consent to receiving rTMS treatment was recorded in the consent form and clinical record. During the initial appointment, the patient was also provided with a Patient Information Sheet (PIS) about the service and evaluation. See Appendix 1.

The rTMS Service accepted referrals from Community Mental Health Teams or GPs. Following the acceptance of a referral, the patient was offered a pre-assessment appointment with the consultant, or a nominated deputy, at the treatment centre. In this appointment the consultant took the appropriate history to determine the indication and suitability for the rTMS treatment.

If the patient opted out of having the measurements and motor threshold (MT) determination on the same day, they were given an appointment on a separate date to undertake the pre-assessment. Outcomes scales for monitoring the clinical improvements were completed weekly. The referrer and the patient's GP received all relevant communication regarding treatment and progress. The development of the rTMS service used eligibility criteria (inclusion and exclusion) for patients within the NICE approved guidelines (NICE, 2015).

Figure 1 (Below) shows the organisational structure of the rTMS service at Glangwili



Inclusion criteria

(based on rTMS society consensus recommendations)

- Receiving acute treatment.
- Who have previously benefitted from rTMS and experiencing recurrence of symptoms.
- Continuous or maintenance treatment for patients who benefit from acute treatment
- Can be reintroduced in patients who are relapsing after initially responding.
- Patients should have capacity and be able to give a valid consent
- Over 18 years of age.

Exclusion criteria

- Patients who do not have capacity to consent.
- Patients under the age of 18
- Patients with previous or current history of seizures or epilepsy.
- Patients who are actively suicidal
- Those with an on-going dependence with alcohol or stimulant drugs which might lower the seizure threshold.
- Concurrent major medical disorder
- Patients with neurological co-morbidities such as space occupying lesions, CVA, aneurysms etc.
- Cochlear implants
- Cardiac pacemaker, implanted medication pumps
- Pregnancy

Evaluation introduction

On 25/10/2021, the TriTech institute was commissioned to undertake a service evaluation of rTMS, using the Magstim® Rapid Plus device. This service evaluation stemmed from a Health Technology Wales (HTW) review of rTMS and was also part of work being advanced by HCRW to explore the potential for a rollout of rTMS in Wales. The evaluation was to address why this technology has not been widely adopted in Wales, NICE guidelines state that evidence show some benefits, but more research is required (IPG542, NICE, 2015). The evaluation was aimed at understanding the factors that might be important to organisations considering whether to adopt rTMS or not.

Evaluation aims

The evaluation intended to answer two questions with regards to rTMS:

- Can rTMS be safely and quickly implemented as a service within NHS Wales?
- Is it acceptable to patients and staff?

Evaluation plan

A mixed-methods approach was utilised to meet the aims of the evaluation via the objectives and outcomes set out below. The evaluation was led by the TriTech Institute as part of HDUHB, with funding from LSHW. A loan device and clinical training was provided by Magstim®. The patient facing component of the evaluation was handled directly by the psychiatry department and TriTech worked with all other parties to facilitate the project management.

The service evaluation period was three months, with a start date of 10th January 2022. The patients were seeing in two cohorts of 6 weeks each, with four patients in the first cohort and six in the second.

Evaluation outcomes

The outcomes of the evaluation are:

1. **Clinical outcomes** – Which are detailed in the methodology section.
2. **Attendance of patient treatments** – Assessed through the reports from clinical teams which will include missed treatment information.
3. **Acceptability to patients** – Assessed via questionnaires completed by patients and from feedback collected by clinical staff.
4. **Acceptability to staff** – From one-one interviews.
5. **Requirements for the service** – A project manager was appointed to help with the running of the project, who took notes about what was needed to get the service going.
6. **Barriers to implementation** – Analysing all available information to determine what the barriers to successful implementation are.

Methodology

Clinical outcomes

The clinical data was collected by the psychiatry team, this was done in person with validated tools. The clinical data was collected at baseline, and then repeated at weeks 2, 4 and then 6. The validated tools used to measure clinical outcomes were:

- **BDI II (Beck Depression Inventory)** – 21 groups of statements, for each group with the instruction to circle the statement that best describes the way a person is feeling. A higher score will indicate increased depression.
- **PHQ-9 (Patient Health Questionnaire)** – 9 statements that are scored a "0" not at all to a "3" nearly every day. An increased score will indicate higher severity of depression.
- **MADRS (Montgomery Asberg Depression Rating Scale)** – Is used by clinicians to assess the severity of depression among patients with a diagnosis of depression. It is designed to be sensitive to change resulting from antidepressant therapy. Increased scores indicate higher severity of depression.
- **CGI (Clinical Global Improvement Scale)** – Used as an efficacy measure of a given treatment.

Attendance of patients

A total of 30 treatment sessions were required for each of the patients. The clinical team kept a record of any missed appointments, this information was also included in the patient exception reports that were produced as part of the service. Missed treatment numbers were validated for the evaluation.

Acceptability to patients

Patient feedback was collected using a questionnaire (please see appendix 2), this questionnaire was accompanied by an evaluation patient information sheet (PIS) and can be seen in Appendix 1. The patient feedback was collected after the 20th session, which was typically at the end of the fourth week of treatment.

The patient feedback questionnaires had three sections, in each section were a number of statements that asked the patient to what extent they agreed or disagreed. The questions were broken down into three sections: Physical comfort, impact of treatment and understanding of treatment. These questions can be seen in appendix 2 which shows the questionnaire the patients completed.

There was also a space for additional comments at the bottom of this questionnaire, these additional responses can be seen in Appendix 3.

Acceptability to staff

The interviews were conducted after the first patient cohort had been completed and whilst the second cohort of patient had started their treatment. The staff feedback was gained using one on one interviews with staff within the service. The questions that were used during these interviews (and the responses) can be seen in Appendix 4.

Requirements for the service

A Project Manager was appointed by HDUHB to oversee the general day to day running of the service at Glangwili and they also kept a log of any challenges that were faced. This project manager also kept notes of any key points or actions that arose from the meetings that took place between the clinical and evaluation teams. A document was kept which included key lessons learning and a risks, actions, issues, and dependences (RAID) log.

Barriers to implementation

Exploring the barriers to implementation was undertaken by reviewing all information collected in the previous sections and broken down into the following areas:

- Patient
- Technology
- Infrastructure

Findings

Clinical outcomes

Clinical scores were recorded from baseline and after every 2 weeks of treatment (weeks 0, 2, 4 and 6).

For the clinical measures the following results were obtained:

- Beck Depression Inventory (BDI II) – 7 out of 10 patients showed an improvement in scores.
- Patient Health Questionnaire (PHQ-9) – 7 out of 10 patients showed an improvement in scores.
- Montgomery Asberg Depression Rating Scale (MADRS) – All 10 patient showed an improvement in scores.
- Clinical Global Improvement Scale (CGI) –7 patients showed minimal improvements, 1 patient was 'much improved', 1 patient was 'very much' improved, and 1 patient showed no change.

The BDI II, PHQ-9 and MADRS results tables can be seen in Appendix 5, the CGI table of results can be seen in Appendix 6. The graphs of results for BDI II, PHQ-9 and MADRS can be seen in appendices 7, 8 and 8 respectively.

Summary notes from clinicians about each patient

- Patient 1 – The patient did not believe that they had any positive effect from the treatment and no significant signs noted by the nursing staff. However, the depression scales indicate a slight response. From baseline scores there has been minimal improvement.
- **Patient 2** – Nursing staff report a change in patients' posture and ability to engage in conversation and show humour. Patient reports that their spouse feels there has been a slight improvement. Patient continues to report a reduction and severity in suicidal thoughts. Depression scales indicate minimal improvement.
- **Patient 3** – Patients' mental health is very complex; they have not shown any signs of improvement. Patient reports no change in mood, however, was grateful for the treatment. Depression scales indicate no significant changes.
- **Patient 4** – Patient reported having a good response in the final weeks of treatment. Nursing staff have noted an improvement in mental state. Patient reports suicidal thinking is less severe. Depression scales indicate an improvement in mood.
- **Patient 5** – Patient reported feeling better since treatment and is making positive changes in their life.
- **Patient 6** – Patient felt that overall had not gotten a benefit from the treatment but remains hopeful for future treatments.
- **Patient 7** – Patient scores show a large improvement and patient reports feeling 'so much better'.
- **Patient 8** – Patient scores have improved, and they report feeling much better since the

start of the treatments. Patient reported that their depression was 'cured' and OCD thoughts are less intense and easier to manage.

- **Patient 9** – Patient reports no improvement from the treatment, and they were in low mood during the final treatments.
- **Patient 10** – Patient struggled to receive all treatments at the intended dose due to pain and discomfort on some occasions. The patient does not feel they had any noticeable benefits from the treatment.

Attendance of patients

Four patients attended the first cohort of treatment. All four completed their treatment with only three sessions missed in the first cohort, the missed treatments were carried out after the end of the sixth week. Three out of four patients in the first cohort completed the SE questionnaire.

Six patients attended the second cohort of treatment. All six of these patients completed their treatments. The bank holiday weekend in April meant that all six of the patients in cohort 2 missed at least two treatment sessions, but these missed treatments were carried out after the end of the sixth week. Ongoing feedback for both cohorts was also collected by the clinical team and was included in this review.

Acceptability to patients

Between the two cohorts of patients, 9 out of 10 patients completed the service evaluation questionnaire (Appendices 10 & 11). On the service evaluation (SE) questionnaires there was space below each of the statements in which the patients could include written statements . Appendix 12 shows the pie charts for the physical comfort questions. Appendix 13 shows the pie charts for the impact of treatment questions. Appendix 14 shows the pie charts for the understanding of treatment questions. Appendix 15 shows a summary of all SE questionnaire responses.

Physical comfort

- Discomfort in head and neck during appointment – There was a mixed response to this statement, 4 (44.4%) did not have discomfort, 2 (22.2%) had a neutral response and (33.3%) did have some level of discomfort. The comments left by patients mostly reflected these responses.
- **Appointment length** – The majority of the patients 6 (66.6%) did not feel that the appointments were too long, 1 (11.1%) was neutral and 2 (22.2%) felt that the appointments were too long. The 2 that felt the appointments were too long also backed this up with comments, concerns around employment responsibilities was the main issue.
- **Any pain or discomfort (not just head and neck)** – This was a mixed response, 3 (33.3%) said no pain/discomfort, 3 (33.3%) had a neutral response and 3 (33.3%) said they did have some pain/discomfort. The comments suggest that those who ticked a neutral response may have also had pain or discomfort, so this was potentially an issue for more than half of the patients.
- **Involuntary movements** – This was a mixed response, 4 (44.4%) said no involuntary movements, 4 (44.4%) said they did experience involuntary movements and 1 (11.1%) response was neutral. The comments left suggest that the involuntary movements experienced by some were tolerable but not pleasant.
- Fatigue as a result of the treatments – This was a majority negative response, with 7 (77.7%) stating they had some kind of fatigue after the appointments. Only 2 (22.2%) said they had no fatigue after the treatments. The comments left suggest this was a real issue for a number of the patients, but comments also suggest that the extra social interaction and time outside of the home also makes them feel tired. So this fatigue may not be entirely due to rTMS.
- **Residual sensations** – This was mixed response, 3 (33.3%) said they did not have any residual sensations, , 3 (33.3%) said they did and 2 (22.2%) had a neutral response. The comments suggest that the residual sensations experienced by some were tolerable.

Impact of treatment

- **Frequency of appointments** – This was a mixed response, 3 (33.3%) said it had no negative impact, 2 (22.2%) had a neutral response and 4 (44.4%) said it had a negative impact. The comments suggest that those it did affect had to make adjustments in their lives to accommodate.
- **Total number of appointments** – Similar to first statement, this was mixed, 3 (33.3%) said it had no negative impact, 3 (33.3%) said it had a negative impact, and 3 (33.3%) were neutral responses. Comments suggest frequency and total number have a similar effect.
- **Difficulty with travel or parking** – This was a positive response, most 6 (66.6%) did not experience any difficulty with travel or parking, 1 (11.1%) and 2 (22.2%) did experience difficulty. Comments from those who did have difficulty with travel suggest this was a real issue for them.
- **Improved experience** – This was a mixed result, 4 (44.4%) stated that nothing needs to be done to improve the patient experience, 3 (33.3%) said that the patient experience could be improved, and the comments suggest pain, comfort in the seat and appointment length/ frequency are the main issues with these patients. 2 (22.2%) had a neutral response.

Understanding of treatment

- **Understanding of treatment** – This was a positive response, only 1 (11.1%) or patients did not feel they understood the treatment after it was explained to them, 1 (11.1%) had a neutral response and the other 7 (77.7%) or patients said they understood the treatment after it was explained to them.
- **Understanding of potential side effects** – This was a very positive response, all 7 (100%) patients said they understood the potential side effects after it was explained to them. Comments suggest all patients were very appreciative of the support and understanding provided by Jess and Dr Khan.
- **Positivity towards treatment at the start** – This was a positive response, 6 (66.6%) or patients were hopeful the treatment would work. 3 (33.3%) of patients were neutral. The comments suggest most patients had high hopes for the treatment and only a few were sceptical.
- **Positivity at week 4 of treatment** – This was still a positive response but less so than at the start, this suggests that some patients were less hopeful. 5 (55.5%) of patients were still positive about treatment at week 4, 3 (33.3%) were neutral and only 1 (11.1%) was feeling negative towards the treatment at week 4. Comments suggest that even if the patients did not think it was working overall, many of them were having better thought patterns, were seeing benefits with getting out of the house more regularly and felt cared for by the rTMS and health boards staff.

Exception report comments

The following comments are extracted from the exception reports from the clinical staff. They are key summary points that were picked up during the sessions and from ad-hoc feedback from staff which might not have been captured on the questionnaires. These comments have been split into positive and negative comments.

Positive comments

- Only two patients in this cohort had difficulty with travelling for the appointments and the time commitments due to being unable to drive.
- Many patients reported that attending the treatment sessions and having attention from the staff was a positive benefit.

Negative comments

- One patient reported that they did not like the length of the treatments, and that it affected their social life.
- Patients found the sessions more difficult when having the treatments by bank staff as the sessions took longer; this was due to the increased time to position the coil.
- Issues with replacement parts needed for the device caused some disruption on two occasions.
- Some patients had some physical side effects during the treatment such as eye twitches and migraines afterwards. The patient with migraines, may have experienced them for reasons outside of the treatment.

Additional patient feedback

Patients provided the following feedback as part of 'additional comments', please see Appendix 3 for these comments. These additional comments left by patients were all positive and optimistic even if the patients did not believe they were getting a benefit after the 20th treatment session. The comments all had mention of the clinical team and how much of

a positive impact they had on the patients

Acceptability to staff

Please see Appendix 4 for staff responses to each of the 10 questions outlined in the methodology section. These responses can be summarised into the following themes: implementation, effectiveness of rTMS, challenges, positives, and future work.

Implementation

- Experience with the device really helped improve the efficiency of the treatments with the second cohort.
- Staffing issues were experienced during the evaluation, bank staff were not using the device regularly enough to become proficient, this had a knock effect to patient comfort.
- Treatment times take a long time to administer, this needs to be taken into consideration as the number of patients that can be seen by the staff is reduced if the appointments take longer.

Effectiveness of rTMS

- The clinical team had a favourable view on the effectiveness of rTMS, both from previous literature and from experience of the technology during the evaluation
- rTMS is cheaper to run and has less complications than ECT and could also reduce the waiting list for ECT by treating patients earlier in the clinical pathway.

Challenges

- Continuity of treatment, or lack thereof was a big concern for the clinical team. It further complicated the patient recruitment process.
- Patient recruitment was a big issue throughout, GPs seemed mostly unaware of the potential benefits so were less likely to refer patients.
- The Magstim® rTMS device was a bit tricky to use in the beginning of the service, but this was a mixture of experience with the technology and some technical issues with the cabling.
- Training on the device is provided, but a lot of experience is necessary for staff to become proficient.

Positives

- Magstim® as a company were rated very highly by the staff. The company were very supportive during training and made themselves available whenever it was requested, they went above and beyond for the evaluation.
- Patients that were treated with rTMS during the evaluation and had also previously undergone ECT all reported a more favourable experience of rTMS.

Future work

- rTMS would not replace ECT as a treatment for serious depressive disorders, but the addition of it could benefit the service as a whole and potentially ease the waiting list for ECT treatments.
- rTMS is seen as a potentially very beneficial technology to bring into services within Hywel Dda. But more research is required to justify the costs and resource requirement to make it work.
- More data is required to assess the feasibility of rTMS as a service. Staff are interested in further research opportunities with this technology, but consideration would be needed with regards to the challenges faced.

Requirements for the service

The RAID log that was completed by the project manager contained information regarding the requirements for getting the service running and some of the challenges that were faced.

These lessons learned were captured by the HDUHB Project Manager who collated notes during the regular team meetings that took place during the service evaluation. The key points from this document are explained below.

1. **Project management** – Was vital to help facilitate the running of a project that had a lot of moving parts and tight timescales. This kind of project management will be crucial for any similar service evaluation in the future. The project management was brought in after the project had officially started.
2. **Back up Staff rota** – There were concerns about the staff coverage that was required to cover the service in case of staff sickness. In addition to the rota of main staff, a backup staff rota was required so there was both doctor and nurse cover in the event of a key member not being able to carry out the treatments
3. **Patient recruitment** – This was a challenge throughout, identifying other services within the health board that have patients that might be suitable would be helpful for the running of an rTMS service.
4. **Training material from supplier** – The company were very good at carrying out training on the device, but they were not always on site. Video training materials and guides that could be studied by the staff would have been very helpful.
5. **Procurement** – There was an issue with the procurement process in which the wrong approver was used. This caused a delay in the device being delivered and setup in the room.
6. **Patient commitment** – There is a large commitment required from patients to attend every session over a number of weeks. Reassurance from staff is required and relationships need to be built with these patients to help ensure they keep turning up for appointments. This was done successfully during this service evaluation, but it is worth bearing in mind for future services or research conducted with rTMS.
7. **On call service with the supplier** – Using the device at the start of the evaluation was difficult, the coil was stiff, and positioning was difficult. This was rectified with a new cable guard, and Magstim® were great at fixing this. But if this was a longer-term service or if several devices were purchased the company might need someone to respond to these issues.
8. **Space to install and run the device** – Finding and securing a room in which to install the device was a big challenge at the start of the evaluation. Several pieces of equipment also had to be ordered and installed to bring the space up to the required standard such as a controlled drugs cabinet (CD) and patient safety equipment.
9. **Promotion of rTMS technology to GPs** – If this kind of service is trialled again in the future or setup fully then promoting the technology and its benefits to GPs should be done much earlier. This would help with patient referrals and recruitment.

Barriers to implementing the service

All of the available information that was gathered during the service evaluation was used to determine what the main barriers to implementation were. These barriers to implementation can be broken down into sections such as, patients, technology, and infrastructure. The barriers in each of these categories are detailed below.

Patient

1. **Patient physical comfort** – The majority of patients experienced some kind of fatigued as a result of attending the appointments. However, this was not enough to stop any of the patients from attending appointments.
2. **Length of treatments** – Most of the patients did not seem too affected by the length ot treatments during the evaluation. But those who it did affect had to make adjustments with their work to fit the treatments in. If a shorter protocol could be used this service might be feasible for a larger number of patients.
3. **Competence of staff** – Many of the patients reported that the treatments were more unpleasant when sessions were carried out by bank staff. Frequent readjustments or incorrect settings made the treatments less tolerable for patients. This can be offset by point 2 below.

Technology

1. **Evidence** – More data is needed with regards to long term effectiveness of the treatments and implications regarding cost saving in other areas to enable this to be adopted in NHS Wales. More research into using rTMS with other conditions would also help adoption within HDUHB.
2. **Training and experience** – Adequate training is supplied by the company; however the staff suggest that a lot of practice is required to become comfortable with the technology. Frequent readjustments to the coil placement extend treatment time.

Infrastructure

1. **Staff resources** – Due to the nature of the treatments, dedicated clinical expertise is required, and a backup rota of staff was required to cover potential staff sickness. For this kind of service to operate effectively all staff would need to be trained to a high standard and be proficient with the technology. If treatment sessions are missed, then there is a risk that patients have to restart from the beginning.
2. **Patient recruitment** – One of the biggest challenges faced during the service evaluation was the recruitment of patients. The short-term nature of the evaluation meant a lack of continuity of treatment, which made the clinicians cautious about patient recruitment. As clinicians did not want to turn away patients who could have benefited. Education of GP practices or general promotion and awareness of the technology could also assist with patient recruitment.

Conclusions

NICE guidelines for rTMS set out three recommendations which were detailed in the situation section. The clinical results obtained during the service evaluation reflect the 1.1 from NICE with regards to the adequate but variable clinical response. Point 1.2 from NICE states that patients should be well informed about the process and that it might not give them benefit. The feedback from patients indicate that most of them understood the treatment and its potential side effects. These two recommendations were being met by the clinical team during this service evaluation.

Point 1.3 from NICE was regarding patient selection and details around type and regime of stimulation used. The treatment regime was documented but the patient selection process has not been included in this evaluation report. 1.3 also mentions exploring of longer-term maintenance treatments and outcomes which were not assessed as part of this evaluation.

Can rTMS be implemented as a service within Welsh NHS?

From all of the information collected during this service evaluation, the current answer is yes. The service was setup and carried out successfully, all 10 patients involved completed all treatments. Positive clinical and personal changes were seen in patients. However, more data regarding long term clinical effectiveness and cost savings in other areas would be required to justify the costs to the service of the device and the resources required to manage it. A value-based health care approach, or further research into other applications for the device so that it could be used with a larger range of patients would help with this.

Does it show to be acceptable to patients and staff?

Yes, this was very acceptable to patients. Those who had gone through ECT treatments before expressed that rTMS was much more favourable. Most patients remained hopeful of treatments throughout the evaluation and stayed hopeful and positive towards the end of treatments even if they were not noticing treatments in themselves. The great attention and care they got from the clinical team likely played a key role in the positive perception towards the treatments.

The majority of patients had an issue with fatigue from the treatments, and several experienced some level of pain or involuntary movements. Only a few patients had issues regularly attending the appointments, and those most affected by the frequency/total number of treatments were in full time employment. However, despite any discomfort or inconvenience caused, all patients completed their treatment and only a small number of individual treatments were missed.

Yes, all staff interviewed had a positive opinions to the technology. The staff who were directly in contact with the patients during treatments rated the device and its clinical potential very highly. There was interest in using the technology for further research to determine the effectiveness of other protocols to reduce the treatment lengths and to test it on other conditions or symptoms. More information is needed to convince all staff of the long-term effectiveness of rTMS, but the technology was well received by staff.

Recommendations

Recommendation 1: Undertake business case – to include robust economic analysis incorporating a value-based health care approach, providing analysis of information around clinical effectiveness (including over long term) and cost-value benefit for the health board to determine potential for service introduction. This would also support point 1.3 from the NICE recommendations.

Recommendation 2: Exploration of clinical awareness and need – As part of the analysis required for business case, undertake a small qualitative piece of work that explores the clinical awareness of rTMS technology with primary care providers and psychiatry departments. Exploration of other patient waiting lists that could benefit from rTMS treatments would also provide additional evidence for cost recovery of the device and staff resources.

Recommendation 3: Research additional applications – A research study should be conducted to explore the clinical benefits to other conditions and symptoms such as anxiety disorder, OCD, and suicidal thoughts. Other treatment protocols such as theta burst should also be explored in determining patient throughput volumes, service efficiencies and effectiveness.

Recommendation 4: Extended service evaluation –explore opportunity to extend and build upon the service evaluation to include larger cohort of patients possible as , less restricted by concerns around continuity of treatment. This undertaken in interim to consideration of a business case and/or post service introduction subject to business case) allowing for follow ups with patients to determine the clinical effectiveness over time and to assess the need for follow up treatments, which relate to 1.3 from the NICE guidelines' recommendations.

Recommendation 5: Evaluation using Theta burst protocol – The Theta burst protocol is substantially shorter than the one used for the service evaluation carried out in HDUHB. The shorter protocol offers potential to allow more patients to be seen in a reduced timeframe whilst retaining clinical effectiveness.

References

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National Institute for Health and Care Excellence (NICE) (2015) Repetitive transcranial magnetic stimulation for depression; Interventional procedures guidance; Published: 16 December 2015 www.nice.org.uk/guidance/ipg542

Taylor, R., Galvez, V. & Loo, C. (2018) Transcranial magnetic stimulation (TMS) safety: a practical guide for psychiatrists; Australas Psychiatry. 2018 Apr;26(2):189-192. doi: 10.1177/1039856217748249. Epub 2018 Jan 17.

Appendices

Appendix 1 – Patient information sheet (PIS)

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

MAGSTIM rTMS SERVICE EVALUATION INFORMATION SHEET

Please ask us if you would like this Information Sheet translated into Welsh.

Version number: 02 **Date: 14-01-2022** **Site: Glangwili Hospital**

Evaluation Title: To evaluate of rTMS therapy as a potential national value-based programme for improved mental health outcomes.

1. **Invitation and brief summary**

We are inviting you to take part in an evaluation of the Magstim rTMS Therapy system, as a service to help with drug resistant depression. The primary purpose of this evaluation is to study the service provision aspects such as the impact of the treatments on your day-to-day life and any problems you may have faced when attending the appointments. This information will help us determine how to extend this service across more NHS trusts in Wales.

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

Hywel Dda University Health Board, TriTech, Magstim, Health Technology Wales (HTW) and Life Science Hub Wales (LSHW) are working together to ensure sure that this treatment and service is suitable for our patients and members of staff. This evaluation will help with us improve our service and treatments being offered in Wales.

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

As a patient who is about to go through treatment with rTMS we would like to get your feedback on how the service has been as a whole. We would like to speak to you at the end of your treatment period so that you can give us honest feedback.

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

No, you do not. Although any feedback you could provide would be very valuable to the health board and any future services, your usual care and treatment will not be affected in any way if you to participate in this evaluation or not.

5. **What will I have to do?**

If you choose to take part, a staff member from health board will have a short interview with you after your final treatment session. Or if you would prefer, we can ask the same questions using a written questionnaire.

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

There are no additional benefits to you for participating in this evaluation, you will already have had your treatment. The feedback we get from this evaluation will help future patients within the health board.

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

This evaluation of the service will not introduce any risks to you or your care.

8. What will happen if something goes wrong?

If you have any concerns about participating in an evaluation of the service, we encourage you to raise your concerns as soon as possible. The evaluation is only to collect feedback at the end of your treatment and will not have any impact on your care in any way. But if you do have any concerns you can contact the NHS concerns team.

Email: **hdhb.patientsupportservices@wales.nhs.uk**
Phone: **0300 0200 159**
Write a letter to **Attention of the Chief Executive** Freepost RTJR-ZKJG-JZTC Patient Support Services Hywel Dda University Health Board Fishguard Road Haverfordwest SA61 2PZ
Fax: **01437 773353**
Text: **07891 142240**

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

Yes, all the information collected about you for 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.

10. 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, TriTech, Magstim, LSHW and HTW to help develop better services and successful delivery of this project will lead the way to the adoption of rTMS devices in Wales which will benefit patients and reduce cost for the psychiatry services in the long term. As stated previously you will not be identified in any written report unless you have given you express consent.

Contacts for further information:

For any advice, please contact the Liaison Unit, Psychiatric Department at Glangwili Hospital:

Email: akhtar.khan@wales.nhs.uk
Phone: 01267674083

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

Email: rachel.e.gemine@wales.nhs.uk
Phone: 03003036115

INFORMED CONSENT FORM - Version number 2 Date 14/01/2022

Evaluation Title: To evaluate of rTMS therapy as a potential national value-based programme for improved mental health outcomes.

Identification Number: **Site: GGH**

Evaluation Team Leads: Dr Rachel Gemine

Contact Telephone Number: 03003036115

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 2 14/01/2022) 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	
3.	I understand that my current and future treatment and care within the NHS will not be affected in any way by participating in the evaluation.	

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

Appendix 2 – Patient questionnaire for service evaluation

Patient Details:

TRITECH
Sefydliad | Institute

Magstim Evaluation Questionnaire

For each of the following questions, please select one response that indicates how much you agree with the statement.

➢ **Physical comfort**

1. I had discomfort in the head and neck during the appointment.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

2. I feel the appointments were too long.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

3. I experienced pain/discomfort during the appointment.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

4. I experienced involuntary movements during the appointment. If so, were they uncomfortable? (This question in reference to the device use instructions).

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

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

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

Patient Details:

TRITECH
Sefydliad | Institute

5. I felt fatigue (tired) as a result of the appointment.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

6. I had residual sensations* after the appointments.
***(*Residual sensation** means that you still have some sensation even after the appointment.)*

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

➢ **Impact of treatment**

1. The frequency of these appointments had an impact on my work/social life.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

2. The total number of these appointments had an impact on my work/social life.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

3. I had difficulties regarding travel to the appointments or with parking.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

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

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

Patient Details:

4. I prefer shorter/longer appointment sessions.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

5. There are some things that can be done to improve my experience of these appointments.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

➢ **Understanding of the treatment**

1. The treatment and its potential benefits were explained to me in a way that I understood.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

2. All potential side effects or risks were explained to me in a way that I understood.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

3. I felt positive about the treatments on my first appointment.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

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

Patient Details:

4. I feel positive about the treatment now.

○ *Strongly Agree* ○ *Agree* ○ *Neither Agree Nor Disagree* ○ *Disagree* ○ *Strongly Disagree*

Tell us more:

If you would like to share any additional comments or experiences about the treatment, please enter below:

Thank You!

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

Appendix 3 – Additional patient feedback

The comments below were from the patient questionnaires completed after the 20th treatment session.

- "Lovely team providing the treatment, both from healthcare and the company"
- "I find it difficult to keep going when I feel it has not yet made any difference. Such is my depression that I experience better days from time to time. I cannot attribute the better days I have experienced to the TMS."
- "The fact that I have had to leave the house every day is good for me. The most important thing is the compassion and empathy I have been shown. That definitely has kept me going to the sessions and has been invaluable. I feel very lucky to have been part of the trial."
- "I know that many patients have benefitted from this treatment, which is wonderful. I feel that maybe my bereavement is more complex and complicated resulting in a different depression/ sadness that's more associated with complex grief, which is something one has to carry and live with void. I am thankful and appreciate all the time and support provided and grateful that I was privileged to be part of trial. Wishing you all success with having equipment permanent, as positive for successful patients. Well done team. Keep up the good work"
- "Difficult to set up the machine. When I had a pain free session, I realised the last week was just unnecessary pain, and probably didn't work. Whilst we all need to learn, more experience of using the machine might have helped. Needs to be pain free"
- "I have had 54 sessions of ECT treatments at the they saved my life. This time I was diagnosed in time to have this treatment. I don't have to go to sleep I haven't lost memories of my life. Very professional nurses and a doctor is with you all the time when needed"
- "Extremely grateful to have been chosen. TMS has changed my life. I would say my depression is 90% better. My OCD symptoms are not so intense + I feel I have gained control over certain thoughts. By the end of week 3 I started to show significant improvements. A huge issue my mental health played was the havoc it played with my digestive system. This is nearly 100% back to normal now. I never used to sleep; I now sleep as the 'average' person would. Huge thanks to the team"

Appendix 4 – Staff feedback responses

Three staff members were available for interviews and their responses are collated by question and can be seen below.

1. Had you heard of rTMS technology before working on this service evaluation? What were your initial views on this?

- Some experience with another rTMS device but it was a different brand, other device's function and handle quite differently. The Magstim® device was appealing than the other device I have worked on, the technology is more advanced, but the chair is not as comfortable for the patient
- Not before this evaluation. Once aware of it, wanted to know more about it and was surprised that the health board was not already funding it.
- Previous rTMS knowledge has come mostly from the literature. Seems promising in the early days of the evaluation, but the implementation of this kind of technology needs more exploring.

2. How have you found working with the device? Prompt - training, ease of use etc.

- Very good to work with, the company have been outstanding and were very responsive to everything we needed. The chair had some issues, and the cable guard gave us some issues during use, this cable guard is quite rigid, and it made positioning the coil a little difficult on occasion. This cable guard was changed during the evaluation, and it helped a great deal.
- Training for the device was very good, but there were struggles with using the device. There are still days that it is a struggle to use properly, the location technology is a great feature, but the system will give feedback and alert when the coil is even slightly out of place. This meant that during the early sessions there was a lot of stopping and repositioning as we learnt how to use the device. These small adjustments during treatment caused delays which were frustrating for patients. The cable needed to be completely straight otherwise it could move during treatment, a shorter protocol could have reduced these frustrations.
- Treatments take a long time to administer, this is a big issue as the number of patients that can be helped by each staff member a reduced.

3. What are your thoughts on this kind of technology? When compared to ECT?

- When compared to ECT it is much cheaper and has less complications for the patient, such as no need for anaesthesia. But it should be noted that from a clinical perspective ECT would be used on the most severely depressed and rTMS would be aimed at slightly less sick patients. So a direct comparison between ECT and rTMS may not be appropriate. The advantage for rTMS treatments is that it could ease the waiting list for ECT treatments as the less sick could be treated with rTMS before their condition progresses further. rTMS would not completely replace the ECT service as they both have a clinical purpose. rTMS would be another step in the patient pathway for more clinical options (medications -> rTMS -> ECT).
- Some patients that were seen during the rTMS evaluation had gone through treatment for both ECT and rTMS and they have reported horrible experiences with ECT. Patients also report much fewer side effects with rTMS than ECT. Some of the GPs we have spoken to were not aware of this technology, more should be done to advertise it.
- Clinically this would not replace ECT, but further research could demonstrate how effective rTMS could be to ECT. But too early to tell, more data is required.

4. What benefits or potential do you see from rTMS?

- It is an effective treatment for drug resistant depression, we have already noticed benefits with some of the patients who have been treated. Feedback from patients has been positive as well.
- Patients during the first cohort did not see huge changes in clinical scores but they were a lot better in themselves. The routine contact and extra contact with staff was helpful to all the patients. From a nursing perspective, getting to work with patients on such a close level was very rewarding.
- The main benefit is that most patients would be more accepting of rTMS as a treatment option than ECT. ECT requires many treatments (8 to 12 sessions) which is fewer than rTMS, but ECT requires other resources such as anaesthesia. ECT is effective though, the bad press it has isn't completely justified.

5. What challenges have you faced so far with this service? Prompt - patient recruitment

- The biggest challenge has been continuity of care, patients have asked about follow-up treatments which we cannot offer. Patient recruitment was challenging, as the continuity of the care was not certain there was some hesitancy to really the recruitment phases, we did not want to have to turn away interested patients as this could have further affected their mental state. If it was an ongoing service, recruitment could have been easier as there would have been less concern about turning patients away. Funding is also an issue as the device costs need covering as well as dedicated staff to carry out the treatments. There was initially difficulty in finding a location for the device.
- Patient recruitment was a big challenge, GPs did not know about this technology, so it was difficult to get them to refer patients. There was a lot of pressure on staff, as so few of them knew the device well they knew that any sick days would really affect the service. The bank staff who were involved were not as comfortable or confident with the device so that caused frustrations with staff and patients during appointments. The training for the device by the company was great and they were very supportive, but this kind of technology needs a great deal of practice before staff can be proficient and feel comfortable with using it. Getting to the appointments regularly was a real challenge for some of the patients. Admin time for the clinical results was a real issue as there were a lot of results and clinical data to collect. Service worked well overall.
- The lessons learned log from the team meetings has all the main points (see next section). However the patient recruitment difficulties was a surprise. We expected more of an interest when we started contacting GPs, but there interest was not there.

6. We know patients found the treatment uncomfortable at times and travelling daily was hard, did they raise any additional points to you?

- No other issues that were not captured by the questionnaires or exception reports came up. The patients felt safe and supported and they spoke with staff regularly
- The published research and information leaflets for rTMS all report that it is not a painful or uncomfortable treatment, but many of the patients felt some level of discomfort or painful symptoms. Some patients even admitting to bracing themselves before a treatment as they knew it would not be pleasant.

7. Do you have any thoughts at this stage about what could make this kind of service work more efficiently?

- If more efficient advertisement of the service had been possible this would have helped a great deal, the hesitancy caused by not wanting to let patients down meant that the recruitment was challenging. Patients were getting handpicked which took longer. More staff resource would also have helped.
- More regular and permanent staff who were comfortable with the system would have helped, being able to promote the technology more with GPs could have really helped referral rates. Being able to offer extra treatments past the 6-week point would have been really helped patient outcomes, many patients were starting to see benefits towards the end and wanted step down treatments. Such as once or twice a week for two weeks after the 6 weeks to help them a bit more. rTMS services in other locations worldwide seem to offer similar step-down treatments with success.
- Dedicated admin staff would be required to help with all the clinical notes and documentation of everything. We could learn from the ECT department in terms of how it is organised as it is a similar size. More data would be needed to assess clinical effectiveness long term and value for the health board. Having extra data for a value-based health care approach would help make this kind of service more manageable and effective.

8. Has working with the first cohort taught you anything that will help you with the second cohort of patients?

- Staff training was important, as was knowledge of the device. The staff were more confident with the device after the first cohort so the appointment times became quicker, and more patients could be seen (4 then 6).
- Experience with using the device really helped, the appointment times were 1 hour and 30 minutes for the first cohort. This was cut down to 1 hour 10-minute appointment times for the second cohort as staff could set the device up faster and have less adjustments during treatment. Becoming more efficient with the patient reports really helped time management in the second cohort as well.

9. Do you think there is value in using rTMS within Hywel Dda?

- Hywel Dda currently only has two things to offer patients (medication, ECT), so this would be a great addition to the service. rTMS could also be helpful with other symptoms such as OCD, and suicidal thoughts. Complex patients were seeing benefits and the side effect profile is very low. Even the patients who did not see a benefit were impressed by service, the attendance rate for the sessions was exceptional.
- Cardiff University have an rTMS device, and they are being trialled in other locations. This should be done in Hywel Dda too. It would also be valuable to try the device for other symptoms and conditions such as anxiety, addiction, and OCD. There would be added value with being able to offer this treatment to a wider range of patients.
- VBHC elements would be needed to assess the real value or rTMS within the service. rTMS would add value to the service, but a longer trial period would be needed to assess the real feasibility.

10. What do you hope will happen following this pilot?

- Would like to keep running the service and to help more patients, but we are unable to advertise and carry it on which is disappointing.
- Working with the patients has been very fulfilling and rewarding, would like to keep working in the service and to have the device kept within the service.
- Opportunities for more in-depth research projects, such as use on other conditions, or follow studies to investigate long term effectiveness and need for repeat treatments. More work is needed on finding out to set up a service like this more effectively.

Appendix 5 – Clinical results tables (BDI II, PHQ09, MADRS)

	BDI II					BDI II (From Baseline)			
	Baseline	Week 2	Week 4	Week 6		Baseline	Week 2	Week 4	Week 6
Patient 1	45	49	26	39	Patient 1	0	4	-19	-6
Patient 2	40	42	33	35	Patient 2	0	2	-7	-5
Patient 3	49	49	52	47	Patient 3	0	0	3	-2
Patient 4	32	35	35	24	Patient 4	0	3	3	-8
Patient 5	37	27	19	22	Patient 5	0	-10	-18	-15
Patient 6	46	45	38	42	Patient 6	0	-1	-8	-4
Patient 7	36	19	18	3	Patient 7	0	-17	-18	-33
Patient 8	33	33	23	8	Patient 8	0	0	-10	-25
Patient 9	55	54	19	35	Patient 9	0	-1	-36	-20
Patient 10	37	28	24	35	Patient 10	0	-9	-13	-2

	PHQ-9					PHQ-9 (From Baseline)			
	Baseline	Week 2	Week 4	Week 6		Baseline	Week 2	Week 4	Week 6
Patient 1	27	25	15	21	Patient 1	0	-2	-12	-6
Patient 2	20	19	13	15	Patient 2	0	-1	-7	-5
Patient 3	26	25	24	24	Patient 3	0	-1	-2	-2
Patient 4	24	23	24	12	Patient 4	0	-1	0	-12
Patient 5	20	13	13	13	Patient 5	0	-7	-7	-7
Patient 6	23	23	22	22	Patient 6	0	0	-1	-1
Patient 7	23	12	10	1	Patient 7	0	-11	-13	-22
Patient 8	18	17	9	4	Patient 8	0	-1	-9	-14
Patient 9	24	25	18	12	Patient 9	0	1	-6	-12
Patient 10	16	14	12	12	Patient 10	0	-2	-4	-4

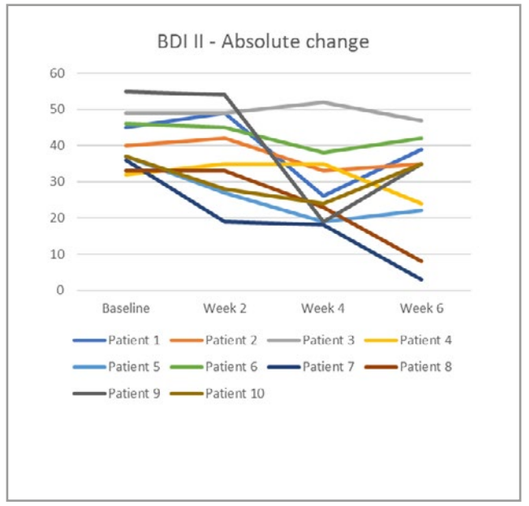
	MADRS					MADRS (From Baseline)			
	Baseline	Week 2	Week 4	Week 6		Baseline	Week 2	Week 4	Week 6
Patient 1	32	26	20	23	Patient 1	0	-6	-12	-9
Patient 2	30	26	24	24	Patient 2	0	-4	-6	-6
Patient 3	46	30	28	28	Patient 3	0	-16	-18	-18
Patient 4	32	28	26	22	Patient 4	0	-4	-6	-10
Patient 5	26	20	16	18	Patient 5	0	-6	-10	-8
Patient 6	38	36	28	28	Patient 6	0	-2	-10	-10
Patient 7	30	16	10	0	Patient 7	0	-14	-20	-30
Patient 8	32	22	18	10	Patient 8	0	-10	-14	-22
Patient 9	46	46	16	14	Patient 9	0	0	-30	-32
Patient 10	22	22	18	14	Patient 10	0	0	-4	-8

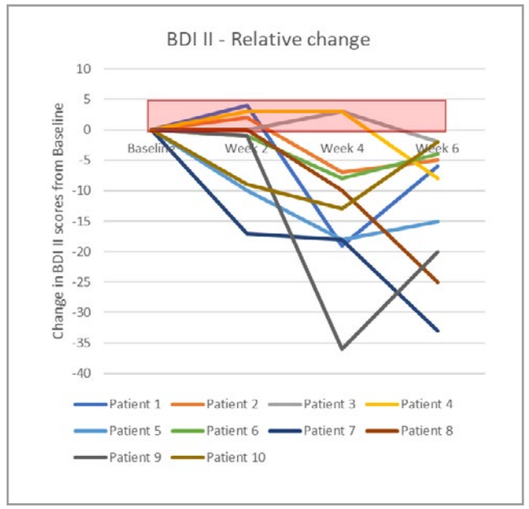
Appendix 6 – Clinical results table (CGI)

CGI (n=10)				
	Baseline	Week 2	Week 4	Week 6
Patient 1	Markedly ill	Markedly ill, No change, 1.00	Moderately ill, Minimally improved, 2.00	Moderately ill, Minimally improved, 2.00
Patient 2	Markedly ill	Markedly ill, No change, 1.00	Moderately ill, Minimally improved, 2.00	Moderately ill, Minimally improved, 2.00
Patient 3	Severely ill	Severely ill, No change, 1.00	Severely ill, No change, 1.00	Severely ill, No change, 1.00
Patient 4	Markedly ill	Markedly ill, No change, 1.00	Markedly ill, No change, 1.00	Moderately ill, Minimally improved, 2.00
Patient 5	Markedly ill 5	Moderately ill 4, Minimally improved 3, 2.00	Moderately ill 4, Minimally improved 3, 2.00	Moderately ill 4, Minimally improved 3, 2.00
Patient 6	Severely ill 6	Severely ill 6, No change 4, 1.00	Markedly ill 5, Minimally improved 3, 2.00	Markedly ill 5, Minimally improved 3, 2.00
Patient 7	Markedly ill 5	Mildly ill 3, Much improved 2, 3.00	Borderline mentally ill 2, Much improved 2,	Normal, not at all ill 1, Very much improved 1, 4.00
Patient 8	Markedly ill 5	Markedly ill 5, No change 4, 1.00	Moderately ill 4, Minimally improved 3, 2.00	Borderline mentally ill 2, Much improved 2,
Patient 9	Among the most extremely ill patients, 7	Among the most extremely ill patients, 7, No	Moderately ill 4, Much Improved 2, 3.00	Mildly ill 3, minimally improved 3, 2.00
Patient 10	Moderately ill, 4	Moderately ill 4, No change, 1.00	Mildly ill 3, Minimally improved 3, 2.00	Mildly ill 3, Minimally improved 3, 2.00

Key
Among the most extremely ill
Severely ill
Markedly ill
Moderately ill
Mildly ill
Borderline mentally ill
Normal, not at all ill

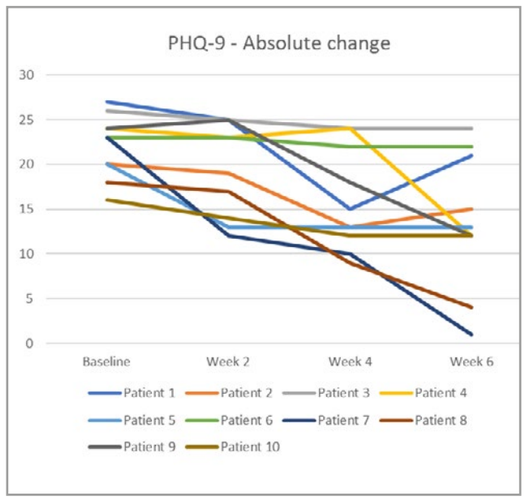
Appendix 7 – BDI II graphs

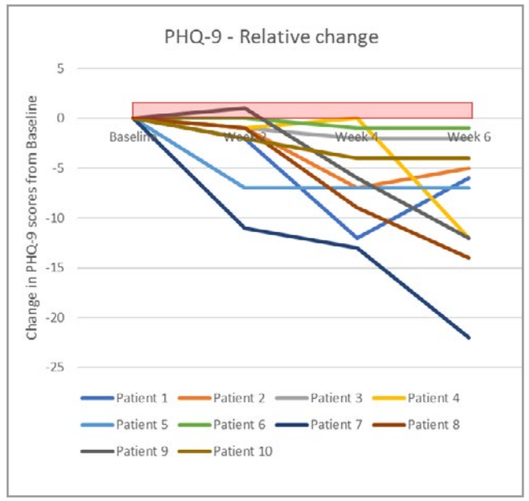




Appendix 4 shows the absolute changes in BDI II scores for each of the patients on the left and the relative changes in BDI II scores from each of the patients own baseline score on the right, where the red area indicates a worsening of score

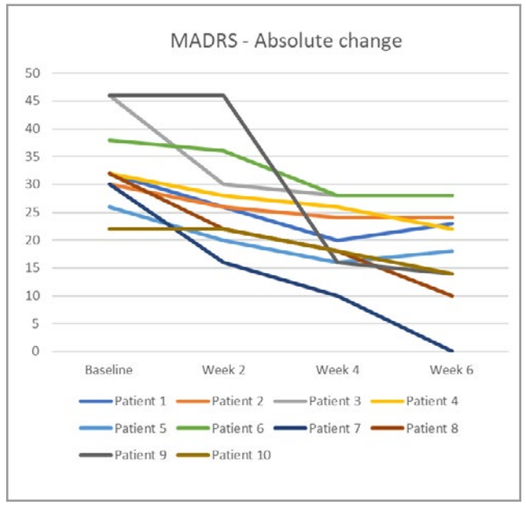
Appendix 8 – PHQ-9 graphs

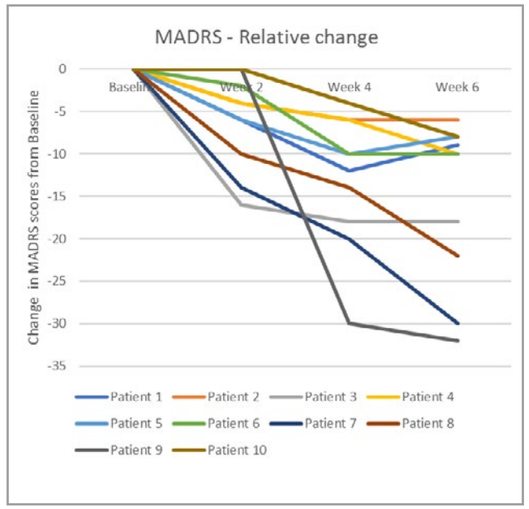




Appendix 5 shows the absolute changes in PHQ-9 scores for each of the patients on the left and the relative changes in PHQ-9 scores from each of the patients own baseline score on the right, where the red area indicates a worsening of score

Appendix 9 – MADRS graphs





Appendix 6 shows the absolute changes in MADRS scores for each of the patients on the left and the relative changes in MADRS scores from each of the patients own baseline score on the right

Appendix 10 – Patient questionnaires (Patients 1 - 5)

Please not patient numbers for the questionnaire are not the same as the patient numbers for appendices 3 & 4.

Physical comfort					
Question	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
1) I had discomfort in the head and neck during the appointment	Neither agree nor disagree	Disagree	Disagree	Agree	Strongly Disagree
	Occasionally the treatment was quite uncomfortable			Just an unpleasant feeling, sometimes felt intense	
2) I feel the appointments were too long	Neither agree nor disagree	Disagree	Agree	Strongly Disagree	Strongly Disagree
3) I experienced pain/discomfort during the appointment	Neither agree nor disagree	Neither agree nor disagree	Disagree	Agree	Strongly Disagree
	Occasionally the treatment was quite uncomfortable	Sometimes I felt that a nerve was being triggered and it caused			
4) I experienced involuntary movements during the appointment. If so were they uncomfortable?	Disagree	Agree	Disagree	Agree	Strongly Disagree
		Occasionally, slightly uncomfortable		Slight eye twitching and watering	
5) I felt fatigue (tired) as a result of the appointment	Agree	Agree	Disagree	Agree	Agree
	Any activity causes similar			Very tired after sessions	
6) I had residual sensations* after the appointments. (*Residual sensation means that you	Strongly disagree	Agree	Disagree	Disagree	Neither agree nor disagree
		Occasionally I would have a migraine, if a nerve had been triggered			

Impact of treatment					
Question	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
1) The frequency of these appointments had an impact on my work/social life.	Neither agree nor disagree	Strongly disagree	Agree	Neither agree nor disagree	Strongly Disagree
	It is a lot of commitment	I don't have a work, or a social life.			
2) The total number of these appointments had an impact on my work/social life.	Neither agree nor disagree	Strongly disagree	Agree	Neither agree nor disagree	Strongly Disagree
3) I had di c ulties regarding travel to the appointments or with parking	Agree	Strongly disagree	Disagree	Disagree	Strongly Disagree
	I do not drive due to illness so relied on lifts/taxis/long walk				
4) I would prefer shorter/longer appointment sessions	Neither agree nor disagree	Neither agree nor disagree	Agree (circled shorter sessions)	Disagree	Neither agree nor disagree
5) There are some things that can be done to improve my experience of these appointments	Neither agree nor disagree	Disagree	Neither agree nor disagree	Disagree	Strongly Disagree

Understanding the treatment					
Question	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
1) The treatment and its potential benefits were explained to me in a way that I understood	Agree	Agree	Disagree	Agree	Strongly Agree
				Well explained and supportive throughout	
2) All potential side e ects or risks were explained to me in a way that I understood.	Agree	Agree	Agree	Agree	Agree
3) I felt positive about the treatments on my first appointment.	Strongly agree	Agree	Neither agree nor disagree	Agree	Neither agree nor disagree
	It gave me a renewed sense of hope				Too ill on the 1st appointment to feel positive
4) I feel positive about the treatment now.	Agree	Neither agree nor disagree	Disagree	Neither agree nor disagree	Neither agree nor disagree
	I am hoping it will work	Even though at present, I don't feel positive effects myself. I still feel	I am dismayed that I have not experienced a breakthrough by	I tried but sadly no change since treatment commenced	

Appendix 11 – Patient questionnaires (Patients 6 - 9)

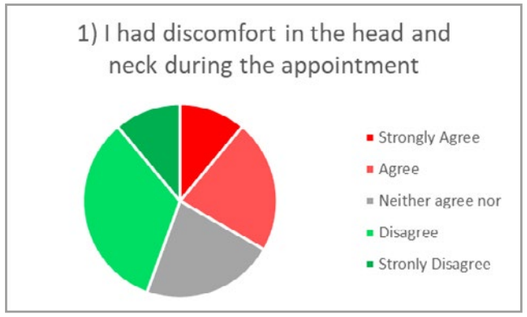
Please not patient numbers for the questionnaire are not the same as the patient numbers for appendices 3 & 4.

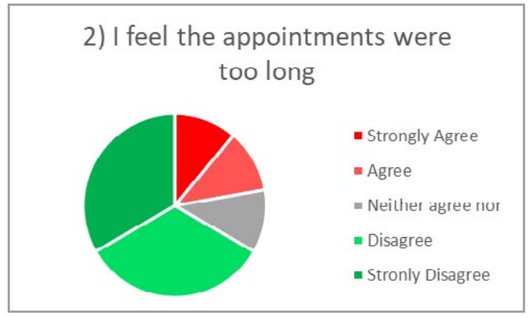
Physical comfort				
Question	Patient 6	Patient 7	Patient 8	Patient 9
1) I had discomfort in the head and neck during the appointment	Strongly Agree	Neither agree nor disagree	Blank	Agree
	Pain in neck from staying in one position	In the third week it was painful in my left side of my head and left eye and tingling in the nose	I didn't have any discomfort in my head or neck	Not painful, but not a particularly pleasant experience
2) I feel the appointments were too long	Strongly Disagree	Disagree	Blank	Strongly agree
		I found the treatment went quite quickly, but could do with some sort of entertainment such as Netflix	I found the length of the appointments copable	Inconvenient when working full time, loss of earnings
3) I experienced pain/discomfort during the appointment	Strongly Agree	Neither agree nor disagree	Blank	Agree
	In the eye, the jaw, on the skull	In my thrd week as explained in Q1	I didn't have any discomfort during the appointment	Again not pain but not pleasant feeling
4) I experienced involuntary movements during the appointment. If so were they uncomfortable?	Strongly Agree	Neither agree nor disagree	Blank	Agree
	Finger twitch and jaw and eye twitch/pain	In my nose and sometimes in my left eye in the third weekand needed to be repositioned.	I didn't experience any involuntary movements during the appointment	Twitching, eyebrows occasionally and face, not painful
5) I felt fatigue (tired) as a result of the appointment	Strongly Agree	Strongly Agree	Blank	Strongly agree
	Straight after and in the evening	I felt very tired after the treatment and when I had to go to work I felt very fatigued	I did not feel fatigue as a result	First two weeks, extremely fatigued. Normality resumed after week 2
6) I had residual sensations* after the appointments. (*Residual sensation means that you	Neither agree nor disagree	Agree	Blank	Agree
	Small headaches	Headaches after a few treatments	I had no sensation after the appointment	Tiredness and headaches first 2 weeks only

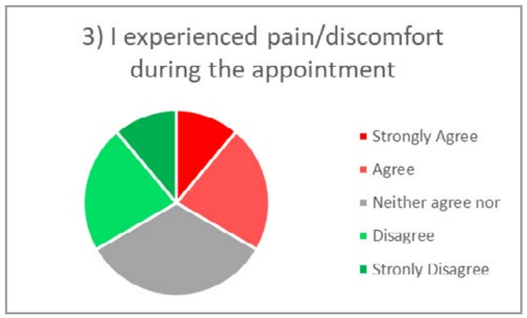
Impact of treatment				
Question	Patient 6	Patient 7	Patient 8	Patient 9
1) The frequency of these appointments had an impact on my work/social life.	Strongly Agree	Agree	Blank	Strongly agree
	Splits up the day, too tired to go back to work	It had a positive impact on my life as I went to a wedding on my own and made new friends	I had to reduce my hours but took holidays to compensate	Inconvenient with working full time
2) The total number of these appointments had an impact on my work/social life.	Strongly Agree	Neither agree nor disagree	Blank	Strongly agree
	Just that it's every day	Yes, I had to go in later and it affected my work even though I had the earliest appointment	I am very fortunate, my manager helped me to arrange hours that I could cope with	
3) I had di c ulties regarding travel to the appointments or with parking	Strongly Disagree	Agree	Blank	Strongly disagree
		My car was in the garage after failing it's MOT and I needed to borrow a car to get to the appointments	I had a person to pick bring me to appointments and he also picked me up	Very convenient
4) I would prefer shorter/longer appointment sessions	Neither agree nor disagree	Neither agree nor disagree	Blank	Strongly agree
		The session was OK, maybe 6 days sessions could have helped as I felt low in myself on Sundays	No	Shorter sessions would be great
5) There are some things that can be done to improve my experience of these appointments	Strongly Agree	Blank	Blank	Agree
	No pain	Make neck rest longer, and need some entertainment	I do not feel there is anything to be done to improve my experience of the appointments	Time - sessions long

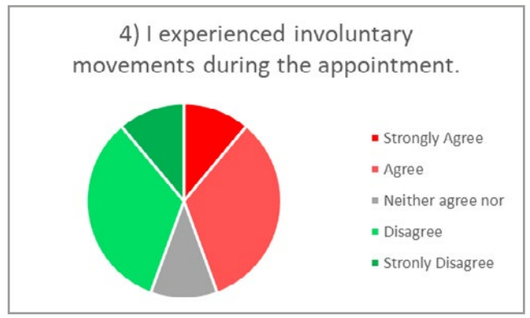
Understanding the treatment				
Question	Patient 6	Patient 7	Patient 8	Patient 9
1) The treatment and its potential benefits were explained to me in a way that I understood	Strongly Agree	Neither agree nor diagree	Blank	Strongly Agree
		Treatment was well explained	Yes they were explained to me in a way I understood	Great, Jess + Dr Khan have been superb, Lucinda from Magstim has also been great
2) All potential side e ects or risks were explained to me in a way that I understood.	Strongly Agree	Agree	Blank	Strongly Agree
		Side effects were explained	Yes they were explained to me in a way I understood	Great, clear communication
3) I felt positive about the treatments on my first appointment.	Neither agree nor disagree	Agree	Blank	Strongly Agree
		Treatment has been positive, it has played a positive part in my life so far	I did feel very confident on my first appointment	
4) I feel positive about the treatment now.	Strongly Agree	Agree	Blank	Strongly Agree
	Seems to be having a positive affect on my life	I feel there has been a positive effect from the treatments, the weekly feedback has been positive even though I can't see it myself	I feel very positive about the treatment now	90% better

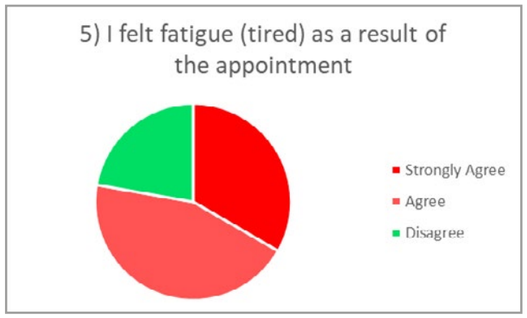
Appendix 12 – Patient questionnaire (Physical comfort)

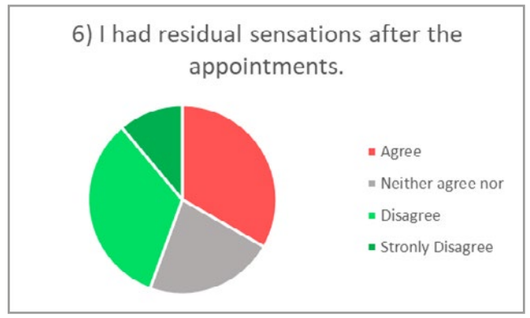




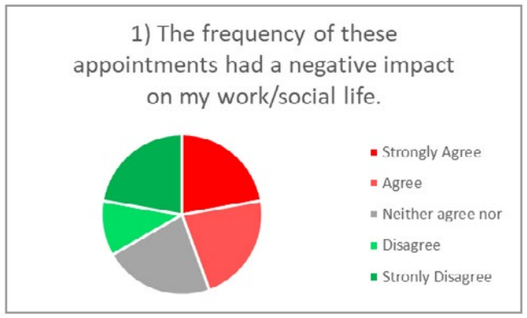


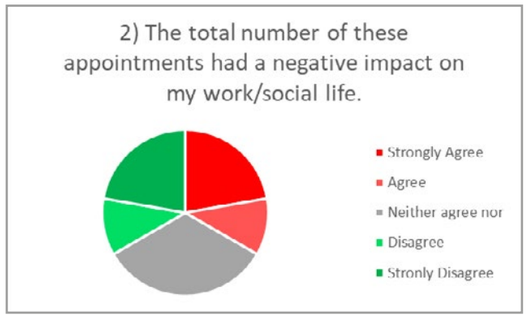


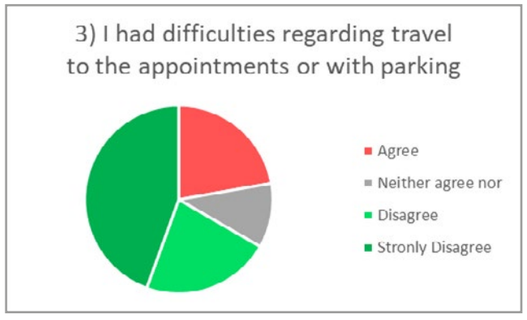


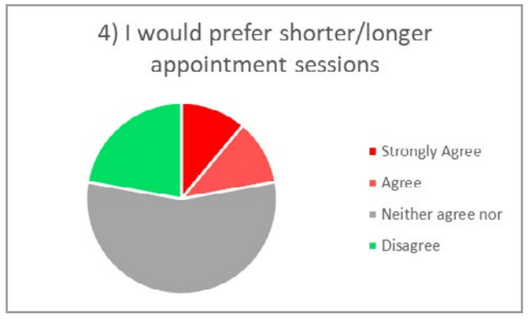


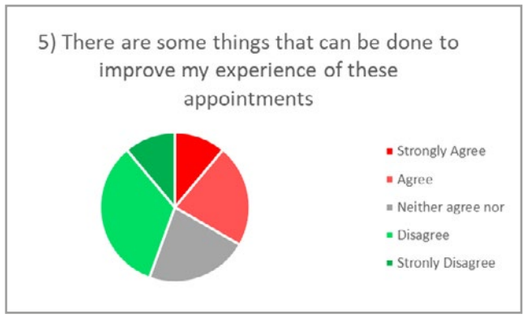
Appendix 13 – Patient Questionnaire (Impact of treatment)



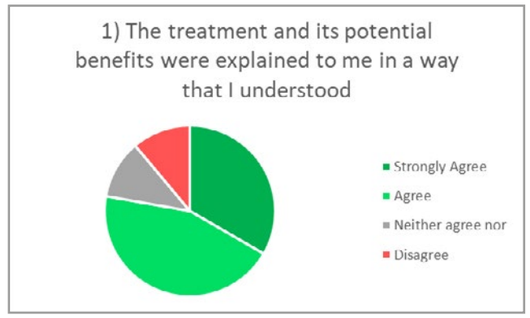


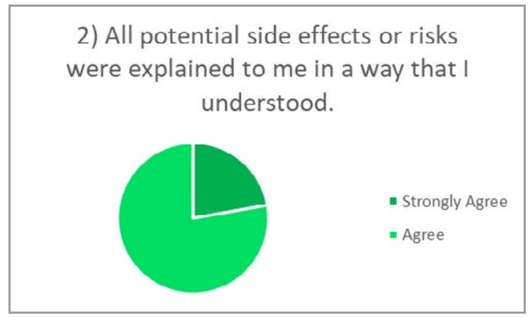


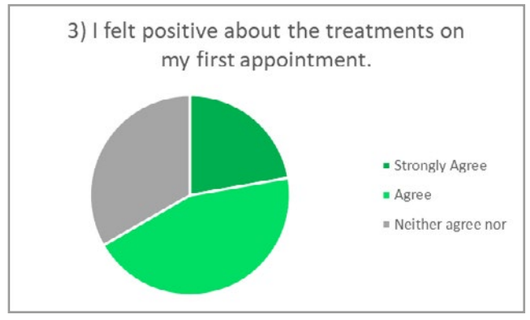


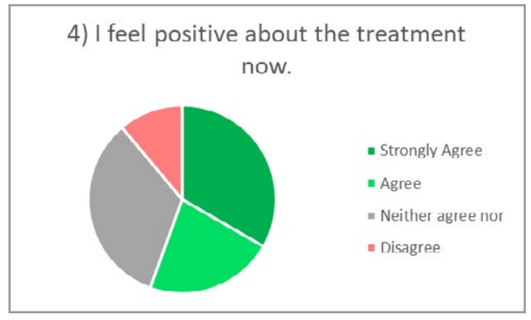


Appendix 14 – Patient Questionnaire (Understanding of treatment)









Appendix 15 – Summary of patient questionnaire responses

	Question	Strongly Agree	Agree	Neither agree nor	Disagree	Stronly Disagree
Physical Comfort	1) I had discomfort in the head and neck during the appointment	1	2	2	3	1
	2) I feel the appointments were too long	1	1	1	3	3
	3) I experienced pain/discomfort during the appointment	1	2	3	2	1
	4) I experienced involuntary movements during the appointment. If so were they uncomfortable?	1	3	1	3	1
	5) I felt fatigue (tired) as a result of the appointment	3	4		2	
	6) I had residual sensations after the appointments.		3	2	3	1
Impact of Treatment	1) The frequency of these appointments had a negative impact on my work/social life.	2	2	2	1	2
	2) The total number of these appointments had a negative impact on my work/social life.	2	1	3	1	2
	3) I had difficulties regarding travel to the appointments or with parking		2	1	2	4
	4) I would prefer shorter/longer appointment sessions	1	1	5	2	
	5) There are some things that can be done to improve my experience of these appointments	1	4		3	1
Understanding of Treatment	1) The treatment and its potential benefits were explained to me in a way that I understood	3	4	1	1	
	2) All potential side effects or risks were explained to me in a way that I understood.	2	7			
	3) I felt positive about the treatments on my first appointment.	2	4	3		
	4) I feel positive about the treatment now.	3	2	3	1	

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