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| Institution: University of Bath | | |
| Unit of Assessment: A4 Psychology, Psychiatry and Neuroscience | | |
| Title of case study: Improving Care for Patients with Chronic and Distressing Tinnitus through Mindfulness Based Interventions | | |
| Period when the underpinning research was undertaken: July 2015 – December 2019 | | |
| Details of staff conducting the underpinning research from the submitting unit: | | |
| Name(s): | Role(s) (e.g. job title): | Period(s) employed by submitting HEI: |
| Dr Elizabeth Marks Dr Paula Smith | Lecturer (Clinical Tutor) Senior Lecturer | July 2015 – present January 2008 – present |
| Period when the claimed impact occurred: 2016 - 2020 | | |
| Is this case study continued from a case study submitted in 2014? N | | |
| 1. Summary of the impact | | |
| <p>Tinnitus is a common and debilitating health condition, requiring clinical intervention in 3% of adults. Dr Marks' research established the effectiveness of a new, innovative Mindfulness Based Cognitive Therapy for Tinnitus (MBCT-t). The research demonstrated clinically significant reductions in tinnitus severity in 62% of treated patients, sustained at six months. Improvements were shown to continue for years, and treatment is associated with decreased patient re-referral rates (just 1%, far lower than standard care), indicating real economic savings. MBCT-t is acceptable to patients, who have described it as 'life changing'. Prior to the research, few UK tinnitus patients had ever accessed mindfulness. Since dissemination, the research has changed clinical practice and at least 5,000 UK tinnitus patients have now been treated with mindfulness. By providing critical evidence for the efficacy of MBCT-t, the underpinning research directly influenced health policy, and for the first time both the European (2019) and NICE (2020) Tinnitus Guidelines recommend MBCT-t be considered as a treatment for tinnitus.</p> | | |
| 2. Underpinning research | | |
| <p>The British Tinnitus Association (BTA) states that 6,000,000 people in the UK report tinnitus, with a substantial societal cost of GBP2,700,000,000 per annum (GBP750,000,000 in healthcare costs, plus significant family costs and productivity loss). Considerable emotional and social impacts are reported by 20% of tinnitus sufferers (depression, anxiety, insomnia, and impaired cognition, functioning and quality of life) [4]. It is estimated that 3% of all adults may require clinical intervention for tinnitus [Ai]. No medical or surgical 'cure' to 'silence' tinnitus exists [Ai]. For decades, the only available treatment was sound therapy, advice to resist tinnitus (e.g. partial masking), relaxation and supportive counselling, despite there being insufficient evidence for clinical or cost effectiveness for such approaches [Ai]. Psychological treatments have far better outcomes [Ai], but these are rarely offered and often inaccessible. Research developing and demonstrating the benefits of such treatments therefore has a significant impact on the huge number of people who are suffering with this challenging condition.</p> <p>Dr Marks' research at the University of Bath, in collaboration with University College London and Royal National Throat, Nose and Ear hospital, has significantly improved the evidence base for psychological treatments for tinnitus. Findings demonstrated that Mindfulness Based Cognitive Therapy for tinnitus (MBCT-t) meaningfully changes how people think about and relate to tinnitus, reducing tinnitus severity and improving quality of life [1,4]. This empirical evidence challenged the fundamental principles underlying traditional treatments: Rather than resisting tinnitus or trying to relax (as standard advice would encourage) mindfulness teaches patients to</p> | | |

Impact case study (REF3)

relate to tinnitus differently. By replacing their struggle against tinnitus with a new, more adaptive relationship to it, patient recovery and quality of life are enhanced [1-5]. Advice to use mindfulness for tinnitus has thus brought a new perspective to tinnitus care, with significant benefits for patients.

In 2020 the underpinning research was cited as the most reliable evidence for mindfulness in tinnitus [Aii], based on a gold-standard, randomised controlled trial published in 2017 comparing MBCT-t to active treatment (relaxation training) [1], robust qualitative studies disseminated in 2019 and 2020 [3,4] and evaluations of a large, complex sample in an NHS clinic published in 2018 and 2020 [2,5]. The standardised protocol is easily replicated, and the qualitative studies offer clear clinical advice.

In 2017 it was shown that MBCT-t led to reliable and clinically significant reductions in standardized measures of tinnitus severity and intensity in 62% of patients, sustained for six months. Treatment showed a moderate effect size (standardized mean difference = 0.59) which compares well with the efficacy of other proven psychological treatments for tinnitus. Clinically significant, reliable reduction in a standardized measure of psychological distress was reported by 49% of patients, with additional reductions in anxiety, depression and disability, all sustained for six months [1]. Some patients felt that mindfulness led to 'better quality of life' [4]. Recent research found that broad benefits can persist for more than five years [5], which reduces re-referral rates and hence offers significant economic savings.

MBCT-t is highly acceptable (rated as 8.2/10 for usefulness, 8.4/10 for relevance) with high session attendance (86%) and low dropout rates (9%) [1]. In a robust qualitative study [4] patients described how mindfulness can "retrain the brain", so they are no longer "at war with the noise", and "the effect of tinnitus (is) dramatically less". In the absence of a 'cure' to 'silence' tinnitus, these findings offer patients real hope [1,2,4].

3. References to the research

The key research has been published in leading peer-reviewed journals in Clinical Psychology, Otorhinolaryngology and Speech and Hearing, with broad reach to a range of professional groups.

1. McKenna, L, Marks, E, Hallsworth, C & Schaette, R 2017, 'Mindfulness Based Cognitive Therapy compared to Relaxation Training for Chronic Tinnitus: A Randomized Controlled Trial', *Psychotherapy and Psychosomatics*, vol. 86, no. 6, pp. 351–361. <https://doi.org/10.1159/000478267>
2. McKenna, L, Marks, E & Vogt, F 2018, 'Mindfulness based cognitive therapy for chronic tinnitus: evaluation of benefits in a large sample of patients attending a tinnitus clinic', *Ear and Hearing*, vol. 39, no. 2, pp. 359 - 366. <https://doi.org/10.1097/AUD.0000000000000491>
3. Marks, E, Smith, P & McKenna, L 2019, 'Living with tinnitus and the healthcare journey: An interpretative phenomenological analysis', *British Journal of Health Psychology*, vol. 24, no. 2, pp. 250-264. <https://doi.org/10.1111/bjhp.12351>
4. Marks, E, Smith, P & McKenna, L 2020, 'I wasn't at war with the noise: How Mindfulness Based Cognitive Therapy changes patient's experiences of tinnitus', *Frontiers in Psychology*, vol. 11, 483. <https://doi.org/10.3389/fpsyg.2020.00483>
5. Marks, E, McKenna, L & Vogt, F 2020, 'Mindfulness Based Cognitive Therapy for tinnitus: Evaluation of long-term outcomes', *Clinical Psychology Forum*, vol. 2020, no. 334, pp. 45-50.

Grant funding:

A Randomized Controlled Trial investigating the efficacy of MBCT for tinnitus. GBP75,739 (Dec 2013 to Dec 2016). Awarded by the BTA to Dr Laurence McKenna (Chief Investigator), Dr Elizabeth Marks, Roland Schaette, Roshini Alles (Co-investigators). The research started at Royal National Throat Nose and Ear Hospital, but a distinct and significant contribution was made by Dr Marks at the University of Bath since 2015 in data collection, management, analysis, writing up and dissemination of all underpinning research. The grant ended in December 2016,

and as with most projects, ongoing dissemination and impact translation activity has continued ever since.

4. Details of the impact

Overview

The research proved MBCT-t is effective and acceptable. Since dissemination in 2017, it changed clinical practice, national and international clinical guidelines, advice offered globally and professional tinnitus training. Multiple centres since report effectiveness and long-term benefits, describing how MBCT-t makes “*an incredible difference to... patients*” [G] and positive patient feedback describing it as “*wonderful*” [D]. Public engagement raised awareness of mindfulness for tinnitus. At least 5,000 UK tinnitus patients have already benefitted from mindfulness treatments, largely because of the research. Considering the prevalence and costs of persistent tinnitus, and lack of evidence for other treatments, the research has led to a significant reduction in the economic and health burden of tinnitus upon individuals, healthcare services and society.

Adoption of mindfulness for tinnitus in UK clinical practice

The British Tinnitus Association (BTA), a world-leading tinnitus charity, supporting a million people globally each year, reports significant clinical changes due to the research. In 2020 they stated that “*because of research evidence... published by Dr Marks*” at least 49 UK audiology services now integrate “*mindfulness... into their treatments for tinnitus*”. Clinical testimonies indicate “*5,000 patients have benefitted from mindfulness in just the past 2–3 years, from a baseline of almost zero prior to dissemination of Dr Marks’ research*”. This estimate of 5,000 is based only upon “*testimonies from five [5] services*” so “*the total number of patients benefitting from mindfulness in the past few years is... likely to be far higher*” [C].

The Clinical Director of a large UK audiology hospital (Royal National ENT and Dental Hospital - RNENTDH) also reported large changes to clinical practice due to the research. From a baseline of 10 patients, mindfulness interventions now reach 865 patients annually (3,000 to date). Mindfulness has become “*embedded within daily clinical practice... the benefits are likely to continue to have a positive impact on... thousands of patients*” [D].

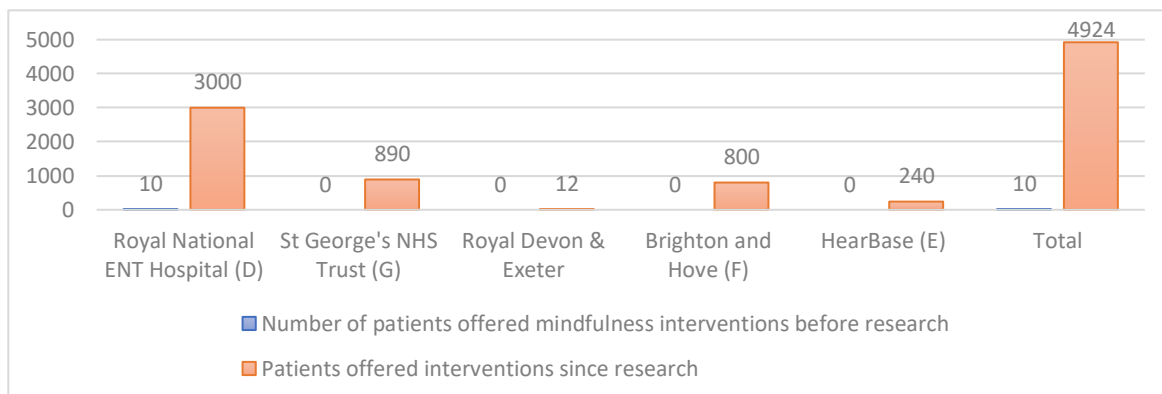


Figure 1: Change in clinical practice in 5 UK audiology services: Number of patients ever receiving mindfulness before research was disseminated (pre-2017) compared to number who have received mindfulness since research was disseminated (post-2017) [C]

The research directly influenced clinical practice in multiple services [C,D,E,F,G]. Mindfulness therapies were rarely offered to tinnitus patients prior to 2017. Publication of the research supported changes in service provision, and mindfulness is now offered to hundreds of tinnitus patients annually (see Figure 1). Reports from the BTA, RNENTDH and other testimonial letters directly attribute these changes to Dr Marks’ research [C,D,E,F,G]. For example, an Advanced Audiologist at St George’s Hospital testifies that Dr Marks’ research “*significantly change(d) the way that we operate our clinical services for tinnitus*” [G].

The research also underpins recommendations in the 2018 Tinnitus Decision Aid [I], a new clinical tool that now promotes mindfulness and other psychological treatments to patients and audiology clinicians. The BTA states this is an *“important development in the field”* [C].

Integrating MBCT into International Policy and Advice

The first NICE guidelines for tinnitus management were published in 2020, stating that *“MBCT should be considered”* [Ai, 1.5.4] within a stepped-care approach. The research [1] clearly influenced this conclusion, being the most robust evidence for mindfulness, rated as “critical” importance and “high to moderate” quality (Aii, pp232-234, table 58) compared with the three other mindfulness trials, rated as “very low” quality (Aii, pp.234-236 tables 59,60). Health economic modelling based on [1] supports MBCT-t as the least expensive option within a stepped-care model [Aii, p.67], demonstrating the significant economic benefits of MBCT-t, as it reduces the burdens of tinnitus in the most cost-effective way. The first European tinnitus guideline (2019) [B] for pan-European healthcare professionals recommends that *“information that should be given to patients”* includes mindfulness since the underpinning research [1] indicates it is *“feasible as a treatment for tinnitus”* [B p.S33].

In 2018 the BTA published new advice on mindfulness for tinnitus, based on the research [1,2], in collaboration with Dr Marks [H]. This advice has reached 1,000s of people (100s per annum) via UK Tinnitus Information Days, and over 9,000 via their website (50% internationally) last year, with numbers increasing over time (Figure 2) [C].

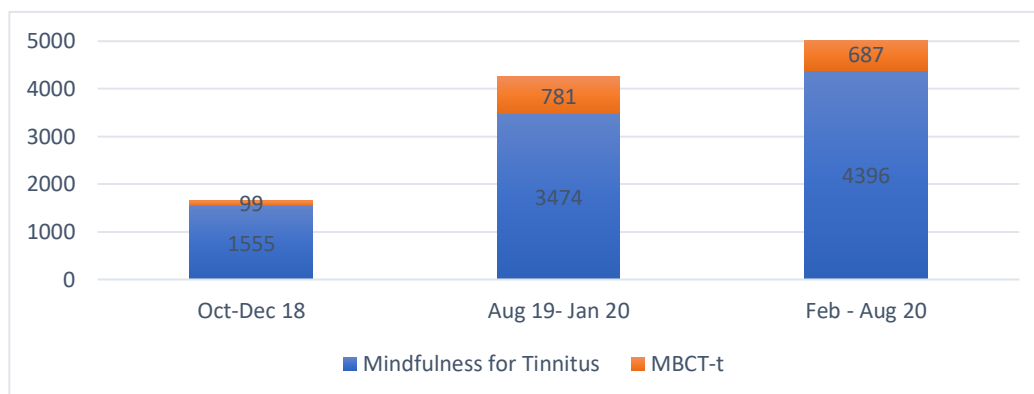


Figure 2: BTA website views of mindfulness advice based on the underpinning research [C]

Improved teaching and training

The research changed professional audiology training. Since 2015, Dr Marks has offered annual masterclasses in MBCT-t at the UCL Ear Institute [C], at BTA training days, and has trained 13 clinicians at the RNENTDH in MBCT-t [D]. Since 2017, a Senior Lecturer in Audiology at the University of Manchester used the research to develop audiology training to include mindfulness [C].

Benefitting patients and reducing re-referral rates

By having a *“direct impact on the clinical activity of multiple audiology services across the UK”* the research has benefitted patients via *“positive experiences, high satisfaction, good outcomes and low re-referral rates”*, a substantial improvement upon the *“low satisfaction and... high re-referral rates (associated) with more traditional treatments”* [C]. In 2019, St George’s Hospital reported that 2 years of delivering MBCT-t had led to reduced tinnitus severity, high patient satisfaction (rated 4.6/5), a re-referral rate of just 1% is *“far lower than those receiving standard care”* [G] and associated cost savings. Feedback from MBCT-t recipients is positive, with MBCT described as *“life-changing”, “excellent”, “magnificent”, and “the best national health treatment I have had”* [D].

Public engagement

Since 2017, growing media coverage has increased awareness of and engagement in mindfulness for tinnitus by patients, clinicians [C] and services [D]. This includes reports in high-profile media outlets (*The Observer*, *BBC Radio Bristol* (2017), *The Times* (2018), *Good Housekeeping Magazine* (2019), *NHK Japan TV* (2020) [D]. Furthermore, in 2018 the research [1] won the prestigious BTA Shapiro Prize and a finalist position in the Bath and Bristol Healthcare Awards.

5. Sources to corroborate the impact

- A. NICE guideline [NG155] Tinnitus: Assessment and Management (2020).
 - i) Overview – As PDF. Also available at: <https://www.nice.org.uk/guidance/ng155>
 - ii) Full evidence review for psychological therapies: <https://www.nice.org.uk/guidance/ng155/evidence/l-psychological-therapies-pdf-255229407253>
- B. Cima, R.F.F, Mazurek, B., Haider,H., Kikidis,D., Lapira, A., Norena, A., Hoare, D.J. (2019) A Multidisciplinary European guideline for tinnitus: Diagnostics, assessment and treatment. *HNO 67 (Suppl1):S10-S42* (TINNET European Guidelines). As PDF. Also available at: <https://link.springer.com/content/pdf/10.1007/s00106-019-0633-7.pdf>
- C. Testimonial letter 1 - Chief Executive, British Tinnitus Association, 1 September 2020.
- D. Testimonial letter 2 - UCLH Manager of Specialist Hospitals, Royal National ENT and Dental Hospitals (RNENTD) 5 February 2020.
- E. Testimonial letter 3 - Hearing Therapist, HearBase, 23 November 2019.
- F. Testimonial letter 4 - Hearing Therapist, Brighton & Sussex University Hospital Trust, 18 August 2020.
- G. Testimonial letter 5 - Advanced Audiologist, St George's University NHS Foundation Trust, 24 December 2019.
- H. Mindfulness for Tinnitus Leaflet (based on underpinning research), for patients and clinicians (April 2019), available on BTA website: <https://www.tinnitus.org.uk/Handlers/Download.ashx?IDMF=2b83f18e-0944-4617-939e-4d02e082969b>
- I. Decision Aid Tool (2018) Pages 1 and 2 (Underpinning research cited on page 1 in support of various psychological therapies for tinnitus which, as the citations indicate, necessarily include mindfulness). <https://www.tinnitus.org.uk/decision-aid>