

Institution: King's College London		
Unit of Assessment: 4		
Title of case study: Development, evaluation and implementation of the world's first cognitive behaviour therapy (CBT) for menopausal symptoms		
Period when the underpinning research was undertaken: 2006 – 2018		
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:
Myra S Hunter	Emerita Professor of Clinical Health Psychology	Dec 2006 – Oct 2019
Eleanor Mann	Post-doctoral researcher	June 2009 – Dec 2011
Beverly Ayers	Post-doctoral researcher	Nov 2008 – Dec 2012
Claire Hardy	Postdoctoral research worker	Nov 2013 – Jan 2018
Period when the claimed impact occurred: 2014 – 2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact

Menopause symptoms such as hot flushes and night sweats are experienced by millions of women worldwide, and their effect can often be debilitating and life altering. Hormone therapy is used by many women, but an effective non-medical alternative was needed. Researchers at King's were the first to develop and evaluate a specific cognitive behavioural therapy (CBT) intervention to meet the need for safe and effective non-hormonal treatments for women with problematic menopausal symptoms. King's CBT produced significant reductions in the impact of hot flushes and night sweats in randomised controlled trials (RCTs), with additional benefits to sleep, mood and quality of life. It is now recommended by the National Institute for Health and Care Excellence (NICE) in the UK, and a position statement from the North American Menopause Society considers it one of the most effective non-medical treatments available. The therapy is implemented in a variety of ways: via a manual and trained health professionals, a self-help book, and freely available online resources in partnership with charities and organisations supporting women and their workplaces. King's CBT is therefore easily accessible to women who need it, bringing relief to many thousands of women worldwide.

2. Underpinning research

The most common symptoms of menopause are vasomotor (hot flushes and night sweats), which affect about 80% of mid-aged women. Around 25% report these symptoms affect the quality of their daily lives, including working capacity and even the intention to remain in work. Symptoms typically last between four and eight years, although may persist for ten, and may differ between ethnic groups. There are over 7,200,000 women in the UK aged between 45-60 (ONS 2020), the ages when menopause most commonly occurs, so around 1,800,000 women could be experiencing problematic symptoms at any one time. For women who experience premature menopause brought about by chemotherapy, ovary removal surgery or anti-oestrogen treatments, symptoms tend to be even more severe. Hormone Therapy (HT) is an effective treatment for moderate to severe symptoms, but is contraindicated for women who have had, or are at increased risk for breast cancer, and avoided by those who are uncertain about health risks and benefits, or who prefer a non-medical option. Medical alternatives to HT, such as anti-depressants, are moderately effective but have side effects, and non-medical options, such as vitamins and complementary therapies, generally lack evidence of effectiveness.

King's researchers established the prevalence of problematic symptoms, and that an alternative was needed to HT to manage these for many women. In a UK study of over 10,000 women King's researchers found that 54% experienced hot flushes and night sweats up to ten years post menopause, with an average of 33 per week, and varying degrees of severity (1),

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therefore establishing a need for safe, acceptable and effective non-hormonal treatments for moderate to severe menopausal symptoms.

King's researchers developed a cognitive behavioural model for women with problematic menopausal symptoms such as hot flushes and night sweats. King's researchers demonstrated that psychological factors including stress, social embarrassment, disgust, feeling out of control and frustration can exacerbate hot flushes; that negative expectations and beliefs and low self-esteem are associated with more problematic symptoms; and that behavioural reactions (such as avoiding social situations) are also associated with more troubling flushes and sweats. Based on these findings, King's researchers designed a model built on the possible relationships between biological, cognitive, behavioural and environmental factors affecting problematic menopausal symptoms, drawing on theories of symptom perception, self-regulation theory, and cognitive behavioural models. King's model describes interactions between psychological and physical factors and proposes that mood might influence the experience and the reporting of symptoms. It recommends psychoeducation and behavioural strategies to manage hot flushes and night sweats (2).

King's researchers then carried out the "MENOS" clinical RCTs. King's researchers showed that both group and self-help CBT reduce the impact of problematic hot flushes and night sweats by an average of 50%, both for breast cancer patients (3) and for women in the general population (4), at 6 weeks and 6 months. CBT also significantly improved aspects of quality of life and measures of mood and memory problems.

King's researchers collaborated internationally to adapt and test the MENOS protocol in multicentre RCTs in the Netherlands. For breast cancer patients who were premenopausal on diagnosis of their breast cancer, but whose treatment had put them into menopause, the delivery of CBT supported by a therapist, and in online self-help formats, effectively reduced the impact of hot flushes and night sweats (5).

King's researchers carried out a multicentre MENOS UK RCT in eight public and private organisations, the first time such an intervention had been tested in the workplace.

King's CBT self-help model had significant and positive impact on hot flushes, night sweats, wellbeing, sleep, work and social adjustment and presenteeism – women being at work without impairment from symptoms (6).

3. References to the research

1. Hunter, M.S., Gentry-Maharaj, A., Ryan, A., Burnell, M., Lanceley, A., Fraser L., Jacobs I., Menon U. (2011) Prevalence, frequency and problem rating of hot flushes persist in older postmenopausal women: impact of age, body mass index, hysterectomy, hormone therapy use, lifestyle and mood in a cross-sectional cohort study of 10418 British women aged 54–65 *BJOG*, 119(1),40-50. DOI: 10.1111/j.1471-0528.2011.03166.x
2. Hunter, M.S. & Mann, E. (2010) A cognitive model of menopausal hot flushes and night sweats. *Journal of Psychosomatic Research*, 69, 491–501. DOI: 10.1016/j.jpsychores.2010.04.005
3. Mann, E., Smith, M. J., Hellier, J., Balabanovic, J. A., Hamed, H., Grunfeld, E. A., & Hunter, M. S. (2012). Cognitive behavioural treatment for women who have menopausal symptoms after breast cancer treatment (MENOS 1): A randomised controlled trial. *Lancet Oncology*, 13, 309-318. DOI: 10.1016/S1470-2045(11)70364-3
4. Ayers, B., Smith, M., Hellier, J., Mann, E., & Hunter, M. S. (2012) Effectiveness of group and self-help cognitive behavior therapy in reducing problematic menopausal hot flushes and night sweats (MENOS 2): A randomized controlled trial. *Menopause*, 19, 749-759. DOI: 10.1097/gme.0b013e31823fe835
5. Atema, V., van Leeuwen, M., Kieffer, J.M., Oldenburg, H.S.A., van Beurden, M....Hunter, M.S. & Aaronson, N.K. (2019) Efficacy of Internet-Based Cognitive Behavioral Therapy for Treatment-Induced Menopausal Symptoms in Breast Cancer Survivors: Results of a Randomized Controlled Trial. *Journal of Clinical Oncology*, 37, 809-822. DOI: 10.1200/JCO.18.00655

6. **Hardy, C., Griffiths, A., Norton, S., & Hunter, M. S.** (2018) Self-help cognitive behavior therapy for working women with problematic hot flushes and night sweats (MENOS@Work): A multicenter randomized controlled trial. *Menopause*, 25, 508-519. DOI: 10.1200/JCO.18.00655

4. Details of the impact

King's research brings an innovative treatment option to women for a problem which has been historically overlooked or trivialised. Women need non-pharmacological treatment options to manage not only the impact of vasomotor symptoms, but also to alleviate depression and anxiety that so often accompany and exacerbate night sweats and hot flushes.

King's research into the use of CBT for the treatment of menopausal symptoms has shaped national and international policy and guidelines. King's CBT research (3) was the only work of this kind cited to support the inclusion of CBT as an effective treatment for anxiety and depressed mood during menopause, in the first menopause NICE Guideline in 2015, NG23: Menopause: Diagnosis and Management [A1]. This work also influenced NICE guidance in recommending that GPs and health professionals should provide menopausal women with information and advice about CBT [A2]. Based on her body of research, King's researcher Professor Myra Hunter was appointed Expert Advisor on the NICE Guideline [A3]. Moreover, based on King's research the Chief Medical Officer's 2015 report recommended CBT for symptoms in working women: '*Non-pharmaceutical treatments such as cognitive behavioural therapy are helpful in reducing the impact of menopausal symptoms.*' [A4].

The North American Menopause Society (2015) is the authoritative US source advising healthcare workers and patients. In their position statement (2015) it recommends CBT as one of the few effective non-hormonal treatments available for menopausal women, referencing King's research. This is a level 1 recommendation, i.e. the strongest possible [A5].

King's research on CBT for menopausal symptoms has been recommended to healthcare professionals in the UK and is being implemented. In a partnership with the British Menopause Society (BMS), King's academics produced a factsheet for healthcare professionals [B1], which was endorsed by NICE in 2017. This has changed practice by providing high quality evidence supporting drug free treatment. It has been on the BMS website since 2017, but download figures are only available for February 2019 – November 2020, during which it had 7,162 page views and 565 downloads [B2]. Furthermore, an annual two-day course set-up in collaboration with the British Menopause Society has been run four times since 2018 and has trained 86 health professionals such as GPs, clinical psychologists, CBT therapists, counsellors, and breast cancer nurses to run CBT groups for women, and there has been further training of breast care teams in hospitals [B2, B3]. A treatment manual published by Routledge in 2015 [B4] has been bought by over 300 health professionals to date as part of their training, to enable them to use the treatment in their practice [B5]. A BMJ Practice paper on non-hormonal treatments for menopausal symptoms recommends CBT for menopause, based on King's research [B6].

King's research has supported tens of thousands of women with affordable and easy to access CBT treatments. Healthcare workers who have taken the BMS two-day course [B2] have successfully reached thousands of women both directly and through other healthcare workers, for example one practitioner in Scotland estimates she has reached 1,850 people [C1]. In partnership with the BMS King's researchers produced an easily accessible fact sheet for women, hosted on the patient arm of its website, Women's Health Concern (WHC) [C2]. Between November 2017 and November 2020 this had 59,184 page views, and 1,291 downloads [B2], being used beyond the UK: "*For many women who utilise our service, Myra, your work has changed their lives. We have a wait of approximately 4 months for a new patient appointment... I routinely send out your Women's Health Concern factsheet prior to their appointment to assist with managing their symptoms*" [C3, C4]. In 2014 King's researchers launched a self-help book 'Managing Hot Flushes and Night Sweats' [C5] to empower women to use the treatments themselves, and in their practices. Now in its second edition, almost 2,000 copies of the book have been sold [B5].

CBT for menopause has also captured the imagination of the media with in-depth coverage by several national outlets [C6]. A 2018 BBC1 documentary *The Truth about the Menopause* presented by Mariella Frostrup featured King's research, with feedback from those who used CBT

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during this programme including comments such as “*transformational*,” “*very useful*” and “*I’m just Miss Chill now*” [C7].

The Australasian Menopause Society also recommends and links to the resources hosted by the WHC [C8].

King’s CBT for menopause has been used in marginalised communities. King’s researchers worked with Handsinc charity in Hackney to develop the “Reclaim the menopause” group sessions for BAME women in the community who might not otherwise easily access services. Around 200 women have attended sessions [D1] and they report: “*Strategies that we learn here, we pass on to other women who are interested. I’m telling my sisters, who are all over 50 and going through it*” [D2].

King’s research has helped women in the workplace manage their menopausal symptoms. The Chartered Institute of Personnel and Development (CIPD) now recommends CBT treatment in their 2019 report ‘The menopause at work: a practical guide for people managers’ [E1] based on NICE recommendations and King’s research in the workplace (3,4,6). The BMS also have a factsheet for employers [E2]. The charity Henpicked is one of the UK’s largest, fastest growing communities for women over 40, and has created online resources [E3] based on King’s research. It also runs seminars in the workplace on menopause, and King’s CBT and research is an important element in their training. Over the past four years hundreds of employers have attended their training sessions, most recently 120 in the three months from September - November 2020 [E4]. Feedback from the Department of Education after a seminar included “*never seen such positive feedback after any session*” [E5]. TUC Wales has produced a toolkit for trade unionists ‘The menopause in the workplace’ [E6] which also draws on many of the resources King’s research has informed [e.g. A1, A4, E2].

King’s researchers partnered with Turning Point, a UK charity that delivers mental health care to over 100,000 people with addictions and severe mental health problems. Its Rightsteps initiative supports over 7,000 people in a workplace health and wellbeing programme that benefitted from King’s research. King’s academics were contracted to develop and launch an online version of CBT for menopause. This was launched on World Menopause Day, 18 October 2020 [E7], and is already available to all Turning Point staff. It is currently being rolled out to service users who wish to know more about menopause, as well as being incorporated in Rightsteps wellbeing packages.

King’s research has underpinned partnerships with cancer charities. Breast Cancer Care (the main UK charity for breast cancer patients), has run 12 CBT group workshops since 2014 in NHS facilities across the UK, attended by 150 women (2019) [B3].

Maggie’s is a charity providing free cancer support and information in centres across the UK and online and has partnered with King’s to make King’s CBT for menopause available to women accessing their services. King’s staff are currently training clinical staff to deliver online CBT in 6 centres, with a further 18 centres planned [F1].

Women report life-changing impact from King’s CBT. Women report King’s CBT brings a restored sense of control: “*I’ve found it to be a godsend - hot flushes don’t last for as long as you think, you can learn what triggers a hot flush and ... at least be prepared that it’s likely to happen*”, with some reporting benefits that extended beyond their menopausal symptoms: “*I’ve found it to be a very interesting, useful read, and some of the skills I’ve learnt I’m now using in other areas of my life with my stressful job for example. Thank you Professor Hunter and Ms Smith - just wish I had been told about these coping skills sooner*” [G1].

5. Sources to corroborate the impact

[A] Sources corroborating the impact of King’s research on guidelines and policies

A1 NICE full Guideline NG23. Menopause: Diagnosis and Management

A2 NICE endorsement of CBT for Menopausal Symptoms factsheet for health professionals

A3 NICE Expert Advisor Letter

A4 Annual Report of the Chief Medical Officer, 2015

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A5 The North American Menopause Society Position Statement: Non-hormonal management of menopause-associated vasomotor symptoms, 2015

[B] Sources to corroborate CBT implementation via healthcare professionals

B1 BMS factsheet for healthcare professionals

B2 Email chain with details of BMS factsheet downloads and numbers attending training

B3 Testimonial from Dr Melanie Smith

B4 Book: Managing Hot Flushes with Group Cognitive Behaviour Therapy

B5 Sales figures for Managing Hot Flushes with Group Cognitive Behaviour Therapy

B6 BMJ Practice Paper

[C] Sources to corroborate King's CBT resources available for women to use themselves

C1 Testimonial from Ruth Devlin, healthcare worker

C2 BMS CBT for menopause factsheet for women hosted on WHC

C3 Martha Hickey clinic email

C4 Stanford email

C5 Book: Managing Hot Flushes and Night Sweats

C6 UK print media examples

C7 The Truth About Menopause

C8 The Australasian Menopause Society "Lifestyle and behaviour symptoms for menopause symptoms"

[D] Sources to corroborate the use of King's CBT in marginalised communities

D1 Handsinc testimonial

D2 Bellot et al (2018) evaluation of Handsinc

[E] Sources to corroborate the use of King's CBT in the workplace

E1 Chartered Institute of Personnel and Development report 'The menopause at work: a practical guide for people managers', 2019.

E2 BMS factsheet for employers on the menopause at work

E3 Henpicked website resources

E4 Henpicked testimonial

E5 Department for Education

E6 Wales TUC report

E7 Turning Point press release

[F] Sources to corroborate King's partnerships with cancer charities

F1 Confirmation of partnership with Maggie's

[G] Sources to corroborate women's experiences of using King's CBT

G1 Amazon reviews of book Managing Hot Flushes and Night Sweats