PRIORITY BRIEFING

The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2-3 days.

Is delivery of mindfulness based cognitive therapy / stress reduction (MBCT/ MBSR) feasible and acceptable to people with depression that co-occurs with a range of chronic physical health problems?

Question ID: 7

Question type: Intervention

Question: Is delivery of mindfulness based cognitive therapy / stress reduction (MBCT/ MBSR) feasible and acceptable to people with depression that co-occurs with a range of chronic physical health problems, and is it effective in reducing the symptoms on a number of key outcomes, including depression, anxiety, quality of life and number of physical symptoms?

Population: People with chronic physical health problems e.g. coronary heart disease, diabetes mellitus, chronic obstructive pulmonary disease, rheumatoid arthritis and fibromyalgia. These conditions are common in primary care and in specialist medical outpatients clinics, and have high rates of co-morbid recurrent depression. We will identify people who present with depression and any of the above chronic physical health problem groups in primary care and from medical outpatients department in the Royal Devon and Exeter NHS trust (with potential for other regional hospitals to also be involved).

Intervention: MBCT/MBSR in either a primary care or specialist medical outpatient clinic. The intervention will be delivered to mixed illness groups with weekly 2 hour sessions for 8 weeks.

Control: Treatment as usual.

Outcome: To demonstrate the feasibility of screening for depression in people with chronic physical health problems in primary care and attending medical outpatients. To determine the acceptability of MBCT/ MBSR to people with chronic physical health problems. To assess effectiveness of the intervention on different psychological outcomes including depression using a range of measures. To fine tune the MBCT/MBSR intervention to make it as potent as possible in helping people with their physical and mental health. To address the most important uncertainties identified in recent reviews and lay the groundwork for a high quality and definitive cost-effectiveness trial that will inform the NICE guidance for depression with co-morbid medical conditions and each of the NICE guidelines for named long term conditions. The research also aims to investigate the processes via which necessary changes to MBSR/CT are identified for different patient groups and how they are incorporated into treatment, thereby developing a blue print by which treatment services and individual practitioners can adapt treatment for the needs of individual patients.

*Please note that the details included in the box are from the original submission and have been edited where necessary for clarity and precision

Depression: With depression an individual has a low mood and other symptoms each day for at least two weeks. Other symptoms include changes in patterns of sleep, eating, energy, concentration and may include feelings of worthlessness, inappropriate guilt and suicidal thoughts. Symptoms have become severe enough to interfere with normal day-to-day activities.
MBCT/MBSR: Mindfulness-based stress reduction (MBSR) is an 8-week, class-based program in which people learn mindfulness practices; recognise patterns of thinking and feeling that cause distress and exacerbate symptoms; improve self-awareness and learn to step out of patterns of reactivity. Over time and with practice, people typically report being better able to cope both with their chronic health problems but also with their lives more generally. Mindfulness-based cognitive therapy is a derivative of MBSR tailored specifically for people with recurrent depression. MBSR/MBCT is based on the premise that the mind is known to be a factor in stress and stress-related disorders, and meditation has been shown to positively effect a range of autonomic physiological processes, such as lowering blood pressure and reducing overall arousal and emotional reactivity. The program brings meditation and yoga together so that the virtues of both can be experienced simultaneously.

The Health Problem:
In the UK, 1/3 of the population have a long-term condition (DoH 2011), this is closer to two thirds of the population aged over 65 years. Mental health problems account for 23% of the total burden of disease in the UK. With five percent of the population suffering with depression at any one time. Evidence from The King's Fund report on long term conditions and mental health suggests that 30 percent of people with a long term condition also have a mental health problem.

Comorbid chronic disease and depression has been shown in multiple studies to increase symptom burden, lead to additive function impairment, increase medical costs, impair self-care and adherence and be associated with increased mortality (Katon and Ciechanowski, 2002). The King's Fund also report that mental health problems in people with long term conditions increases the cost of treating the long term condition by 45-70% in the UK. On this basis they predict that 12-18% (£8 - 13 billion of NHS spending in England) of all expenditure on long term conditions is linked to poor mental health.

No specific data could be found on the number of people in Devon and Cornwall living with a long-term condition and co-morbid mental health condition. However, in Devon based on 2001 census data 18% of the population live with a life limiting illness and 12% of the population suffer from depression, similarly in Cornwall 20% of the population live with a life limiting illness and 13% suffer from depression (www.nepho.org.uk).

It is recognised that the presence of a physical illness can complicate the assessment of depression and some symptoms, such as fatigue, are common to both mental and physical disorders (NICE 2009). The King's Fund also reports evidence that suggests that depression in people with a long-term condition often goes undetected and therefore untreated.

Guidelines:

NICE guidelines 'Depression in adults with a chronic physical health problem' (2009) states that patients with chronic conditions should be assessed for depression including assessment of functional impairment and disability that might be associated with the depression. The NICE guidelines for depression (2009) recommend MBCT for recurrent depression but neither guideline recommends MBCT for depression with comorbid conditions. Both guidelines recommend research that looks at the effectiveness and cost-effectiveness of new psychosocial interventions and approaches to combine pharmacological and psychosocial approaches in patients with chronic health conditions.

NHS Priority:

The Governments mental health strategy document prioritises the importance of people with mental health problems having good physical health and moves the responsibility for dealing with common mental disorders to local Improving Access to Psychological Therapies (IAPT) teams. NHS reforms indicate that clinical commissioners have a duty to provide integrated services, i.e. for mental and physical health.

Regional

SW SHA Priorities framework 2008-11 (please note this has not yet been updated for 2012)

- Adults with mild to moderate depression and anxiety to have access to psychological therapies in every Primary Care Trust by 31 March 2011, three years ahead of the national requirement
- People receiving acute hospital care for physical conditions to have access to a full range of mental health liaison services by 31 March 2010
- Ensure that all people with a long-term condition have a personalised care plan that supports their self-management by 31 March 2010
- Fully implement the quality requirements of the National Service Framework for Long-term Conditions ahead of the national timescale of 2015

Local

- NHS Devon: – Improving Mental Health and Wellbeing: Integrating Physical and Mental Health
- Torbay and Southern Devon Health and Care NHS Trust improving care for

- people who need mental health and learning disability services by: Ensuring that all people receiving NHS Care for physical conditions to have access to a full range of psychiatry services
- Helping people to stay healthy including mental health is a priority area for all southwest PCTs
- Improving mental health and wellbeing is a priority for Cornwall and Plymouth PCTs
- QIPP priorities include adopting best practice care pathways for long term conditions and improving mental health
- The PenCLAHRC public engagement group (PENPIG) has called for greater attention to more integrated approaches to physical and mental health.

Existing Research:

Published research

In the past two years at least three reviews have been conducted looking at mindfulness-based stress reduction for people with chronic diseases[1,2,3]. In 2010 a meta-analysis (a systematic review with quantitative analysis) was conducted which looked at the effect of MBSR on depression, anxiety and psychological distress across different chronic diseases[1] including cancer, chronic pain, fibromyalgia, chronic fatigue, heart disease and rheumatoid arthritis. The analysis found that MBSR had small to medium impacts on each of these outcomes (effect size range 0.26-0.47), though the review was only based on eight studies. The other two systematic reviews[2,3] found more studies to include (one included 18 studies) and they all found evidence to support the positive effects of MBSR on stress and coping in people with a range of chronic diseases. A systematic review of the evidence for MBCT / MBSR on the prevention of mental distress has also been written (but not published) by a local team. They concluded that "Ten trials were found for MBSR and eight for MBCT. Overall four trials were considered of good methodological quality. All were MBSR trials. Five of ten MBSR trials and seven of eight MBCT trials showed results appearing to favour the intervention for at least one relevant outcome... More clarity is needed regarding whether these treatments have any specific effects or work via treatment-specific mechanisms."

More recently a number of other trials have been conducted[4,5,6]. One trial conducted in New Zealand looks at the health benefits of using MBSR in 29 people living with a range of chronic physical conditions (including irritable bowel syndrome; chronic fatigue syndrome, hypertension, cardiac problems; pain). [4] This study found significant improvements in depression, anxiety and stress scores and the pain visual analogue scale from baseline to post-intervention. The other two trials look at the use of MBSR/MBCT in people living with fibromyalgia and other inflammatory rheumatic joint disorders. The study on 177 females living with fibromyalgia was an RCT which looked at the impact on health related quality of life as well as depression, pain and anxiety[5]. The result of this study

suggested that although there were some improvements in the intervention group the differences between the groups were not significant. The final study was also an RCT which looked at using group MBCT to reduce psychological distress and fatigue in 67 patients with inflammatory rheumatic joint diseases[6]. The study reported significant differences between the intervention and control groups post treatment and after 12 months of follow-up. The improvements were seen in psychological distress (adjusted mean between-group difference −3.7, 95% CI −6.3 to −1.1), pain self efficacy (9.1, 95% CI 3.4 to 14.8), emotional processing (0.3, 95% CI 0.02 to 0.5), fatigue (−1.1, 95% CI −1.8 to −0.4), self-care ability (1.0, 95% CI 0.5 to 1.6) and overall well-being (0.6, 95% CI 0.1 to 1.2). There were no significant differences reported in regards to pain, disease activity or emotional expression.

Ongoing research

Research on MBCT/MBSR seems to be a rapidly increasing area of interest. Four ongoing trials were identified in this area of interest.

A Dutch trial testing the effectiveness of a mindfulness-based intervention to reduce emotional distress in outpatients with diabetes (DiaMind) is a RCT which is expected to finish in 2012. They are conducting a 6 month follow-up on outcomes such as depression, anxiety, stress, self-esteem, self-care and complications. It is funded by the Dutch Diabetes Research Foundation and Tilburg University.
http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/878/CN-00785878/frame.html

Another trial is registered to be being conducted in the US on Amygdala Retraining Program (which includes mindfulness techniques) in Patients With Chronic Fatigue Syndrome, Chronic Fatigue and fibromyalgia 2010. This study is measuring impact on the symptoms of the condition and quality of life and was due to complete in Jan 2012.
http://www.clinicaltrials.gov/ct2/show/NCT01046370?term=mindfulness+and+fibromyalgia&rank=2

There is another trial registered in the US looking at Mindfulness-based Stress Reduction in COPD 2010 This has not been updated since Jan 2010.
http://www.clinicaltrials.gov/ct2/show/NCT01058499?term=mindfulness+and+%28chronic+obstructive+lung+disease%29&rank=2

There is one trial registered at Bristol University which is a feasibility study of mindfulness based cognitive therapy in patients with COPD and/or asthma and co-morbid symptoms of anxiety and/or depression. It is funded by the NIHR and the National School for Primary Care Research. The trial has stopped recruiting and is currently in the follow-up stage.
http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=9536

There is a trial being conducted in the southwest by the question submitters (NIHR-HTA MBCT PREVENT) which looks at the use of MBCT for recurrent depression which is includes medical co-morbidities as one of the secondary outcomes. (http://www.prevent-southwest.org.uk/)

Feasibility:

Local expertise includes that located in the Mood Disorders Centre of the University of Exeter, a world-leading centre in the development and evaluation of mindfulness based interventions, and the Mental Health Research Group of Peninsula College of Medicine and Dentistry, that hosts expertise in the causes, effects and treatments of depression in people with chronic physical health problems.

Funding has been received from the South West Strategic Health Authority for a project entitled “Mindfulness Training for IAPT: Developing Clinical and Research (MBCT trials preparation) Capacity across the South West Peninsula” (£43,000, 2012-2014). This enables 14 MBCT/MBSR therapists across the Peninsula to be trained, which puts in place the therapist capacity for the proposed project.

The project already includes partnership with the PenCLAHRC public engagement group and the regional work on mindfulness to date has built a strong partnership with service users (Mood Disorders Centre Lived Experience Group and PenCLAHRC PENPIG) that would be actively engaged with this project as a full member of the project team.

There have been a number of enquiries from potential collaborators in the NHS and in academic settings who have identified these co-morbidities as pressing clinical problems that do not currently have clear care pathways.

The question submitter gave a detailed view of what the research might look like if a trial that looked in to the effect of MBSR/MBCT on a limited number of conditions was supported. These details have not been attached here but would be provided if the project is supported.

References:

1. E. Bohlmeijer, R. Prenger, E. Taal and P. Cuijpers;The effects of mindfulness-based stress reduction therapy on mental health of adults with a chronic medical disease: a meta-analysis. Journal of Psychosomatic Research 2010 68(6) p539-44

OBJECTIVES: The objective of this study was to examine the effectiveness of mindfulness-based stress reduction (MBSR) on depression, anxiety and psychological distress across populations with different chronic somatic diseases. METHODS: A systematic review and meta-analysis were performed to examine the effects of MBSR on depression, anxiety, and psychological distress. The influence of quality of studies on the effects of MBSR was analyzed. RESULTS: Eight published, randomized controlled outcome studies were included. An overall effect size on depression of 0.26 was found, indicating a small effect of MBSR on depression. The effect size for anxiety was 0.47. However, quality of the studies was found to moderate this effect size. When the studies of lower quality were excluded, an effect size of 0.24 on anxiety was found. A

small effect size (0.32) was also found for psychological distress. CONCLUSIONS: It can be concluded that MBSR has small effects on depression, anxiety and psychological distress in people with chronic somatic diseases. Integrating MBSR in behavioral therapy may enhance the efficacy of mindfulness based interventions.

2. M. Merkes Mindfulness-based stress reduction for people with chronic diseases. Australian Journal of Primary Health 2010 16(3) p200-10

Mindfulness-based stress reduction (MBSR) is a structured group program that uses mindfulness meditation to improve well-being and alleviate suffering. This article reviews the impact of MBSR for people with chronic diseases. The review includes original research that was published in English and peer-reviewed and reported outcomes for adults with chronic diseases who had participated in an MBSR program. Fifteen studies were identified. Outcomes related to mental and physical health, well-being, and quality of life. The studies included different research designs, and used self-report and physiological outcome measures. Participants' clinical diagnoses included fibromyalgia, chronic pain, rheumatoid arthritis, type 2 diabetes, chronic fatigue syndrome, multiple chemical sensitivity, and cardiovascular diagnoses. All 15 studies found that participation in an MBSR program resulted in improvements. No negative change was reported between baseline and follow up. Outcomes in regard to specific variables were difficult to compare and equivocal. Overall, positive change predominated. Chronic diseases are associated with a range of unwelcome psychological and physical consequences. Participation in an MBSR program is likely to result in coping better with symptoms, improved overall well-being and quality of life, and enhanced health outcomes. As an adjunct to standard care, MBSR has potential for much wider application in Australian primary care settings.

3. K. Niazi and S. K. Niazi; Mindfulness-based stress reduction: A non-pharmacological approach for chronic illnesses. North American Journal of Medical Sciences 2011 3(1) P20-23

Background: Mindfulness Based Stress Reduction (MBSR) therapy is a meditation therapy, though originally designed for stress management, it is being used for treating a variety of illnesses such as depression, anxiety, chronic pain, cancer, diabetes mellitus, hypertension, skin and immune disorders. Aim: The aim of this systematic review is to determine the efficacy of MBSR in the treatment of chronic illnesses; it's mechanism of action and adverse effects. It describes an alternative method of treatment for physicians and patients that may help patients cope with their diseases in a more effective way. Materials and Methods: COCHRANE, EMBASE and MEDLINE were systematically searched for data on outcome of treatment with MBSR used alone or in conjunction with other treatments. The data available on prevention of diseases through MBSR was also analyzed. Results: All the 18 studies included in this systematic review showed improvement in the condition of patients after MBSR therapy. These studies were focused on patients with chronic diseases like cancer, hypertension, diabetes, HIV/AIDS, chronic pain and skin disorders, before and after MBSR therapy. Conclusions: Although the research on MBSR is sparse, the results of these researches indicate that MBSR improves the condition of patients suffering from chronic illnesses and helps them cope with a wide variety of clinical problems.

4. Simpson, J. and T. Mapel (2011). "An investigation into the health benefits of mindfulness-based stress reduction (MBSR) for people living with a range of chronic physical illnesses in New Zealand." New Zealand Medical Journal 124(1338): 68-75.

AIM: To establish the efficacy of Mindfulness-based Stress Reduction (MBSR) for people with chronic health problems in managing symptoms and coping with their illness in an Aotearoa/New Zealand context. METHOD: Twenty-nine participants completed a wait-list control study. Physical and psychological health and well-being were measured before, after and 6 months after the 8-week training programme using a variety of internationally recognised screening tools. RESULTS: Statistically significant improvements were demonstrated in almost all categories measured. CONCLUSION: MBSR demonstrated health benefits for chronic illness sufferers. An economical

and effective adjunctive therapy for decreasing morbidity associated with chronic illness in New Zealand, MBSR provides both clinicians and patients with an additional option for the better management of chronic illness.

5. Schmidt, S., P. Grossman, et al. (2011). "Treating fibromyalgia with mindfulness-based stress reduction: results from a 3-armed randomized controlled trial." Pain 152(2): 361-369.

Mindfulness-based stress reduction (MBSR) is a structured 8-week group program teaching mindfulness meditation and mindful yoga exercises. MBSR aims to help participants develop nonjudgmental awareness of moment-to-moment experience. Fibromyalgia is a clinical syndrome with chronic pain, fatigue, and insomnia as major symptoms. Efficacy of MBSR for enhanced well-being of fibromyalgia patients was investigated in a 3-armed trial, which was a follow-up to an earlier quasi-randomized investigation. A total of 177 female patients were randomized to one of the following: (1) MBSR, (2) an active control procedure controlling for nonspecific effects of MBSR, or (3) a wait list. The major outcome was health-related quality of life (HRQoL) 2 months post-treatment. Secondary outcomes were disorder-specific quality of life, depression, pain, anxiety, somatic complaints, and a proposed index of mindfulness. Of the patients, 82% completed the study. There were no significant differences between groups on primary outcome, but patients overall improved in HRQoL at short-term follow-up (P=0.004). Post hoc analyses showed that only MBSR manifested a significant pre-to-post-intervention improvement in HRQoL (P=0.02). Furthermore, multivariate analysis of secondary measures indicated modest benefits for MBSR patients. MBSR yielded significant pre-to-post-intervention improvements in 6 of 8 secondary outcome variables, the active control in 3, and the wait list in 2. In conclusion, primary outcome analyses did not support the efficacy of MBSR in fibromyalgia, although patients in the MBSR arm appeared to benefit most. Effect sizes were small compared to the earlier, quasi-randomized investigation. Several methodological aspects are discussed, e.g., patient burden, treatment preference and motivation, that may provide explanations for differences. In a 3-armed randomized controlled trial in female patients suffering from fibromyalgia, patients benefited modestly from a mindfulness-based stress reduction intervention. Copyright ACopyright 2010 International Association for the Study of Pain. Published by Elsevier B.V. All rights reserved.

6. Heidi A Zangi[1], Petter Mowinckel[1], Arnstein Finset[2], Liv R Eriksson[3], Turid Ø Høystad[4], Anne Kristine Lunde[5], Kåre B Hagen[1] (2011). "A mindfulness-based group intervention to reduce psychological distress and fatigue in patients with inflammatory rheumatic joint diseases: a randomised controlled trial." Annals of the Rheumatic Diseases.

Objective To evaluate the effects of a mindfulness-based group intervention, the Vitality Training Programme (VTP), in adults with inflammatory rheumatic joint diseases. Methods In a randomised controlled trial, the VTP—a 10-session mindfulness-based group intervention including a booster session after 6 months—was compared with a control group that received routine care plus a CD for voluntary use with mindfulness-based home exercises. The primary outcome was psychological distress measured by the General Health Questionnaire-20. Self-efficacy (pain and symptoms) and emotion-focused coping (emotional processing and expression) were used as co-primary outcomes. Secondary outcomes included pain, fatigue, patient global disease activity, self-care ability and well-being. Effects were estimated by mixed models repeated measures post-intervention and at 12-month follow-up. Results Of 73 participants randomised, 68 completed assessments post-intervention and 67 at 12 months. Significant treatment effects in favour of the VTP group were found post-treatment and maintained at 12 months in psychological distress (adjusted mean between-group difference −3.7, 95% CI −6.3 to −1.1), self-efficacy pain (9.1, 95% CI 3.4 to 14.8) and symptoms (13.1, 95% CI 6.7 to 19.3), emotional processing (0.3, 95% CI 0.02 to 0.5), fatigue (−1.1, 95% CI −1.8 to −0.4), self-care ability (1.0, 95% CI 0.5 to 1.6) and overall well-being (0.6, 95% CI 0.1 to 1.2). No significant group differences were found in emotional expression, pain or disease activity. Conclusion The VTP improved most primary and secondary outcomes compared with individual use of CD exercises. Improvements were maintained at 12 months, suggesting that the VTP is a

beneficial complement to existing treatments for patients with inflammatory rheumatic joint diseases.