



Dr Peter Malinowski
Reader in Cognitive Neuroscience
Research Centre for Brain and Behaviour
Byrom Street, Liverpool, L3 3AF
☎ +44 151 904 6297 ✉ p.malinowski@ljmu.ac.uk

PRF - Project Report

Project: Mindfulness and Persistent Post-Surgical Pain
PI: Dr Peter Malinowski
PhD student: Rebecca Hort-Atkinson
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Project Aim: The aim of the project is to investigate the potential of a low-cost mindfulness-based intervention to alleviate acute post-surgical pain and to reduce the likelihood of the development of persistent post-surgical pain (PPSP) in women undergoing planned hysterectomy surgery for benign causes. Mindfulness-based approaches have been shown to be effective in reducing chronic pain and in helping individuals suffering from pain to cope with such experiences in a more positive, less debilitating way. The approach investigated in this project deviates from standard mindfulness-based interventions as it aims to support individuals at risk *before* they develop chronic pain, rather than after the manifestation of a chronic pain condition. In particular, the expectation is that by engaging with mindfulness practices during the time of recovery after surgery, it will be possible to reduce acute pain and the development of chronic pain. It thus implements mindfulness practices as a *preventative* approach, rather than a treatment. While the current focus of the project is limited to a particular population and condition, it is anticipated that the results will also be generalisable to other conditions where measures for preventing the chronification of pain are feasible.

Systematic Review: The project builds on a systematic review of research literature pertaining to mindfulness-based interventions targeting aspects of physical health and wellbeing. 13 mindfulness-based intervention studies that consider physical health as central outcome variable have been identified and their quality has been independently assessed by three raters. The analysis of the study outcomes is currently ongoing and it is planned that a resulting manuscript will soon be submitted for publication.

Study 1: Due to significant delays with gaining ethical approval for the intervention study with woman who are undergoing planned hysterectomy, the project was extended to also include a mindfulness-based intervention for woman with chronic pelvic pain for benign causes, not currently undergoing surgery. This '*mindfulness for chronic pelvic pain study*' has recently completed participant recruitment. So far, 90 participants have fully completed the study whilst a number of further participants are still going through the process. It is anticipated that the final number of participants in this study will exceed 100.

Study 2: The *mindfulness for persistent post-surgical pain study* after hysterectomy has meanwhile received ethical approval and is currently actively recruiting participants. At present, approximately 50 participants have been enrolled in this study. Due to difficulties in recruitment resulting in relatively low participant numbers the recruitment strategy is being

reviewed. An amendment will be submitted to the NHS ethics committee to involve several other charities and online support groups in promoting the study. Additionally, approval will be sought to collect some additional data from participants. We are hoping to conduct some brief interviews or provide a short qualitative questionnaire to gain some insight into their experiences of being participants, and thus the feasibility of such a study.

Study design: The two studies use almost identical designs: All participants who are recruited into the studies continue to receive their ongoing treatment (TAU – treatment as usual). They are randomly allocated to one of three groups; a mindfulness intervention group (TAU-M), a relaxation training group, functioning as active control condition (TAU-AC) and a ‘passive’ control group (TAU-C), who merely complete the different questionnaires, without any intervention.

In *Study 1* participants are asked to complete a range of questionnaires in week zero (before the intervention), in week 2 (2 weeks into the intervention) and in week 8 (after the intervention).

In *Study 2* questionnaires are completed at 5 time points: directly after recruitment, as close as possible (maximum 72 hours) before undergoing surgery, 2-weeks post-surgery, 8-weeks post-surgery, and 6-months post-surgery.

Intervention approach: The intervention approach for both studies is very similar. Participants in the mindfulness group receive a mindfulness-training pack. Two mindfulness-training packs were developed for the TAU-M groups of both studies. Both training packs comprise of general information about pain, a summary of the evidence of the benefits of mindfulness training and the rationale for the relevant study. The training pack for *Study 1* includes additional information regarding chronic pelvic pain, while the training pack for *Study 2* includes additional information regarding pre-surgical preparation and post-surgical recovery. Both training packs include the same six mindfulness-based exercises. The exercises included in the training packs are adapted version of well-established mindfulness exercises and are comparable to exercises used in standard mindfulness programmes such as mindfulness-based stress reduction (MBSR) or mindfulness-based cognitive therapy (MBCT). However, MBSR and MBCT programmes typically include yoga exercises and other ‘movement meditations’ which were excluded from the training to avoid conflict with any medical advice given to participants. Several exercises also include elements of mindful self-compassion. The training packs furthermore include audio guidance for each exercise as well as contact information for relevant charities and support organisations were appended.

For participants in the relaxation control group two specific training packs were developed, comprising of six relaxation-based exercises, matching the mindfulness exercises as closely as possible in terms of expected engagement. Again, both study packs contain general information about pain, a summary of evidence for the benefits of relaxation training and a rationale for the study, along with contact details for relevant support organisations. Similar to the mindfulness-training pack, the *Study 1* pack contains information relating to chronic pelvic pain, whereas the *Study 2* pack also contains information regarding pre-surgical preparation and post-surgical recovery. Both relaxation training packs are made available in the same formats as the mindfulness training packs discussed above. TAU-AC participants were given the same instructions regarding number of exercises, frequency of practice and duration of practice as their TAU-M counterparts.

All training are made available to participants of all other groups in that particular study upon its completion.

Participants were offered the training packs online via the dedicated study websites or in printed form, including a CD with audio recordings. So far, all participants opted for the downloadable version.

The study websites can be accessed here:

Study 1: <https://www.pelvicpainresearch.co.uk/>

Study 2: <https://www.hysterectomyresearch.co.uk/>

Questionnaires: All participants completed a range of questionnaires online, assessing different aspects of pain experience, health and wellbeing, emotional processes and mindfulness. *Study 2* also includes brief questionnaires related to the experience of the surgery. In addition, participants in the intervention conditions are also asked to maintain a practice diary to gain some qualitative insights regarding their engagement with the exercises.