

# **A Study Protocol of Phase I Randomized Crossover Trial Study Effect of Flow Practice to Mitochondrial Function, Neuro-autonomic Biomarker, and DNA Telomerase Activity.**

## **The Flow-MiND study**

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**Background:** Many studies have found that mindfulness-based stress reduction (MBSR) improves the sense of well-being, cognition and sleep quality. The hypothetical mediators include increased vagal tone, reduced cortisol, increased melatonin which all influence mitochondrial function and DNA telomerase activity as a final common pathway. The Flow practice is an innovative, mindfulness-based, 45 minutes intervention. This includes five series of activities: quiet observation; body relaxation; facial and eye relaxation; spreading loving kindness to all beings; and energy massage. This adapted method aims to be less cognitively demanding and more feasible for people with limited cognitive reserve or serious illness. Our study is a phase I trial which aims to explore the possible mechanism beyond vocational effect and to study side effects in a healthy person.

**Methods:** Fifty volunteer male and female nurses working in a university hospital, age 25-55 years old with no active serious illness, are to be enrolled in the residential retreat program. All volunteers will receive a mind-body medicine lecture. They will be randomly assigned to either flow practice or relaxation on site (control vacation effect group) for 5 hours a day for 3 days. There will be a washout period of 3 months between the two treatments. Primary outcomes to be measured are oxidative stress (8OH2dG); telomerase activity from the peripheral blood mononuclear cell; and neuro-autonomic biomarkers - heart rate variability (HRV), serum cortisol and serum melatonin levels. Secondary outcomes include cognition measured by the Montreal Cognitive Assessment (MoCA) and sleep quality measured by the Pittsburgh SleepQuality Index (PSQI).

**Trial registration and expected results:** This trial was registered at the Thai Trial Registration on March 10, 2018; TCTR20180313001. The preliminary result from the first cohort is expected in October 2018.