Official title: Physical Therapy Intervention for Puerperal Mastitis

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Introduction

Puerperal mastitis is one of the most commonly reported problems during breastfeeding (1-3). Women frequently report breast pain, tenderness, redness, engorgement, fever, malaise, chills, lethargy, sweating, headache, nipple damage and a hot spot on the affected breast (4-6). These highly distressing symptoms may severely impact on a woman's daily activities and quality of life and might lead to the premature cessation of exclusive breastfeeding, which may have significant impact on infant health and survival.

The role of physical therapy in reducing pregnancy/postpartum-related disorders including breast problems is gaining momentum and importance in obstetrics (7). However, to date, only low-level evidence has shown positive effects of breast massage, a physical technique, on pain, milk supply and symptom relief in women with breastfeeding problems (7). This is encouraging, however further research is needed to explore whether physical therapy is effective to reduce symptoms of

puerperal mastitis. Therefore, the aims of this study were to explore clinical effects of therapeutic ultrasound, education and massage on mastitis symptoms and to compare the effectiveness of therapeutic ultrasound, education and massage versus usual obstetric care and sham ultrasound treatment on patient-centered outcomes in the short- and medium-term.

Methods

A randomized controlled trial was conducted from May 2021 to April 2023. Postpartum lactating women aged from 21 to 45 with breast symptoms were recruited through the Obstetrics and Gynecology Clinic of National Cheng Kung University Hospital, the postpartum care centers, websites and community. Eligible participants were randomly allocated to the ultrasound group, sham group, or usual care group. Participants allocated to the 'Ultrasound' arm of the trial participated in four one-hour treatment sessions with the physical therapist over one week. The treatment included educating the patient about mastitis and self-management strategies, treating with therapeutic ultrasound and administering and teaching breast massage. Participants allocated to the 'Sham' group received the same education and breast massage sessions as described above. In addition, the sham control group received 5 minutes of 'sham' ultrasound at 0 W/cm2 intensity from a physical therapist. Participants

allocated to the ‘Usual care’ group received usual obstetric care, which included verbal advice/printed patient information regarding mastitis and breastfeeding from the medical or nursing staff. The outcome measures including severity of breast symptoms (breast and nipple pain, breast engorgement), breast hardness, body temperature, breast temperature, breastfeeding self-efficacy, and milk volume were assessed at baseline, immediately post-intervention, and at 3 months following baseline. The acceptability of the intervention program and adverse events were recorded immediately post-intervention and at 3 months following baseline.

Statistical analysis plan

The data were analyzed using intention-to-treat principles with the SPSS version 20.0 for Windows. The last observation carried forward imputation was used for imputing missing data. Descriptive statistics were used to summarize and report data. All outcome data were assessed for normality using the Kolmogorov-Smirnov test. Repeated measures analysis of variance with Bonferroni post hoc comparisons was used to compare changes in outcome variables between groups. The equivalent non-parametric tests (i.e. Friedman test and Kruskal Wallis test) were used if data were not normally distributed. Numbers, percentages, mean, standard deviation, median, interquartile range, and p-values were reported. All analyses were tested with a

significance level of $p<0.05$.

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