Title: The Effect of a Father Inclusive Psychoeducation Program on Postnatal Depression: a

Randomized Controlled Trial

Investigators

Fei Wan Ngai, School of Nursing, The Hong Kong Polytechnic University

Paul Wai-Ching Wong, Department of Social Work and Social Administration, The University of Hong

Kong

Pui-Hing Chau, School of Nursing, The University of Hong Kong

Ka-Fai Chung, Department of Psychiatry, The University of Hong Kong

Background

Having a first child is a key marker of the transition into parenthood that requires substantial adjustment of couples' life. A recent meta-analysis published in the Journal of American Medical

Association reports that both women (23.8%) and men (10.4%) suffer from perinatal depression [1].

The father's involvement during pregnancy can positively influence health outcomes not only for the

man, but his partner, and their children [1,2]. However, the effectiveness of father's involvement in

prenatal care in preventing paternal and maternal depression, is still unknown.

Aims

This study seeks to: (1) evaluate the effect of a father inclusive psychoeducation program for first-time Chinese mothers and fathers on depressive symptoms (primary outcome), marital relationships and quality of life at 6 weeks, 6 months and one year postpartum; and (2) explore fathers' involvement, their perceived benefits of participating in the program and factors influencing the effectiveness of the program.

Methods

This study employs a longitudinal, randomized, pre and post-test design. A convenience sample of 576 couples will be recruited at antenatal clinics and randomly assigned to one of three groups: (1) the experimental group with both couples receives the intervention on top of usual perinatal care; (2) the comparison group with only the women receives the intervention on top of usual perinatal care; and (3) the control group receives usual perinatal care only. The intervention consists of a single 3-hour session during pregnancy and two telephone follow-up at postpartum week one and week two.

Primary outcome on postnatal depression will be assessed by Edinburgh Postnatal Depression Scale.

Secondary outcomes on marital relationship and quality of life will be assessed by Dyadic Adjustment Scale and Medical Outcomes Study Short Form 12-item Health Survey, respectively, at baseline, 6 weeks, 6 months and one year postpartum. Process evaluation will be conducted at 6 weeks

postpartum using individual telephone interview on 20 couples randomly selected from the experimental group.

Data Analysis

Data analyses will be conducted using the Statistical Package for the Social Sciences (SPSS) for Windows. Intention to treat principle will be used. Descriptive statistics will be used to summarize the data, such as demographics and outcome variables. Homogeneity among the study groups on the demographics and baseline variables will be assessed using one-way analysis of variance (ANOVA) and chi-square test. A repeated-measures multivariate analysis of variance (MANOVA) will be performed separately for the two gender to test for significant differences among the three groups on the outcome variables including depressive symptoms, marital relationship, and quality of life at baseline, 6 weeks, 6 months and one year postpartum; and post-hoc comparisons for between groups differences. Interview data will be analyzed by content analysis.

References

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