

Exploratory randomized trial on the effect of a brief psychological intervention on emotions, quality of life, discontinuation, and pregnancy rates in in vitro fertilization patients

Alice D. Domar, Ph.D.,^a Jill Gross, M.S.,^a Kristin Rooney, B.A.,^a and Jacky Boivin, Ph.D.^b

^a Domar Center for Mind/Body Health, Boston IVF, Harvard Medical School, Boston, Massachusetts; and ^b Cardiff Fertility Studies Research Group, School of Psychology, Cardiff University, Wales, United Kingdom

Objective: To determine whether a brief self-administered cognitive coping and relaxation intervention (CCRI) would lead to decreased treatment termination in in vitro fertilization (IVF) patients compared with routine care (RC).

Design: Randomized, controlled, prospective study.

Setting: Private academically affiliated infertility center.

Patient(s): One hundred sixty-six women about to begin their first IVF cycle.

Intervention(s): Randomization to the self-administered CCRI or RC control group and then observation for 12 months.

Main Outcome Measure(s): Treatment discontinuation within 12 months (primary outcome), clinical pregnancy rate and psychological well-being (secondary outcomes).

Result(s): The 12-month pregnancy rate was similar for the RC and CCRI groups (odds ratio [OR] 1.02; 95% CI, 0.53–1.98). Of the patients who were not pregnant on the first cycle, 15 of 46 (15.2%) patients assigned to RC discontinued compared with 5 of 55 (5.5%) patients assigned to the CCRI (OR 3.11; 95% CI, 0.756–12.80). The CCRI group engaged in statistically significantly more positive reappraisal coping (OR 0.275; 95% CI, 0.16, 0.39) than the RC control group (OR 0.097; 95% CI, –0.03, .23). The CCRI group had an improved Fertility Quality of Life (FertiQoL CORE: OR 4.07; 95% CI, 2.07, 6.06; FertiQoL Emotional: OR 5.95; 95% CI, 2.89, 9.00) compared with the control group (Core OR: 0.67; 95% CI, –1.55, 2.89; Emotional: OR –0.02, 95% CI, –3.36, 3.32). The CCRI group reported less global anxiety (OR 0.275; 95% CI, 0.16, 0.39) than the control group (OR 0.471; 95% CI, –2.40, 3.34). The CCRI reported positive evaluations for the intervention (e.g., ease of use, helpfulness, perceived stress reduction).

Conclusion(s): Use of the CCRI tool led to improved psychological status but not statistically significantly more treatment cycles or a higher pregnancy rate.

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Key Words: Cognitive coping and relaxation intervention, compliance, depression, discontinuation, dropout, IVF, Positive Reappraisal Coping Intervention, stress management

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Reprint requests: Alice D. Domar, Ph.D., Domar Center for Mind/Body Health, 130 Second Avenue, Waltham, Massachusetts 02451 (E-mail: domar@domarcenter.com).

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Until recently, it was assumed that insured in vitro fertilization (IVF) patients would continue to pursue treatment until a viable pregnancy was achieved or their physician gave a recommendation to end treatment due to a poor prognosis (active censoring). However, a recent review of 22 studies on patient discontinuation (1) found that the most common reasons given were patient

postponement of treatment, discontinuation due to the psychological burden of treatment, or personal and relational problems (1). Based on such findings it has been suggested that reducing the burden of treatment could be an important way to maximize the chance of success with IVF by encouraging greater treatment adherence (2, 3). Reducing premature treatment termination must become a priority for the entire team; if the psychological burden is a major contributor, then psychological interventions designed to reduce that burden need to be thoroughly investigated and implemented.

Although there are numerous published articles on the efficacy of various psychological interventions with infertility patients, up to now the focus has been on the relief of emotional distress and/or increases in pregnancy rates using individual or group face-to-face interventions. Although many interventions have shown benefits, patients are often unable or unwilling to use in-person interventions because of perceptions of difficulty in scheduling such sessions, traveling for appointments, and cost (4). This reluctance is surprising given the levels of emotional distress reported by many infertility patients (5). Thus, any intervention that is effective but does not require a patient to travel for appointments would provide an important addition for the emotional care of infertility patients.

Prior research indicates that the period of time between embryo transfer and the pregnancy test is the time of greatest distress for many IVF patients (6). This distress not only decreases the quality of life for patients but might also lead patients to decide to drop out of treatment if that cycle is not successful. However, there is minimal research on psychological interventions that are effective during this time period. Emotional support in the form of phone calls during the waiting period does not lead to decreases in stress levels (7). In a recent study, insured patients who had dropped out of IVF treatment in the United States were contacted and asked what might have been done to prevent their decision to terminate treatment, and the most commonly given answer was written stress management materials (8).

A recent randomized controlled trial (9) supported the efficacy of a self-help cognitive intervention, the Positive Reappraisal Coping Intervention (PRCI) (10, 11), in helping IVF patients cope with the waiting stage of assisted reproduction treatment (ART). The PRCI is composed of an explanatory leaflet and 10 statements to be read twice a day during the waiting period. The PRCI promotes positive reappraisal coping, which is a form of coping that helps people take account of positive aspects of stressful situations, a strategy that is particularly useful for unpredictable and uncontrollable stressors such as waiting (10). The PRCI has been shown to be feasible, acceptable, and helpful in ART (10) and to sustain positive emotions (e.g., feeling encouraged, hopeful, content) during the 2-week waiting period (9), replicating the earlier results of a preliminary validation study (11). However, the PRCI did not reduce negative emotions such as feeling nervous, tense, or worried (9). Overall the PRCI tool is effective in supporting coping during ART, but its effects could be enhanced if they were paired with an intervention specifically designed to reduce negative emotions.

Relaxation techniques have been widely shown to reduce negative emotions in a range of medical patients (12). Indeed, relaxation, as embedded in the Mind/Body Program for Infertility, has been shown to significantly reduce anxiety scores in women in diverse stages of infertility treatment (13). Combining a cognitive approach (the PRCI) and relaxation instructions could be cost effective and could easily be integrated into the infertility clinic setting because both interventions can be self-administered and the instructions can be easily and inexpensively provided to patients with little staff time required. Further, because these are take-home tools, patients can use them as and when they are needed to manage the demands of treatment (10), thereby potentially improving their overall quality of life during treatment.

Reducing negative emotions while increasing positive emotions and quality of life may create the emotional environment necessary for patients to stay in treatment long enough to achieve pregnancy. Recent meta-analyses show that 22% of patients discontinue their treatment primarily for psychological reasons, despite a good prognosis and the ability to cover the treatment's cost (14). Discontinuation before the optimal three cycles of ART is associated with a 15% lower pregnancy rate (14). Domar et al. (13) showed improved pregnancy rates with the use of relaxation. Recent nonrandomized research also suggests that the PRCI is associated with an improved biochemical pregnancy rate (15), although this effect needs to be confirmed in randomized research. Thus, supporting patients to create an optimal treatment environment could help patients achieve their goal of parenthood as well as benefit clinics through patient retention and improved success rates.

An important aspect of intervention development is to determine for whom the intervention might work best (16). Psychotherapy outcome research shows that interventions work best for patients with greater needs, a proposal supported by past intervention studies in infertility. In an evaluation of an infertility e-health intervention, women with higher preintervention anxiety scores benefitted more from the relational component of the intervention (sexual concerns) than did women with lower levels of anxiety (17). Similarly, women with an avoidant coping style (e.g., avoid social situations with pregnant women) reported a greater reduction in social concerns than did women who used less avoidance. In our study, we examined whether pretreatment levels of trait anxiety and emotional distress (e.g., anxiety, depression) moderated the effects of the CCRI. We also examined whether already being an experienced user of positive reappraisal coping strategies would reduce its benefits because people would not be learning a new skill.

The goal of the proposed exploratory randomized trial was to determine the feasibility, acceptability, and efficacy of a combined cognitive coping and relaxation intervention (CCRI) on dropout behavior in ART patients. The primary outcome was treatment discontinuation within 12 months of the first IVF cycle. It was hypothesized that the CCRI group would undergo more treatment cycles after a failed first treatment cycle and consequently achieve a higher pregnancy rate than would the control group. It was also hypothesized that the CCRI group would report better psychological

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