Effectiveness of a psychosocial counselling intervention for first-time IVF couples: a randomized controlled trial

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BACKGROUND: The objective of this study was to evaluate a psychosocial counselling intervention for first-time IVF couples. In this article the results on women’s distress are presented. METHODS: Two hundred sixty-five couples admitted to an IVF treatment programme at the Erasmus MC were asked to participate in this study. Eighty-four couples agreed and were randomized according to a computer-generated random-numbers table into either a routine-care control group or an intervention group. The intervention consisted of three sessions with a social worker trained in Experiential Psychosocial Therapy: one before, one during and one after the first IVF cycle. Distress was measured daily during treatment by the Daily Record Keeping Chart. Depression and anxiety were measured before and after treatment by the Hospital Anxiety and Depression Scale. RESULTS: No significant group differences were found. CONCLUSIONS: The results of this study do not support the implementation of our counselling intervention for all first-time IVF couples. The low response rate suggests that there is little perceived need for psychosocial counselling among couples during a first IVF treatment cycle.

Key words: distress/effectiveness/IVF/psychosocial counselling/stress

Introduction

IVF treatment can be a stressful experience to couples. The demands of treatment—daily injections, semen analysis, scans, and invasive procedures—may be a cause of distress to both partners. Additionally, many couples have to deal with treatment failure and are often confronted with emotionally difficult treatment choices, such as whether or not to freeze embryos (Greenfeld, 1997). There has been a number of clinical reports on the emotional impact of IVF treatment. Common emotional responses to infertility and its treatment are depression, anger, guilt, frustration and sadness (Mahlstedt, 1994). Prospective studies have shown that women demonstrate elevated anxiety levels during IVF treatment (Demyttenaere et al., 1991; Boivin and Takefman, 1996). Treatment failure appears to be associated with an increased prevalence of both mild and moderate depression in both women and men (Newton et al., 1990; Thiering et al., 1993). Indeed, anxiety and depression are considered to be causes for the relatively high dropout rate observed after the first failed IVF cycle (Mahlstedt et al., 1987; Olivius et al., 2004). It has also been suggested that elevated anxiety and depression may cause lower pregnancy rates (Klonoff-Cohen et al., 2001; Smeenk et al., 2001). Most authors agree that fertility clinics should not only address the medical needs of their patients, but also their emotional needs. Boivin et al. (2001) advocate that psychosocial counselling should be available during all stages of IVF treatment. According to the Human Fertilisation and Embryology Authority (1998) the following tasks of counselling can be distinguished in the context of infertility treatment: information gathering and analysis, implications and decision-making counselling, support counselling and therapeutic counselling. Laffont and Edelmann (1994) suggest that many couples undergoing IVF may welcome some form of psychosocial counselling. Seventy-five per cent of the participants in this study, who had been through at least one IVF attempt, expressed a wish for pre-treatment counselling, while almost half of the study group requested counselling during treatment.

Despite the high agreement on the necessity of counselling IVF patients, there is a lack of studies addressing the efficacy of psychological interventions for this population. To date, only a few randomised, controlled, prospective studies have been conducted to assess the effect of counselling on distress related to infertility and its treatment. In a study by Domar et al. (2000) infertile couples received 10 weekly sessions in either a cognitive–behavioural group or a support group. These intervention groups were not linked to an IVF programme. At 6 months follow-up, participants in both intervention groups showed healthier scores than the controls on several psychological variables: anxiety, marital distress,
confusion, mood disturbance, stress management skills, health-promoting style and vigour. Six months later, fewer group differences were found. Overall, the participants in the cognitive–behavioural group showed more health-promoting behaviours, especially concerning interpersonal support and stress management. Surprisingly, both subjects in this group and the control group showed fewer depressive symptoms than did subjects in the support group.

The study by Domar et al. (2000) shows a long-term psychological approach to infertility. In other studies couples were offered specific support during IVF treatment. In a recent study by Emery et al. (2003), couples were offered a pre-IVF counselling intervention in a couple format, which focused on their narrative capacities. Six weeks after the first IVF treatment cycle had ended, participation in counselling was not associated with fewer symptoms of depression and anxiety. Couples in a study by Connolly et al. (1993) received not only a pre-treatment counselling session, but also one counselling session after their first cycle of IVF treatment. Counselling was directed at difficulties associated with IVF treatment, such as interpersonal and psychosexual problems. The authors concluded that counselling did not have an additional effect on anxiety or depression over information provision alone.

One possible explanation for the lack of effect of counselling in the latter two studies could be the use of general stress questionnaires as opposed to infertility-specific stress questionnaires. Furthermore, none of the above studies measured the effect of counselling on stress patients experienced during treatment, e.g. procedural stress. The aim of this study was therefore to evaluate a psychosocial counselling intervention for couples undergoing their first cycle of IVF treatment using an infertility-specific distress questionnaire. We hypothesized that counselling during the first IVF treatment cycle may reduce women’s procedural distress levels during IVF treatment.

Materials and methods

**Subjects**

A total of 265 couples admitted to an infertility treatment programme at the Erasmus MC (Rotterdam, The Netherlands) were asked to participate in this study between June 2001 and May 2003. Inclusion criteria for this programme were: indication for IVF treatment, women aged <41 years, a stable relationship and no severe psychological problems, as assessed by a physician during the couples’ initial visit to the hospital. This information is gathered using a standardized protocol. Because there is some evidence that the first ever IVF treatment cycle is the most stressful to patients (Slade et al., 1997; Salvatore et al., 2001), only first-time IVF patients were recruited for this study. Both partners had to be able to complete the questionnaires in Dutch. Eighty-four couples agreed to participate (32%). Reasons for non-participation are displayed in Table I.

**Intervention**

Couples in the intervention group received three counselling sessions, each of ~1 h duration. Similar to Connolly et al. (1993), we offered couples a pre-treatment and a post-treatment counselling session. The pre-treatment session took place ~1 week before the first day of pituitary down-regulation or the first day of ovarian stimulation (in the case of GnRH antagonist co-treatment); the post-treatment session took place ~2 weeks after the day of the pregnancy test. Additionally, participants received a counselling session 6–9 days after the embryo was transferred, because most IVF patients consider this stage of IVF treatment to be the most stressful. The waiting period is associated with more uncertainty and lack of control than other treatment stages (Connolly et al., 1993). All counselling sessions took place at the Erasmus MC. During the non-directive sessions couples were invited to discuss their feelings and thoughts on topics related to infertility and IVF treatment. Depending on the needs of the clients, the counsellor alternately used the four basic aspects of infertility counselling: information gathering and analysis, implications and decision-making counselling, support counselling and therapeutic counselling. Counselling was provided by a social worker who had been trained in Experiential Psychosocial Therapy (Bouwkamp and de Vries, 1992), which has been derived from Kempler’s (1981) Experiential Family Therapy. According to this method, problems are believed to originate from an imbalance between the basic human needs autonomy and relatedness and should therefore be solved in the context of a relationship. The main goal of experiential psychosocial therapy is teaching clients new (interpersonal) skills by forming not only a professional but also a personal relationship with them. Instead of being an objective observer, the counsellor expresses her own feelings and ideas about the client in order to create new interpersonal experiences for the client. It is assumed that through these personal experiences with the therapist clients learn how to cope with (inter)personal problems.

**Measures**

**Demographics**

Information on demographics and infertility history was gathered from all women by a standardized questionnaire.

**Daily Record Keeping Chart (DRK)**

In contrast to previous intervention studies in this area, distress was measured with an infertility-specific questionnaire, e.g. the Daily Record Keeping Chart (Boivin and Takefman, 1996; Boivin, 1997). This questionnaire consists of 21 items that represent emotional reactions common to women undergoing infertility treatment. Each item is rated on a 4-point-Likert scale (‘none’ to ‘severe’). Scores on four subscales can be obtained: depression/anger, uncertainty, positive affect and anxiety (range 0–12). The DRK showed good criterion-related validity and good convergent validity with other conceptually related scales, such as the Spielberger State Anxiety Inventory (Boivin, 1997). However, factor analysis showed overlap between the ‘negative’ subscales. We therefore decided to use the General Distress Scale for this study, which combines the depression/anger, uncertainty and anxiety subscales into one.

### Table I. Reasons for non-participation

<table>
<thead>
<tr>
<th>Reason</th>
<th>n</th>
<th>%</th>
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<tbody>
<tr>
<td>No time for counselling</td>
<td>57</td>
<td>31.5</td>
</tr>
<tr>
<td>No need for counselling</td>
<td>16</td>
<td>8.8</td>
</tr>
<tr>
<td>Discontinuation of IVF treatment</td>
<td>7</td>
<td>3.9</td>
</tr>
<tr>
<td>Work in hospital</td>
<td>4</td>
<td>2.2</td>
</tr>
<tr>
<td>Too stressed</td>
<td>4</td>
<td>2.2</td>
</tr>
<tr>
<td>No interest in study participation</td>
<td>2</td>
<td>1.1</td>
</tr>
<tr>
<td>Unknown reason</td>
<td>91</td>
<td>50.3</td>
</tr>
</tbody>
</table>

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negative affect scale (range 0–21). The DRK showed good internal consistency: Cronbach coefficient alphas varied from 0.76 to 0.88 for the individual subscales, while the coefficient alpha for the General Distress Scale was 0.87. The original items of the DRK were translated into Dutch.

Hospital Anxiety and Depression Scale (HADS)
To enable comparisons with other effect studies, a general stress questionnaire was also administered. The Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983) was developed as a screening tool to detect anxiety and depression in medical patients. All 14 items are scored on a 4-point-Likert scale from 0 to 3. Each of the two subscales consists of seven items (range 0–21). For this study, the Dutch version of the HADS by Spinhoven et al. (1997) was used, which has shown good test–retest reliability, homogeneity and internal consistency. Cronbach alphas for the total scale and both subscales varied from 0.71 to 0.90. Since the total HADS scale showed a better sensitivity and positive predictive value in detecting psychiatric disorder than the two subscales, the anxiety and depression scores were also combined in a total HADS score (0–42).

Study design
The couples were randomized according to a computer-generated random-numbers table into one of two groups. Forty-one couples were randomized in a routine-care control group, 43 couples into an intervention group. All participants completed the HADS before the couples’ initial visit to the hospital (baseline). During the first week after that visit the DRK was completed daily by the women (baseline) and again daily during their first IVF cycle: depending on the ovarian stimulation protocol used, women started monitoring on either the first day of down-regulation (GnRH agonist long protocol co-treatment) or the first day of ovarian stimulation (mild ovarian stimulation using GnRH antagonist co-treatment). Monitoring ended 2 weeks after the day of the pregnancy test and after the third counselling session. On that same day all participants completed the HADS for the second time. Since previous studies have shown that men experience lower levels of distress during IVF treatment than women (Boivin et al., 1998), male participants did not fill in the DRK. Results on the men’s HADS scores have been reported elsewhere (de Klerk et al., 2003).

Procedure
The study was reviewed and approved by the Erasmus MC Ethical Review Board. Couples were informed about this study during information evenings for couples about to start their first IVF cycle at the Erasmus MC. During these meetings all couples received written information with regard to the study and the baseline HADS. In the ensuing weeks, patients who met the study criteria received a telephone call and were invited to participate in the study. Couples who agreed to take part in this study met with one of the researchers before their first medical appointment at the hospital. After the objectives of the study had been discussed, both partners signed an informed consent form. The completed baseline HADS was collected and all women received a diary with one DRK for every treatment day and they were instructed to complete the DRK at a fixed time during the day. Finally, couples were informed whether they would receive additional counselling sessions with a social worker. The questionnaire on demographics was sent by mail before the start of the first IVF treatment cycle. A second HADS was sent by mail 2 weeks after the first cycle had ended.

Statistical analyses
Demographic data were analysed using Student’s t-test for continuous variables and χ²-test for categorical variables. For the group analyses, a distinction was made between seven individual IVF treatment stages: stimulation, day of oocyte retrieval, fertilization, day of embryo transfer, waiting period, day of the pregnancy test and post-treatment. However, no results are available for the post-treatment stage, since most women discontinued monitoring with the DRK after the day of the pregnancy test. Stage scores for both positive and negative affect were calculated by averaging daily scores on the DRK within each treatment stage. In addition, the stage scores from the stimulation days until the day of the pregnancy test were averaged into two separate overall treatment scores: one for positive affect and one for negative affect. These overall treatment scores were used to obtain a rough estimate of the level of the overall distress of the women in our study during their first IVF treatment cycle. Due to cycle cancellation, not all women went through every one of the previously mentioned treatment stages. Analyses of covariance for group comparisons for overall treatment scores were therefore adjusted for the total number of treatment stages the women passed through during their first IVF cycle. Next, analyses of covariance were conducted for group comparisons of both positive and negative affect during each individual treatment stage, adjusting for baseline affect scores. Analyses for the day of the pregnancy test and the overall treatment were also statistically controlled for pregnancy outcome. Finally, analyses of covariance were performed for the post-treatment HADS scores on both the subscales and the total scale, controlling for the baseline HADS scores. Data analysis was performed with the couples’ original group assignment (intent-to-treat design principle). Since we hypothesized that the intervention group would experience less procedural distress during the first IVF treatment cycle than controls, significance testing on all outcome measures was done at P < 0.05 (one-tailed). Effect sizes were measured using Cohen’s d (Cohen, 1988). The SD of the control group was used as the denominator of Cohen’s d.

Results
Demographics
Non-respondents did not differ in age from women who participated in this study. Of the 84 couples who were recruited, 40 couples (48%) discontinued participation during the study (Figure 1). Twenty-four women did not return their diary, three couples no longer wanted counselling, 11 couples did not proceed with IVF treatment, and two couples required extensive counselling. The couples who completed the programme did not differ significantly from the couples who dropped out in demographics and stress as measured by the HADS at baseline. The biochemical pregnancy rate after the first IVF treatment cycle was 27% for the intervention group and 32% for the control group. This difference was not significant. Table II shows the demographic characteristics for both intervention and control groups. No significant differences were found for any of the demographic variables between groups. Six couples were not able to attend all three counselling sessions due to practical reasons.

Positive and negative affect during the first IVF cycle
Table III shows the means and SD of the DRK scores in both groups for all treatment stages individually as well as overall
Anxiety and depression after the first IVF treatment cycle

No differences between the intervention (i; n = 18) and control (c; n = 15) groups were found on the depression subscale (mean_i = 3.1, SD_i = 2.6; mean_c = 4.3, SD_c = 2.6), on the anxiety subscale (mean_i = 4.5, SD_i = 2.6; mean_c = 5.3, SD_c = 2.6), or on the total scale of the HADS (mean_i = 7.6, SD_i = 4.5; mean_c = 9.6, SD_c = 4.5). Effect sizes were 0.46, 0.29 and 0.43 respectively.

Discussion

The objective of the present study was to evaluate the possible effect of a psychosocial counselling intervention for couples undergoing their first cycle of IVF treatment. This intervention consisted of three sessions with a social worker during the most demanding stages of the IVF cycle. In contrast to previous studies, the effect of counselling on the procedural distress women experienced during IVF was assessed before they were aware of the pregnancy outcome. Furthermore, this was the first intervention study in which a validated infertility-specific distress questionnaire was administered, namely the DRK. This questionnaire was expected to be more sensitive to distress related to infertility compared to the general stress questionnaires used in other studies.

Consistent with previous studies, no effect of counselling was found when stress after the first IVF cycle was measured with a general stress questionnaire (HADS). Moreover, no effect for counselling was found with the use of the DRK. On the day of the pregnancy test, however, there was a trend towards less negative affect for women in the intervention group when compared to women who had not received counselling. Women who had received additional care seemed to be better prepared for a negative treatment outcome. Indeed, one of the goals of our counselling intervention is to reduce unrealistic expectations couples might have concerning IVF treatment outcome. Even though the difference was marginally significant, we consider it promising, since the day of the pregnancy test was the most stressful stage of treatment for both the intervention and the control groups.

The relatively low response rate of this study suggests that there is little perceived need for psychosocial support among couples during a first IVF cycle. This is in keeping with the results of a study by Boivin et al. (1999) in which the majority of 143 infertile patients did not consider themselves to be distressed enough to need counselling. The less distressed patients in this study reported that they received sufficient support from informal sources such as their spouse, family and friends. The patients who were so distressed that they wanted to consult a counsellor did not do so for practical reasons, such as the perceived difficulty of scheduling sessions. Likewise, most couples who declined to participate in our study stated that they did not have the time for three additional visits to the hospital. Although our response rate (32%) is comparable to the response rate in a study by
Table III. Positive and negative affect assessed by the Daily Record Keeping Chart for each treatment stage

<table>
<thead>
<tr>
<th></th>
<th>Negative affect</th>
<th>Positive affect</th>
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<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td></td>
<td>Mean (95% CI)</td>
<td>d^a</td>
</tr>
<tr>
<td>Baseline</td>
<td>21 5.1 ± 1.4</td>
<td>20 6.9 ± 2.0</td>
</tr>
<tr>
<td>Stimulation</td>
<td>21 7.7 ± 2.2</td>
<td>20 7.4 ± 2.3</td>
</tr>
<tr>
<td>Oocyte retrieval</td>
<td>20 12.0 ± 3.5</td>
<td>19 12.1 ± 3.6</td>
</tr>
<tr>
<td>Fertilization</td>
<td>20 11.8 ± 3.9</td>
<td>18 10.9 ± 4.1</td>
</tr>
<tr>
<td>Embryo transfer</td>
<td>17 10.4 ± 4.0</td>
<td>15 10.1 ± 4.3</td>
</tr>
<tr>
<td>Waiting days</td>
<td>17 11.1 ± 3.2</td>
<td>15 9.3 ± 3.4</td>
</tr>
<tr>
<td>Pregnancy test</td>
<td>16 13.7 ± 5.7</td>
<td>14 20.5 ± 6.1</td>
</tr>
<tr>
<td>Overall</td>
<td>22 10.1 ± 2.8</td>
<td>22 12.0 ± 2.8</td>
</tr>
</tbody>
</table>

^aCohen’s d as a measure of effect size: 0.2 = small; 0.5 = medium; 0.8 = large.

McNaughton-Cassill et al. (2002), Connolly et al. (1993) were able to obtain a response rate of ~98%. In their study, counselling sessions were combined with medical appointments. However, we had intended to offer support at the most stressful treatment stages, the days before and after the pregnancy test. During these days couples do not have medical appointments. Considering our relatively low response rate, it is possible that the couples who really would have benefited from our counselling intervention did not participate in this study. In the future, effort should be made to integrate our counselling intervention into the IVF treatment to meet the needs of IVF couples. The women who did not want to participate in this study did not differ in age from the women who did agree to participate. It would be very interesting to further examine the characteristics of non-respondents in a future study. Targeting counselling interventions towards couples who have already undergone IVF treatment may be of greater benefit. The study of Laffont and Edelmann (1994) suggests that these couples show more interest in counselling.

Aside from the low response rate, this study also suffered from a high attrition rate. Many women did not return their diary. Additionally, many women stopped monitoring their distress after the day of the pregnancy test. Although women who dropped out of the study did not show more feelings of anxiety or depression before the start of the IVF treatment than women who did not drop out, this subgroup of women may have experienced higher levels of distress during IVF treatment. In future studies, administering the DRK for a shorter time period than in this study may prevent dropout.

Since the low response and high attrition rate have also affected the statistical power of our study, the results of this study should be interpreted with caution. These results do not favour routine psychosocial counselling for all first-time IVF patients, a finding that is in line with the results of two previous randomized controlled studies (Connolly et al., 1993; Emery et al., 2003). In a recent review (Boivin, 2003), it is suggested that group interventions that focus on education and skills training (e.g., relaxation training) would be more effective than counselling interventions such as the one applied in this study. However, most women in this study seemed to be able to cope with the procedural distress of their first IVF treatment without additional counselling. Since couples accepted for IVF treatment have to be in a stable relationship, it is likely that most are able to support each other during treatment or have other sources of support available to them, such as family or friends. Also, the women in our study may have benefited from a supportive medical staff. Finally, it is not unlikely that the monitoring of distress itself may have had a positive effect on women’s distress. It was not possible to carry out subgroup analyses due to the modest sample size of this study. One could hypothesize that benefits of counselling would be greater for those people who started the intervention with higher levels of distress. In our opinion, future research should therefore be directed at identifying couples who are particularly vulnerable to distress during their first IVF treatment cycle. Psychosocial counselling could be offered to couples who are most likely to benefit from additional support.

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