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# Brief Cognitive Behavioral Intervention in Groups in a Brazilian Assisted Reproduction Program

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### Brief Cognitive Behavioral Intervention in Groups in a Brazilian Assisted Reproduction Program

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## Brief Cognitive Behavioral Intervention in Groups in a Brazilian Assisted Reproduction Program

Ricardo Gorayeb, Andréa C. T. Borsari, Ana Carolina J. S. Rosa-e-Silva, and Rui A. Ferriani

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The study's objective was to assess the effect of a cognitive behavioral group intervention on the pregnancy rates of patients submitted to *in vitro* fertilization (IVF) techniques or to intracytoplasmic sperm injection (ICSI). The study was conducted on 188 patients, 93 who participated in a group of psychological intervention before the IVF and ICSI procedures and 95 patients submitted to IVF and ICSI during the same period of time, who did not participate in the intervention (control group). Clinical pregnancy was the outcome measure. Demographic and clinical variables were compared between groups in order to assess the group's homogeneity. Participants in the psychological intervention obtained a pregnancy rate of 39.8%, significantly higher than the 23.2% rate of nonparticipants ( $\chi^2 = 6.03, p = .01$ , odds ratio of 22 (CI: 1.16–4.13)). The data suggest that group psychological intervention before IVF and ICSI in order to control stress seems to increase the rate of success of these procedures.

**Keywords:** cognitive behavioral intervention, infertility, distress, IVF patients, psychology

Infertility is defined as the absence of conception after one year of regular sexual activity without the use of any contraceptive method, with this time being shorter in the presence of male or female risk factors of infertility.<sup>1</sup>

The experience of being unable to achieve pregnancy may be described as a source of anxiety, fear, sadness, frustration and anger for couples who desire children,<sup>2–5</sup> causing feelings of worthlessness and important distress symptoms.<sup>3,6,7</sup> Infertility may be felt as a stigmatizing condition,<sup>8</sup> being described by those who experience it as the most distressful event in their lives.<sup>9</sup> Questions such as the lack of spontaneity in sexual life, lack of control of one's own life and social pressure to have children are some of the difficulties reported by infertile women,<sup>10</sup> who may feel infertility as an insult to their self-esteem and femininity.<sup>5</sup>

The scientific literature has dealt with the psychological causes of infertility and has attempted to evaluate the emotional consequences of this clinical condition. The psychogenic model, which dominated up to the 1980 decade, has

been replaced with investigations of the distressing effects of involuntary lack of pregnancy.<sup>7</sup>

There is no consensus about whether the psychological difficulties are the cause or the consequence of infertility,<sup>11,12</sup> with some investigators<sup>5,13</sup> considering both hypotheses, recognizing both the effect of distress on the hypothalamus-pituitary-ovary axis leading to anovulation, and the emotional difficulties resulting from infertility. Likewise, studies report the association between socio-psycho-behavioral factors and male semen quality, and indicated that health programs focusing on lifestyle and psychological health would be helpful for male reproductive health.<sup>14</sup> The relationship between psychological parameters and the success in the IVF is more complex than it is usually believed.<sup>15</sup>

Moreira et al. stated that the influence of emotional status on reproductive function is linked to multifactorial aspects which make it difficult to establish cause-effect relationships in a linear manner.<sup>13</sup> According to these investigators, the presence or absence of mental disorders and the existence of social support and of strategies for coping with stressful situations are some of the factors that may interfere with the organic responses of an individual in a distressful situation.

In addition to the investigation of marital infertility, an exhausting and tiresome procedure, there are the procedures of assisted reproduction (AR) which, although representing a chance of pregnancy, may also increase the frustration of the couple since they do not guarantee a successful result.

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Although some studies did not succeed in proving that the psychological stress may have any influence on AR results,<sup>16-18</sup> Cohen et al<sup>19</sup> have related the distress initially felt by the patients in the AR process to the results of each step of the procedure, including the pregnancy rate, indicating that, the higher the distress, the poorer the results of the procedure. Another study,<sup>20</sup> comparing the levels of depression of patients submitted to in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI), detected lower depression levels among the patients who did become pregnant.

Many of the psychotherapeutic interventions for infertile patients emphasize the importance of the control of negative psychological effects on the infertility condition. Moreover, the infertility counseling, whether individual, couples and group interventions, may offers the opportunity to seek ways of living more satisfying.<sup>21</sup> Motivation, fears and level of information about AR are some of the variables to be considered when psychological intervention is offered to couples during infertility treatment.<sup>22</sup>

Currently, it is observed that the use of the internet can be an alternative to help with information and social support, and has a significant lower cost. Preliminary results of a study suggest that general stress may be significantly reduced in infertile women using an online cognitive behavioral approach.<sup>23</sup> To date, in Brazil, there are no reports of online cognitive-behavioral intervention for helping infertile patients.

Liz and Strauss emphasized the positive results of individual or group psychotherapy for infertile patients, demonstrating that both modalities contribute to a reduction of anxiety.<sup>24</sup> McQueeney, Stanton, and Sigmon reported that psychological groups directed at the ability to cope and focused on the specific problem and/or on emotion, proved to be relevant as strategies of positive adjustment in infertility.<sup>25</sup>

In another study, patients submitted to IVF, that used acupuncture, reported significantly lower anxiety after embryo transfer and a greater feeling of optimism when compared to the control group. The study showed that, although no increase in pregnancy was observed, acupuncture was associated to greater optimism and relaxation.<sup>26</sup>

Several reports<sup>27,28</sup> have stated that behavioral treatment should be considered for infertile couple before or in parallel to AR techniques and have demonstrated that infertile women who regularly execute relaxation techniques may present reduced levels of tension, anxiety and depression and increased conception rates. Moreover, cognitive behavioral treatment has been proven effective in reducing depression in infertile women.<sup>29</sup>

Psychological support by means of cognitive behavioral and relaxation training techniques has been pointed out as a facilitator of successful fertilization, suggesting that the reduction of distress improves the rates of conception. Thus, the objective of the present study was to use a model of cognitive behavioral treatment in order to investigate the effect

of psychological support on the pregnancy rates of patients candidates for IVF and ICSI techniques at an Assisted Reproduction Centre of a tertiary public university hospital in Brazil, considering positive only pregnancies with 12 or more weeks of gestational age.

## METHODS

The study was conducted on couples to be submitted to AR techniques (IVF and ICSI) during a period of four years of assistance in a tertiary hospital, after routine medical investigation (videolaparoscopy, hysterosalpingography and hysteroscopy, in addition to clinical, hormonal and serologic tests, as well as semen evaluation).

The study was approved by the Ethics Committee of the University Hospital where the couples underwent the IVF and ICSI procedures and psychological intervention, and all couples who agreed to participate gave written informed consent at the time of the ambulatory medical visit, regardless of the group to which they were assigned.

Patients were evaluated for age, sociodemographic variable such as schooling and profession, cause of infertility and type of AR procedure. Also, as the number and quality of embryos transferred are relevant for the success of pregnancy we compared these two variables in order to reduce bias in our analysis.

### Study Design

In an initial telephone contact, 325 couples were asked about their interest in participating in a group of cognitive behavioral intervention before the beginning of IVF and ICSI. On that occasion they were informed that it would not be possible to include all couples and that the participants would be confirmed later after drawing lots. This procedure was adopted in order to guarantee that both the group submitted to psychological intervention and the control group would evaluate the psychological aid in a positive manner.

All cases considered (study and control) had experienced at least two years of infertility, had a stable union and the socioeconomic conditions needed to cover the costs of the medications necessary for IVF and ICSI.

### Inclusion Criteria

Telephone contact was limited to couples residing at a maximum distance of 150 km from the Reproduction Centre in order to facilitate the weekly presence of the patients during the intervention sessions.

Of the total couples contacted, 285 accepted to participate and were selected randomly distributed throughout drawing lots in each group. As patients were more likely to drop out the study in the intervention group (IG) due to recurrent absence in sessions, we opted to assign more patients to the

IG than to the control group (CG), in a proportion of 4:3 (161 for cognitive behavioral intervention and 124 couples who received no intervention (CG) (Figure 1).

All patients presented FSH levels lower than 12,0mIU/ml were excluded and all patients with endocrinological disorders were previously controlled (eg, hyperprolactinemia or thyroidopathy), these were criteria regularly adopted by our service when including patients for infertility treatment.

Besides, in this study, patients with repetitive abortion or women older than 40 were not invited to participate.

**Exclusion Criteria**

In order to permit a more effective psychological intervention, the couple and/or spouse that did not attend at least two of the five group meetings were excluded.

All patients in both groups were submitted to IVF and ICSI procedures during the same period of time. Since the objective of the study was to compare the success rates of IVF and ICSI evaluated by pregnancy rates, all patients that did not achieve embryo transfer were excluded from the study.

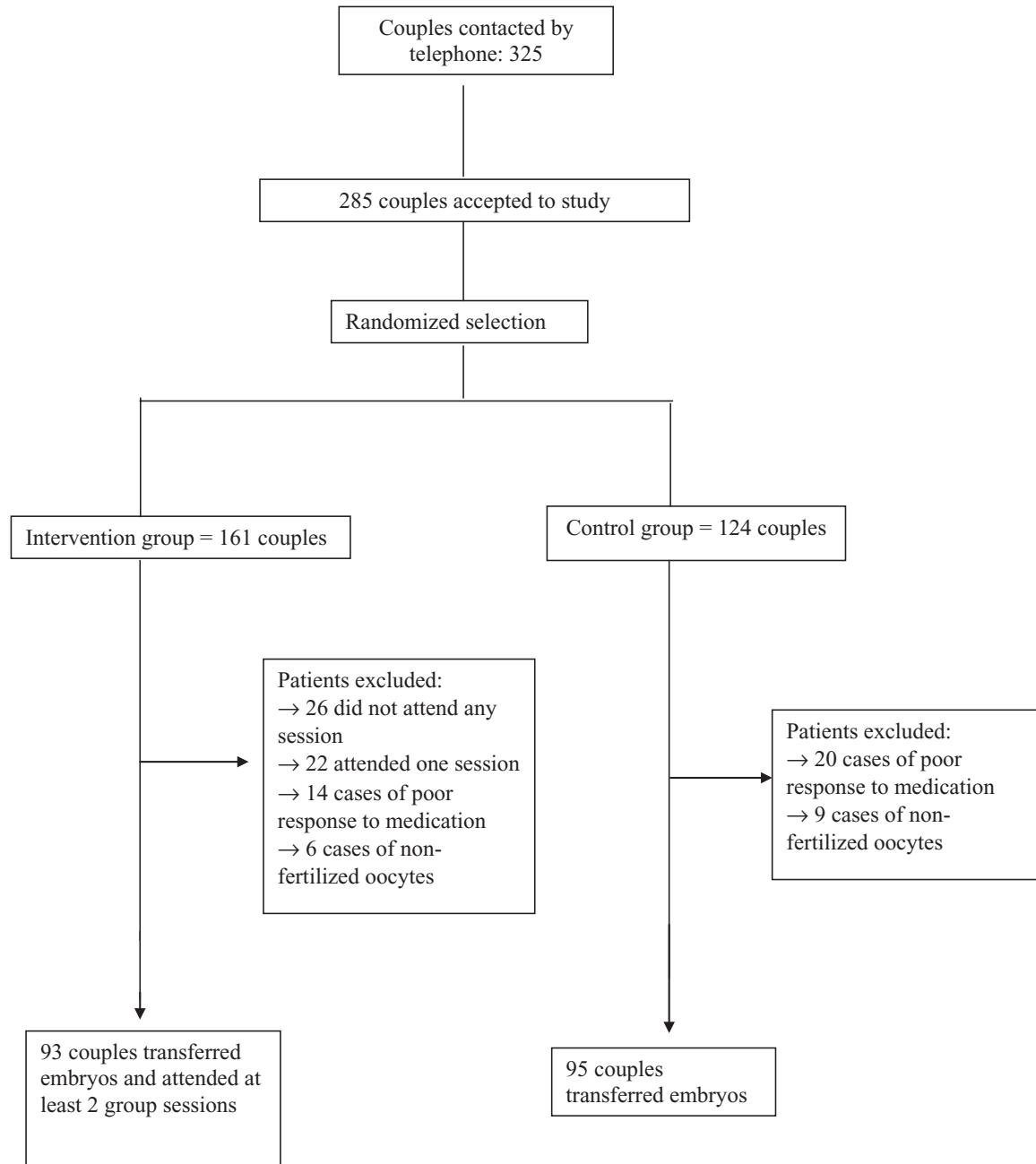


FIGURE 1 Patient’s inclusion flow diagram.

Thus the total number of patients who completed the study was similar in both groups (93 couples in the IG and 95 in the CG) (Figure 1).

The sample size was calculated considering a 80% power test, with a significance of 5%. The estimated number of patients for each group was around one hundred, to detect a difference of  $45\% \times 25\%$  in pregnancy rates.

Statistical analysis was performed using the SPSS for Windows software, version 15.0, (SPSS, Inc., Chicago, IL, USA). Contingency tables were constructed and the data regarding all variables were analyzed by the chi-square test. The groups were compared for age using the Student t-test, because the age variable has normal distribution (Shapiro-Wilks test). The Mann-Whitney test was used for number of embryos transferred because the distribution of this variable is not normal. The level of significance considered was  $p \leq .05$ .

### STRUCTURE OF THE PSYCHOLOGICAL INTERVENTION

The psychological intervention group consisted of five weekly meetings lasting two hours each, with the last session being held during the week preceding the AR procedure. The focus of the psychological treatment was cognitive behavioral, emphasizing the influence of automatic thoughts often impregnated with equivocal beliefs, on the feelings and behaviors of an individual. The techniques used in this approach aim to analyze the automatic thought system used by the patients and try to replace negative or distorted beliefs with more constructive ones.<sup>30</sup>

The group session, short and focal, was directed at the condition of infertility and the IVF and ICSI procedures. The meetings, a source of exchange of experience and of support for the couples, covered the perception of cognitions and feelings involved in the clinical situation, exploring the link between patient beliefs and expectations and the emotional distress in this context. On this basis, the sessions dealt with topics such as social and personal requirements to have children, marital relationship (affective and sexual), fears regarding AR techniques, and the presence of social support, with an attempt made to find ways of coping in a functional manner in each of these areas.

Techniques of stress control were used after being developed on a punctual manner on the eve of treatment. Anti-stress attitudes were defined, including concepts related to quality of life in an attempt to control emotional states and their physiological effects. In this respect, the group was taught to use the progressive muscle relaxation technique of Jacobson<sup>31</sup> during a period of 30 minutes in the last four sessions, thus producing sensations contrary to those experienced in anxiety states. The importance of the frequent practice of relaxation at home during the week was emphasized. In addition, a gynecologist participated in one of the

sessions to provide information about the AR techniques and to resolve remaining doubts about them and about the condition of infertility, in order to insure a reduction of anxiety or fear related to lack of information about this area. So, the psychological intervention aimed to control stress by the use of relaxation techniques and cognitive restructuring. The social support and information were additional tools.

The meetings were held in a room appropriate for group sessions located in the Department of Gynecology and Obstetrics of the University Hospital. The room contained chairs and mattresses for muscle relaxation training. The intervention was always conducted by the same psychologist, who was responsible for the investigation.

At the end of the last session, the patients presented informally an evaluation of the group, discussing aspects they judged relevant at that time in their life and adding suggestions or criticisms.

### RESULTS

For sample characterization, patient's age, demographic variables, causes of marital infertility, AR procedures and embryo quality, and the number of transferred embryos were determined both for the intervention group (IG) and for the control group (CG). Patient's age, an important variable in the area of infertility, was compared between groups in order to determine whether the groups were homogeneous. Mean ( $\pm$  SD) patient age was  $32.04 \pm 3.94$  years for IG patients and  $32.42 \pm 3.72$  years for CG patients, with a  $p$  value of .49.

No significant difference was detected between groups regarding demographic variables such as profession and schooling. Regarding the profession, there were patients who worked in various sectors (commerce, administration, liberal arts, or primary production level), as well as patients who did not work ( $p = .13$ ). Regarding schooling, 43.0% of IG patients (40) and 36.84% (35) of CG patients had completed middle school, and 27.95% (26) of IG patients and 33.68% (32) of CG patients had higher education, with  $p = .71$ . Family income was not stated by the patients but could be inferred from their profession.

A comparative analysis regarding the causes of infertility detected in both groups indicated that primary infertility (IG = 80.6%  $\times$  CG = 75.8%,  $p = .42$ ); severe male factor (IG = 11.8%  $\times$  CG = 7.4%,  $p = .30$ ); tubal infertility factor (IG = 26.9%  $\times$  CG = 30.5%,  $p = .58$ ); polycystic ovary syndrome (IG = 14%  $\times$  CG = 14.7%,  $p = .88$ ); endometriosis (IG = 33.3%  $\times$  CG = 26.3%,  $p = .29$ ) as well as other clinical factors did not statistically differ, indicating that both groups were homogeneous in relation to infertility characteristics.

Another variable considered was the AR procedure used (ie, IVF or ICSI) with the use of a testicular puncture or biopsy. These different variables were considered separately in order to determine case homogeneity, considering that

more complex clinical situations require more sophisticated AR techniques. The results show that there was no statistically significant difference related to techniques used between IG and CG ( $p = 1.0$ ). (FIV: 28% IG vs. 27.40% CG; ICSI: 58.10% IG vs. 58.9% CG; ICSI with a biopsy: 14% IG vs. 13.70% CG).

In relation to the transferred embryos we observed that there was no difference in the mean number of embryos transferred ( $2.7 \pm 0.8$  vs.  $2.6 \pm 0.9$  embryos in the control and intervention groups, respectively,  $p = .57$ ); and for a more accurate information we verified that 72.6% (69/95) of the patients included in the control and 71% (66/93) in the intervention group had at least one good quality embryo transferred (Mann Whitney test,  $p = .06$ ). The absence of statistically significant differences among these variables describes the effectiveness of the randomization process.

Patients receiving the psychological intervention presented higher pregnancy rates (IG = 39.8%) when compared to the control group (CG = 23.2%), ( $\chi^2 = 6.03$ ,  $p = .01$ , odds ratio of 2.2 (CI: 1.16–4.13)). This results suggest that IG patients had a 2.2-fold higher chance to become pregnant than CG women.

### COMMENT

The objective of the present investigation was to assess the effect of a group psychological intervention of the cognitive behavioral type on the pregnancy rates of women to be submitted to IVF and ICSI techniques at an Assisted Reproduction Centre of a tertiary public university hospital in Brazil.

The investigation was based on the premise coherent with the international literature that group psychological intervention before the AR procedure might reduce anxiety and contribute to increased rates of successful AR. Cognitive behavioral interventions for infertile couples submitted to IVF have proved to be an effective strategy for the reduction of anxiety and for coping with the distress involved in the treatment of infertility.<sup>32,33</sup> Similarly, in a Chinese study,<sup>34</sup> psychological intervention significantly reduced the levels of anxiety in women submitted to IVF compared to a control group.

A randomized study<sup>35</sup> conducted on infertile patients with moderate depression revealed that the cognitive behavioral psychotherapeutic group proved to be effective, with a statistically significant reduction of depression and anxiety levels compared to a control group and to patients only exposed to psychotropic intervention. Even from an organic viewpoint, an Italian study<sup>36</sup> demonstrated that a program of cognitive behavioral treatment significantly reduced the autonomic and neuroendocrine stress responses (arterial pressure, heart beat and cortisol) in women waiting for IVF compared to a control group.

Thus, the outcome measured was clinical pregnancy. The positive cases of the present study corresponded to clinical pregnancy, which occurs when there is complete fixation in the uterus with the presence of a gestational sac and embryo visualized by ultrasound examination. It was not an objective to assess the effects of the intervention performed before the IVF and ICSI procedures for a prolonged period of time after intervention. The study refers to the measurement of the final result of fertilization to be started one week after the end of the group intervention. Thus, the patients who did not undergo IVF or ICSI due to a poor response to ovulation induction and/or the patients who did not transfer embryos in either the intervention or the control group were not considered to be participants in the study.

An important limitation of this study is that no quantitative psychological instrument objectively evaluated the infertility related stress; we were forced not to do so because there are no psychological instruments in Portuguese to measure specifically infertility related stress validated to our population. The use of general anxiety scales was not considered since these scales may not be sufficient to cover questions related to the clinical aspects of marital infertility.<sup>37</sup> In addition, several anxiety scales included items that measure physical symptoms, with might be related to the gynecological problem or even the medical procedures. It must be pointed out that our primary objective was to investigate the effect of a psychological intervention on the results of AR itself and not on psychological status. Anyway, this is a limitation of this study, since psychological measures are important, so future studies are being designed by our group to objectively analyze this matter.

Regarding the study methodology, care was taken to establish inclusion criteria that would yield homogeneous groups. Thus, in order to guarantee that both IG and CG patients would evaluate psychological care in a positive manner, each patient was questioned about her interest in participating in the intervention.

In addition, the invitation to participate in the study was limited by distance, with a limit of 150 km being fixed between the Centre for Reproduction and the city of origin of the couple in an attempt to make it feasible for the patients to participate in the weekly sessions of intervention. This aspect was considered in view of the high demand for attendance at this university hospital which, by working at the public and tertiary level, ends up by attending patients coming from a distance of as much as 1,000 kilometers.

Both groups contained patients with mild, moderate and severe conditions of female and/or male infertility who were assigned to the AR technique most adequate to their diagnosis. In addition, care was taken to determine that important AR variables were equivalent in the two groups. The quality and the number of the embryos transferred were also compared between the two groups, as this is a very important factor when pregnancy rates are the main outcome; however there was no difference between the groups.

There is a consensus in the area of AR that the probability of pregnancy decreases with increasing female age, especially after 35 years. Thus, age is considered to be an important variable in the area of infertility. In the present study, no significant difference was detected between groups regarding age.

A limitation of the present study was the lack of care directed at the CG, which only received medical intervention, whereas the IG received both medical and psychological assistance. Information and attention in general could have been offered in an unsystematic manner to both groups by the doctors and nurses who perform the procedure. The care provided by psychological intervention, in turn, was systematized and its objective was to control stress. Further studies are needed in order to compare different types of care and how they interfere in the coping of the patient at a time of stress.

Cognitive behavioral intervention is provided through the internet in other countries. However, we did not offer this approach to the present patients because this type of treatment does not exist as yet in our country.

The emotional aspects of the clinical signs and symptoms of marital infertility have been extensively discussed and investigated the world over. The area includes investigations that attempt to assess the differences in the levels of distress and sexual and marital satisfaction between fertile and infertile women and studies that investigate sex differences in the experience of infertility. Many of these investigations concern infertile women and/or couples at Assisted Reproduction Centers.

The topic of anxiety and/or distress linked to infertility is possibly one of those that most attract the interest of researchers who try to understand its influence on both the causes and consequences of involuntary lack of pregnancy. Groups of psychological support intending to increase the pregnancy rates of infertile patients represent a substantial aid for the solution of a problem that encompasses and affects the social, professional and emotional areas of each spouse.

Cognitive behavioral therapy intervention has proved to be effective in reducing anxiety and depression levels in infertile patients and has been used in programs of psychotherapeutic intervention at Assisted Reproduction Centers. The present study, carried out at an Assisted Reproduction Centre of a Brazilian public hospital, shows that group cognitive behavioral therapy can increase the rates of success of AR techniques, in agreement with international reports. These data indicate that the global experience can be extrapolated to Brazil and support the importance of the role of the psychologist as part of the multi professional team.

In the present study, an attempt was made to develop strategies for coping with stress using directive and focal techniques at the time of the AR procedure. Many studies have assessed this specific time or intervened in it, while others did it at different times during the technical presentation

of the procedure, mainly to help the patients to deal with the negative psychological effects of infertility. It was decided to intervene, in this study, at the time of the execution of the AR technique since this is a moment of acute stress and with greater possibilities of interfering in the fecundation rates. Studies of this type demonstrate the importance of cognitive-behavioral intervention for the control of stress and an increased pregnancy rate.

It is of fundamental importance to conduct further studies in this area considering the psychosocial aspects of infertility syndromes. New studies are required for evaluation of the impact of psychological interventions on the condition of infertility and the results of proposed treatments, as well as on the control and/or reduction of the high prevalence of anxiety in these couples. Medical intervention cannot forgo psychological assistance since no disease is free of emotional repercussions.

The use of psychotherapy should be considered as part of the general therapeutic framework of infertility.<sup>38</sup> Marital infertility cannot be considered a disease to be cured only with AR techniques. Distress, beliefs, and thoughts related to the picture should be the target of psychological interventions aiming at better coping, a better marital relationship, and a better quality of life of infertile patients as they try to have children.

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