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A longitudinal comparative study of a multicouple group and single-couple psychosocial intervention while experiencing infertility

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Abstract

This is a quasi-experimental, nonequivalent design study investigating the efficacy of multicouple group and single-couple intervention formats aimed at diminishing the psychosocial impact of infertility. The review studies carried out to date that have assessed this subject do not show consistent findings and although increasing the efficacy and efficiency of intervention formats more than justifies their analysis, there are no studies making this particular comparison. Eighty-seven infertile couples who were in assessment for their infertility and/or were close to undergoing some kind of assisted reproductive technology process participated in a psychosocial intervention either under the multicouple group or single-couple subconditions, or acted as controls. The variables of depression, anxiety, and fertility quality of life were used for evaluating psychosocial impact. Comparisons were made: (a) between the intervention condition and controls and (b) between the two subconditions. The results support the efficacy of the intervention both in the dyadic latent growth curve models analysis carried out and in the *treatment effect* calculation. Although in the comparison between the multicouple and single-couple format, some differences generally favoring the single format one were found, they were not conclusive. Therefore, the results are in line with review studies that did not find the group format to be more effective. Although this study provides valuable information, its limitations mean that further research needs to be carried out. When selecting the intervention format, therapists should also weigh up others aspects, such as the intervention goal,

patient's needs and characteristics, reproductive history, and current stage of infertility.

KEYWORDS
dyadic LGCM, infertility, multicouple group, psychosocial intervention format, psychosocial outcomes, single couple

INTRODUCTION

Infertility is a problem that affects 8%–12% of couples of childbearing age (Vander Borght & Wyns, 2018), and use of advanced technologies to overcome infertility has increased, with more and more infertility patients benefiting from assisted reproductive technology (ART; Hu et al., 2020). Infertility is defined as the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse and is considered to be a disease that generates disability as an impairment of reproductive function (Zegers-Hochschild et al., 2017). Its psychological symptoms may be similar to those associated with other serious medical conditions (Domar et al., 1993).

Although carrying out ART processes to reverse this situation can generate optimism, these techniques can also lead to various types of stresses and strains and concerns for those who make use of them (Schmidt, 2006), which can have a negative impact that could be coupled with adverse ART experiences (Rockliff et al., 2014). The stressful experience of infertility can be exacerbated by the burden of treatment and the negative impact of failed ART attempts (Gameiro & Finnigan, 2017), therefore infertile subjects' scores for the mental health indicators routinely used in this field of study (i.e. anxiety and depression) are less healthy than those of the fertile population (De Berardis et al., 2014). Other well-being indicators have been used to measure this psychosocial impact of infertility, so *fertility adjustment*, *infertility-related stress*, *emotional maladjustment*, and *fertility quality of life* are terms used with instruments that have been developed to measure them.

In this context and with the aim of reducing and/or reversing that negative impact, carrying out psychosocial interventions for people who experience infertily has been recommended (Chow et al., 2016). Psychosocial interventions are defined as any interventions that address the psychological or social needs of the patient and can be delivered in any format, including group or individual (Chan et al., 2006). Specifically in the infertility field, these have been effective in modifying certain psychosocial health indicators, according to the findings of reviews and meta-analyses that have been undertaken, i.e. (Boivin, 2003; Chow et al., 2016; de Liz & Strauss, 2005; Frederiksen et al., 2015), although it has been indicated that in general, the heterogeneity and methodological limitations of the studies limit how conclusive this statement can be and more studies are needed in order to overtake those issues. The main shortcomings highlighted by review and meta-analysis studies carried out to date are: (1) considerable variability in interventions (type, timing, number of sessions, duration, format, and person delivering the intervention), (2) variability in the instruments used and the time points for measuring outcomes, (3) the lack of sample participants randomly selected from a pool of potential participants and randomly assigned to experimental conditions, which would help ensure those conditions were appropriate for analysis (4) the lack of longitudinal designs, (5) the absence of effect size (ES) descriptions, and (6) publication bias, i.e. (Chow et al., 2016; Frederiksen et al., 2015; Hämmerli et al., 2009).

So, there is a broad range of psychosocial interventions for infertility (Lemmens et al., 2004), which can differ in various aspects. Clarifying the differential effects of these variations has been widely recommended, as it would enable the most effective elements of psychosocial interventions to be identified.

Both individual subjects and couples may be the target of interventions. Review studies have shown the efficacy of certain couple interventions for other disorders as well as infertility.

Cognitive-behavioral couple-based interventions appear to be at least as effective as individual interventions across a variety of psychological disorders and also tend to provide the unique, added benefit of improving relationship functioning (Fischer et al., 2016). In infertility, a study has found couple interventions to be associated with effective reduction of depression, anxiety, stress, and relational complaints (Thompson, 2021). As stated, infertility distress is more effectively processed together as a dyad than by someone alone (Koser, 2020) due to the interpersonal nature of infertility. It can be considered a marital problem, rather than a male or female problem (Lemmens et al., 2004), for which couple based-interventions may focus more on specific elements, such as a couple's sense of partnership (Chow et al., 2016), mutual support, and dyadic coping: factors that can buffer the effect of stressors (Bodenmann, 2008) like infertility. So, evidence suggests that where possible, couples, rather than individuals should be the target of psychosocial interventions in this field.

One aspect of the psychosocial intervention format that needs to be tested is whether there is a difference in efficacy between a group format, involving the presence of other infertile subjects/couples, and a single-couple format (Hämmerli et al., 2009). If similar results were obtained with both, given the group format reaches more subjects over the same period of time, use of this would optimize the efficiency of the intervention. Also, it has been noted that in group interventions, specific therapeutic mechanisms are activated, which produce different effects from those of individual interventions (Yalom & Leszcz, 2005). If mechanisms such as instillation of hope, universality, imparting information, altruism, group cohesiveness, or others that have been recommended are activated, this could lead to infertility having a less harmful effect (Chamorro & Chamorro, 2018). So finding out how effective support groups are in the field of infertility warrants important consideration.

In both multicouple group or single-couple format structured interventions, there are a predetermined number of meetings and specific goals are set for each session (Boivin, 2003), focusing on one or more of these components: coping training, stress reduction, sex therapy, receiving preparatory information about medical tests or treatments, cognitive restructuring, methods for emotional expression, education programs, relaxation training, sexual counseling, couple therapy, cognitive-behavioral therapy, and mind–body interventions (Chow et al., 2016). Moreover, group interventions include directed discussions that can be conducted with other infertile people, not just the therapist and the partner. These may constitute an additional support resource that activates mechanisms, as mentioned above.

Some review studies and meta-analyses that have examined the efficacy of intervention formats have concluded that the most successful interventions in terms of variables related to psychosocial impact involve an element that is often achieved in a group format, i.e. (Boivin, 2003; Chow et al., 2016). In particular, one of them (Frederiksen et al., 2015) concluded that a statistically significant effect was found for the group format ($g = 0.76$; $p < 0.001$) in relation to combined psychological outcomes, while the effect size (ES) for intervention in formats such as individual, couple, and online did not reach statistical significance. However, other studies of the same type have not found differential efficacy favoring the group intervention format, i.e. (de Liz & Strauss, 2005; Hämmerli et al., 2009). For instance, the first of these established an ES of 0.36 for group therapy and an ES of 0.17 for individual/couple therapy in the anxiety variable but found that the ES was nonsignificant for depression.

Thus, the aim of this study was to assess the efficacy of a psychosocial intervention and to compare two intervention formats (multicouple group vs. single couple) in relation to three individual psychosocial outcomes (depression, anxiety, and fertility quality of life) using a quasi-experimental, nonequivalent study design. Couple-based interventions were carried out with both partners as the target, in contrast to typical infertility intervention studies that have generally been aimed at women, or when they have been geared toward couples, the results taken for analysis have more often been those of the woman than of both partners. This research, to the best of our knowledge also serves to overcome an existing limitation in this field due to the fact that studies assessing some kind of group intervention have been carried out using only that format.

METHOD

This study, registered at clinicaltrial.gov (NCT04572659), was carried out in Spain, where the fertility rate (no. of children per woman) ranged between 1.33 (in 2005) and 1.26 (in 2018). The rate for the European Union went from 1.51 (in 2005) to 1.62 (in 2010) to 1.56 (in 2018), while that of all countries worldwide went from 2.58 (in 2005) to 2.42 (in 2018). In Spain, an increase in ART treatments has been registered over the past five years and 9% of all births result from such treatment (Gabinete de Prensa, 2020). The government can cover the cost of carrying out a certain number of ART cycles but only in accordance with certain established criteria, so not everyone is eligible for this, nor is it available in cases where certain health insurance policies cover a percentage of the cost. This study was conducted in two private clinics carrying out ART in two different cities, some 530 km apart.

Participants

Totally, 174 subjects (87 couples), who attended one of the two clinics where the study was conducted, took part. The couples fulfilled the inclusion criteria of being heterosexual and childless. Also at the time of agreeing to take part in the study and at the start of it, they were not engaged in any ART process and the woman was not pregnant.

The criterion of primary infertility was established to enable researchers to have samples that are in some way homogeneous, since the experience of primary infertility is different from that of secondary infertility (Moreno-Rosset, 2009). Table S1 shows the couples's sociodemographic and reproductive variables. The average age of the participants was 37.28 (SD = 4.169). The mean age of the males was 37.75 (SD = 4.522) with a range = 25 (30–55) and for the females, 36.8 (SD = 3.750) with a range = 29 (27–46). 5.7% had basic education (*compulsory education*), 25.9% intermediate education (*high school / technical education)*, and 68.4% higher education (*bachelor degree*, *equivalent or higher*). 94.5% were employed and 5.2% were unemployed. There were no significant differences between the conditions and subconditions mentioned above in the three variables and none were found when the sample was split by gender.

Specifically, regarding couples' reproductive variables, 35.63% of the couples had not undergone any ART cycles at the start of the study while 64.36% had done so. Of the total number of couples, 18.39% had undergone intra-uterine insemination (IUI) cycles, and the mean for this group was 2.4 (SD = 1.12) with a range of 3 (1–4 cycles). 57.45% had undergone in vitro fertilization cycles (IVF), with a mean of 2.88 (SD = 1.75), range of 7 (1–8 cycles). Out of the 64.35% who had received ART, 11.49% had undergone both IUI and IVF, 45.97% IVF only and 6.89% IUI only. 33.3% had experienced miscarriages and in this group of couples, the mean was 1.40 (SD = 0.91). 28.7% had previously canceled cycles for some reason, the mean being 1.55 (SD = 0.827). The participants themselves bore the costs of the infertility assessment and ART cycles in the event that any were carried out after the study began.

Design

This is quasi-experimental, nonequivalent design study investigating the efficacy of intervention aimed at addressing the psychosocial impact of infertility. The design had an independent variable, which was the psychosocial intervention format, with two conditions: control (C) in which there was no intervention and intervention (I), which in turn was split in two subconditions: multicouple group intervention (MCG) and single-couple intervention (SC). There were three dependent variables: depression, anxiety, and fertility quality of life.

Procedure

After receiving authorization from the respective research ethics committees of the two clinics where the study was conducted (*Research Ethics Committee of the Virgen Macarena University Hospital Center in Seville -number CI 1940—and the Clinical Research Ethics Committee of the Puerta de Hierro University Hospital in Madrid -proceeding number 292-*, *Spain*), recruitment of participants was carried out during different periods between spring 2015 and spring 2016. During this period and subsequently, intervention sessions were conducted. Couples who attended the ART clinics were asked whether they wished to participate by staff who dealt with matters such as arranging appointments, billing and responding to queries. Around 1000 couples were offered the opportunity to participate and were first asked to fill out a brief questionnaire with anonymous data. Only 30% actually decided to go ahead, completing that questionnaire. They were subsequently contacted by telephone in order to explain how the study worked in greater detail and this information was also available to potential participants in printed form. Approximately 70% of those contacted refused to take part or agreed to do so but then did not fill out the informed consent, the initial questionnaires and the instruments, so finally there were 87 couples (174 participants). 80% of the participants were recruited from one of the two clinics and the remaining 20% from the other. In general, during the recruitment process, it was difficult to quickly form a group of couples who could participate, given the inclusion criteria and the fact that the consent and availability of both partners was necessary.

The eighty-seven couples were each assigned to one of the two experimental conditions (I and C). Although the aim was to assign the couples on a totally random basis, it was impossible to do so in practice. Assignment was determined by the availability of both partners of the couple to attend the intervention sessions together, as well as by the schedules set for delivering both the couple and group interventions. Therefore, couples in which one or both partners were not available to attend all the sessions were assigned to the control group. Those who were available for the scheduled group sessions were assigned to the MCG subcondition, while those who could not fit in with that schedule were assigned to the SC subcondition. Finally, 92 participants (46 couples) were included in condition C and 82 (41 couples) in condition I; with 40 subjects (20 couples) in SC and 42 (21 couples) in MCG. In that latter condition, 4 groups of between 4 and 6 couples were created. Couples were assigned to the groups once a sufficient number of couples were available at the same time for each of those 4 groups.

In the two subconditions in which intervention took place (MCG and SC), all the participants attended a six-session treatment program developed by the same person: a psychologist who acted as a therapist and a member of the research team. The sessions were carried out weekly or fortnightly and each one lasted approximately 90 min. The choice of the number of sessions and the time used for follow-up were based on the findings of review articles on the suitable range for structuring potentially effective interventions and for devising follow-up action, i.e. (Boivin, 2003; Hämmerli et al., 2009). Moreover, all the participants received the same routine care implemented by the clinics in relation to their psychosocial state. Therefore, they were informed of the option to attend sessions with the clinics' psychology service regardless of the experimental condition to which they were assigned.

Instruments

Demographic data and medical information relating to reproduction were obtained by the couples filling out a questionnaire specific to the study, as well as through data from their electronic medical records (EMR). Data on their age, level of education, employment, length and type of relationship, time they had been trying for children, and time they had been undergoing ART processes were recorded via participants' self-report. Number of intra-uterine insemination (IUI) cycles carried out, number of in vitro fertilization (IVF) cycles performed, number of miscarriages, number of canceled ART cycles, and the reasons for those cancellations were both self-reported and confirmed via EMR,

along with details, where appropriate, of any pregnancy at that time confirmed by the medical center. The instruments for assessing the dependent variables (depression, anxiety, and fertility quality of life) were used at three different times: (1) pretest (Time 1): at the start of the study, (2) post-test (Time 2): after the intervention had been carried out or at the equivalent time for the control group, and (3) at follow-up (Time 3): six months after the post-test measurement. All participants were asked to fill out the questionnaires independently at those three points, although whether they actually did so independently cannot be confirmed in all cases. Also, before the post-test and follow-up measurements were taken, changes in reproductive events were recorded so that they could be compared with the previous measurements in the same way.

The instruments used (all in their Spanish versions) were (1) the Beck Depression Inventory (BDI-II; Beck et al., 2011) that has an alpha coefficient of 0.87 for internal consistency and some suitable values for different types of validity. In this study it showed reliability measured by Cronbach's Alpha at a value of 0.890 pretest, 0.917 post-test and 0.910 at follow-up. (2) The State–Trait Anxiety Inventory (STAI), (Spielberger et al., 1982) from which the state anxiety scale was analyzed and which has an internal consistency between 0.90 y 0.93. In this study, reliability measured by Cronbach's alpha was 0.946 pretest, 0.959 post-test and 0.968 at follow-up. (3) FertiQoL (Guerra et al., 2012), using mainly the overall score (Core FertiQoL). In the English version, the test has a Cronbach's Alpha reliability index ranging between 0.72 and 0.92 for its four subscales (Boivin et al., 2011), although such data was not available for the Spanish version. In this study, Cronbach's alpha for the pretest, post-test, and follow-up scores ranged between 0.895 and 0.914 for the total score.

Intervention

In order to select the intervention content, given it was desirable to include several elements (Boivin, 2003), two programs were used for reference. One was the Mind/Body Program (Domar et al., 1990; Kolt et al., 1999), from which some elements such as cognitive restructuring, emotional expression, coping skills training and support groups were chosen. The other, developed at the Leuven University Fertility Center (Lemmens et al., 2004), was a group-format program for couples attending all sessions, from which participation of the couples in the introduction and selection of topics were chosen, along with content related to the emotions provoked by infertility and its impact on relationships, and coping with the reactions of others. In keeping with some of the goals of this latter program, (i.e. improving communication between the partners in the couple, reducing both partners' stress, strengthening their ability to cope with being childless and fertility treatment) and the evidence cited in the introduction, the authors considered that intervention aimed at couples, not just women or the partners separately, could provide a better understanding of how each partner was affected and would contribute to them coping better with the situation together.

The sessions were designed so as to minimize the possible negative psychosocial impact of infertility and to improve the coping process. In the different sessions, the following were addressed: expression of emotion and thoughts regarding infertility that can affect people, coping with social situations and attitudes when communicating, managing emotions in social situations, identifying dysfunctional thoughts, cognitive restructuring, cognitive distortions and reviewing topics to be considered in depth based on the participants' concerns. The content relating to their concerns was: conceptions and concerns about paternity and maternity in cases where the involvement of a third party in the ART process is considered, information on ART procedures, fluctuations in emotional state and managing that state while undergoing ART processes and where there are negative results, ambiguous situations in decision-making regarding ART, as well as findings on the causal relationship between stress as the source of infertility and the consequences. Obviously by its very nature, the group support element was only developed in MCG, although in the case of SC, the therapist could make comments, where appropriate, about the impact on other infertile couples, ways of reacting

and their consequences. This was the difference between the intervention content in the multicouple group format (MCG) versus the single-couple format (SC). It should be noted that in each session with couples or groups, there could have been differences in the depth of consideration given to a particular topic, due to the specific interests of the participants, although in any event all the concerns set out in the program were addressed. Table S2 shows the elements of the intervention and the tasks carried out in each session.

The authors hypothesized that during the intervention, the following mechanisms would be activated: (1) emotional expression, which contributes to easing the burden of infertility to some extent, (2) cognitive restructuring: analyzing the possible negative emotions related to infertility and the thoughts that sustain them, (3) coping skills: reviewing and developing coping strategies that could be more adaptive, (4) group support, specifically in subcondition MCG: instillation of hope, universality, imparting information, altruism, group cohesiveness, and others (5) sharing information and discussion about relevant content, which could reduce uncertainty and promote a stronger feeling of predictability, and (6) in relation to couple intervention, a possible increase in perceived support and a buffering role perceived between the partners, a joint coping effort and optimization of such coping, based on the interdependence of the relationship. Interdependence refers to the process where one individual's emotions, cognitions, and behaviors influence his or her partner's emotions, cognitions, and behaviors (Kelley et al., 2003).

Statistical analysis

Descriptive analyses were computed using the Statistical Package for the Social Sciences (SPSS 25.0) to examine sample characteristics. For couples' sociodemographic and reproduction-related variables, the Student's *t*-test was used pretest, first to check the homogeneity between I-C and second between MCG-SC, and the Mann–Whitney *U* test was used for the ordinal couple demographic variables (Table S1). For potential gender differences, paired *t* tests were conducted pretest.

To examine the possible differences between intervention couples and the control ones for each dependent variable, dyadic latent growth curve models (LGCM) were estimated within a structural equation model -SEM- (Kenny et al., 2006) using M*plus* 8.0 (Muthén & Muthén, 1998–2017). This approach may detect whether certain outcomes follow a similar nonlinear trajectory, where the intervention might show an initial positive impact, i.e. at post-test (Time 2, after intervention) that would decline over time, i.e. at follow-up (Time 3, in this case six months later). It examines the influence of group treatment at each time point rather than aggregate change over time and seems very suitable for analyzing these types of effects (Coop Gordon et al., 2018) in a dyadic data situation with couples and where members of each couple must be nonexchangeable, as is the case in this study (man and woman). The analysis reports gender-based differences in results and is carried out with dummy variables, so it was first run between I-C and second between MCG-SC for each dependent variable. The dyadic LGCMs were estimated to examine fixed and random calculations of intercept and slope for the three variables, in which the intercept represented the level of the dependent variable at the beginning of the study and the slope represents the trajectory from Time 1 to Time 2 and Time 3. Figure 1 shows the A priori *model of the tested dyadic latent growth curve models*. As certain couples reported pregnancies at Time 2 or Time 3, and in order to control the potential effect of pregnancy on health outcomes, analyses were repeated excluding from the sample couples who reported a pregnancy at Time 2 and then those who reported a pregnancy at Time 3. So, at post-test (Time 2) there were 75 couples (n = 35 C; 40 I with 21 MCG and 19 SC) and at follow-up (Time 3) there were 49 (n = 21 C; 28 I with 16 MCG and 12 SC).

Overall model fit was tested by considering together commonly used fit indices as follows: a non-statistically significant chi-square value; comparative fit index (CFI) and Tucker–Lewis index (TLI) values of 0.95 or higher; a root mean square error of approximation (RMSEA) below 0.05, or the relevant test must at least not rule out the hypothesis that its value is below 0.05; and a standardized

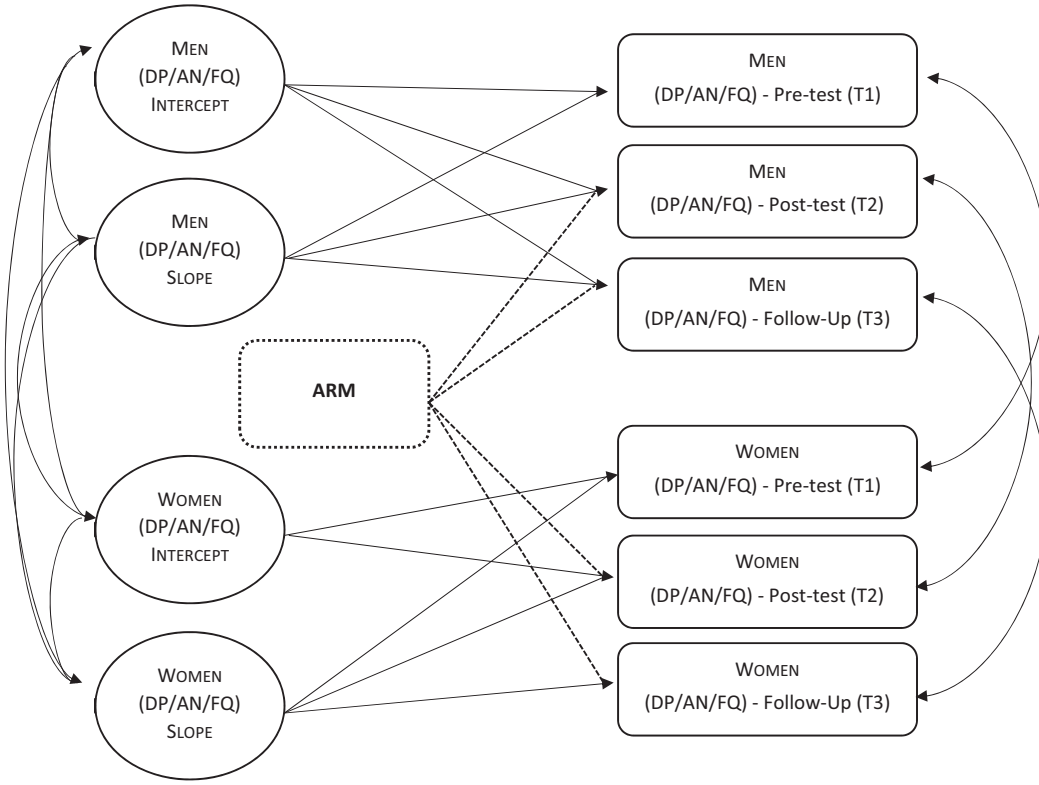

FIGURE 1 A priori model of the tested dyadic latent growth curve models. AN, Anxiety; DP, Depression; FQ, Fertility Quality of Life

root-mean-square residual (SRMR) below 0.10 (Kline, 2016). When any change after intervention was found at Time 2 or Time 3 in the comparisons, the effect size or treatment effect was calculated with Cohen's *d* statistic as per Morris' recommendation (Morris, 2008), and interpretation was based on the categories set out by Cohen.

Furthermore, in order to assess evidence of significant change in each subject, pre-post differential scores (specifically post-test—pretest: Time 2-Time 1) were calculated for the three dependent variables, subtracting the pretest scores from the post-test scores. The subjects were categorized based on whether or not there had been significant changes in their pre-post scores. Where there had been significant changes, those scores were then categorized as positive (healthy) or negative (unhealthy), in line with a strategy used in a prior study (Frederiksen et al., 2017). Regarding depression, the calculation was based on a comparison of subjects who showed a positive change between categories with the rest of the subjects, as well as a comparison of those who showed a negative change with the rest. This was done by taking the cutoff points established for the test as a reference (Beck et al., 2011): a score between 0–13 (minimal depression), between 14–19 (mild depression), between 20–28 (moderate depression), and between 29–63 (severe depression). For the state anxiety and fertility quality of life variables, in the absence of validated cutoff points, the criterion used for significant change was a positive or negative score higher than that established by the calculation of the *Minimum Important Difference* (*MID*) based on the scores obtained in the study (Corsaletti et al., 2014; Guyatt et al., 2002). Comparisons were made (I-C and MCG-SC) by calculating the odds ratio, an index used to quantify the impact of a deliberate intervention, and the appropriate term to use in these cases is *treatment effect* (Borenstein, 2009). The results of the odds ratio calculation were expressed as transformed by *Yule's Q* statistic, which has a range between −1 and + 1 and was interpreted as follows:

no effect ($Q = 0$), very weak effect ($0 < Q < 0.25$), weak ($0.25 < Q < 0.50$), moderate ($0.50 < Q < 0.75$), strong ($0.75 < Q < 1$), and maximum ($Q = +/-1$; Knoke & Bohrnstedt, 1991).

Study hypothesis

There were three study hypotheses. First, that the couples receiving interventions would demonstrate improved health outcomes (depression, state-anxiety, and fertility quality of life) compared to control couples, while controlling for each partner's dependent variable score at baseline. Second, that MCG couples would demonstrate more positive changes than SC couples in those indices due to the specific mechanisms that would be activated in group situations. We hypothesized that changes would also appear in the odds ratio comparisons in line with those first two hypotheses. Third, we expected that postintervention changes in couple functioning were likely to occur in a nonlinear fashion, with changes in healthy outcomes declining between Time 2 and Time 3, as intervention effects decrease over time after sessions end.

RESULTS

As shows Table S1, Student's *t*-test in the I-C comparison of the pretest scores revealed differences in the number of miscarriages and the number of canceled cycles. Mann–Whitney *U* test in the comparison MCG-SC revealed differences in time trying for children ($U = 606.0$; $p = 0.023$) and type of relationship ($U = 644.0$; $p = 0.011$). Table S3 shows mean and standard deviation of total sample, men and women, for experimental conditions and subconditions measured at three points in time in depression, anxiety and fertility quality of life. Paired *t*-tests were carried out pretest according to gender, yielding significant results in the three variables (p value < 0.001). Tables 1–3 set out indices of the dyadic LGCM estimated models, unstandardized parameter estimates, and effect sizes for treatment effect in depression, anxiety, and fertility quality of life, and Table 4 shows the mean scores and standard deviations for the differential pre-post scores and the odds ratio analysis. Results are presented according to each dependent variable.

Depression

The final model of the dyadic LGCM for the I-C comparison showed that the treatment group reported statistically significant better scores for depression at Time 2 both in women and in men, but no effect was found at Time 3, as appeared in Table 1. Effect size was small for men ($d = 0.313$) and intermediate for women ($d = 0.537$). When couples who reported a pregnancy were removed from the analysis, the results were similar, both in significance and effect size. Figure 2 shows the plots regarding the comparison I-C for the three variables analyzed at the three measurement times, men's and women's plots are presented separately. Figure 3 shows the comparison MCG-SG plots.

In the MCG-SC comparison, at Time 2 there was a p value = 0.068 with a small effect size in favor of SC both in men ($d = 0.207$) and women ($d = 0.302$). These results for both genders were similar (p value = 0.045) when the couples who reported pregnancies at Time 2 were removed. There were no significant differences at Time 3 (women's p value = 0.758 and men's p value = 0.138), and the removal of the couples who reported pregnancies had no effect.

In order to analyze whether the raw score changes had any clinical or psychological significance, we examined whether the subjects improved, worsened, or remained in the same depression category after treatment, since the BDI provides this score classification. Thus, a calculation of the percentage of people who improved/worsened in each group was performed, using the odds ratio to compare. As shown in Table 4, for the subjects whose pretest scores put them in a higher depression

TABLE 1 Indices of the dyadic LGCM estimated models, unstandardized parameter estimates and effect sizes for treatment effect in depression

Comparison	Mean (SD)	Variance		*B* (SE)	Cohen's *d*	Final model indices
I-C						
Mean intercept			Treatment condition → T2			$\chi^2 = 11.05$ ($p = 0.051$) CFI = 0.978/TLI = 0.906 RMSEA = 0.118 ($p = 0.104$) SRMR = 0.072
Men	4.90 (0.55)***	37.68 (7.37)***	Men	1.43 (0.66)**	−0.313	
Women	9.08 (0.84)***	67.09 (13.56)***	Women	1.43 (0.66)**	−.537	
Mean slope			Treatment condition → T3			
Men	−0.71 (0.03)**	8.43 (2.20)***	Men	0.48 (0.87)	---	
Women	−1.59 (0.47)**	12.81 (4.19)**	Women	−0.44 (1.07)	---	
MCG-SC						
Mean intercept			Treatment sub-condition → T2			$\chi^2 = 1.98$ ($p = 0.085$) CFI = 0.999/TLI = 0.999 RMSEA< 0.001 ($p = 0.877$) SRMR = 0.042
Men	5.66 (0.82)***	34.67 (10.07)**	Men	−1.53 (0.84)*	0.207	
Women	11.73 (1.24)***	82.47 (20.75)***	Women	−1.53 (0.84)*	0.302	
Mean slope			Treatment sub-condition → T3			
Men	−0.46 (0.49)	7.84 (3.08)**	Men	−1.88 (1.26)	---	
Women	−2.25 (0.61)***	16.06 (5.23)***	Women	−0.44 (1.45)	---	

Note: C, Control; I, Intervention; MCG, Multi-Couple Group; SC, Single Couple intervention. Means (standard deviations) and Variances of growth curve factors. *B* = Unstandardized regression coefficients. Cohen's *d* = Effect sizes for treatment effect.

*$p < 0.010$, **$p < 0.05$, ***$p < 0.001$.

TABLE 2 Indices of the dyadic LGCM estimated models, unstandardized parameter estimates and effect sizes for treatment effect in anxiety

Comparison	Mean (SD)	Variance		*B* (SE)	Cohen's *d*	Final model indices
I-C						
Mean intercept			Treatment condition → T2			$\chi^2 = 8.13$ ($p = 0.148$) CFI = 0.989/TLI = 0.953 RMSEA = 0.085 ($p = 0.245$) SRMR = 0.068
Men	18.91 (1.04)***	106.53 (21.74)***	Men	0.98 (1.13)	---	
Women	23.84 (1.29)***	123.18 (28.79)***	Women	0.98 (1.13)	---	
Mean slope			Treatment condition → T3			
Men	−1.178 (0.62)*	15.90 (7.19)**	Men	−2.03 (1.68)	---	
Women	2.745 (0.92)**	25.12 (11.88)**	Women	−1.04 (2.31)	---	
MCG-SC						
Mean intercept			Treatment sub-condition → T2			$\chi^2 = 5.91$ ($p = 0.315$) CFI = 0.993/TLI = 0.971 RMSEA < 0.067 ($p = 0.374$) SRMR = 0.044
Men	20.43 (1.55)***	12.59 (33.82)**	Men	−1.75 (1.56)	---	
Women	27.29 (1.89)***	95.38 (42.15)**	Women	−1.75 (1.56)	---	
Mean slope			Treatment sub-condition → T3			
Men	−0.55 (0.88)	22.64 (9.06)**	Men	−3.05 (2.55)	---	
Women	−3.92 (1.37)***	17.68 (21.11)***	Women	−0.54 (3.48)	---	

Note: C, Control; I, Intervention; MCG, Multi-Couple Group; SC, Single Couple intervention. Means (standard deviations) and Variances of growth curve factors. *B* = Unstandardized regression coefficients. Cohen's *d* = Effect sizes for treatment effect.

*$p < 0.010$, **$p < 0.05$, ***$p < 0.001$.

TABLE 3 Indices of the dyadic LGCM estimated models, unstandardized parameter estimates and effect sizes for treatment effect in fertility quality of life

Comparison	Mean (SD)	Variance		*B* (SE)	Cohen's *d*	Final model indices
I-C						
Mean intercept			Treatment condition → T2			$\chi^2 = 10.59$ ($p = 0.052$) CFI = 0.986/TLI = 0.943 RMSEA = 0.117 ($p = 0.107$) SRMR = 0.087
Men	77.92 (1.27)***	150.13 (28.19)***	Men	0.24 (1.08)	---	
Women	70.18 (1.62)***	235.14 (41.99)***	Women	0.24 (1.08)	---	
Mean slope				Treatment condition → T3		
Men	1.40 (0.68)**	18.69 (8.32)**	Men	1.80 (1.84)	---	
Women	2.66 (0.84)***	35.34 (11.30)**	Women	3.46 (2.06)	---	
MCG-SC						
Mean intercept			Treatment sub-condition → T2			$\chi^2 = 8.09$ ($p = 0.151$) CFI = 0.985/TLI = 0.939 RMSEA = 0.123 ($p = 0.197$) SRMR = 0.076
Men	76.65 (1.89)***	120.98 (36.55)**	Men	4.01 (1.67)**	0.137	
Women	66.29 (2.65)***	288.77 (74.40)***	Women	4.01 (1.67)**	0.319	
Mean slope			Treatment sub-condition → T3			
Men	0.09 (0.91)	−0.49 (12.73)	Men	5.97 (2.53)**	0.393	
Women	2.33 (1.27)*	39.51 (19.55)**	Women	3.72 (3.11)	---	

Note: C, Control; I, Intervention; MCG, Multi-Couple Group; SC, Single Couple intervention. Means (standard deviations) and Variances of growth curve factors. *B* = Unstandardized regression coefficients. Cohen's *d* = Effect sizes for treatment effect.

*$p < 0.010$, **$p < 0.05$, ***$p < 0.001$.

TABLE 4 Mean scores and standard deviations for the differential pre-post scores and comparison of changes in each subject found between the experimental conditions or sub-conditions

Variables	Condition	Differential score Posttest – Pretest, mean (SD)	With favorable change (*n*)	Without change (*n*)	With unfavorable change (*n*)	Comparison	Favorable change, odds ratio	Favorable change, Q de Yule	Unfavorable change, odds ratio	Unfavorable change, Q de Yule
Depression (BDI)	I	−2.10 (4.71)	11	64	5	I-C	3.560	0.561	0.516	−0.318
	C	0.92 (4.90)	3	59	8	MCG-SC	0.466	−0.364	3.894	0.591
	MCG	−1.23 (4.87)	4	34	4	MCG-C	2.350	0.403	0.815	−0.101
	SC	−3.05 (4.39)	7	30	1	SC-C	5.043	0.669	0.209	−0.653
State Anxiety (STAI)	I	−3.23 (9.82)	21	51	8	I-C	3.203	0.524	0.753	−0.140
	C	0.14 (7.66)	7	54	9	MCG-SC	0.767	−0.131	3.0	0.50
	MCG	−1.38 (10.20)	10	26	6	MCG-C	2.812	0.475	1.129	−0.060
	SC	−5.28 (9.07)	11	25	2	SC-C	3.666	0.571	0.376	−0.452
Infertility Quality of Life (FertiQol)	I	3.75 (8.47)	11	67	2	I-C	5.420	0.688	2.029	0.339
	C	1.20 (6.37)	2	67	1	MCG-SC	1.10	0.047	Infinity	NaN
	MCG	2.00 (9.20)	6	34	2	MCG-C	5.666	0.70	3.450	0.550
	SC	5.67 (7.22)	5	33	0	SC-C	5.151	0.674	0	−1

Abbreviations: C, Control; I, Intervention; MCG, Mult-Couple Group; NaN, Not a Number; SC, Single Couple.

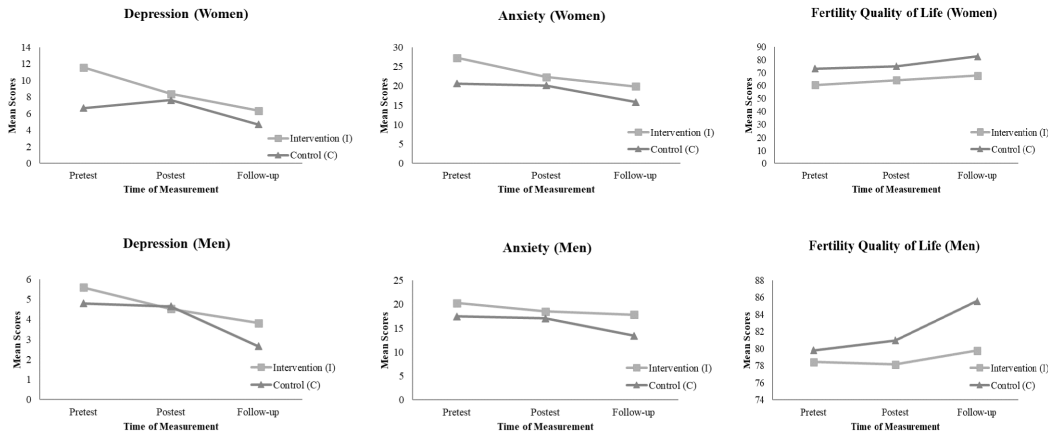

FIGURE 2 Depression, anxiety and fertility quality of life over time for men and women. Comparison: Intervention-Control (I-C)

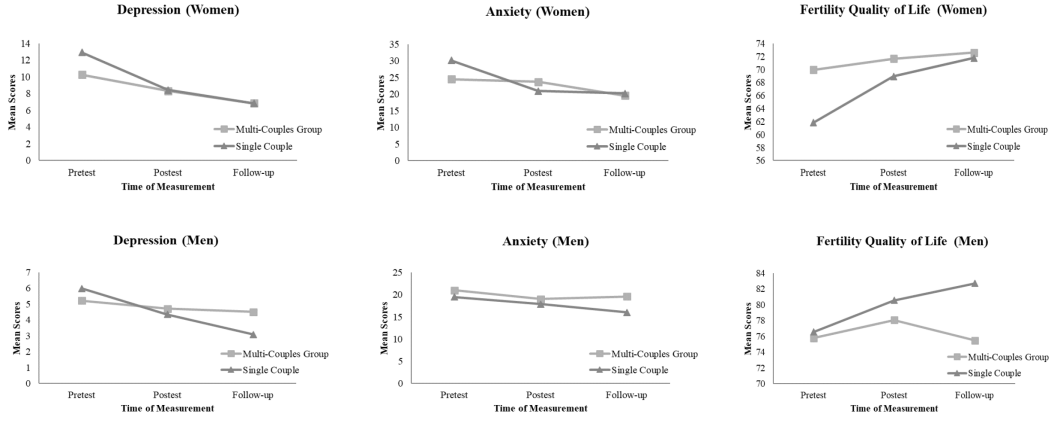

FIGURE 3 Depression, anxiety and fertility quality of life over time for men and women. Comparison: Multi-Couples Group – Single Couple (MCG-SC)

category and who then dropped to a lower category, i.e., who showed a positive change, the odds ratio values favored the I condition, showing a medium effect ($Q = 0.561$), over the C condition. There was also a weak effect in favor of SC in the MCG-SC comparison ($Q = -0.364$). Regarding the subjects who underwent an adverse change between pretest and post-test, the odds ratio indicated a weak effect for the I condition in comparison with the C condition, with a higher percentage of these subjects appearing in the control condition ($Q = -0.318$). As regard the MCG–SC comparison, there was a moderate effect, with a higher percentage of these subjects in MCG ($Q = 0.591$).

Anxiety

Regarding the state anxiety variable, as shown in Table 3 and represented in Figure 1, the dyadic LGCM revealed that there were no significant differences in treatment effect between pretest and post-test in the I-C comparison or between post-treatment and follow-up. Likewise, no significant differences were found for men or women in the MCG-SC pretest and post-test comparison, or in the

comparison between post-treatment and follow-up. When couples who reported pregnancies were removed from the analysis, the results were similar in both comparisons.

In relation to the subjects who underwent significant change between pretest and post-test, as set out in Table 4, the odds ratio showed a moderate effect favoring I ($Q = 0.524$) over C in terms of subjects who exhibited a positive change and a very weak effect in the MCG-SC comparison ($Q = -0.131$). Regarding the subjects who underwent adverse change, the odds ratio indicated a very weak higher proportion in the I-C comparison ($Q = -0.140$) and a weak effect in favor of the SC in the MCG-SC comparisons ($Q = 0.5$). There was a higher percentage of these subjects in MCG.

Fertility quality of life

The models estimated by the dyadic LGCM did not show significant differences between the scores before and after treatment (p value = 0.824) in the I-C comparison or between post-test and follow-up (p value = 0.328 for men and 0.093 for women), with similar results when couples who reported pregnancies were excluded. In the prepost analysis, significance (taking a p value = 0.067 as significant) was found in the MCG-SC comparison in favor of SC for both men and women, although for men ($d = 0.137$) is deemed to be no effect and for women ($d = 0.319$) is deemed to be a weak effect, as it appear in Table 3. Also there was significance in the post-test-follow-up analysis for men (p value = 0.019) with an effect size of 0.393. The results did not change when the couples who reported pregnancies were excluded.

When analyzing the differences based on the proportion of subjects showing changes that were greater than the MID, differences were observed (MID total = +/−12.77). Regarding those subjects who showed positive changes in the post-test—pretest differential score, the odds ratio was moderate in favor of the I condition when compared to the C condition ($Q = 0.688$). As regard the MCG-SC comparison, the effect was very weak ($Q = 0.047$).

Regarding the subjects whose prepost scores showed adverse changes, the odds ratio analysis indicated a higher percentage of such subjects in the I condition with a weak effect ($Q = 0.277$) in the I-C comparison. In the MCG-SC comparison, the lack of SC subjects who worsened in the total score gave misleading Yule's Q results (infinity/NAN), with no SC subjects worsening and very few in the MCG condition.

DISCUSSION

In terms of testing the efficacy of the intervention, the dyadic LGCM analysis found that in the depression variable there were significant differences between I and C in the pre-post score comparisons, with an effect size or treatment effect ranging between 0.313 and 0.537, while no noteworthy changes were observed in state anxiety or fertility quality of life. However, the odds ratio analysis revealed differences between couples who underwent intervention and controls in the three variables, which in the subjects who improved ranged between 0.524 and 0.688. Moreover, there was a higher proportion of subjects who worsened in depression and anxiety in C ($Q = 0.318$ and -0.140), as well as a higher proportion of subjects who worsened in the fertility quality of life total score in I with a weak effect ($Q = 0.277$). From these results, we could conclude that the intervention results provide support for the efficacy of the intervention carried out and to some extent, the results are in line with those of previous studies, which by assessing the impact on the depression variable (Frederiksen et al., 2015), anxiety, i.e. (Verhaak et al., 2007) and quality of life (Seyedi Asl et al., 2016) found that psychosocial interventions had a positive effect. Overall, the changes between post-test and follow-up scores were similar in theese variables when comparing I and C, with no significant differences found and showing less healthy changes with the exception of fertility quality of life.

In the dyadic LGCM, the pre-post score comparison between MCG-SC revealed significant differences in depression and fertility quality of life, while in the post-follow-up score comparison for men there was only a significant difference in the fertility quality of life variable. The odds ratio analysis showed a difference or effect that was categorized as very weak or weak between the two ($Q = -0.364$, -0.131 $y - 0.047$) in the subjects who improved in the three variables, while the differences were a little more significant and not as unhealthy for SC in the comparison of those who got worse between the pretest and post-test scores (0.591, 0.5, and the misleading data of infinity). Based on the results found, we would not conclusively conclude that the differences between the group and couple formats are significant, at best they appear to be very slight, therefore it would be inappropriate to state that one format was more effective than the other. The group and single formats share elements of the therapeutic relationship, but also have some distinctive elements, as has been mentioned in previous sections, however, an evident difference between the two formats was not found in this study. We could therefore infer that the specific hypothesized mechanisms for multicouples group format were not activated, or if they were, this was not reflected in the measured outcomes. Our hypothesis that group intervention would be more effective was not borne out by the results.

In any case, the indications from this study have to be treated with caution, since it had a series of limitations. This is therefore the case regarding any conclusions indicating that the changes observed could be attributed to the interventions carried out. First, it must be pointed out that the study had a very small number of participants, therefore studies with larger samples should be carried out. Second, it should be noted that ART processes create a very unique situation in terms of their impact on the psychosocial area, with several variables marked by continuous dynamism that could have some relationship to the measured outcomes and thereby hinder the task of isolating those effects. As well as a negative impact on mood as a result of ART processes being carried out (Oddens et al., 1999) and unsuccessful results (Milazzo et al., 2016), there are fluctuations in perceived stress levels that have to be taken into consideration (Sexton et al., 2010), depending on the point reached in the cycle, which alternate between optimistic overestimation that occurs at certain times (Boivin & Takefman, 1996) and negativity, the so-called *emotional roller coaster* of infertility. Thus, the effect found may be differential if the interventions are carried out at different points in time on the subjects (Streuli et al., 2017), an aspect that is practically an inherent part of group interventions in this area.

In addition, the representativeness of the sample is influenced by the fact that the study was carried out in private clinics, which is linked to the participants having certain socioeconomic characteristics. Representativeness could also be affected by the fact that the subjects who agreed to participate in MCG or SC were more favorably inclined toward psychological care and more affected by the issues used as psychological variables, not only schedule clashes or lack of time/availability. The pretest score comparison between I and C favors this conclusion, although the analysis carried out was used to minimize the effect of this limitation. This is a matter to be analyzed in subsequent research. There is also the question of subjects in the intervention conditions who significantly worsen, which happened in some cases in this study, and they required adjunctive treatment. Perceived impact and the likely more favorable inclination of the subjects toward psychological care, along with the fact of subjects living in different locations from those of the clinics and their availability to attend the sessions as a result of that or for other unknown reasons, limited our assessment and the possibility of carrying out rigorous analysis from an experimental perspective using totally random assignment, as indicated. The effects found here may not only be due to the impact of the interventions but also other factors, such as the interaction between those effects and the characteristics of the participants, or other aspects, like the mechanisms the subjects try to use to cope with their infertility. This topic deserves exhaustive research.

A further limitation is that although the odds ratio is an appropriate method for testing treatment effect, in the absence of validated cutoff points for the anxiety and fertility quality of life variables we used, a criterion based on clinical rather than statistical difference is always more recommendable. The last limitation to highlight is related to the treatment approach chosen, along with the number of sessions. Although it has been explained that there are findings in favor of this, it would be advisable

to conduct comparative studies with different treatment approaches and different numbers of sessions, in order to have a range of results that may or may not support those observed here.

Nevertheless, despite these limitations, we believe that this study constitutes the first viable consideration of a differential comparison between both formats and that it highlights factors to be taken into account for analysis. We think that the study has been carried out on a sample that to a large extent reflects the distinctive conditions that characterize couples who seek psychological treatment for infertility and that this pioneering work in this field offers valuable information on the situation in Spain.

It can also be concluded from our study that not only is it necessary to broaden the approaches for comparing types of formats but also to examine the variables with which they could interact and which could explain their efficacy. The personal traits of the subjects, their reproductive history and characteristics, the coping strategies they put in place, the social support they receive from different sources and the different forms of support, the interaction between the ART process and the times when intervention is received, and in the case of group intervention, the composition of such groups are some of the variables worth studying. Research on elements such as those that have been mentioned could provide greater evidence on the influence that the psychosocial intervention format has on infertility and the mediating factors.

CONCLUSION

The results provide support for the efficacy of the psychosocial intervention carried out in this study and when comparing the two formats used, conclusive differences were not found. So overall, the results are in line with the review studies that did not find the group format to be more effective. More studies are necessary in order to verify the findings of this one and their consistency. The findings of this initial longitudinal comparative study cannot be deemed conclusive and further studies that focus on factors that explain any differences that may be found, which are carried out using different intervention approaches and are not subject to the limitations of this study are required. That would allow one or the other type of intervention format for the infertile population to be prescribed in clinical practice based on their efficacy and efficiency, as well as enable them to be optimized. Furthermore, the adaptation of treatment formats to the needs and characteristics of the subjects must be something that is carried out in clinical practice and is also an aspect that should be the topic of further research. The central focus should not only be which format is more effective but also how and when to employ each one to appropriately assist couples experiencing infertility. It is therefore advisable for therapists to select the intervention format taking into account factors other than the format itself. If the main aim is to share thoughts, feelings, and experiences with others, then group intervention is appropriate. However, it would not be advisable in cases where the primary goal is to improve partner support, or where patients' needs and traits, reproductive history, or the stage of their infertility indicate that privacy is required.

The potential of group intervention, apart from its efficiency, lies in the mobilizing of resources that could reach different realms within the field of infertility from those reached by nongroup interventions. More research and implementation to assess the merit of group interventions should be undertaken.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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