

Stress reduction in male infertility patients: a randomized, controlled trial

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Objective: To assess the impact of preparatory information about the fertility workup on the patients' well-being.

Design: Two-group, randomized controlled study.

Setting: An andrology clinic.

Patient(s): Two hundred fifty men enrolled for fertility workup.

Intervention(s): A two-page leaflet with preparatory information about the fertility workup, which was mailed to half of the participants after they had made an appointment.

Main Outcome Measure(s): Questionnaire score for infertility-related distress at clinic attendance, proportion of participants that still had not attended 6 months after the scheduled appointment.

Result(s): Distress scores and the proportion of nonattendees were significantly reduced in the group receiving the leaflet. An additional analysis revealed that 55% of the receivers did not know that the andrology clinic has its own web site, which was mentioned in the leaflet several times.

Conclusion(s): Although it is uncertain how many patients actually read a routinely sent leaflet, preparatory information in written form is beneficial, at least for a significant subgroup of men who consider undergoing fertility workup. Fertility services might reduce the number of nonattendees by sending out leaflets. (Fertil Steril® 2005;83:68–73. ©2005 by American Society for Reproductive Medicine.)

Key Words: Counseling, distress, Internet usage, number needed to treat, nonattendance

Low uptake rates of psychological services for infertility patients have led to the question of whether the counseling needs of these patients have been overrated. Accordingly, it has been suggested that only 20% of infertility patients need counseling, whereas the availability of information is sufficient to reduce distress in the majority (1). However, little research has been conducted regarding what type of information is beneficial specifically for male infertility patients.

At least one randomized controlled trial included both sexes (2). In that study, couples starting fertility diagnostics were assigned to one of three groups, varying in the amount of preparatory information they were to receive. In one group, the participants viewed a videotape with information about the infertility examinations. In another group, the participants viewed a tape with information about infertility examinations and about possible emotional reactions to them. Members of the last group also viewed the tape with information about infertility investigations and about possible emotional reactions to them, but additionally received a booklet about potential sexual difficulties and possible cop-

ing strategies. The information was provided at the beginning of fertility diagnostics.

Participants' well-being was assessed before fertility diagnostics and again 6 months later, after having received the diagnosis. At follow-up, it was not the two groups that had been given extensive information about problems and coping possibilities but the group receiving only procedural information that showed a significant decrease in infertility-related distress.

The study outlined above (2) represents a good starting point in the research on preparatory information for infertility patients. Its results, however, did not deliver clear evidence that patients benefit from procedural information, because studies in which no specific preparatory information had been provided also showed a decrease of distress in infertile men after fertility workup (3, 4). One study (5) even suggested that distress declined in patients who had visited an andrology clinic to provide a semen specimen, even before they met the physician for the physical examination at the second clinic visit (i.e., before receiving the results of the semen analysis or having the possibility to discuss their questions).

The latter study indicates that evaluation of preparatory information is of limited value without control for the usual

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course of distress, but it is also of interest as regards the design of preparatory information for male patients, because it indicates that fears concerning semen collection could be worth targeting. Unfortunately, empirical research has delivered little information about other investigation-related worries of male infertility patients. On the basis of our own clinical observations made during psychological counseling, it seems that some patients fear—apart from difficulties in delivering a semen specimen—various forms of invasive examinations, conceivably performed in a kind of gynecological chair.

One might ask whether efforts are needed to reduce these worries, because empirical research suggests that infertility patients are seldom distressed in a clinically significant way (6). However, a study in an outpatient diabetes clinic revealed that procedural information sent 2 weeks before the scheduled appointments reduced the nonattendance rate (7). If a similar effect could be found for fertility services, both patients and medical services could benefit from routinely sent preparatory information. Therefore, the present study examined whether preparatory information reduces distress scores of male infertility patients and the proportion of nonattendees.

MATERIALS AND METHODS

Participants

A total of 250 consecutive patients applying for fertility workup in an andrology clinic were included. For inclusion, three criteria had to be met: [1] the appointment had to be made on the patient's initiative, with either the patient or his wife calling the clinic, [2] the caller had to answer in the affirmative when reassuringly asked by the reception staff whether s/he was applying for fertility diagnostics, and [3] the participants had to be first-time visitors to the andrology clinic where the present study was being conducted.

Typically, approximately 50% of the clinic's fertility patients were self-referred, whereas the other half were referred by general practitioners or other medical services. A substantial subgroup of all attendees had undergone some fertility diagnostics (e.g., a semen analysis) before visiting the clinic. Although these previous fertility diagnostics rarely consisted of a complete fertility workup, the respective patients had already received a diagnosis. Details of the present sample are given in the Results section.

Procedure

Either the patient or his wife called the andrology clinic and requested a fertility workup. Appointments were immediately given during the initial phone call. No patient was scheduled for earlier than 2 weeks after calling. During the phone call, the reception staff recorded the patient's address. Directly after the call, the reception staff allocated the next available number for entry into the study to the patient.

Once each day, the reception staff received information about the assignment of the numbers. The assignment was

based on a computer-generated randomization list, which was kept by both authors. After being informed about the group assignments, the reception staff posted the leaflet to those patients randomized into the treatment group. The great majority of leaflets were sent out within 24 hours of a patient calling for booking; only in the case of patients calling on a Friday afternoon might there have been a delay until Monday morning.

Upon arriving at the andrology clinic, before the medical examination, the patients filled out the Infertility Distress Scale (described in Variables section). The medical examination was the same for every participant. It consisted of a medical history and a physical examination, including sonography of the testes and a semen analysis. After all laboratory tests had been performed, the patients received the reports of the fertility workup by mail.

The local ethics committee concluded that patient consent was not necessary for the present study, because the intervention was minimal and the outcome variables were routinely obtained during clinical practice.

Intervention

Whereas nothing was sent to the control group, the treatment group received a leaflet outlining the contents and sequence of the different components of the fertility workup. The leaflet also dealt with typical questions asked by the physician. The upcoming examinations were described in detail. Any kind of invasive procedure exceeding the taking of a blood sample from a cubital vein was explicitly ruled out. Wherever possible, sensory aspects were included in the leaflet, because combined sensory and procedural information have been found to be most beneficial for reducing distress (8). For example, the leaflet mentioned that a gel would be applied for sonography, which is at room temperature, is odorless, and can easily be removed with a dry tissue.

The room for delivering the semen specimen was also described. Its seclusion from the doctor's office or waiting areas was emphasized. It was pointed out that there would be no time pressure, because no subsequent patient would be guided to the room until it had been vacated and laboratory staff had cleaned it and taken away the specimen of the previous patient. Fears of problems in producing a semen specimen were addressed by characterizing these worries as very common and natural, by referring to former patients who conceded a discrepancy between their anticipatory worries and the minor actual problems, and by outlining the further procedure in the event of actual problems.

The leaflet did not include any mention of the date or time of the appointment. It comprised approximately 1000 words on two pages. No photos or figures were included. The information given in the leaflet was not provided by any other official source of the andrology clinic (e.g., the web site).

Variables

The Infertility Distress Scale was used as the main outcome variable. It assesses the stress resulting from infertility as perceived by the participants and consists of eight items on 5-point Likert scales. The items ask for ratings of [1] the distress due to the spouse's last menstruation, [2] the distress due to infertility on a whole, [3] the importance of a child, [4] the appraisal that infertility represents a challenge, [5] the appraisal that infertility represents a threat, [6] feelings of helplessness due to infertility, [7] the frequency of thoughts about infertility, and [8] the desire for a child.

The Infertility Distress Scale has been evaluated extensively [see Pook and Krause (9) for a review]. Factor analyses revealed and confirmed that there is a single dimension underlying the eight items. Internal consistency ($\alpha = .89$) and retest reliability (e.g., $r = .74$ for a follow-up of 4 months) were found to be good. The scale correlated highly with an already-validated measure of infertility distress. Correlations with widely used measures of depressiveness are in the small-to-medium range. High scores on the scale were associated with a subsequent decline in sperm quality (10, 11). Additional findings indicate that the Infertility Distress Scale is sensitive to change (4, 5). Patients can score between 0 and 32 points; scores of 21 points or more indicate seriously distressed individuals.

On the sheet of the Infertility Distress Scale, two questions concerning the web site of the andrology clinic were added. In a little survey, the patients were asked whether they had visited the web site (yes/no), and patients not having had visited the web site were additionally asked whether they were aware of its existence (yes/no). The analysis of the survey on the usage of the web site provided some opportunity to evaluate how well information given in the leaflet had been assimilated by the patients, because the existence of the web site had been mentioned in the leaflet repeatedly.

Apart from the distress score, nonattendance was also considered as an outcome measure. However, we were not simply interested in the proportion of failed appointments. Instead, subjects not attending a scheduled fertility workup and never reapplying for another appointment were of particular interest for us. Our clinical observation suggests that a significant subgroup of men who do not attend scheduled fertility workups never reapply for another appointment. It rather seems that this kind of nonattendance is more prevalent for fertility workups than for other services at a dermatology and andrology clinic.

To be able to finish the study in a tenable period of time, as the second outcome variable we chose the proportion of participants who had still not attended 6 months after the scheduled appointment. The time span also seemed to be sufficient to provide ample opportunity for the patient to reapply for an appointment after default due to practice or patient error.

Calculation of Sample Size

We assumed that the mean distress score of the treatment group was reduced by one third of a standard deviation ($d = .33$). To have a 75% chance of detecting a significant ($P < .05$, one-tailed) difference between treatment and control groups, 100 patients each were required for each group. To compensate for nonattendees, as well as for non-evaluable patients, a total of 250 consecutive patients applying for fertility workup in an andrology clinic were included.

RESULTS

Of the 250 participants included, 125 were assigned to each group. Although assigned to the treatment group, 1 patient did not receive the leaflet because his address had been recorded incorrectly, so the mail was undeliverable. When contrasting characteristics of the treatment and the control group, no relevant differences could be detected (Table 1).

First, the main outcome variable was analyzed. It had been hypothesized that patients receiving the leaflet would be less distressed than nonreceivers. A total of 16 participants did not attend even 6 months after the scheduled appointment. Among the attendees, 29 patients (treatment group: 14; control group: 15) were additionally excluded from analysis. The reasons for exclusion are described in detail in Table 2. To be more conservative, in view of his low distress score, the patient assigned to the treatment group but not receiving the leaflet was excluded from analysis. Thus, a total of 204 attendees were included in the analysis.

Mean (SD) score on the Infertility Distress Scale was 16.6 (6.0) (95% confidence interval [CI] 15.4–17.7) in the treatment group and 18.1 (6.2) (95% CI 16.9–19.3) in the control group; the distress scores were significantly different [$t(202) = 1.71, P < .05$]. Thus, the hypothesis was supported that patients receiving a leaflet with preparatory information about the fertility workup are less distressed when attending the clinic than patients not receiving the leaflet.

Next, we analyzed whether the efforts to send out a leaflet are useful for the andrology clinic in terms of reducing the number of nonattendees. The nonattendance rate was defined as the proportion of participants who had still not attended 6 months after the scheduled appointment. Because 125 leaflets were actually sent out, all 250 participants were included in the analysis. Of the 16 nonattendees, 4 had been randomized into the treatment group and 12 into the control group. An odds ratio of .31 (95% CI .098–.993) indicates that the nonattendance rate was significantly reduced in the treatment group. For further analysis of the benefit for the andrology clinic, the number needed to treat (NNT) was estimated. For the present data set, the NNT is 16 (95% CI 8–545). This means that the leaflet has to be sent to 16 patients for one of them to avoid becoming a nonattendee.

Finally, the mini-survey on web site usage, which had been added to the sheet of the Infertility Distress Scale, was

TABLE 1

Patient characteristics.			
	Treatment group	Control group	Difference
Duration of infertility (mo)	31.4 ± 27.0	31.2 ± 25.7	$t(201) = 0.05, P < .96$
Patients			
Age (y)	33.2 ± 6.2	34.0 ± 6.1	$t(206) = 0.94, P < .35$
Previous fertility diagnostics			$\chi(1) = 0.4, P < .88$
No	69 (63.9)	62 (62.6)	
Yes	39 (36.1)	37 (37.4)	
Previous diagnosis			$\chi(1) = 0.0, P < 1.00$
No impaired fertility	14 (37.8)	13 (37.1)	
Impaired fertility	23 (62.2)	22 (62.9)	
Patients' wives			
Age (y)	31.5 ± 5.3	30.5 ± 5.2	$t(200) = 1.40, P < .16$
Previous fertility diagnostics			$\chi(1) = 1.2, P < .31$
No	20 (18.9)	25 (25.3)	
Yes	86 (81.1)	74 (74.7)	
Previous diagnosis			$\chi(1) = 2.6, P < .15$
No impaired fertility	57 (76.0)	44 (63.8)	
Impaired fertility	18 (24.0)	25 (36.2)	

Note: Data are presented as mean ± SD or n (%).

Pook. Stress reduction in infertile men. Fertil Steril 2005.

analyzed. Patients were asked whether they had visited the clinic's web site and, if not, whether they were aware of its existence. In the leaflet, the web site was referred to several times. Thus, the analysis of the survey on the usage of the web site provided an opportunity to evaluate how well information given in the leaflet had been grasped by the patients. The results of the survey are presented in Table 3. In the treatment group, awareness of the existence of the clinic's web site was much greater. Nevertheless, more than half of the patients receiving the leaflet were unaware of its existence.

DISCUSSION

In the present study, the effect of information given to patients before fertility workup was examined. Two outcome variables were included: the patients' level of infertility distress and the proportion of nonattendees. The randomization of patients into treatment and control groups supports the conclusion that the leaflet caused positive effects on both of the variables. Unfortunately, for one of the variables—the proportion of nonattendees—it is uncertain how the leaflet caused the positive effect. Any conclusion that the smaller proportion of nonattendees in our treatment group indicates

TABLE 2

Reasons for patient exclusion.		
Reason	Treatment group	Control group
Attending for other diagnostics than for fertility workup	4	6
Poor knowledge of German	4	2
Wrong questionnaire (or none) given	4	5
Questionnaire filled out incompletely	2	2
(No treatment received)	(1)	

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TABLE 3

Internet usage of participants.		
	Treatment group n (%)	Control group n (%)
Having visited the web site	19 (18.4)	5 (5.6)
Having not visited the web site but aware of its existence	27 (26.2)	2 (2.2)
Unaware of the web site's existence	57 (55.3)	83 (92.2)
Incomplete data	5	6

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reduced investigation-related worries and distress would be unsound.

When designing the study, it became obvious that only a single control condition could be included. Here, the usual clinical routine was preferred over the introduction of another new condition. In our clinical routine, no appointment reminders are sent, so none were sent to the present control group. Unfortunately, a control group receiving a simple appointment reminder would have been necessary to differentiate between stress-relieving and reminding effects of the leaflet used.

Because the leaflet did not include any mention of the date or time of the appointment, however, it is uncertain whether the smaller proportion of nonattendees should be attributed solely to a reminding effect of the leaflet or whether it can be ascribed at least in part to a reduction of investigation-related worries. In any case, it would seem necessary to send some mail to the patient to reduce nonattendance. When looking at the main outcome variable of the present study—the patients' individual level of infertility distress—it becomes obvious that it is much more favorable to send out informational leaflets than a simple reminder.

In fact, the present study is the first to deliver evidence of a stress-relieving effect of preparatory information for infertility patients. To the best of our knowledge, it is even the first randomized controlled trial to show that infertility-related distress can be reduced effectively. In previous randomized studies to evaluate more extensive psychological support, too often either randomization was broken owing to difficulties in patient assignment (e.g., 12, 13) or no stress-reducing effect could be detected (e.g., 14, 15). It is to be hoped that the success of the present study will encourage the development and evaluation of alternative forms of support for infertility patients.

Although our treatment group was less distressed than the control group, the effect size of the difference was relatively small ($d = .24$). Because infertility patients are seldom distressed in a clinically significant way (6), there was little reason to expect a clinically relevant reduction of the mean distress score in a study of unselected, typical infertility patients. Moreover, if the leaflet increased the attendance rate because of a reduction of investigation-related worries, the small effect size might reflect that there were some moderately to highly distressed patients in the treatment group who finally decided to attend because of the leaflet. In the control group, such patients might have decided not to attend because of their worries.

It must also be considered, however, that many patients who received the leaflet might not have read it. This suspicion is supported by the large number of receivers unaware of the clinic's web site, because the existence of the web site had been repeatedly mentioned in the leaflet. The Internet address was conspicuously centered in a separate line. In addition, the reader was explicitly referred to the web site for pictures of the clinic's rooms and staff, for a route map to the

clinic, and for general information beyond the content of the leaflet. Perhaps distress made it difficult for patients to grasp this information from the leaflet.

One might also speculate, of course, whether the existence of the clinic's web site had been ignored by the majority of receivers simply because of irrelevance. On the other hand, there is some evidence that patients of fertility services widely use the Internet for gathering information about infertility (16, 17). In light of these former research findings, one might expect that even casually read information about the web site would usually be assimilated by patients receiving the leaflet. Thus, either this assumption was wrong or, in fact, many patients did not read the leaflet at all. Similar to formerly high expectations on the uptake-rate for counseling services for infertility patients, some delusions concerning the usage of preparatory information among infertile men might be debunked by further research.

Although it is uncertain how many patients actually read a routinely sent leaflet, preparatory information in written form is beneficial at least for a significant subgroup of men scheduled for fertility workup. However, additional research is needed to explore whether information leaflets can also reduce more persistent pressure, such as involvement in repeated in vitro fertilization. Nevertheless, the present findings are not only promising with respect to the patients' benefit. Fertility services can also benefit from leaflets, because they obviously decrease the number of nonattendees. If removing investigation-related worries is confirmed as relevant for this decrease, there will be a large area of application for detailed information leaflets about fertility workup. Among the many infertile men who never consult andrology services at present (18), there are probably many doubts and reservations about fertility workup that need to be dispelled.

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