

The Impact of the FertiStrong Mobile Application on Anxiety and Depression in Men: A Randomised Control Pilot Study

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ABSTRACT

Background: Male factor accounts for up to half of all cases of infertility. Previously, research has focused on the psychological effects of infertility on female partners, but recent studies show negative consequences on male patients as well. Despite evidence that men are affected by infertility, there is limited studies focusing on coping methods for them. **Aims:** Determine if a cognitive-behavioral and relaxation mobile application, targeted at men experiencing infertility, could lead to decreases in psychological distress. **Settings and Design:** Randomized controlled. **Materials and Methods:** Thirty-nine men participated in a randomized pilot study of the FertiStrong application. Participants completed a demographic form, the Hospital Anxiety and Depression Scale (HADS) and Fertility Problem Inventory (FPI) at baseline and one month follow-up. The intervention group downloaded the FertiStrong application and used it when needed. Control participants received routine infertility care. **Statistical Analysis Used:** Normally distributed data is presented as mean \pm SD; Differences in proportions were tested using Chi-square test and within group comparison were performed using paired t-test. **Results:** One participant was excluded, resulting in 38 participants, 19 in each group. There were no baseline differences in demographic characteristics ($P>0.31$). For the HADS anxiety domain, the control group had a small increase between baseline and follow up, while the intervention group had a small decrease. For the HADS depression domain, there was a slight increase in the controls. For the FPI, the control group had a two-point increase, from moderately stressed to extremely high while the intervention group had a five-point decrease, from extremely high to moderately high, but was not significant. Each FPI domain-specific score in the intervention group decreased and one, Rejection of Childfree lifestyle, was significant ($P=0.03$). The increase in stress level was significantly greater in the control group ($P<0.02$). **Conclusion:** Recruitment was challenging due to the short recruitment phase and the sample size was smaller than planned. However, there were several significant improvements noted in the intervention group and on all testing, the intervention group trended to less distress. More research is needed on convenient interventions for men experiencing infertility.

KEYWORDS: Anxiety, depression, infertility, male infertility, mobile application

INTRODUCTION

Conventionally, the female partner was assumed to be the cause of infertility. With the advent of semen analysis and the technological advances of the past few decades, a male factor is now thought to be responsible for up to 50% of all cases

of infertility.^[1] Similarly, the emotional impact of infertility was thought to be felt most strongly by the

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female partner, and until recently, men were often not included in studies to assess the emotional aspects of infertility. However, recent research has documented the negative consequences of the diagnosis for both men and women. In a recent study of 352 women and 274 men in treatment, 32.1% of men scored in the clinical range for depression and 60.6% of men scored in the clinical range for anxiety.^[2]

A systematic review from 2016 was the first to focus on the psychological adjustment of men to infertility.^[3] Only 12 published studies from three continents have addressed such issues, and the findings demonstrated that psychological symptoms significantly increased 1 year after the infertility evaluation and that risk factors for maladjustment included depression, anxiety, poor partner communication and catastrophising.

In addition, there has been research that psychological stress may affect male hormones and semen quality. Studies have shown decreased testosterone levels, higher luteinizing hormone (LH) and follicle stimulating hormone (FSH) levels, higher prolactin levels and higher cortisol levels in male patients who scored higher on depression and anxiety assessments.^[4,5] This further highlights the need for research that identifies methods for men to alleviate the stress that comes with an infertility diagnosis and treatment.

Despite the evidence that men are also psychologically affected by infertility, there is limited work focusing on coping methods and stress management for them. In terms of studies on interventions to decrease stress in men, a PubMed search did not reveal any acceptable quality randomized controlled trials to investigate a psychological intervention.^[6] The systematic review did find that protective factors against depression included coping strategies related to seeking social support, emotional expression and reconstruction of life goals. This review concluded that speaking openly about infertility and feeling supported decreased distress.^[3] In addition, a study of men with male factor infertility found that therapy with the aim to develop adaptive coping strategies led to improved mental well-being.^[7]

However, counselling may not always be accessible to patients and some men may be reluctant to discuss their issues with infertility. Previous research has shown that men are half as likely to seek professional help for mental concerns compared to women and this is consistent across countries, racial and ethnic groups.^[8] A meta-analysis correlated male reluctance to seek psychological counselling with conformity to masculine norms.^[9] For this reason, men may seek alternatives to traditional counselling such as online forums. Several studies explored men's use of

anonymous online forums to find support and cope with the challenges of infertility. These studies showed that men felt that an online forum allowed them to seek support in ways that allowed anonymity and were more comfortable than offline meetings.^[10] The online setting was perceived as a 'safe space' for men to share their feelings and decrease their feelings of isolation.^[11]

Given the increased comfort with online interventions amongst men dealing with infertility, an easily accessible mobile application could be a useful tool for men undergoing fertility treatment. A recent mixed methods research study detailed the development and implementation of a mobile application that provided administrative and psychological support to women undergoing *in vitro* fertilization (IVF) treatment cycles. This study demonstrated that an application can feasibly be integrated into patient care but has not yet shown if it is helpful or supportive to patients.^[12]

There is a paucity of studies evaluating digital tools for men coping with infertility. However, a systematic review did evaluate the effects of psychosocial interventions, such as cognitive behavioural therapy and psychoeducation, in female and male infertile patients. It found that for men, combined psychological outcomes did not have statistically significant changes with psychological interventions. The effect size specifically for infertility-related distress, anxiety and depression did not reach statistical significance for men.^[13] Thus, there is a lack of effective tools available to men dealing with the psychological effects of infertility.

Considering the feasibility of a mobile application and the lack of tools for men coping with infertility, we designed a randomized controlled pilot study to determine if a newly created mobile application designed to be used by the male partner of an infertile couple to decrease distress and increase coping was indeed effective in minimizing negative psychological symptoms.

MATERIALS AND METHODS

The FertiStrong mobile application was created to provide cognitive-behavioural coping strategies and relaxations for the 50 situations thought to be the most stressful for the male partner of an infertile couple. The content was written by experts in the field, psychologists Drs. Janet Takefman and William Petok. Half of the strategies are directed to treat the distress of the male partner and half are suggestions on how the male partner could better support the coping of his female partner. There are 12 specific categories to reflect the potential current stress situation and these are: my partner, communication, pregnancy loss, work, social events, relationship survival 101, sex, family and friends, medical aspects, when is enough?, mind/body and

emotions. Each category has 4–6 subcategory-specific situations and for each of these situations, there are six coping strategies: 10 prerecorded relaxation sessions, cognitive techniques, behavioural techniques, his needs, social solutions and finding the humour.

Two of the authors of this study, Alice D Domar (ADD) and Elizabeth A Gril (EAG), have a financial interest in the FertiStrong app, therefore, to prevent any potential conflict of interest there was a firewall created between them and all aspects of the study. They had no impact on recruitment, had no contact whatsoever with any of the participants, had no connection with data collection and were exempt from the data analysis, which was performed by an independent paid statistician. The study was performed at fertility centers of Illinois (FCI), and neither author has or had any relationship with this clinic. This study was registered as a clinical study on ClinicalTrials.gov (NCT03519607).

The recruitment phase of the study was short in duration; the application build was completed only a month before the licensing sponsor scheduled its release to coincide with Father's Day. A month before the build was to be completed, the study authors were able to apply for and receive IRB approval and adhered to the principles of the Helsinki Declaration, receive funding for the study, recruit and train a research assistant, determine the most appropriate psychological questionnaires and recruit participants. Due to the sponsor's launch requirements, there were only 2 weeks to recruit and participant exposure to the application could only be for 28 days. The sample size was limited by the 2-week recruitment and it was smaller than anticipated despite an extremely vigorous recruitment campaign at FCI. Recruitment took place the 1st 2 weeks of May 2018, and the men randomised to the application group had 1 month with access to the application. It had been hypothesised that 100 men would be recruited and randomised into the study based on the number of couples undergoing treatment during this time. However, responses to recruitment efforts were far lower than anticipated. There were two separate E-mail blasts to 5237 FCI patients as well as Facebook, Twitter and Instagram ads, office flyer distributions and physician encouragement. A total of 73 men responded to the recruitment efforts, and 66 of these agreed to receive a consent form. A total of 43 signed the consent form and of these, 39 completed the questionnaires. Thus, 59% of the respondents signed the consent form and of those who signed the consent form, 91% completed the questionnaires.

Participants/measures

Thirty-nine men who were each part of a couple experiencing infertility participated in a 1:1 randomised study of the FertiStrong app. Participants completed both the Hospital Anxiety and Depression Scale (HADS)^[14]

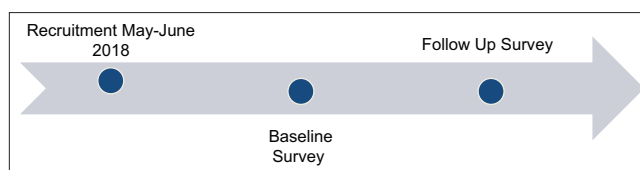


Figure 1: Timeline of data collection

and the Fertility Problem Inventory (FPI)^[15] at baseline and follow-up [Figure 1].

The HADS consists of 14 statements that are evenly split between an anxiety domain and a depression domain, with higher scores indicating greater levels of anxiety or depression. The FPI consists of 46 statements that are split into five domains, with higher scores indicating greater levels of infertility-related stress. Follow-up surveys were completed approximately 1 month after baseline surveys.

Participants were randomised using a computerised random numbers table and pure randomisation. The randomisation was allocated using a computerised output. HADS and FPI responses were converted to numeric values for analysis. Due to limited recruitment time, a sample of convenience was used. The Shapiro–Wilk test was used to test for normality of distributions, and normally distributed data are presented as the mean \pm standard deviation. We tested differences in proportions using a Chi-square test. Individual-level differences in mean HADS and FPI scores between baseline and follow-up within each group were tested using a paired *t*-test. To compare groups, we used a *t*-test to calculate a *P* value for the mean change from baseline to follow-up in the intervention group compared to the mean change from baseline to follow-up in the control group. *P* < 0.05 was statistically significant. All analysis was performed using SAS 9.4 (SAS Institute, Cary, NC, USA) and GraphPad Prism (GraphPad Prism for Windows, San Diego, CA, USA).

RESULTS

Demographics

One participant from the control group was excluded due to having duplicate baseline responses, yielding a total of 38 participants, with 19 in each of the intervention and control groups included in the analysis [Figure 2]. Participants ranged from 25 to 48 years of age, with a mean overall age of 33.7 ± 4.5 years [Table 1]. The mean overall time spent trying to conceive was 24.0 ± 11.5 months, while participants' mean overall duration as an FCI patient was 11.0 ± 10.1 months. Participants had high levels of education, with over 40% having completed a graduate degree. Approximately one-third had diagnosed with female factor fertility and 21.1% had diagnosed with male factor infertility.

Table 1: Demographic characteristics

Characteristic	Intervention (n=19)	Control (n=19)	P
Age (years), mean±SD	34.1±4.9	33.2±4.1	0.55
Time trying to conceive (months), mean±SD	24.7±13.8	23.3±9.0	0.72
Time as an FCI patient (months), mean±SD	11.3±9.8	11.7±10.7	0.85
Education			
Some college	2 (10.5)	4 (21.1)	0.35
College	6 (31.6)	9 (47.4)	
Some graduate school	1 (5.3)	0	
Graduate school	10 (52.6)	6 (31.6)	
IF diagnosis			
Female factor	6 (31.6)	7 (36.8)	0.50
Male factor	5 (26.3)	3 (15.8)	
Both male and female factor	2 (10.5)	0	
Unexplained	4 (21.1)	5 (26.3)	
Not yet known	2 (10.5)	5 (21.1)	
Respondent/partner currently in treatment	18 (94.7)	17 (89.5)	1.00
IVF	8 (42.1)	10 (52.6)	0.52
Oral medications	7 (36.8)	8 (42.1)	0.74
Injectable meds	3 (15.8)	5 (26.3)	0.42
Natural cycle IUI	4 (21.1)	4 (21.1)	1.00
IVF with embryo genetic testing	3 (15.8)	3 (15.8)	1.00
IVF with donor egg/sperm	1 (5.3)	0	0.31
IVF with testicular sperm retrieval	0	1 (5.3)	0.31
IVF with gestational carrier	0	0	-

Data are shown as n (%) unless otherwise noted. SD=Standard deviation, IVF=*In vitro* fertilisation, IF=Infertility, IUI=Intrauterine insemination

Table 2: Change in Hospital Anxiety and Depression Scale scores between baseline and follow-up amongst intervention and control participants

Statement	Intervention (n=19)		P*	Control (n=19)		P*	Intervention versus control P†
	Baseline	Follow-up		Baseline	Follow-up		
Anxiety domain	7.89±3.14	7.63±3.11	0.62	7.16±2.73	7.21±3.17	0.90	0.35
I feel tense of 'wound up'	1.26±0.45	1.16±0.50	0.43	1.32±0.58	1.26±0.65	0.58	0.74
I get frightened as if something awful will happen	0.53±0.51	0.37±0.50	0.08	0.58±0.61	0.47±0.51	0.16	0.64
Worrying thoughts go through my mind	1.11±0.94	1.16±0.76	0.79	0.68±0.75	0.89±0.81	0.16	0.52
I can sit at ease and feel relaxed	0.58±0.69	0.37±0.60	0.30	0.26±0.56	0.42±0.61	0.27	0.13
I get a frightened like 'butterflies' in the stomach	1.37±0.83	1.47±0.70	0.61	1.21±0.79	1.21±0.79	1.00	0.74
I feel restless as if I have to be on the move	0.53±0.61	0.68±0.67	0.27	0.74±0.56	0.74±0.56	1.00	0.33
I get sudden feelings of panic	1.11±0.46	0.95±0.71	0.38	1.26±0.65	1.16±0.50	0.43	0.81
Depression domain	3.95±2.97	3.95±2.97	1.00	3.53±2.41	3.58±2.87	0.90	0.93
I still enjoy the things I used to enjoy	0.84±0.69	0.89±0.66	0.83	0.84±0.37	0.68±0.67	0.38	0.48
I can laugh and see the funny side of things	0.74±0.65	0.79±0.63	0.67	0.53±0.51	0.74±0.73	0.10	0.93
I feel cheerful	0.63±0.83	0.68±0.95	0.75	0.21±0.42	0.32±0.67	0.49	0.81
I feel as if I am slowed down	1.63±0.90	1.32±0.82	0.11	1.53±0.90	1.26±0.65	0.20	0.85
I have lost interest in my appearance	0.32±0.58	0.63±0.68	0.01	0.53±0.77	0.68±0.75	0.33	0.42
I look forward with enjoyment to things	0.68±0.58	0.79±0.63	0.43	0.63±0.68	0.68±0.67	0.67	0.77
I can enjoy a good book or radio or TV program	0.53±0.61	0.32±0.48	0.30	0.37±0.50	0.26±0.45	0.43	0.09

*P calculated using a paired t-test for baseline score versus follow-up score within each group, †P calculated using a t-test for the mean change from baseline to follow-up in the intervention group versus the mean change from baseline to follow-up in the control group. Data are shown as mean±SD. SD=Standard deviation

Ninety-two percent of participant couples were undergoing IVF at the time of the study. There were no differences between the intervention and control groups in any demographic characteristics (all P ≥ 0.31).

Hospital anxiety and depression scale

At baseline, the mean HADS score on the anxiety domain was between normal (score of 0–7) and borderline abnormal (scores of 8–10) for both the

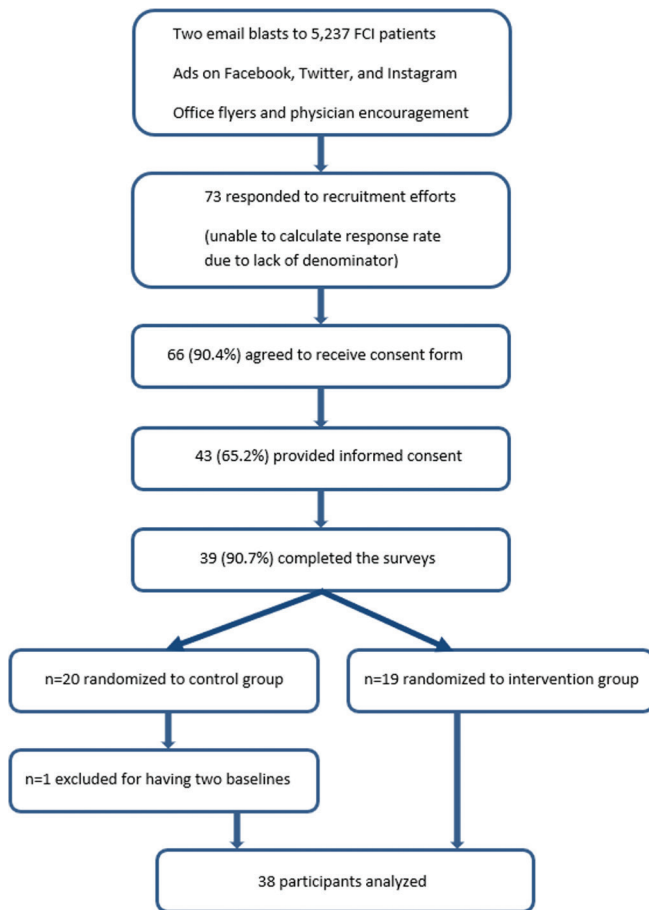


Figure 2: Flow Chart of Patient Recruitment Efforts and Randomization. FCI: Fertility Centers of Illinois

intervention (7.89 ± 3.14) and control (7.16 ± 2.73) groups [Table 2]. While this score increased slightly in the control group at follow-up (7.21 ± 3.17), indicating slightly higher anxiety, it decreased slightly in the intervention group (7.63 ± 3.11), indicating slightly lower anxiety; these changes were not statistically significant within either the intervention ($P = 0.62$) or control ($P = 0.35$) groups [Figure 3]. The mean change in the overall anxiety score amongst the intervention group did not differ significantly from the mean change in the overall anxiety score amongst the control group ($P = 0.35$).

At baseline, the mean HADS score on the depression domain was in the normal range (score of 0–7) for both the intervention (3.95 ± 2.97) and control (3.53 ± 2.41) groups. This score remained the same in the intervention group (3.95 ± 2.97) and increased slightly in the control group (3.58 ± 2.87), indicating slightly increased depression symptoms; these changes were not statistically significant within either the intervention ($P = 1.00$) or control ($P = 0.93$) groups. The mean change in the overall depression score amongst the intervention group did not differ significantly from the mean change in the overall depression score amongst the control group ($P = 0.93$).

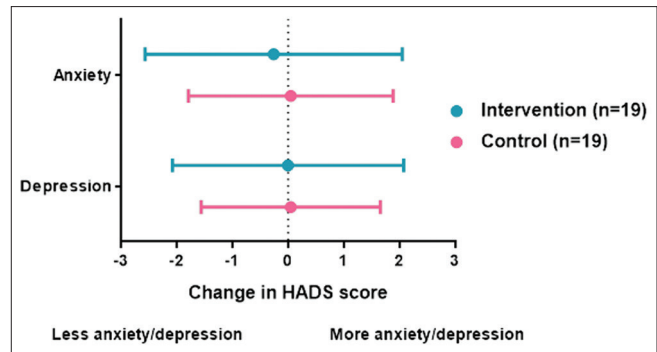


Figure 3: Change in hospital anxiety and depression scale scores between baseline and follow-up. HADS: Hospital anxiety and depression scale

Fertility problem inventory

At baseline, the mean overall FPI score was in the range of extremely high infertility stress (scores of ≥ 147 –276 amongst men) amongst the intervention group (149.84 ± 36.94) and in the range of moderately high infertility stress (scores of $114 < 147$ amongst men) amongst the control group (146.53 ± 26.96) [Table 3]. While this score increased by more than two points in the control group at follow-up (148.79 ± 27.66), reaching the range of extremely high infertility stress, this score decreased by nearly five points in the intervention group at follow-up (144.53 ± 39.86), moving the score into the range of moderately high infertility stress; these changes were not statistically significant within either the intervention ($P = 0.18$) or control ($P = 0.47$) groups [Figure 4]. The mean change in the overall FPI score amongst the intervention group did not significantly differ from the mean change in the overall FPI score amongst the control group ($P = 0.54$). Several statements ('I feel like friends and family are leaving us behind', 'my partner doesn't understand how infertility affects me', and 'it's hard to feel like a true adult without a child') increased in both groups at follow-up, though the increase in stress level was significantly greater in the control group than in the intervention group (all $P < 0.02$). For no statements did the intervention group showed significantly increased stress compared to the control group.

DISCUSSION

It is somewhat concerning that there has not yet been an adequate randomised controlled trial of psychological interventions on men experiencing infertility, even though in recent years, it has become obvious that men experience significant psychological distress as they pursue fatherhood. It has been observed by mental health professionals in the Reproductive Endocrinology and Infertility field that it is far more challenging to recruit men to attend support groups and other in-person psychosocial interventions

Table 3: Fertility problem inventory scores (lower scores are better) at baseline and follow-up amongst all participants

Statement	Intervention (n=19)		Control (n=19)		P [†]	Intervention versus control P [*]
	Baseline	Follow-up	Baseline	Follow-up		
Overall	149.84±36.94	144.53±39.86	146.53±26.96	148.79±27.66	0.18	0.47
Social concern	30.11±12.22	29.74±12.52	32.63±10.60	32.74±11.55	0.79	0.93
It doesn't bother me when I'm asked questions about children [†]	3.42±1.26	2.95±1.61	3.84±1.54	3.84±1.54	0.10	1.00
Family members don't seem to treat us differently*	2.95±1.72	2.58±1.64	2.74±1.37	2.63±1.34	0.20	0.69
The holidays are especially difficult for me	3.00±1.76	3.16±1.80	3.21±1.87	3.21±1.81	0.53	1.00
Family get-togethers are especially difficult for me	2.95±1.75	3.00±1.70	3.05±1.72	3.21±1.87	0.85	0.45
I compare myself with friends who have children	3.95±1.81	3.79±1.72	4.21±1.40	4.00±1.73	0.48	0.45
I still have lots in common with friends who have children*	2.47±1.07	2.26±1.05	2.89±1.20	3.05±1.27	0.26	0.67
I find it hard to spend time with friends who have young children	2.79±1.55	2.95±1.47	3.37±1.67	3.11±1.85	0.70	0.29
When I see families with children I feel left out	3.26±1.76	3.21±1.55	3.26±1.79	3.47±1.90	0.82	0.43
I feel like friends or family are leaving us behind	2.53±1.87	2.95±1.65	2.79±1.65	3.37±1.67	0.10	0.06
It doesn't bother me when others talk about their children*	2.79±1.51	2.89±1.66	3.26±1.37	2.84±1.68	0.74	0.27
Sexual concern	23.11±10.26	22.74±10.70	20.26±8.16	19.95±7.46	0.71	0.80
I've lost my enjoyment of sex because of IF	3.16±1.95	3.16±1.61	3.16±1.64	2.89±1.52	1.00	0.41
I feel just as attractive to my partner as before*	2.26±1.52	2.53±1.61	2.53±1.54	2.37±1.34	0.44	0.61
I don't feel any different from other members of my sex*	2.74±1.56	2.58±1.50	2.84±1.46	2.89±1.45	0.58	0.85
I feel like I've failed at sex	3.05±1.87	2.74±1.73	2.26±1.79	2.37±1.50	0.23	0.68
During sex, all I can think about is wanting a child/another child	2.42±1.80	2.63±1.95	1.79±1.08	1.89±0.94	0.48	0.67
Having sex is difficult because I don't want another disappointment	2.89±2.05	2.89±1.70	2.11±1.37	2.16±1.46	1.00	0.86
If we miss a critical day for sex, I can feel angry	3.32±1.20	3.42±1.50	2.68±1.67	2.79±1.58	0.77	0.71
The pressure can make having sex difficult	3.26±1.97	2.79±1.51	2.89±1.79	2.58±1.64	0.15	0.27
Relationship concern domain	27.53±10.23	26.89±11.90	24.53±9.25	26.37±9.26	0.63	0.03
I can't show my partner how I feel because it will upset him/her	3.47±1.78	3.53±1.74	3.05±1.72	3.42±1.61	0.88	0.20
My partner doesn't understand how IF affects me	2.74±1.69	2.95±1.78	2.63±1.42	3.16±1.38	0.30	0.047
We work together handling questions about our IF*	2.21±0.71	2.00±0.82	2.58±1.50	2.42±1.12	0.10	0.63
It bothers me that my partner reacts differently to IF	3.26±1.45	2.84±1.64	2.16±1.30	2.74±1.56	0.13	0.05
My partner is quite disappointed with me	2.32±1.77	2.11±1.56	1.63±1.26	1.95±1.47	0.45	0.08
We could talk more openly with each other about IF	3.79±1.72	3.47±1.87	3.37±1.61	3.32±1.77	0.37	0.84
I couldn't imagine us separating because of this*	2.32±1.34	2.32±1.63	1.89±1.82	1.74±1.37	1.00	0.27
When we talk about IF, it leads to an argument	2.37±1.54	2.42±1.64	2.11±1.33	2.42±1.39	0.86	0.25
Because of IF, I worry we're drifting apart	2.47±1.47	2.53±1.58	2.32±1.49	2.32±1.45	0.80	1.00
When we talk about IF, I can comfort my partner*	2.58±1.22	2.74±1.15	2.79±1.03	2.89±0.99	0.33	0.63
Rejection of a childfree lifestyle domain	28.26±6.92	25.53±7.11	29.53±6.74	29.32±7.57	0.03	0.81
Couples without a child are just as happy as those with children*	3.05±1.47	3.00±1.00	3.37±1.50	3.21±1.32	0.83	0.51
I could see advantages if we didn't have a child*	3.58±1.26	3.11±1.59	4.26±1.63	3.89±1.52	0.12	0.23
I could visualize a happy life without a child*	3.00±1.49	2.68±0.95	3.32±1.29	3.47±1.31	0.27	0.63
At times, I seriously wonder if I want a child*	4.84±1.64	4.05±1.58	4.58±1.57	4.63±1.38	0.05	0.85
Not having a child would allow for satisfying things*	3.58±1.64	3.05±1.58	3.79±1.51	3.53±1.31	0.14	0.45

Table 3: Contd...

Statement	Intervention (n=19)		P [†]	Control (n=19)		P [†]	Intervention versus control	
	Baseline	Follow-up		Baseline	Follow-up		P [*]	
Having a child is not necessary for my happiness*	3.53±1.17	3.63±1.30	0.78	3.63±1.07	3.89±0.88	0.29		0.41
We could have a great relationship without a child*	2.89±1.45	2.74±1.19	0.55	2.79±1.32	2.84±1.26	0.83		0.76
A certain freedom without children appeals to me*	3.79±1.47	3.26±1.52	0.01	3.79±1.36	3.84±1.42	0.75		0.08
Need for parenthood domain	40.84±9.48	39.63±8.89	0.21	39.58±7.59	40.42±7.67	0.27		0.76
Pregnancy/childbirth are the most important relationship events	4.37±1.54	4.11±1.05	0.38	3.89±1.10	3.95±1.08	0.83		0.58
For me, being a parent is more important than a satisfying career	4.42±1.35	4.47±1.17	0.82	4.53±0.84	4.58±0.90	0.67		0.68
My marriage needs a child	3.84±1.92	3.89±1.70	0.80	3.53±1.58	3.37±1.42	0.61		0.78
It's hard to feel like a true adult without a child	3.05±1.72	3.26±1.52	0.46	2.79±1.36	3.68±1.49	0.01		0.01
A future without a child would frightens me	3.89±1.37	4.05±1.31	0.68	4.05±1.51	3.68±1.20	0.15		0.64
I feel empty because of our fertility problem	3.32±1.83	3.00±1.67	0.08	3.05±1.39	3.11±1.59	0.77		0.30
Having a child is not the major focus of my life*	4.37±1.21	3.95±1.27	0.25	4.79±1.18	4.21±1.58	0.07		0.04
I have often felt that I was born to be a parent	4.42±1.46	4.21±1.40	0.39	4.16±1.38	4.58±1.17	0.09		0.54
As long as I remember, I've wanted to be a parent	4.58±1.61	4.21±1.51	0.049	4.16±1.64	4.68±1.38	0.004		0.57
I will do just about anything to have a child	4.58±1.30	4.47±1.35	0.49	4.63±1.12	4.58±1.30	0.83		0.57

*Scored inversely, †P calculated using a paired t-test for baseline score versus follow-up score within each group, ‡P calculated using a t-test for the mean change from baseline to follow-up in the intervention group versus the mean change from baseline to follow-up in the control group. IF=Infertility

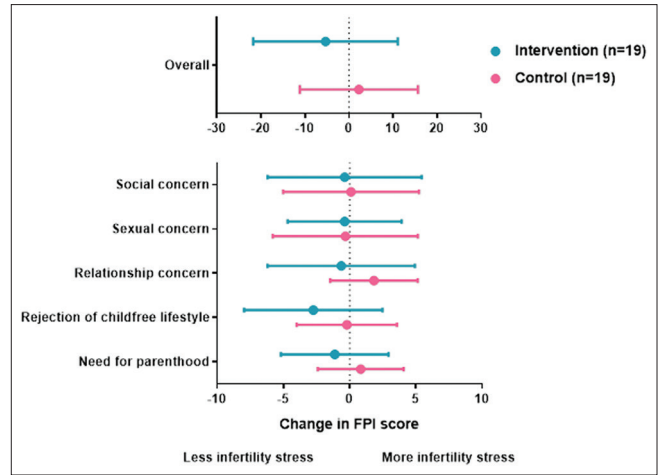


Figure 4: Change in fertility problem inventory scores between baseline and follow-up. FPI: Fertility problem inventory

designed toward men than it is to attract women to comparable opportunities. These observations have been confirmed by studies that analysed online forums for men dealing with infertility which found an increased comfort amongst men with online, anonymous support.^[10,11]

For these reasons, the research team believed that the creation of a mobile application, designed to treat the negative psychological consequences experienced by a man in an infertile couple, would provide the ideal solution. Men would not have to talk to any health professionals about their distress level, they would not have to attend any additional clinic visits, and they could read about and incorporate stress-reducing strategies privately. In addition, since so many men report a sense of frustration in terms of their efforts to better support their partner, the incorporation of numerous strategies and suggestions for them to better meet the specific needs of that partner would seem to have served as an attractive solution. However, our limited ability to recruit patients may indicate a lack of willingness or need for a digital application. Yet, those that did participate seemed to have some positive benefits.

The current study was successful in some parameters. A small sample of men did agree to participate in the study. There were several significant improvements reported by the men in the intervention group and with such a small sample size, this would indicate a large effect size. The control group had no improvements, and in fact experienced some worsening of symptoms over the month-long study period. Therefore, there is a modest indication that the application was in fact useful and effective in treating emotional distress in men experiencing infertility. In addition, this mobile application is the first of its kind aimed towards helping men cope with infertility.

Clearly, there are significant and severe limitations with this study. For one, the sample size was far lower than had been anticipated. A large effort was made to inform FCI patients about the study and the fact that only 73 men responded to these efforts is disappointing and puzzling. It may reflect the fact that the male partner of an infertile couple is less likely to want to express a need for emotional support since research on female infertility patients tends to lead to higher recruitment rates. It may also indicate that male partners are not interested in participating in psychological intervention research. However, once a prospective participant did express interest, the resultant recruitment rate was remarkable. Of those who signed the consent form, 91% completed the study.

A longer recruitment period would have allowed a more reasonable number of participants to be recruited. The study was unable to have a true control group because of the longer-than-anticipated build time of the application and its immovable launch date with free availability in the United States. The study period was for only 1 month, potentially drastically limiting the efficacy of the intervention. Once the application was launched, there was no way to ensure that control participants were not downloading it themselves. As previously mentioned, there was only a brief period between the completion of the building of the application and the planned launch, which was to coincide with Father's Day. To keep the study as clean as possible, it was decided not to continue following the participants due to the potential for contamination of the control group. The application was made publicly available for 2 years. However, due to poor uptake, the licensing was not renewed. The potential reintroduction of the application should be considered after further research elucidates how to optimise its effects on psychological metrics in the male infertility population.

Despite these limitations, the study does answer some previously unknown questions. It is possible through assertive efforts to recruit men into a study on a psychosocial intervention, albeit in small numbers. It appears that the use of a mobile application is indeed associated with some modest improvements in psychological distress. It is obvious that further research is necessary utilising a larger sample size followed over a far longer period. However, this pilot study is a step in the direction of beginning to meet the psychosocial needs of the male partner in the infertile couple.

CONCLUSIONS

Men as part of an infertile couple experience significant distress, yet research on methods to address their negative psychological symptoms is lacking. Because

men have shown to be hesitant to participate in live methods of psychological interventions, it was proposed that a mobile application would best meet their needs. This small pilot study, limited by only a 2-week recruitment phase and a 1-month intervention phase, still has documented some indication that a mobile application for these men can have some benefit, even reaching statistical significance in a few measures despite the small sample size. Clearly more research in this arena is needed.

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Conflicts of interest

There are no conflicts of interest.

Data availability statement

De-identified data is available upon reasonable request.

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