



CLINICAL CONSENSUS GUIDELINE FOR PSYCHOSOCIAL CARE IN ASSISTED REPRODUCTIVE TECHNOLOGY (ART) 2024

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Clinical Consensus Guideline

The Indian Fertility Society's Executive Committee recognized the need to develop a comprehensive psychosocial consensus statement tailored to the unique social context of India. In response, they commissioned a consensus document group to review and adapt the European Society of Human Reproduction and Embryology (ESHRE) psychosocial guidelines. (2015).

This initiative aimed to address the specific challenges and considerations pertinent to the Indian population undergoing Assisted Reproductive Techniques (ART).

The primary aim of this clinical consensus guideline is to provide a comprehensive guide to enhance psychosocial care delivered to sub fertile couples by the practicing fertility team. By offering 78 evidence-based recommendations, information and best practices, the consensus guideline endeavours to establish a framework considering the dynamics of the Indian family system, social norms, and cultural values and practices. Through a synthesis of clinical expertise and cultural sensitivity, the guideline aims to furnish tailored support that resonates with the diverse fabric of Indian society.

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Foreword

I am both honored and delighted to pen the foreword for the "Clinical Consensus Guideline for Psychosocial care in Assisted Reproduction Technology (ART)". Counseling emerges as a pivotal element throughout the fertility treatment and is mandatory requirement in every Assisted Reproduction technology clinic as per the new law in India.

This consensus is first of its kind in the field of subfertility in India. It thoroughly looks into the various aspects of counselling by the Counselors and health care providers of the Assisted Reproduction Technology clinic. The recommendations are based on the scientific evidences and good practice points by the experts of this field. Each subsection of the consensus reflects the meticulous attention to detail and a compassionate approach to patient care.

This Consensus Guidelines serves as a valuable resource for Psychologists, Gynecologists, General Physicians, devoted Nurses, Embryologists, IVF coordinators, and other supportive staff in ART clinics addressing fertility treatment challenges.

I am thankful to our International experts Dr Sofia Gamerio, Dr Ana Galhardo and Ms Karen Kirchheiner Jensen for giving their valuable inputs and gratitude for their unwavering commitment to advancing the field of Counselling in reproductive medicine. Heartfelt congratulations to the Indian Fertility Society authors, Dr Poonam Nayar and her team who have put together an excellent compilation of topics and I commend them for their invaluable expertise and dedication.

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Foreword

I am delighted to write this forward for the Indian Fertility Society and introduce the Clinical Consensus Guideline for Psychosocial Care in patients undergoing Assisted Reproductive Technology (ART).

As chair of the Routine psychosocial care in infertility and medically assisted reproduction – A guide for fertility staff, sponsored by the European Society for Human Reproduction and Embryology (ESHRE), I am often invited by scientific societies and other organisations, to discuss provision of psychosocial care at fertility clinics. It was in this context that I had the pleasure to engage with the Indian Fertility Society, specifically with their Psychology and Counselling Special Interest Group.

Led by Dr Poonam Nayar, this is an extremely active group that has been consistently advancing the quality standards of psychosocial care provision in India and widening training in these issues across the country. Our collaboration culminated in my involvement in their work to produce the Consensus Guidelines.

Everyone who works at fertility clinic in India under any capacity or role should get acquainted with the Consensus Guideline for the management of psychosocial conditions in Patients undergoing Assisted Reproductive Technology (ART). In this document, the group compiled a set of research informed best practice recommendations to support care provision for people undergoing fertility treatment in India. The Consensus Guidelines departs from the ESHRE Routine psychosocial care in infertility and medically assisted reproduction – A guide for fertility staff, and therefore targets the whole clinic team (not only for psychologists, counsellors, or other mental health professionals). It significantly extends the scope of the ESHRE guidelines to take into account the Indian family system, social norms, and cultural values and practices. One example of this is the use of mental health screening questionnaires that are validated for the Indian population, instead of those recommended in the ESHRE guidelines. Another example is the addition of a section on psychosocial care for couples undertaking third-party reproduction.

The Consensus Guidelines results from the application of a systematic and rigorous methodology that included setting a multi-disciplinary working team of experts and international advisors, training provision for the team, multiple evidence synthesis and critical appraisal exercises, development of evidencebased recommendations, consensus building about recommendations, and peer review.

It has been an absolute privilege to collaborate with such a team of committed and enthusiastic experts and see this amazing document come to light. I am confident in saying that the Consensus Guidelines will act as a reference framework and standards setting document for the work done in India for many years to come. I am certain that the Indian Psychology and Counselling Special Interest Group will support its implementation across the country via awareness raising, training, and advisory support, so that every single fertility patient in India can receive the absolute best care.

Sofia Gameiro

Chair of the Routine psychosocial care in infertility
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Legal Disclaimer:

This Clinical Consensus Guideline for Psychosocial care of patients undertaking Assisted Reproductive Technology (ART) has been developed by a committee of experts established by the Indian Fertility Society ("Committee"). The statements and recommendations contained within this Guideline are provided for informational purposes only and are not intended to serve as legal advice or directives for healthcare professionals.

The Committee acknowledges that the statements and recommendations presented in this Guideline are based on a review of evidence-based practices, as well as the opinions and expertise of the participating experts. However, it is important to note that the content of this Guideline is not exhaustive and may not encompass all possible scenarios or considerations relevant to the management of psychosocial conditions in patients undergoing assisted reproduction.

Furthermore, healthcare professionals are reminded that the information provided in this Guideline is not intended to supersede their clinical judgment or override established medical protocols or standards of care. Each patient's unique circumstances and individual needs should be carefully considered when making clinical decisions, and healthcare professionals are encouraged to exercise their discretion and professional judgment in accordance with prevailing norms and guidelines.

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1. Introduction

1.1 Scope

The Indian Fertility Society has formulated a comprehensive scope to delineate the parameters and objectives of the Clinical Consensus Guideline for Psychosocial Care in patients undergoing Assisted Reproductive Technology or ART.

This document seeks to elucidate the core objectives and guiding principles of the consensus, aimed at addressing the multifaceted psychosocial challenges encountered by individuals and couples embarking on the journey of assisted reproduction.

Integral to the ethos of this consensus is the identification and prioritization of knowledge gaps within the domain of psychosocial care in Assisted Reproductive Technology or ART. By identifying, acknowledging, and addressing these gaps, the guideline aspires to foster continuous improvement and innovation in care provision, ensuring that patients receive the highest standard of support throughout their treatment journey.

Moreover, the applicability of existing guidelines for psychosocial care by the European Society of Human Reproduction and Embryology (ESHRE 2015) in the Indian social and cultural context has been critically evaluated, enabling the adaptation and contextualization of best practices to suit the specific needs and preferences of Indian patients and healthcare providers.

The needs of specialized care required for major psychiatric disorders, financial counselling for patients undergoing treatments for infertility, and procedural counselling as mandated by regulations are excluded from the scope of this document. These aspects necessitate specialized attention and may involve collaboration with relevant professionals and regulatory bodies.

1.2 Target Users of the Guideline:

The Clinical Consensus Guideline on psychosocial care of patient's undergoing Assisted Reproductive Technology is tailored to serve as a resource for the entire infertility team, encompassing a diverse array of healthcare professionals and administrative staff. Target users include doctors specializing in reproductive medicine, nurses proficient in patient care, embryologists involved in laboratory procedures, counsellor's adept at providing emotional support, administrative staff such as clinic coordinators facilitating smooth operations, and financial counsellors offering guidance on financial aspects. This guideline equips these professionals with evidence-based information and best practices to enhance psychosocial care provision, fostering a collaborative approach to support patients through the intricate journey of assisted reproduction within the Indian socio-cultural context

1.3 Key Outcomes

In the Clinical Consensus Guideline for psychosocial care in patients undergoing Assisted Reproductive Technology, key outcomes are evaluated considering behavioural, relationship, emotional and cognitive needs. Such outcomes include improvements in patient satisfaction and psychological well-being throughout the treatment journey. Additionally, the guideline assesses the adoption of recommended practices by healthcare professionals within the infertility unit, ensuring adherence to evidence-based strategies for addressing psychological distress and promoting resilience among patients. Furthermore, the guideline aims to identify and address knowledge gaps within the domain of psychosocial care in assisted reproduction, fostering continuous improvement and innovation in care provision. By evaluating these key outcomes, the guideline endeavours to optimize patient-centred care, ultimately enhancing the overall experience and outcomes for individuals undergoing medically assisted reproduction.

2. An Introduction to Psychosocial Care During ART:

An overview of the ESHRE guidelines (2015) is essential as it provides an important foundational framework for routine psychosocial care during ART. The evidence-based insights are simple and clear, throwing light on the needs and preferences of the couple during different stages of fertility care as well as the ways and means by which these needs may be addressed. It provides an invaluable road map into the process of client-centred care for patients during ART. Hence a summary is given below. However, keeping in view the culture, language, and social context, a survey of the key recommendations of ESHRE was conducted to find out areas of agreement (Annexure 1) On the basis of the report of the survey as well as expert group discussion, some changes are recommended for better adaptation to our patient population. Also, the review and recommendations reported below have attempted to incorporate studies done after ESHRE 2015 guideline.

First important change is in the domain of identification of couples at risk using the best available tools in India. The tests which have been developed and standardised on the Indian population have been recommended for use during initial screening for distress levels. These have been described in detail in later sections. Though these are generic tools for measuring severity of distress and general wellbeing, these are very useful for screening purposes. The suitable adaptations of fertility specific tools such as SCREEN IVF or FERTIQOL are yet to be standardised in the local languages. Screen IVF and FERTIQOL are recommended by ESHRE (2015) as they give valuable information about what the patients are struggling with while experiencing infertility or ART. Hence it is recommended that suitable translations and standardisation be done for the fertility-specific tools for more precise psychometric data.

Second is the in-depth collation of data available on yoga based techniques (YBT) of physical exercises, breath regulation and meditation. These are culturally consonant methods of self-regulation which are widely accepted in India and thus may be integrated into the routine psychosocial care for ART. If the practices are initiated during the pretreatment period as group interventions that focus on education and skills training, they may be very useful during subsequent treatment and post-treatment phases to buffer high emotional distress.

The third aspect which has been discussed is the practice of psychological care after successful ART pregnancy, Along with the yoga-based techniques YBT i.e. yogic exercises, regulated breathing, and meditation for self, there is a unique added feature i.e.

meditative focus on the baby with positive affirmations, visualizing and bonding with the baby. This can be integrated along with the standard antenatal care as recommended by the obstetricians (Neel et al 2018; Pragya et.al. 2023) to enhance the positive psychological state of the mother which influences the birth parameters as well as the early childhood development. The totally new research section covers the role of yoga based techniques for the male factor infertility

Fourthly, the social fabric and value system are rapidly changing hence there is heterogeneity in education, western values shaped by the media and the global exchange of information and ideas. The deeply held traditional values intermingle with the individualistic Western orientation. Unfortunately, practices like gender preference for male children persist in some families. The consensus group has made recommendations as to how such a situation may be dealt with. The family dynamics in a joint family system will also require more work for us to develop clear-cut guidelines about how the muchneeded support system for the patient can be developed.

We sincerely hope that the consensus statements will provide a starting point for subsequent explorations and research on improving as well as opening ever-growing new perspectives to enhance the psychosocial care during ART within our socio-cultural settings.

Eshre Guidelines (2015) Routine Psychosocial Care During Medically Assisted Reproduction: A Summary Overview

Caring for the emotional needs of the patient demands continuity of care. It means providing patient-centred care in all aspects and all stages of infertility treatment. The empathetic clientcentered approach provides the basic core context of ongoing psychological support for all patients.

The European Society of Human Reproduction and Embryology (ESHRE) guideline 2015 has differentiated patient support into two complementary levels of psychosocial care:

- Routine Psychosocial Care, meaning that psychosocial care practices are embedded in the routine care that is offered to patients as they progress through their treatment pathway
- Specialized Psychosocial Care which needs the attention of a mental health professional. It includes: i. Infertility Counselling (e.g., crisis intervention, grieving support, implications counselling) ii. Psychotherapy (for patients with diagnosed mental health disorders)

It is accepted that most patients (i.e 80%) report a common set of challenges to the treatment process. These can be addressed via routine psychosocial care. Routine psychosocial care is the responsibility of all fertility staff to be given continuously in an ongoing manner throughout the treatment pathway.

Specialized psychosocial care should be targeted to those 20% or so of patients who are at risk of experiencing significant emotional problems. This group needs to be identified early during the infertility treatment so that they can be referred for specialized psychosocial care to a qualified mental health practitioner.

The evidence indicates that providing routine psychosocial care can positively affect many patient outcomes, reduce emotional distress and increase compliance with treatment, decrease concerns about medical procedures, change lifestyle behaviors (i.e., nutrition, exercise), improve fertility knowledge, and improve well-being. This can enhance the treatment outcome.

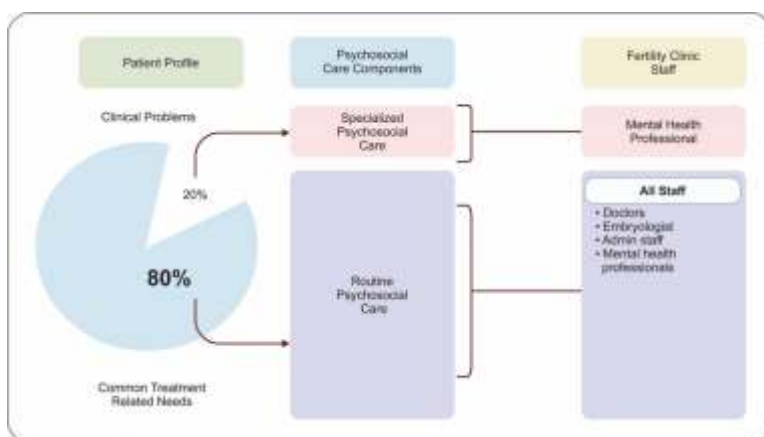


Fig. 1: Schematic representation of the clinical profile of infertility patients, the corresponding psychosocial care needs, and the staff who can address the psychological needs of the patient (ESHRE 2015)

Routine Psychosocial Care

Routine psychosocial care is a client-centred approach intended to address the changing needs of patients across different stages of fertility treatment. The four needs of the patient have been described. This differentiation addresses the WHO definition of health as holistic and multidimensional

Cognitive Needs: The patient's need to know and understand the various facets of infertility diagnosis and management to clear the doubts and concerns, to be meaningfully engaged in shared decision-making processes. This enables the patient to make informed choices and be prepared for possible unfavourable outcomes as and when they arise.

Emotional Needs: There is a need to identify and address depression, anxiety, psychopathology, and general well-being. Unresolved emotional distress is a major contributor to drop-out as well as litigations against the medical team. The coping methods used by the couple determine how they face the challenge of infertility diagnosis or treatment.

Relational and Social Needs: The relational needs refer to marital/relationship satisfaction, relational stress, sexual relationship and differing views of the partners on the need to have a child. It also includes social concerns such as sensitivity to comments, reminders of infertility, feelings of social isolation, and alienation from family, peers, and the occupation or work

Behavioral Needs: The lifestyle affects both general as well as reproductive health. Patients may need support for their weight loss program or to modify other lifestyle risk factors such as unhealthy diet, irregular sleeping-waking cycles etc. Compliance with treatment protocols is also a behaviour which can impact the treatment outcome. Hence, there is also a need to understand and address the reasons for poor compliance with the treatment protocols.

Evidence suggests that the needs of patients (behavioural, relational social, emotional and cognitive) change during the different phases of treatment, that is, before, during, and after treatments. It has been stated that if the staff are aware of the most common needs that patients experience at different stages, then implementing routine procedures to address these needs can maximize the impact of psychosocial care for patients.

Identifying and Addressing Patient Needs at Different Stages of Treatment

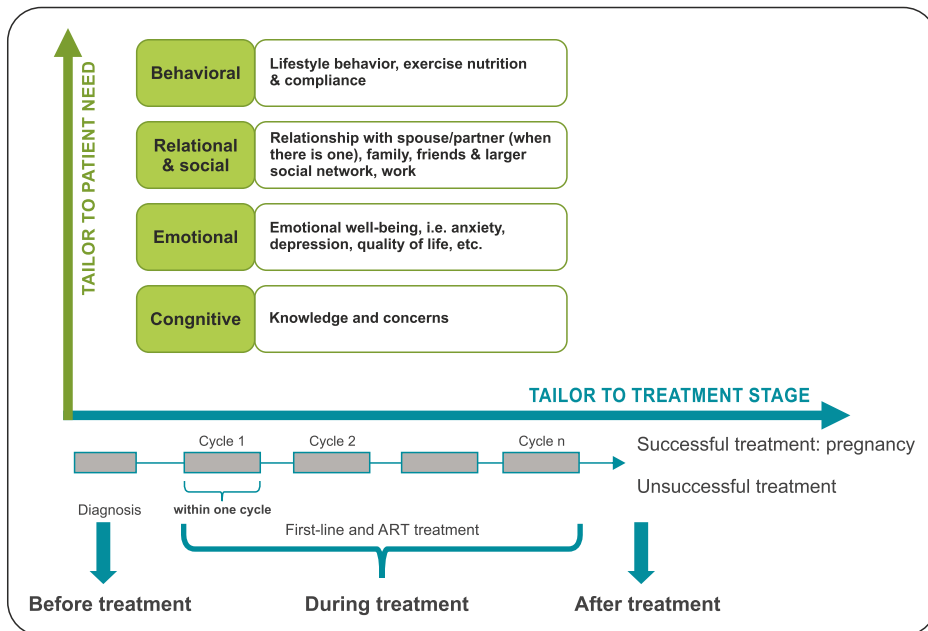


Fig. 2: Schematic representation of the guideline approach for the provision of psychosocial care tailored to specific treatment stages and patient needs (ESHRE 2015)

The Psychosocial Care Before Starting Art Treatment

Cognitive Needs

The most important need of the patient at the beginning is to understand what is going to happen, what lies ahead in the treatment processes. Knowing what is to come, helps to allay emotional distress associated with uncertainty.

Addressing cognitive needs

Providing information tailored specifically to the patient's diagnosis and management is one of the most important components of routine psychosocial care at each and every stage of the infertility treatment. Also, the manner of disseminating the information needs to be done according to the level of awareness and education of the couple. This can be kept in mind by the fertility staff, as it forms an important part of the psychosocial care at all stages of treatment.

1. The patients prefer written treatment-relevant information. They need explanations about treatment results and treatment options, understandable, customized and personally relevant. Written information in hand gives them time to read, understand, ask questions and clear doubts.
2. Verbal explanations and information is likely to be partially remembered and hence may create scope for confusion, doubt and later misgivings. The clinician, as well as other team members often use medical terms which are not understood by the patient.
3. It is important to obtain feedback from the couple about how much of the information they actually understood. It can be done by asking the patient to summarize and explain what all they understood, at various points. Doubts and misconceptions need to be addressed. This process also helps to build a sense of trust and rapport between the patient and the medical team..

There is a need to allocate specific duty to one or more team members to ensure that information is correctly understood. At times, the patient may be hesitant to ask questions or clear doubts from the consultant. The patients then go to other ancillary staff like receptionists, nurses on duty for clarifications who may not be able to give the full information relevant for a particular patient.

Emotional Needs

Before first-line or ART treatment, the women didn't have psychopathological symptoms or psychiatric disorders (Volgsten et.al.2008;2010;Zaig 2013). A systematic review of 25 years of research (Verhaak et.al. 2007) using different measures of depression reported that women starting IVF treatment are not more depressed than the general population. Evidence about anxiety (state and trait anxiety) is inconsistent (Lykeridou et.al.2009). These inconsistencies are related to cultural issues. The study on subjective well- being of 120 Indian infertile couples showed it was the same in infertile women as in normal women. However, men were significantly lower than normal on subjective well-being(Dhaliwal et.al. 2004). It may be that patients with strong pronatalist views, i.e. those cultures or societies advocating or supporting a high birth rate, show higher depression and / or anxiety and lower general being before the start of treatment (Kumbak et.al.2010).

Risk factors or predictors of high emotional distress (ESHRE 2015)

- Presence of pre-existing psychiatric illness increases vulnerability. This needs to be identified during case history taking right at the beginning of the infertility treatment.
- Women are more susceptible to emotional maladjustment than men. They experience higher levels of depression and infertility stress than men.
- Women whose partner has male factor infertility experience higher anxiety than women with female factor, mixed, or unexplained infertility. Type of infertility diagnosis is not related to depression
- Men also find infertility treatment stressful
- The use of passive, avoidant coping (e.g., rumination, withdrawal) is associated with poor adjustment. Active coping (e.g. goal-oriented problem-solving, thinking rationally about the problem) is a protective factor. This can be ascertained with help of psychological tests.
- Patients with a lower occupational status experience higher infertility stress and anxiety than patients with a medium or high occupational status.

Screening High Risk Cases

Patients with high distress need to be identified first and foremost at the very start with the help of psychological tests. The SCREEN IVF and FERTIQOL have been recommended for use by ESHRE 2015. It has been translated in many languages world over ;however,the Indian adaptation is yet to be developed. The patients obtaining scores on the psychological tests indicative of significantly elevated emotional distress, poor coping styles and /or presence of risk factors, need to be referred for specialised psychosocial care right at the outset so that they do not suffer adverse mental health consequences during the treatment cycle.

Relational and Social Needs

There are no indications of psychosexual problems at the start of the treatment. At the beginning, women starting first-line or ART treatments have the same marital satisfaction as in the general population (Verhaak et.al. 2005). This is seen from consensus i.e. playing equal roles in domestic and social decisions and cohesion i.e. the degree to which interests and experiences are shared. The prevalence of erectile dysfunction in males was as follows: 18% had mild, 4% had moderate erectile dysfunction (Shindel et.al. 2008). These were not higher than those observed in general population

Risk factors for increased relational stress are as follows:

- Couples who have different views on the importance of parenthood and social concerns show lower relationship satisfaction than those who have similar views. (Moura-Ramos et.al. 2016).
- Women report worse marital adjustment and relational stress than men. They experience higher social and sexual stress and concerns than men (Peterson et.al. 2007)
- Avoidant, emotion based or passive coping gives rise to greater fertility specific marital and social distress in the relationships as compared to meaning based, active coping.(Peterson et.al. 2008)

Addressing the relational and social needs

It is necessary to involve both partners in the diagnosis and treatment process right from the beginning. This facilitates the couple's management of treatment as a team by improving communication between the couple and medical staff. The differences in motivation for having children, differences in reaction to infertility and in coping styles need to be kept in view when dealing with the couple. Individual and couple counselling by mental health professionals may be necessary if there are major differences in viewpoints regarding these issues.

Within the Indian cultural context, the role of the extended family is very important. The couple must come to a consensus regarding how much information they want to share with the whole family, especially in cases requiring third party reproduction.

The provision of information about social support options e.g. contact details of support groups, online support options, access to infertility counselling, or psychotherapy has been found to be useful. (Gameiro et.al. 2012)

Behavioral Needs

Treatment Compliance

As per the international estimates, about one-tenth of patients planning for treatments discontinue during diagnosis, before starting treatment. Dropout occurred also while on waitlist to start ART. Research on treatment compliance, shows that only about 55% of people seek fertility treatment and of those that do, 22% discontinue IVF treatment before completing a course of recommended treatment. Patients refer to specific psychological needs not being met as important reasons for having discontinued treatment prematurely. (Gameiro et.al. 2012)

Treatment compliance is improved by providing personally relevant treatment information. Studies have shown that providing information leaflet explaining what would happen during appointment, content and sequence of components of fertility workup, detailed description of the medical examinations, reassurance regarding procedures, description of sperm sample preparation improved compliance significantly more than those not receiving the information (Pook et.al. 2005)

Lifestyle Behaviours:

A significant proportion of patients have lifestyle behaviours that are not optimal for conception i.e. smoking, alcohol use, excessive exercise, unhealthy diet affecting BMI, use of anabolic steroids (Schilling et.al. 2012). These lifestyle behaviours negatively affect their general and reproductive health.

Addressing lifestyle risk

- Infertile women coming for treatment are not well informed about the detrimental effect of lifestyle risk factors. Providing patients with information about unhealthy lifestyle behaviours. They need to be made aware of the importance of health optimization before and during pregnancy, infectious disease screening, risks of smoking, recreational drug abuse.
- Fertility treatment can start with preconception care. We have unique access to patients in the preconception period. RCTs show that even short interventions work. Weight loss programs offered pre-ART can be effective in reducing weight and BMI (Moran et.al. 2011), however their impact on live birth rates needs to be ascertained due to low quality of existing research, which remains inconclusive (Boedt et.al. 2021)

Psychosocial Care Of The Patient During The Treatment

The treatment period refers to the time when the treatment is started. It includes ovarian stimulation, oocyte retrieval, embryo transfer, the waiting period until the first measurement of pregnancy outcome and reactions to treatment outcome.

The couple's distress i.e. depression, anxiety, stress, negative affect i.e. anger, tension, grief begins to increase during IVF/ICSI cycle (Verhaak et.al. 2010). Patients' experience high emotional distress when they are informed that the treatment was unsuccessful. After treatment failure, 10- 20% women experience clinically significant levels of depressive symptoms. There is a marked increase in psychiatric disorders; 10-25% women and 10% men have a depressive disorder and about 14% women and 5% men have an anxiety disorder. This is much higher than global norms (WHO, 2017) of anxiety disorders (i.e. 4.6% in females and 2.6% in males) and depression (i.e. 5.1% in females and 3.6% in males); thus there is three to fourfold increase in women and men who develop common mental disorders like anxiety and depressive disorders. It highlights the urgent need as well as the ethical responsibility of the infertility team, to mitigate the negative impact of infertility treatment especially failed treatment which will be inevitable in 60-70% cases.

Social and Relational Needs

In a dyad, the way one partner reacts to the subfertility condition/diagnosis is associated with how the other partner reacts; each partner's depressive symptoms are associated with their own and their partner's infertility-specific distress. (Peterson et.al. 2014)

Addressing social and relational needs

The two partners can have varying attitudes towards childlessness and conflicting opinions on how infertility influences their relationship and sexual life (Lalos et.al. 1999). It is not always that the couple receives the information as a unit; one needs to deal with two separate individuals with different reactions and behaviour. Thus, there is a need for individual supportive counselling parallel to the psychological treatment of the couple. In order to manage the relational stress, there is a need to address decision conflict and encourage active participation in decision making, helping the couple to identify alternatives and new life perspectives.

Patients may need help in dealing with strains on the relationship related to subfertility or its treatment through support for grief work. The marital and or individual counselling may be carried out by the mental health professional if the distress is high as reflected in psychological tests and clinical observations.

Cognitive Needs

The patient's biggest concern is achieving desired results, which remains high from beginning of treatment to ET stage. Other concerns regarding side effects of hormones, finances, undergoing surgery, work related concerns decreased as the treatment progresses. There is persistent preoccupation and obsessive rumination about a possible pregnancy or lack of it. These ideations are related to infertility-specific distress in women, after controlling for depression and anxiety. The uncertainty leads to worry as various possible outcomes are considered. Although the objective probability of achieving pregnancy during IVF is low, women may disregard or downplay factual information about IVF pregnancy rates and hold beliefs such as having embryo transfer on a 'lucky' day, or on optimistic feedback from medical staff (Boivin et.al. 2010). Their expectations may therefore be more optimistic or pessimistic than actual probabilities.

The couple also need to decide whether to continue in the treatment after failure of one cycle, how many cycles to try, when to end the treatment and turn to adoption, surrogacy. Other difficult decisions during treatment include multifetal pregnancy reduction, embryo disposition and single Vs multiple embryo transfer.

Addressing cognitive needs

It is necessary to give patients the opportunity to discuss and clarify their treatment related concerns such as uptake or not of recommended treatment by the process of shared decision making. In shared decision making, physicians and patients take decisions together using the best available evidence. Patients are helped to make informed choices by considering the options, and the likely benefits and disadvantages of each option.

However, the way the clinician provides information may strongly affect people's preferences, prompting the need for standardized information to be used as patient decision aids. (International Patient Decision Aids Standards (IPDAS) (Stacy et.al, 2021) Many decision aids are based on a conceptual model or theoretical framework. Patient decision aids supplement, rather than replace, clinicians' counselling about options. The decision aids describe the options in enough detail that the couple can imagine what it is like to experience the physical, emotional, and social effects, or they guide them to consider which benefits and harms are most important to them. They have been used in helping patients make decisions about single vs double embryo transfer and in the cases of fertility preservation. (Stacey et.al. 2017)

The decision aids are different from health education materials which help couples to understand the diagnosis, treatment, and management in general terms. Educational materials are not focused on decision points which occur during the treatment hence the educational material do not help patients to participate in decision making. The latest foci of research are on developing decision support tools to help patients deliberate their choices, and to have less decisional regret.

Emotional Needs

The women have consistently reported heightened anxiety during following points in the treatment i.e.

1. Before any invasive procedure
2. At the time of Oocyte pickup
3. Embryo transfer
4. Waiting period
5. Breaking bad news.

Addressing emotional needs

There are several meta-analyses of psychological interventions. The psychotherapeutic approach with emphasis on emotional expression and support and/or discussion about thoughts and feelings related to infertility are comparatively less effective. The body of effectiveness research showed that the most effective interventions are group interventions that focus on education and skills training e.g., relaxation training, mindfulness, selfregulation with help of Yoga based techniques and developing coping skills. Hence, it is recommended to focus on specific needs which have been clearly and consistently identified. There is a need to develop a protocol for the five clearly demarcated points of exacerbated distress listed above. (ESHRE, 2015)

Many women undergoing IVF procedures are employed (Landcastle et al 2008) extra attendance at clinics for counselling is inconvenient. Also, such interventions are of doubtful efficacy. Delivered by trained professionals, the financial costs are also there. As a consequence, only 10– 15% of infertile patients used the counselling provided (Boivin et.al. 1999). Moreover, there is typically no requirement to attend a clinic for medical procedures or tests during the waiting period. The sources of informal expert support (e.g. patients undergoing the same procedures and medical staff) are not as easily available as they were at earlier stages of the IVF treatment cycle. Due to these practical issues, a home-based intervention which women can use without supervision is needed for the IVF waiting period.

Some Therapeutic Methods Which May Be Used During The Treatment Cycle:

The following can be taught to women during the treatment, so that they can continue the practice on their own during the days when they do not visit the infertility clinic (Stanton et.al.1999)

1. Relaxation Techniques

There are a wide variety of relaxation techniques that have been useful in inducing the relaxation response. This inhibits the negative physiological responses to stress (e.g., increased heart rate, blood pressure, respiratory rate, and muscle tension). Relaxation techniques include diaphragmatic breathing; progressive muscle relaxation (PMR); autogenic relaxation training; imagery (e.g., guided imagery and covert sensitization); meditation, chanting, biofeedback; systematic desensitization. Whether relaxation training is a specific goal of psychotherapy or a patient 'homework' assignment, men and women were found to benefit equally. (Dumbala et.al.2020)

2. Positive Reappraisal Coping Strategy

One meaning-based coping strategy that is easy to learn is positive reappraisal coping, which is based on cognitive efforts or as cognitive manoeuvre to redefine the experience that changes the meaning of the situation. Positive reappraisal coping involves effortful derivation of benefit from a difficult situation, individuals start focussing on the positive aspects of a situation rather than ruminating distressing and negative aspects. Such efforts in the IVF context may involve focusing on the fact that a partner is especially loving and supportive and the most advanced fertility treatment is being used. The positive reappraisal strategies are associated with increased positive affect and sustained ability to cope in unpredictable and uncontrollable stressor situations. It has beneficial effects in difficult health-related circumstances such as the failed fertility treatment (Landcastle et.al. 2008)

Following items are part of the Positive Reappraisal Coping Inventory (Ockhuijese 2014). It is a small convenient pocket-sized card containing statements to promote positive reappraisal coping efforts. It is easy to use and can be used whenever patients feel the need. It is costeffective and can be freely available to all patients. It is generic enough to be used by any patient waiting for the results of medical tests and procedures. Patients are asked to read these daily, at least twice a day. To illustrate, some of the items from Positive Reappraisal Coping Inventory (PRCI) are given below:

During this experience I will:

- Try something that makes me feel positive
- Focus on the positive aspects of the complex circumstances
- Highlight something good in what is happening
- Make the best of the situation with positivity
- Try something meaningful and productive
- Focus on the benefits and not just the difficulties

Breaking Bad News

In the ART context bad news is a frequent occurrence: the infertility diagnosis, the repeated failures in the treatment, low rates of success and the clinical ineffectiveness of medical treatments are all bad news that professionals need to communicate. From the couple's point of view, involuntary childlessness is not a question of once receiving bad news but repeatedly receiving bad news during the infertility investigation and treatment. Clinicians are usually not prepared to manage this kind of communication, as literature on assisted reproductive technology (ART) lacks specific guidelines for breaking bad news. (Neighbour, 2005)

Consequences of bad communication between patients and healthcare professionals include patients' poor satisfaction with care, lower treatment compliance, reduced quality of care, physician burn-out and increased medico-legal litigation. Since the supreme court brought the patient–doctor relationship and medical treatment under the ambit of consumer protection act in 1995, number of medico legal cases have increased in India

A variety of reactions can occur in the patient. These symptoms follow the pattern observed in a crisis situation, in which four main phases have been identified: 1. shock (e.g. denial), 2. reaction (e.g. anger, depression), 3. adaptation (e.g. acceptance) and 4. resolution (planning of solution).

However, the crisis of infertility differs from that of a general traumatic crisis, in which the duration of the reactive phase is usually 6 weeks. New events, new hopes and new forms of bad news prevent the adaptation to and resolution of the previous trauma, e.g. an ectopic pregnancy, a miscarriage or an acute laparotomy. As a consequence, there can be a state of prolonged chronic crisis during infertility treatment. This is further exacerbated due to the tendency of infertile

couples to be isolated with their problems and experiences; they vacillate between hope and despair around the menstrual period perhaps until menopause.

Needless to say, this is a very important area of infertility counselling which needs the intervention of the mental health professional

Psychosocial Care Of Patients After Treatment

Successful treatment: Pregnancy

When the mother's own egg and father's self-sperm are used in IVF the parents have both a genetic and gestational link to the child in the same way as parents of naturally conceived children. The women have similar self-esteem and mental health to women who conceive spontaneously. The way they relate to their fetus is similar whether the fetus is conceived with ART treatment or spontaneously. Hence, they require routine antenatal care. However, women who experienced multiple failed ART cycles or high stress during treatment may be more likely to experience pregnancy specific anxiety during pregnancy. They may need extra psychosocial support during pregnancy.

Unsuccessful Treatment

It's difficult for the patients to decide when to stop seeking treatment. Frequently one partner wants to end treatment before another. Acceptance of childlessness is hampered by denial or the persistent hope for a miracle (Edelmann et.al. 2000)

The treatment failure and subsequent inability to accept non-biological parenthood have long term consequences. Patients who remain childless 5 years after unsuccessful IVF/ICSI treatment may use more sleeping pills, smoke more often, and consume more alcohol than former patients that become parents via adoption, or spontaneously. They are three times more likely to separate than patients that become parents via adoption, or spontaneously. Women with a persistent desire for pregnancy 3 to 5 years after unsuccessful treatment may experience more anxiety and depression than women who find new life goals or women who become mothers. Long term studies show that those couples who are able to get a child through adoption or otherwise are able to adjust back. Those who remain childless but are able to find alternate meaningful life goals also remain normal. (ESHRE 2015)

The ability to disengage from the goal of biological parenthood is critical to long-term wellbeing rather than the specific absence of a child. Counselling or specialized care by a mental health professional is necessary. The transition from

wanting biological children to accepting non –biological parenthood or coming to terms with being childless is possible with help from mental health professional. It is very important to offer patients the opportunity to discuss the implications of ending unsuccessful treatment. They need to redefine the success of infertility treatment. The couples are enabled to see their childlessness from another perspective. They redefine it as a child free state where they are free to pursue other goals. This allows them to reshape their lives and achieve life satisfaction.

Implication counseling in third party reproduction

Many patients achieve parenthood through adoption, surrogacy, donor gametes or embryos. Even after the birth of the baby, they continue to think about how the child was conceived (Mahlstedt et.al. 1989). A growing number of children are being born by the donation of sperm, eggs or embryos, resulting in the absence of a genetic link with the mother or father or both. In surrogacy there is an absence of gestational link with women. The absence of a genetic and/or gestational connection between one or both parents and the child and the secrecy about the child's biological origin affects the parent/ child bond and subsequently the welfare of the child (Richards et.al. 2012). Other family types in which social parenthood is dissociated from biological parenthood are adoptive families in which both parents are biologically unrelated to the child. It is an important aspect of infertility counseling which requires the presence of a mental health professional and the in-depth psychological exploration of the couple to ensure that they understand the implications of having such a child. There is a need to redefine the concept of parenthood.

Summary

1. The treatment for infertility requires ongoing psychosocial care. Majority i.e. 80% couples can be managed by routine psychosocial care. Patients have clear preferences about the psychosocial care they want. The staff should be aware of these preferences and consider addressing them. These include a sensitive, empathetic staff, who are aware of the emotional impact of infertility. The couple needs to be involved in decision making right from the beginning. The clinic environment with professional competence, continuity of care, ability to connect with other patients and physical comfort is important. Cross-sectional research showed that the different staff and clinic characteristics that patients value are indeed associated with higher emotional wellbeing.
2. The patients value information, especially written customized information about treatment options and explanations of results, as well as available psychosocial support options. Information provision, in particular the provision of preparatory information, decreases patient infertility-specific anxiety and stress. In addition, tailored psycho-educational interventions also improve the emotional well-being of patients, especially when they are highly distressed during specific points in the course of treatment. Pre-treatment preparation with stress management techniques like yoga, relaxation, and positive reappraisal coping is simple, easy to learn by the patient and can be administered in groups.
3. Some patients are more vulnerable than others to demands of treatment. They need to be identified early so that appropriate psychosocial support with the help of a mental health practitioner can be given.
4. The needs of patients vary across treatment stages and therefore psychosocial support should be provided accordingly. Before treatment, patients' needs are related to behaviours that do not optimize their chances of pregnancy, namely non-compliance with recommended treatment and unhealthy lifestyle behaviour. Pre-treatment programs to improve lifestyle have been found beneficial for enhancing general as well as reproductive health. During treatment, patients have multiple needs. At the behavioural level, 1 in 5 patients do not comply with recommended treatment. At the relational level, women may lack adequate support from significant others and are absent from work due to treatment. Emotional and cognitive needs are related to the uncertainty about the outcome of treatment, and tend to

peak just before the oocyte retrieval, embryo transfer, and the pregnancy test. The escalating distress during the treatment can be addressed using skill based, psycho-educational self-help stress reduction programs which can be taught as part of routine psychosocial care and practiced by women at home. Ability to regulate and manage stress with help of relaxation, yoga, and positive appraisal helps them throughout the treatment cycles. The use of decision aids and shared decision making processes helps in educating and improving awareness of the couple regarding various treatment options. Finally, patients experience intense distress when treatment is unsuccessful. Protocols have been suggested for breaking bad news.

5. After treatment, infertile patients who achieve successful pregnancy do not differ from couples who conceived spontaneously. The women who had experienced repeated treatment failure are more anxious about their pregnancy and need psychosocial care and support during this phase also. The women who experienced unsuccessful fertility treatment and remained childless after treatment present worse emotional well-being than women with children. They need specialized psychosocial care to accept non-biological parenthood or redefine their life goals without children. Otherwise they are at risk of psychological disorders, maladjustment and impaired quality of life, long after the treatment has ended.
6. The options of use of donor gamete, or donor embryo surrogacy are all challenging decisions. They need to be well thought out with implications for the future of the child, its effect on the family and the donor. The counsellor and the psychosocial support becomes an essential part of the treatment process. Hence it is of utmost importance to prepare the couple for the end, right from the beginning

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3. Tabular Summary of Recommendations

4.1 What is the Psychosocial Impact of Subfertility and ART on the Patients?

4.1.1 What is the psychosocial impact of subfertility and ART on women?

RECOMMENDATIONS The fertility care team should be aware that:	GRADE
<ul style="list-style-type: none"> There is a significant association between subfertility, psychological distress and depression. 	A
<ul style="list-style-type: none"> Women with female factor infertility show a significantly higher prevalence of anxiety, although the association of subfertility with anxiety is inconsistent. 	A
<ul style="list-style-type: none"> Before ovum pick up, and embryo Transfer and in the subsequent waiting period, there is a marked increase in anxiety. 	A
<ul style="list-style-type: none"> Threat to self-esteem, identity and purpose, deterioration of the couple and weakened support network is experienced by women. 	C

4. Key Questions and Recommendations

4.1.2 What is the psychosocial impact of subfertility and ART on men?

RECOMMENDATIONS The fertility care team should be aware that:	GRADE
<ul style="list-style-type: none"> Men also experience either depression or anxiety or both during infertility 	C
<ul style="list-style-type: none"> Men also experience adverse psychosocial effects if unsuccessful ART occurs during the first year. which subsequently, decreases after 2-5 years. 	C
<ul style="list-style-type: none"> The diagnosis male factor infertility is accompanied by lowered selfesteem, socially avoidant behaviour and negative dyadic coping which decreases if the sperm is detected in testicular aspiration. 	C
<ul style="list-style-type: none"> The new onset of erectile dysfunction, reduced intercourse satisfaction, and orgasmic function may occur after unsuccessful TESE. 	C
<ul style="list-style-type: none"> The fertility care staff should be aware of the fact that men value information regarding the treatment, possible outcomes, success rates, complications, and recovery, a clear, long-term treatment plan, with alternatives, such as donor sperm or adoption. 	C
<ul style="list-style-type: none"> The men in fertility settings feel marginalized and need direct communication and support from the clinicians, highlighting their need for inclusion and involvement in fertility treatment. 	C

4.1.3 What are the differences in the response of men and women to subfertility and ART?

RECOMMENDATIONS The fertility care team should be aware that:	GRADE
<ul style="list-style-type: none"> Although both women and men suffer from significantly raised levels of either depression or anxiety or both, the levels in women are much higher, with a poorer quality of life than men. 	B
<ul style="list-style-type: none"> In women, anxiety levels increased before oocyte retrieval, embryo transfer, and the waiting period for a pregnancy test, but men experience increase in depression before treatment 	C
<ul style="list-style-type: none"> Both men and women undergoing fertility treatment experience relationship and sexual concerns, which have the strongest connections to depression and suicidal ideation. 	C
<ul style="list-style-type: none"> The adverse effects of unsuccessful ART is more intense and prolonged in women than men. 	C

4.1.4 What is the impact of subfertility and ART on sexual function in couples?

RECOMMENDATIONS The fertility care team should be aware that:	GRADE
<ul style="list-style-type: none"> The psychosocial strain of subfertility and ART can induce, worsen or maintain sexual disturbances and disorders in both partners. 	A
<ul style="list-style-type: none"> Identifying sexual disorders during the entire course of diagnosis and treatment is necessary for the psychosocial well-being of the couple. 	GPP

4.2. What are the Psycho-social Causes of Distress in Fertility Care?

RECOMMENDATIONS The fertility care team should be aware that:	GRADE
<ul style="list-style-type: none"> Unemployed, uneducated and older women have a higher risk of psychosocial distress. 	C
<ul style="list-style-type: none"> Patients with prolonged duration of sub-infertility, repeated fertility treatments and miscarriage are at higher risk of psychosocial stress and may need specialised care. 	B
<ul style="list-style-type: none"> Positive attitude, optimism, and resilience protect the couple against anxiety. 	C
<ul style="list-style-type: none"> Encouraging the partners to work together as a team can be a valuable resource to moderate the stress of subfertility and ART 	C
<ul style="list-style-type: none"> Fertility care staff should be aware that the better the belief of the couple in the ability to control events, the more use they make of adaptive coping, the less are the anxiety and depressive symptoms. 	C

4.3. How can Fertility Care Teams Do Risk Prediction and Psychosocial Assessment?

4.3.1 What tests can screen out couples at risk for significant psychological distress?

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> The PGI Health Questionnaire N2 can be a generic measure for screening out couples with high distress. 	GPP
<ul style="list-style-type: none"> PGI Well-being scale can be used as a generic measure of overall well-being. 	GPP
<ul style="list-style-type: none"> The fertility specific tests like SCREEN IVF, FERTIQOL must be translated and standardised for the Indian patient 	GPP

4.3.2 How can fertility counsellors make a comprehensive assessment of high risk cases during ART?

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> Fertility counsellors can use the in-depth interview schedule as well as one or more of the available psychological tools for indepth assessment. 	GPP

4.4. What are the Changing Psychosocial Needs of the Couple During ART?

4.4.1 What are the psychosocial needs of the patient before starting treatment?

RECOMMENDATIONS The fertility care team should be aware that:	GRADE
<ul style="list-style-type: none"> There is a need to provide personalised information about the treatment processes, prognosis, side effects of medications, stress, lifestyle and address concerns of the couple. 	A
<ul style="list-style-type: none"> There is a need to give information about lifestyle behaviours that negatively affect reproductive health and support patients in changing them. 	A
<ul style="list-style-type: none"> It is recommended to involve both partners in the diagnosis and treatment process. 	A
<ul style="list-style-type: none"> There is a need to identify at-risk couples (risk factors and screening) and refer them to specialised psychosocial care. 	A

4.4.2 What are the psychosocial needs of a couple during treatment?

RECOMMENDATIONS The fertility care team should be aware that:	GRADE
<ul style="list-style-type: none"> There is a need for psychosocial care during the five clearly demarcated points of exacerbated distress during treatment, i.e. before any invasive procedure; at the time of oocyte pickup; embryo transfer; during the waiting period; before the outcome of ART procedures and after receiving bad news. 	A
<ul style="list-style-type: none"> The high-risk cases identified during the earlier stage, i.e. before treatment and new cases showing a significant increase in psychosocial distress levels need referral to specialised psychosocial care for individual and /or couple counselling 	A

4.4.3 What are the psychosocial needs of patients after unsuccessful treatment?

RECOMMENDATIONS The fertility care team should be aware that:	GRADE
<ul style="list-style-type: none"> There is a need to provide special psychosocial care to those who end the treatment but are unable to give up the wish to be a parent. 	B
<ul style="list-style-type: none"> Special psychosocial care is needed for couples with treatment failures who are not ready to accept the end of treatment or adopt. 	B
<ul style="list-style-type: none"> The men need to be specifically counselled and given psychosocial support in the form of informative discussions leading to acceptance and inclusion of coping skill mechanisms when treatment fails. 	GPP
<ul style="list-style-type: none"> There should be specialised psychosocial care tailored to the needs of pre-adoptive couples, focusing on coping skills, decision-making support, and emotional processing. 	GPP

4.4.4 What are the psychosocial needs of patients after successful treatment?

RECOMMENDATIONS The fertility care team should be aware that:	GRADE
<ul style="list-style-type: none"> Psychosocial care should be ongoing in couples with ART pregnancy to address their concerns. 	GPP
<ul style="list-style-type: none"> Couples with ART pregnancy, and more so twin pregnancy, are more prone to anxiety and depression with higher chances of postpartum depression not resolving with time 	GPP
<ul style="list-style-type: none"> Women should be continuously supported in the postpartum period in ART pregnancies, more so with multiple pregnancy 	GPP

4.5 What Causes the Patient to Drop Out from the Treatment?

RECOMMENDATIONS The fertility care team should be aware that the couple may drop out from ART due to:	GRADE
<ul style="list-style-type: none"> • Psychosocial care should be ongoing in couples with ART pregnancy to address their concerns. • Financial reasons like inability to pay out of pocket and depletion of financial resources. • Lack of social support, communication breakdown or noncooperation of spouse in treatment. • Factors related to treatment like insufficient response to stimulation, poor prognosis, unsuccessful treatment cycle, and unacceptable treatment options. • Factors related to the clinic, like lack of organised and continuous care, and absence of facilities. • Factors related to pregnancy, like biochemical pregnancy, missed abortion, ectopic pregnancy and spontaneous pregnancy. 	<p>C</p>

4.6. What is the Role of the Fertility Care Team in Delivering Psychosocial Care to Couples?

4.6.1 Which psychosocial care components can be delivered routinely and continuously by the entire fertility team from the start to the endpoint of the fertility treatment?

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> The fertility care staff must be aware that a client-centred approach with sensitivity, respectful communication and empathy are important for the couple's well-being. 	A
<ul style="list-style-type: none"> The fertility care staff must be aware that the couple values the individualised treatment-specific information, which is shared in a continuous manner. 	A
<ul style="list-style-type: none"> The fertility care staff must be aware that the couple value both partners being involved in the treatment and decision-making process. 	C
<ul style="list-style-type: none"> The fertility care staff must be aware that the couple's well-being is linked to satisfaction with care and better compliance, resulting in improved ART outcomes. 	C
<ul style="list-style-type: none"> It is recommended that fertility staff be trained to detect high-risk individuals right at the beginning of treatment as well as during the phases of treatment. 	GPP

4.6.2 How can fertility staff address the needs of patients during treatment?

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> It is recommended that psychosocial interventions should be offered to couples undergoing fertility treatment. 	A
<ul style="list-style-type: none"> Cognitive Behavioural Therapy (CBT) can be recommended as a psychological intervention in women undergoing ART 	A
<ul style="list-style-type: none"> It is recommended that Acceptance and Commitment Therapy (ACT) be offered to couples undergoing fertility treatment to improve psychological wellbeing. 	B
<ul style="list-style-type: none"> Mind Body Therapy (MBT) can be recommended as a psychological intervention in women undergoing IVF 	A
<ul style="list-style-type: none"> It is recommended that the fertility care team must integrate the Mindfulness-Based Program, including meditation, into standard treatment protocols for couples facing infertility to help deal with infertility-related stress considering that no adverse effect of this therapy has been found. 	A
<ul style="list-style-type: none"> It is recommended that the fertility care team should utilize a group format for MBPI sessions, allowing participants to share experiences. 	B
<ul style="list-style-type: none"> It is recommended that the fertility care team must advise patients to incorporate yoga into fertility treatment plans, before and during treatment, to alleviate stress, anxiety, or depression related to ART treatment and potentially lead to increased treatment success. 	A
<ul style="list-style-type: none"> It is recommended that yoga must be used as an adjunct in the management of male infertility. 	A

4.6.3 How can fertility staff address the needs of patients after unsuccessful treatment?

RECOMMENDATIONS The fertility care team should be aware that:	GRADE
<ul style="list-style-type: none"> • Short-term and long-term psychosocial care is recommended for couples with unsuccessful treatment. 	A
<ul style="list-style-type: none"> • The concept ‘SPIKES’ should be used to manage imparting bad news in fertility care 	B
<ul style="list-style-type: none"> • Couples who make decisions both to leave treatment or continue after an unsuccessful cycle need referral for special psychosocial care 	A
<ul style="list-style-type: none"> • Follow-up with psychosocial support beyond one year is recommended in couples who have had an unsuccessful cycle, specialised grief counselling being directed at helping individuals relinquish their parenthood goals. 	B
<ul style="list-style-type: none"> • Acceptance, making meaning and pursuing alternative goals should be the target when giving psychotherapeutic guidance for long-term management of the couples after unsuccessful treatment 	B
<ul style="list-style-type: none"> • Specialized psychosocial care is needed for couples with unsuccessful treatment who are planning adoption, focusing on coping skills, decisionmaking support, and emotional processing. 	B
<ul style="list-style-type: none"> • Men should be specifically counselled and given psychosocial support in the form of informative discussions leading to acceptance and inclusion of coping skill mechanisms when treatment fails. 	B

4.6.4. How can healthcare staff address the needs of patients after successful treatment?

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> It is recommended that prenatal yoga-based techniques (YBT) be part of routine care as these have an effect on reducing anxiety, depression, and perceived stress and increasing normal vaginal birth with a shorter duration of labour. 	A
<ul style="list-style-type: none"> It is recommended to implement prenatal interventions such as cognitive defusion, generative meditation, mindfulness, positive affirmations, visualisations, and emotional bonding, which enhances the psychological well-being of the mother, birth outcomes and child development 	C

4.7 How can the Fertility Care Team Provide Psychosocial Care for Couples Undertaking Third Party Reproduction?

4.7.1 What is the psychosocial stress of third-party reproduction in a couple undergoing ART?

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> Fertility care staff should be aware that specialised psychosocial care is needed during the process of treatment with donated oocytes, as the experiences of distressing psychologic symptoms, social stigmatisation, and negative coping mechanisms in recipient women, such as denial of pregnancy and complexity may follow it. 	C
<ul style="list-style-type: none"> Fertility care staff should be aware that specialised psychosocial care is needed as surrogacy may present moral, ethical, legal, cultural, religious, socioeconomic, and psychological concerns, due to the inability to reconcile the split between surrogacy as a compassionate act or a transactional business. 	C

4.7.2 How can fertility staff address the needs of couples undertaking Third party reproduction?

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> It is recommended that fertility care staff should impart appropriate pretreatment counselling for third-party reproduction with the aim of maintaining the psychological and emotional well-being of all parties involved. 	A
<ul style="list-style-type: none"> It is recommended that all couples undertaking third-party reproduction (donor gametes) and surrogacy to have Counselling sessions with mental health professionals so that they can make an informed decision about acceptance of non-biological parenthood. 	GPP
<ul style="list-style-type: none"> The health care worker must stress commitment to contract to the donor and the recipient of the gamete. 	GPP

4.8. What are the Special Cases of Couples Undergoing ART?

4.8.1. How is counselling for single women seeking motherhood through ART different?

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> Fertility staff should offer pre-treatment counselling on various aspects like ART with donor sperm, implications for pregnancy care, child raising, and financial and legal long-term consequences to all women wanting to become solo mothers to help them to make informed decisions before embarking on fertility treatment. 	GPP
<ul style="list-style-type: none"> Mental health professionals should carefully assess the mental health status of single women to ensure that it is not an emotional and ambivalent decision. 	C

4.8.2 What is the Counselling for couples with gender preference undergoing ART?

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> Counselling by healthcare staff should be consistently and continuously gender-neutral throughout the treatment cycle, stressing the need for delivery of healthy children without any gender preference. All fertility Staff must reinforce the same concept to the couple who desire to have a boy. All staff must be aware of the laws which prohibit sex determination. The Preconception and Prenatal Diagnostic Techniques (Prohibition of Sex Determination) Act (PC-PNDT) which prohibits sex determination. The couple needs to be well informed about the same and the reason for making the law. 	GPP

Key Questions 4.1

- 4.1 What is the psychosocial impact of subfertility and ART on the couples?**
 - 4.1.1 What is the psychosocial impact of subfertility and ART on women?
 - 4.1.2 What is the psychosocial impact of subfertility and ART on men?
 - 4.1.3 What are the differences in response of men and women to subfertility and ART
 - 4.1.4 What is the impact of subfertility and ART on sexual function in couples?

Introduction

Both the conditions— the subfertility and its treatment—cause stress. It is associated with psychological disturbances. The stress of subfertility and its treatment with ART has been ranked second to the bereavement or loss by the death or divorce of a family member. Patients undergoing ART are at risk of developing psychiatric disorders. (Aimagambetova et al., 2020; Gabnai-Nagy et al., 2020)

It is now well established that subfertility and ART affect one's psychological state in a very profound manner (Wright et al., 1989; Greil, 1997; Dube et. al., 2022). It can become the central focus for identity, especially for women. Being unable to conceive is accompanied by feelings of loss of control, helplessness and depression. The self-perception of being defective, with a reduced competence, status-less and ambiguous, the women question their worth and lose self-esteem. They blame themselves and feel shame. The social stigma, and alienation from family and friends with children may lead the couple to avoid social gatherings as they see their friends progress on to parenthood. Due to the preoccupation and concerns regarding the medical procedures, expenses, possible causes of infertility, the patient's focus may move away from the positive, satisfying engagements with life. the couple may experience an existential crisis of sorts. The stress can impact the marital and sexual relations; with some couples, there may be a deterioration of the couple; nevertheless others become more connected, improve their relationship and emerge stronger. Hence, although the experience of infertility and ART is a very challenging one, many people do navigate through it and remain well adjusted

Understanding these psychosocial effects may be the first fundamental step towards raising the awareness of the healthcare team towards the complexity of the inner narratives and lived experiences of couples undertaking ART. It can help the counsellors to make an individualised intervention plans to provide the appropriate psychosocial support of the couple. Earlier studies had mainly focused on the impact on women. The more recent researches have evidenced the effect on men, the dyadic relationship and the sexual relationship. The studies on the gender differences i.e. the response of men, women have been summarized.

4.1.1 What is the psychosocial impact of subfertility and ART on women ?

Evidence

ESHRE Guideline on Routine Psychosocial Care (2015) has summarized important findings on the changing psychosocial needs at the different stages of ART. The psychosocial needs i.e. the cognitive, emotional, relational and behavioral aspects, have been summarized. At the beginning, before starting ART, the couples show similar levels of anxiety, depression, and marital relations as the fertile couples. However, during treatment, there is a significant increase in anxiety before any invasive procedure i.e. ovum pick-up, embryo transfer and the two-week waiting period before getting the results. This is followed by intense grief when the results are negative. The unresolved grief may lead to dropping out. Repeated cycles and failures lead to clinically significant distress and mental health problems, which may persist long after the unsuccessful ART treatment is terminated.

Hazlina et al., (2022), in a systematic review with meta-analysis, evaluated psychological distress, depression and anxiety. A systematic search in MEDLINE (PubMed), CINAHL (EBSCOhost) and ScienceDirect. from the inception of these databases until 23.11. 2022, The quantitative synthesis by meta-analysis was done on 32 studies with low risk of bias involving a total of **124 556 women** were included. Data from different countries were involved i.e. Iran, Turkey, Italy, America, Sweden, the Netherlands, Finland, Africa, Saudi Arabia, Japan, China, Pakistan and Greece. Two studies from India were included also.

Four studies assessed **the distress caused by subfertility**. The pooled meta-regression analysis showed a statistical significance between subfertility and psychological distress among females with the odds being 1.63 (95% CI 1.24 to 2.13; $I^2=57\%$).

Eight studies were included to assess the association **between depression and subfertility** among females. Four studies showed significant associations, and four showed no significant associations. The pooled meta-regression analysis showed a statistical significance between depression and infertility among females, with the odds being 1.40 (95% CI 1.11, 1.75; $I^2=50\%$) compared with those fertile.

The association between **anxiety and subfertility** in the six studies with a pooled meta-regression analysis of OR of 1.68 (95% CI 0.71, 3.98; I² =98%) is not significant

Dube et al., 2021 conducted a cross-sectional , observational study on 35 women. The study sample included N= 21 women (aged 25–41 years) with a duration of subfertility of more than 12 months and N= 14 mental health professionals. Data is based on a qualitative approach using individual interviews and group interviews with focused questions with the sub-fertile women and also mental health professionals from the field of subfertility

Thematic analysis identified the patterns and themes from the qualitative data. Five themes, each divided into sub-themes, were developed into a model of infertility-related distress. This can provide useful insights for the counselling work.

1. Anxiety was an important feature , and reflected in anxious rumination, (Born et al., 2016; Donkor et al., 2017), narrowed focus on infertility to the exclusion of other activities, and an excessive information seeking.(Porter et.al. 2008 ; Slauson-Blevins et.al. 2013; Becker et.al. 1992)
2. Mood disturbances were there, as seen in the high rate of clinical depression (Chen et.al. 2004; Nelson et.al. 2008; Volgsten et.al 2008). The ART with uncertain outcomes lead to repeated experiences of emotional ups and downs (Becker et.al.1992), described as an 'emotional rollercoaster', as well as the feelings of emotional exhaustion and burnout, with a sense of loss of control (Berger et al., 2013; Born et al., 2018; 2016; Dierickx et al., 2018).
3. The women experienced the threat to self-esteem, identity and purpose with feelings of role loss or role failure. They developed a negative self-view, and they tended to blame themselves for their sub-fertility. (Becker et.al. 1992; Berger et .al., 2013; Born et. al., 2018 27)
4. The deterioration of the couple's relationship (Born et al., 2016; Dierickx et al., 2018; Donkor et al., 2017) was seen in the partners' differences in coping. Women took an active role and expressed their emotions more openly than the men. This led them to perceive their partners as less involved in the goal of conceiving. This had a negative effect on the couple's sex life.
5. Weakened social support systems (Berger et al., 2013; Dierickx et al., 2018) due to avoidance of social interactions and facing questions from family and friends. Struggles with their loved ones due to stigma and lack of education surrounding infertility led to social isolation

Focused psychotherapies targeting sub-fertility and ART-related distress need to look at the specific sub-themes described above.

Kiani et al. (2020) screened Persian and English studies published from the early 2000s to May 2019 in international (i.e., PubMed, the Cochrane Library, Web of Science, Scopus, Embase, and PsycINFO) and national (i.e., SID, Magiran) databases as well as through Google Scholar. Data from 13 studies with a collective sample size of 5055 infertile women was taken for meta-analysis.

For only female factor infertility (not male factor or both or unknown factors, reports on anxiety) The pooled prevalence of the anxiety was 36.17% (95% confidence interval (CI): 22.47–49.87) This is higher than the anxiety in the general population which is approx 3%. (WHO, 2017). The pooled prevalence levels in low- and middle-income countries and high-income countries were 54.24% (95% CI: 31.86–78.62) and 25.05% (95% CI: 15.76–34.34), respectively. The prevalence of anxiety among infertile women is greater in the studies that used a questionnaire to diagnose anxiety symptoms. Pooled anxiety prevalence levels were 16.47% (95% CI: 10.45 -- 22.50) and 44.93% (95% CI: 26.85 -- 63.29) in clinical interview and questionnaire, respectively.

Fallahzadeh et al., (2019). In a systematic review and meta-analysis using multiple databases including World Health Organization, PubMed, Cochrane Library, Scopus, Science Direct, Medline EMBASE and Persian databases including Scientific Information Database (SID) and Iran Medx between 2005 and 2017. The total number of subjects was 2312, from Italy, Iran, Nigeria, Turkey and Poland.

The results of this study showed that the standard effect size (hedges' g) for the difference in anxiety scores in the infertile couples than the fertile couples was 0.653. This finding showed a **moderate difference in anxiety** between fertile and infertile couples; so that the anxiety levels were higher in infertile couples than fertile couples. The odds ratio showed that **infertile women have three times more chance of anxiety than fertile women.**

In addition, the standard effect size (hedges' g) for the difference in depression scores in the infertile group compared to the fertile group was 1.21. This finding showed a **large difference in depression** between fertile and infertile couples; so that the depression levels were higher in infertile couples than fertile couples. The odds ratio was 8.97. This suggests that the **depression in infertile couples is about nine times higher than fertile couples.**

Summary

The association between subfertility and depression in women has been consistently reported to be significantly high in studies, Anxiety and subfertility were not found to be consistently associated and statistically not significant (Fallahzadeh et al., 2019; Hazlina et. al. 2022) However, women with female factor subfertility showed significantly elevated anxiety. The prevalence rate was 36.17%, which is greater than the prevalence among the general public and healthy women. (Kiani, et. al. 2020).

Subfertility may have adverse effects on self-esteem, identity and life purpose, with possible deterioration of the couple and a weakened support system. (Dube et al., 2020). There is a significant elevation in anxiety during any invasive procedure like ovum pickup, embryo transfer and during the two-week waiting period. The end of unsuccessful treatment with unresolved grief poses a significant risk to mental health long after the treatment has ended (ESHRE, 2015)

RECOMMENDATIONS	GRADE
The fertility care team should be aware that there is a significant association between subfertility, psychological distress and depression. (Hazlina et. al. 2022; Fallahzadeh et. al. 2019) in women.	A
The fertility care team should be aware that women with female factor infertility show a significantly higher prevalence of anxiety (Kiani et.al. 2020), but the association of subfertility with anxiety is inconsistent.	A
The fertility care team should be aware that before Ovum pick-up and Embryo Transfer and during the subsequent waiting period, there is a marked increase in anxiety for the women (ESHRE, 2015).	A
The fertility care team should be aware that threats to self-esteem, identity and purpose, deterioration of the couple and weakened support network are experienced by women (Dube et al., 2022).	C

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4.1.2 What is the psychosocial impact of subfertility and ART in men ?

Psychosocial responses of men has not been subjected to extensive research as with women .The findings suggest that men do suffer the emotional distress , especially during the diagnosis and treatment of MFI

Evidence

Wu et al., (2023) in a systematic review, focused on men with diagnosis of MFI who had completed or were in the process of surgical or medical male infertility treatment. The evidence concerning the psychosocial and sexual burden of male infertility treatment on men, and their needs during ART were synthesised .It included all English language studies which were published before August 2022 . The studies assessed the level of stress, quality of life, and self-esteem, using quantitative and qualitative measures , in cross-sectional and longitudinal studies . The treatment settings included TESE alone, TESE and intracytoplasmic sperm injection (ICSI), as well as urological treatment. Despite the diversity in the study design, setting, and outcome variables, some consistent findings emerged throwing light on the experience of subfertile men. The study summarised the following:

The relationship quality and self-esteem was reported by Bendayan et al.2022.

The *relationship well-being* of 44 men with non-obstructive azoospermia (NOA) was assessed using the Dyadic Adjustment Scale (DAS) 3 months before and 3 months after TESE and as a function of TESE outcome. Men with sperm extracted successfully reported a significant improvement in the overall score after the procedure (mean \pm s.e.m.: 120.3 ± 3.2 to 126.3 ± 2.5 , $P < 0.001$), with significant improvements in their consensus, satisfaction, and affection subscores of DAS. In contrast, men with failed TESE had significantly lower overall scores (mean \pm s.e.m.: 114.7 ± 3.0 vs 126.8 ± 1.6 , $P < 0.0001$) as well as scores of all DAS domains after the procedure.

The self-esteem was also impacted by the TESE outcome. Patients who had successful TESE with viable sperm for ICSI ($n = 24$), had a significant improvement in overall self-esteem after the procedure (Coopersmith Self-Esteem Inventory [SEI] global score, mean \pm standard error of the mean [s.e.m.]: 41.1 ± 2.0 to 44.0 ± 1.2 , $P = 0.01$), largely due to a significant improvement in family-related self-esteem (mean \pm s.e.m.: 6.7 ± 0.3 to 7.5 ± 0.2 , $P = 0.002$). Conversely, patients with failed TESE ($n = 20$) had a significantly lower level of overall self-esteem after the procedure (mean \pm s.e.m.: 39.5 ± 0.9 vs 43.8 ± 0.7 , P

< 0.001), with a significant decrease in all SEI domains of personal (mean \pm s.e.m.: 22.2 ± 0.3 to 21.1 ± 0.5 , $P < 0.01$), social (mean \pm s.e.m.: 7.4 ± 0.2 to 6.1 ± 0.3 , $P < 0.01$), professional (mean \pm s.e.m.: 7.3 ± 0.2 to 6.2 ± 0.4 , $P < 0.01$), and family-related (mean \pm s.e.m.: 6.9 ± 0.4 to 6.1 ± 0.4 , $P < 0.01$) self-esteem..

The thematic analyses of semi-structured interviews of 19 men who had undergone treatment for male infertility (DeVries et al., 2024; Stevenson et al., 2019) revealed themes of avoidance and affective symptoms. Through-out six months of treatment with a fertility-trained urologist, men with MFI avoided thinking about their infertility problem and disclosing their situation to friends and family. They distanced themselves from friends with children altogether. This was also seen by men with OA who had failed and terminated ICSI following surgical sperm extraction. Psychological symptoms of shock, depression, and grief progressed with diagnosis, treatment, and treatment failure. A feeling of inadequacy due to a threatened sense of masculinity was reported. Interestingly, this was followed by a regain of self-esteem when sperm was detected through TESE..

The effect of the procedure on the sexual functioning of men with NOA was evaluated by other longitudinal studies that compared the International Index of Erectile Function (IIEF) scores before and after TESE. In 66 Turkish men with NOA (Akbal et al., 2010), only those with failed TESE (40.0%) reported a significant decrease in mean IIEF-5 scores 6 months after the procedure; those with successful TESE reported an improvement that was insignificant. Furthermore, 12/13 (92.3%) of those who developed new-onset erectile dysfunction (ED) did not have sperm retrieved. Patients with new-onset ED also reported depression and anxiety as seen from the Hospital Anxiety and Depression Scale (HADS) and demonstrated a significant decrease in serum total testosterone (TT) levels (mean \pm s.e.m.: 7.8 ± 2.0 ng ml⁻¹ to 2.8 ± 2.0 ng ml⁻¹, $P < 0.001$). The authors, therefore, concluded that unsuccessful TESE may have a negative impact on erectile function due to both hormonal and psychological factors.

This was confirmed by Bendayan et al.(2022) in his study with NOA. TESE failure patients (45.0%) demonstrated significantly worse erectile function 3 months after the procedure compared to three months before (IIEF-15 erectile function domain, mean \pm s.e.m.: 26.5 ± 0.9 vs 28.0 ± 0.7 , $P = 0.04$). The significantly lower scores in the IIEF-15 domains of sexual intercourse satisfaction and orgasmic function after the procedure were found. TESE success patients reported significantly higher levels of intercourse satisfaction, orgasmic

function, sexual desire, and overall satisfaction after the procedure. The current study differed from the previous in that it also compared pre- and post-procedure changes in serum TT between the two groups and found no significant differences, despite a significant decrease in serum TT in the overall study population after the procedure. It was, therefore, suggested that TESE outcomes have an impact on erectile function and other sexual functions, independent of changes in serum TT.

Male needs in fertility care were revealed by the qualitative phenomenological studies. The men's subjective needs related to patient-centred care during treatment are important. *The provision of information* regarding treatment is important. (Dancet et al.; 2010). Men struggled with uncertainty regarding the logistics and outcomes of treatment, hence valued the detailed information regarding the process of TESE, success rates, complications, and recovery, with alternatives, such as donor sperm or adoption. Written information along with a clear, long-term treatment plan was appreciated, and enabled informed decision-making. Uncertainty regarding treatment and appreciation for information were important matters to infertile men; it is associated with lower levels of infertility stress. Therefore, adequate education and resource provision constitutes a crucial component of patient-centered care

The need for emotional support and better communication from medical staff were also emphasized. There was a feeling of marginalization among men who terminated ICSI following TESE. A positive treatment experience was there when emotional support was provided by the fertility care team, especially by direct and normalizing communication.

Cao et al., (2022) in a cross-sectional study, used network analysis to examine the patterns of psychological distress in sub-fertility patients and to test the most central symptoms of anxiety, depression, and stress. Generalized Anxiety Disorder (GAD 7), Patients Health Questionnaire-9 (PHQ-9), and Fertility Problem Inventory were administered to N = 741 subfertility patients; 51.4% (N = 380) were women and 48.6% (N = 360) were men. The mean duration of infertility was 3.03 years (SD = 2.66). The mean number of treatments was 3.92 (SD = 1.55).

“*Restlessness (GAD_5)*” was the most central symptom across all centrality indices, followed by “*Trouble relaxing (GAD_4)*” and “*Uncontrollable worry (GAD_2)*”. Following these, “*Feelings of guilt (PHQ_6)*” was the most central symptom in depression. It had the highest strength in depression. “*Relationship concern stress*” and “*sexual concern stress*” had the strongest connections in the

network. Stability estimation indicated that the order of node strength centrality was more stable than the order of closeness and betweenness (the CS-coefficients were 0.75, 0.13, and 0.67, respectively).

Sexual concern stress, which is associated with suicidal ideation, maybe also a priority target. Providing more sexual health education and social support to infertility patients, and reducing their avoidance responses, may reduce sexually related stress.

By eliminating or reducing the central symptoms, activity across the network may be reduced (or prevented).

The network structure and global strength were the same across genders, and hence it may be important to identify and address. thereby helping to reduce other connected symptoms in the network.

Yang et al., (2017), reported the prevalence of depression, anxiety, and a combination of both psychological symptoms with a cross sectional survey in a sample size of 771 Chinese men. Depression was reported in 20.8%, anxiety in 7.8%, and mixed anxiety and depression in 15.4%. Multiple logistic regression analysis was done to analyse the association of depression and anxiety with demographics and concomitant medical conditions.

Differences in demographics (age, education, and income) had no noticeable impact on the development of psychological symptoms in men. Clinical conditions such as type of treatment and quality of sperm were not significant risk factors for any of the psychological symptoms.

Presence of other concomitant disorders i.e. varicocele, epididymal cyst, and erectile dysfunction (ED) however was a significant risk factor for depression, (OR = 1.47; 95% CI [1.14, 1.90]; $p < .001$) or combination of both anxiety and depression. (OR = 1.56; 95% CI [1.17, 2.08]; $p < .001$). However, anxiety alone was not significantly associated with concomitant disorders. Anxiety has a significant association with longer duration of infertility (OR = 3.94; 95% CI [1.20, 12.93], $p < .02$).

Martin et al., (2016) in systematic review of the male psychological adaptation to unsuccessful ART treatments over time suggests a tendency towards poorer psychological adaptation to fertility treatments in the year following the initial evaluation. The infertility related stress (Schmidt et al., 2005a) and depression increase (Bak et al., 2012; Berghuis and Stanton, 2002); dimensions of mental health (Peronace et al., 2007) and sexual functioning (Bayar et al., 2014) show

decline. Men also feel less supported and have to increase their efforts to cope with this stressor (Peronace et al., 2007; Pook et al., 2002)

Men's *long-term psychological adaptation to failed treatment*, two (Moller et al., 1991) and five years (Schanz et al., 2014) point towards stability regarding psychological distress (Moller et al., 1991), well-being, and partnership quality. Men's wishes to have a child decrease 5 years after having received a diagnosis, even while they continue pursuing fertility treatment (Schanz et al., 2014).

Men with non-obstructive azoospermia (NOA) face a much stronger risk of being unable to have biological children compared with the risk faced by other sub-fertile men in treatment. Additionally, this group of men has to endure embarrassing and painful treatment procedures. This group showed high anxiety levels in the first month after receiving the diagnosis and with longer duration, depression increased while anxiety decreased.

In summary, the men also experience anxiety, depression or both during subfertility (Yang, et al., 2017). Male psychological adaptation to unsuccessful ART treatments suggests a poorer psychological adaptation to fertility treatments in the year following the initial evaluation. The infertility related stress, depression increase (Berghuis and Stanton, 2002; Bak et al., 2012), and dimensions of mental health (Peronace et al., 2007) sexual functioning (Bayar et al., 2014) show decline. Men's long-term psychological adaptation to failed treatment, two (Moller et al., 1991) and five years (Schanz et al., 2013) point towards stability regarding psychological distress, well-being, and partnership quality. Men's wishes to have a child decrease five years after having received a diagnosis, even while they continue pursuing fertility treatment (Schanz et al., 2013). Wu et al., (2023) summarised the effect of MFI on stress, QOL, self-esteem. Men with sperm extracted successfully reported a significant improvement in self-esteem, dyadic adjustment and sexual functioning after the procedure. In contrast, men with failed TESE had significantly lower self-esteem, dyadic adjustment ($p < 0.0001$) as well as sexual functioning. ED may emerge for the first time (Bendayan et al., 2022)

RECOMMENDATIONS	GRADE
The fertility staff should be aware that men also experience either depression, anxiety or both during infertility (Yang et al. 2017).	C
The fertility staff should be aware that men experience adverse psychosocial effects if unsuccessful ART occurs during the first year. which subsequently decreases after 2-5 years (Martin et al. 2016; Schanz et al., 2013).	C
The fertility staff should be aware that diagnosis of male factor infertility is accompanied by lowered self-esteem, socially avoidant behaviour and negative dyadic coping which decreases if the sperm is detected in testicular aspiration (Bendayan et al., 2022; DeVries et. al., 2024; Stevenson et. al.2019).	C
The fertility staff should be aware that new onset erectile dysfunction, reduced intercourse satisfaction and orgasmic function may occur after unsuccessful TESE (Bendayan et al., 2022).	C
The fertility care staff should be aware of the fact that men value information regarding the treatment, possible outcomes, success rates, complications, and recovery, a clear, long-term treatment plan, with alternatives, such as donor sperm or adoption (Dancet et al.; 2010).	C
The fertility care staff should be aware of the fact that men in fertility settings feel marginalized and need direct communication and support from the clinicians, highlighting their need for their inclusion and involvement in fertility treatment. (Stevenson et al.2019 ; Johansson et.al 2011) .	C

4.1.3 What are the differences in psychosocial responses of men and women to subfertility and ART?

An understanding of the different reactions of the men and women to infertility and ART is important. The dyadic relationship of the couple is a close, long-term relationship with interdependence and mutually reciprocal influence which can be a source of both positive and negative emotions.

Yaser et. al. (2023) reported systematic review with meta-analysis to find the difference between infertile men and women in terms of psychiatric morbidity and quality of life. The final data base selected for analysis included 35 studies from 18 countries published between 2001 and 2022. It included 29 cross-sectional studies, four prospective cohort studies, and two case-control studies. The number of couples in the sample ranged from 26 to 818, mean age of men varied from 29.00 ± 3.50 years to 41.60 ± 5.90 years, while the mean age of women varied from 27.48 ± 4.21 years to 40.80 ± 4.70 years. The duration of subfertility ranged from 1.73 ± 1.15 years to 7.44 ± 5.30 years. The results were as follows:

Stress: Eleven studies evaluated stress among men and women. A random-effects design was used due to the high heterogeneity ($\text{Chi}^2 = 21.82, p = 0.016, I^2 = 54.18\%$). The forest plot found that SMD was <0.001 , indicating that women were more stressed than men

Depression: Among the 35 included studies, 20 studies, including 24 cohorts, have evaluated depression among men and women. The forest plot revealed that SMD was <0 , indicating that women were much more likely than men to experience depression (SMD: -0.335 ; 95% CI: $-0.380 - -0.290$; $p < 0.001$)

Anxiety : Among the 35 included studies, 14 (19 cohorts) evaluated anxiety among men and women. The random-effects design was used due to a high heterogeneity. Infertile women experience higher levels of anxiety compared to infertile men. The analysis revealed that SMD was <0 , which indicated that anxiety was far higher in women than in men (SMD: -0.337 ; 95% CI: $-0.387 - -0.287$; $p < 0.001$)

Quality of life: Among the 35 included studies, 14 were evaluated for the quality of life among men and women. The forest plot demonstrated that SMD was >0 , which indicated that men's quality of life was much higher than women's (SMD: 0.422 ; 95% CI: $0.366 - 0.478$; $p < 0.001$)

Subgroup analysis according to region

Stress: The work's geographical origin and the study design were sources of heterogeneity for the stress outcome ($p = 0.020$, $p < 0.001$, respectively). Asia had the highest standardized mean stress difference-

Depression: Regarding depression, there was no significant difference between the different continents ($p = 0.358$). The different measures of test gave varied results

Anxiety: When looking at the geographical origin of the work as a moderator, the SMD of anxiety significantly differed between studies ($p < .001$). The highest standardized mean difference in anxiety between infertile men and women was detected in Europe (SMD = -0.253), followed by Africa (SMD = -0.450).

Quality of life: The SMD of quality of life did not significantly differ between studies when the geographical origin of the work was set as a moderator ($p = .129$). Indeed, the highest SMD of quality of life between infertile men and women was detected in South America (SMD = $.589$), while the lowest SMD was reported in Africa (SMD = $.367$).

Ying, et al 2016 covered a systematic review of non-experimental studies exploring the *psychological effects of different stages of IVF treatment on couples facing infertility*. The purpose was to provide a comprehensive picture of men and women's emotional reactions to infertility treatment, specifically In Vitro Fertilization (IVF) and to identify any differences between the genders. Database was from six electronic databases (2000 to 2014) with a total of 22 quantitative and 4 qualitative studies were identified and included in this review. Although both men and women experienced psychological distress during the treatment, gender differences existed.

Pre-treatment emotional reaction :

Of the nine studies that were identified, only one (Wichmann et. al., 2011) included statistical testing for *gender differences in pre-treatment emotional reactions*. This study, consisting of 160 couples with infertility, reported that women had a significantly higher score than men in symptoms of depression (BDI, $m = 4.0$ vs. 2.7). The women scored significantly higher than men in state anxiety using State and Trait Anxiety Inventory (STAI)-S, ($M = 32.8$ vs. 30.4) and perceived stress (PSS, $M = 11.2$ vs. 9.9).

During the course of the IVF cycle, the stressful time points for women are the time of the oocyte retrieval, the embryo transfer, and the period prior to the pregnancy test (ESHRE, 2015). Men reported feeling a higher level of depression before the pregnancy test, however differences in depression at pre- and post-treatment were not significant. Anxiety levels were similar across the cycle.

Reactions to Treatment Failure: Women who had experienced a failed cycle felt greater stress than those with successful cycles, had higher levels of anxiety and depression, and lower self-esteem and satisfaction with life even years after the treatment. Women who remained childless four to nine years after unsuccessful IVF treatment reported less satisfaction with life than those who finally became parents (Bryson et al., 2000). The results indicated that it is the unsuccessful outcome of IVF instead of IVF itself that would have long-term psychological consequences (Verhaak et al., 2005). Couples with infertility who had a failed cycle experienced unresolved grief three years after treatment (Vogelstein et al., 2010). The findings of this review are consistent with the statement that the grieving process in the IVF cycle is often long (Alesi et al., 2005). Couples were together experiencing unresolved grief in the long term after the IVF failure.

The socialization processes of men might also play a role in the interpretation of the results. During their life cycle, men are usually expected to be strong and to suppress their emotions when adversity occurs, which might contribute to a higher prevalence of depression and hardly any changes in anxiety level (Beevers et al., 1999).

RECOMMENDATIONS	GRADE
The fertility care staff should be aware of the fact that although both women and men suffer from significantly raised levels of depression. or anxiety or a combination of both due to sub-fertility (Ying et al 2016), the levels in women are much higher, with a poorer quality of life than men (Yaser et. al. 2023; ESHRE, 2015).	B
The fertility care staff should be aware that in women anxiety levels increased before oocyte retrieval, embryo transfer, and the waiting period for pregnancy test results. ESHRE,2015). However, men may experience elevated depression before treatment . (Ying et al., 2016).	C
The fertility care staff should be aware of the fact that both men and women undergoing fertility treatment experience relationship and sexual concerns which may have the strongest connections to depression and suicidal ideation (Cao et al., 2022).	C
The fertility staff should be aware that the adverse effects of unsuccessful ART seem more intense and prolonged in women than men (Schanz et al., 2013; Ying et al., 2016).	C

In summary, the studies that examined the emotional states of individuals and couples during the pre-IVF treatment period revealed that women experienced higher levels of depression and anxiety. This is in line with the findings of the ESHRE guidelines (2015). Men in general also had elevated depression levels, while the results on the level of anxiety were inconsistent (Ying et al., 2016). While women experience a marked increase in anxiety during oocyte retrieval, embryo transfer and during the waiting period (ESHRE, 2015) men did not experience anxiety, but an elevated depression before the test results. The adverse effects of unsuccessful ART seem more intense and prolonged in women (Ying et al., 2016). For men, there may be stability regarding psychological distress, well-being and relationship quality (Schanz et al., 2013).

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4.1.4 What is the impact of subfertility and ART on the sexual function of the couples?

Introduction

Infertility and ART affect both female and male sexual health, but only recently the interest in the effect of ART on the couple's sexuality has come into a sharper focus. However, much more attention has been paid to male than female sexuality (Ciocca et al., 2015).

The psychological strain caused by fertility treatment or ART can lead to impaired well-being and negative consequences on sexuality, further affecting sexual satisfaction in couples. Sexual dysfunctions can appear in both partners of the infertile couple in every step of the diagnostic to treatment protocols. It can impair the ART treatment outcomes (Luca et al., 2021).

Sexuality has a key impact on quality of life and on reproductive health. Despite this, addressing sexuality is not a standard component of infertility counselling. The clinician as well as the couple consider discussing sexuality to be more challenging than other aspects of reproductive medicine.

Evidence

Leeners et al., (2023) reported an exhaustive systematic literature search with meta-analysis based on Pubmed, EMBASE and Psycinfo from January 1966 to April 2021. Primary outcomes of the meta-analysis were defined as the odds ratio (OR) for Female Sexual Dysfunction (FSD) in infertile versus fertile women and the OR of Erectile dysfunction (ED) and Premature Ejaculation (PE) in infertile versus fertile men. Secondary outcomes were the score differences in total and subcategories of sexual dysfunction as represented by questionnaires Female Sexual Function Index (FSFI) for women and the International Index of Erectile Function (IIEF) for men. The FSFI is divided into six domains: i.e. Desire, Arousal, Lubrication, Orgasm, Satisfaction and Pain.

Sexual difficulties and disorders resulting from infertility

In both partners, infertility can induce, worsen or maintain sexual disturbances and disorders. The meta-analysis showed a significantly higher overall level of Female Sexual Dysfunction (16 studies, covering 2667 infertile women vs. 2710 fertile women; OR 1.68, 95% CI 1.38, 2.05, $I^2 = 59\%$); and a lower total FSFI score (17 studies, covering 5849 women dealing with infertility vs. 2736 fertile women; MD -1.60, 95% CI -2.58, -0.62) in infertile women. This was further

confirmed by the meta-analysis of good and fair-quality studies with a reduction of the heterogeneity. They showed significantly higher FSD in the infertile group (11 studies covering 1949 infertile women vs. 2023 fertile women ; OR 1.83, 95% CI 1.52, 2.21)). The results for specific sexual disorders were significantly different between infertile and fertile men; however, there were no differences in the total IIEF score (four studies, covering 1732 infertile men vs. 1192 fertile men ; MD -1.63, 95% CI -3.55, 0.29).

Hypoactive sexual desire disorder and frequency of sexual contacts.

Many women, men and couples experienced a reduction in their sexual desire when aware of infertility. The meta-analysis showed no differences in fertile from infertile women but significantly higher scores of sexual desire in fertile men compared with men with infertility (three studies, 276 infertile men v. 290 fertile men MD -0.47, 95% CI -0.67, -0.27). In addition to a lack of sexual desire, infertile men may experience anxiety about decreasing sexual desire (Nene et al., 2005). The meta-analysis of IIEF Score parameters showed no differences in intercourse frequency between infertile and fertile men.

Dyspareunia or pain

According to the meta-analyses, fertile women show lower values for sexual pain in the FSFI (17 studies, 2556 women with infertility v 2736 fertile women ; MD -0.37, 95% CI -0.56, -0.18). Dyspareunia was described to be particularly pronounced in the case of infertile compared to a fertile partner (Ozkan et al., 2016).

Erectile dysfunction (ED)

Meta-analysis showed significantly higher rates of ED in infertile men (six studies, 2276 infertile men vs. 1492 fertile men ;OR 2.92, 95% CI 1.71, 4.96). The meta-analysis of IIEF score parameters showed significantly higher scores for erectile function in the fertile group (three studies, 276 infertile men vs. 290 fertile men ; MD -0.63, 95% CI -1.05, -0.21) A sensitivity analysis after the exclusion of low-quality studies confirmed higher rates of ED in the infertile group (four studies: 2030 men with infertility vs. 1254 fertile men ; OR 3.69, 95% CI 2.19, 6.22)

ED is particularly frequent in cases of male-factor infertility, especially in azoospermic men (Lotti et al., 2016). Men may develop ED after being informed of infertility or their azoospermic status (Berger, 1980; Nene et al., 2005). Not only the prevalence but also the severity of ED seems to be significantly greater in infertile men compared to fertile men (O'Brien et al., 2005).

Having to masturbate for diagnostic or therapeutic purposes, a pathological result or an unsuccessful testicular sperm extraction represent further risk factors. In one study, 11% of men with a previously abnormal semen analysis were unable to produce the sperm needed for a second spermiogram (Saleh et al., 2003). Masturbation to obtain sperm for fertility treatments fails in approximately every 16th treatment cycle or in about 8.3% of men (Li et al., 2016; Pottinger et al., 2016). Especially when pregnancy is the goal, ED imposes increased stress on men (Gao et al., 2013; Lotti et al., 2016; Shindel et al., 2008b;).

Orgasmic dysfunction

Meta-analysis showed no differences in orgasm in relation to IIEF scores between infertile and fertile men while FSFI subscales for orgasm were higher in fertile women (16 studies, 2460 women with infertility vs. 2640 fertile women ; MD -0.22 , 95% CI -0.43 , -0.01) (Leeners et al., 2023).

Premature ejaculation

The meta-analysis showed significantly higher rates of PE in infertile men (two studies, 1668 men with infertility vs. 1142 fertile men ; OR 2.10, 95% CI 1.53, 2.87) (Leeners et. al. 2023). While demographic variables showed no statistically significant associations with PE in couples with an infertility diagnosis, the highest prevalence of PE was observed in men with azoospermia, followed by those with at least one abnormal sperm parameter (Lotti et al., 2016; Shindel et al., 2008b;).

Sexual satisfaction and quality of sexual encounters

The meta-analysis of IIEF score parameters showed no differences in sexual satisfaction between men with infertility and men without this condition, but higher subscales of sexual satisfaction as measured by the FSFI in fertile women (17 studies, 2556 women with infertility vs. 2736 fertile women ; MD -0.23 , 95% CI -0.39 , -0.07) (Leeners et. al. 2023).

In contrast to a source of intimacy and connectedness between two partners, sub-fertility may transform sexual encounters. Couples may increasingly seek sexual intercourse when they are less and less inclined to do so. When experiencing being desired only in view of a chance for conception or feeling to serve just as a sperm donor, sexual activity can become an area of conflict (Bokaie et al., 2015; Lundin and Elmerstig, 2015). The lower the acceptance of the inability to get pregnant, the less sexual satisfaction before and after infertility treatment was observed (Pepe and Byrne, 1991).

While a higher education level and a higher quality of the non-sexual relationship were found to have a positive influence on sexual satisfaction (Ramezanzadeh et al., 2006; Drosdzol and Skrzypulec, 2009), male-factor infertility, unexplained infertility and infertility-related stress have been associated with lower satisfaction (Daniluk, 1988; Drosdzol and Skrzypulec, 2009; Nakić Radoš et al., 2020, Smith et al., 2009; Vizheh et al., 2015;).

In couples facing infertility, reduced sexual satisfaction negatively influences overall well-being, coping abilities and sexual functioning (Alirezai et al., 2018; Mahadeen et al., 2020). Levels of sexual satisfaction rise with the achievement of a pregnancy (Benazon et al., 1992).

Factors involved in the association between sexual problems and subfertility and ART

A diagnosis of infertility and receiving intrauterine insemination has been found to be associated with reduced arousal in women (Marci et al., 2012). Diagnosis of male infertility is often the trigger for sexual problems and may be followed by a period of impotency, a depressive, withdrawn mood in the male partner, and feelings of hostility and/or guilt in the female partner (Berger, 1980). The negative effect of male-factor infertility on men's sexual functioning is independent of age, age of partner, race, religion, educational level, employment status and prior pregnancy (Drosdzol and Skrzypulec, 2008, 2009; Smith et al., 2009; Lotti et al., 2016). Some studies show associations with the severity of semen impairment (Lotti et al., 2016; Kızılay et al., 2018), while others do not confirm such an association (Elia et al., 2010).

Self-confidence, self-esteem and mental health

In both men and women, the lack of desired parenthood affect self-esteem and sex-role identification, with reduced confidence in oneself and in one's sexual abilities (Mai et al., 1972; Berg et al., 1991; Glover 1996; Lee et al., 2001; Nelson et al., 2008; Shindel et al., 2008a; Xing et al., 2013; Wischmann et al., 2014; Bokaie et al., 2015; Lundin and Elmerstig, 2015; Alirezai et al., 2018; Jamil et al., 2020). One's own body is often evaluated more negatively and sometimes even perceived as an 'enemy'. In infertile men and women, a reduction in self-esteem and a negative body image may directly increase the risk of sexual dysfunction, for example, a lack of sexual desire, inadequate relaxation during sexual activities, and ED, as well as factors indirectly influencing sexual activity, such as marital adjustment and general life satisfaction (Alkai et al., 2019; Karamidehkordi and Roudsari, 2014; Kohan et al., 2015). A variety of studies

confirm feelings of guilt and shame in women and men facing infertility, which may negatively affect sexual relationships (Lee et al., 2001; Galhardo et al., 2011; Slade, 1981;).

In family-based societies, culture places great emphasis on procreation and fertility. Social status is related to parenthood, and childlessness is highly stigmatized; this influences seeking medical support (Ergin et al., 2018; Inhorn, 2002; Lee et al., 2000; 2001; ; Onat et al. 2012; Tabong et al., 2013;). In many cultures, women are held responsible for childlessness (Lee et al., 2000; Nene et al., 2005; Tabong et al., 2013). Therefore, couples with an infertility diagnosis often experience social and family pressure to conceive (Bayar et al., 2014; Jumayev et al., 2012; Lee et al. 2000). This may impair sexual life, either directly or indirectly (Monga et al., 2004; Nene et al., 2005; Al-Homaidan, 2011; Tabong and Adongo, 2013).

Depression and anxiety, which are well documented in subfertility and ART, are risk factors for sexual dysfunction (Cook et al., 2007; Czyżkowska et al., 2016; Galhardo et al., 2011 ; Gao et al., 2013; Lotti et al., 2012; Marci et al., 2012; Naumova et al., 2021; Oddens et al., 1999; Ozkan et al., 2015; Shahraki et al., 2018; Shindel et al., 2008a; Wischmann et al., 2001). Anxiety is highest in azoospermic men compared to men with at least one sperm abnormality and to normozoospermic men (Lotti et al., 2016). Women with higher anxiety scores report more sexual problems, i.e. desire and arousal disorders, dyspareunia, lubrication problems, difficulties in reaching orgasm and reduced sexual satisfaction, with the highest correlations found for sexual satisfaction (Lundin et al., 2015 ; Pakpour et al., 2012; Purcell-Lévesque et al., 2019; Youseflu et al., 2020). Anxiety in infertile men is associated with arousal disorders, ED, PE and reduced sexual satisfaction (Lotti et al., 2012, 2016; Gao et al., 2013; Purcell-Lévesque et al., 2019).

Depression is associated with reduced sexual function, such as lack of desire and arousal, lubrication problems, ED, PE, difficulties in reaching orgasm, dyspareunia, impaired pleasure and reduced satisfaction in infertile couples (Pakpour et al., 2012; Gao et al., 2013; Kucur Suna et al., 2016; Cao et al., 2019; Youseflu et al., 2020). However, the meta-analysis of the two studies that matched infertile and fertile women for depression showed comparable levels of FSD (215 infertile women vs. 350 fertile women)

Infertility is associated with an increased risk of sexual coercion, defined as the use of verbal pressure or force to obtain sex from an unwilling partner, especially

towards the male partner (Peterson and Buday, 2020) as well as higher incidences of physical and sexual violence towards women (Poornowrooz et al., 2019).

Duration of infertility, primary and secondary infertility

The meta-analysis of the impact of primary and secondary infertility on overall sexual function in women showed no significant differences (3 studies, 240 women with primary infertility vs 175 women with secondary infertility ;OR 1.04, 95% CI 0.53, 2.07); In contrast, male IIEF overall scores were higher in primary vs secondary infertility (2 studies, 297 primary vs 160 secondary infertility MD 1.93, 95% CI 1.09, 2.76),(Leeners et al. 2023).

Effect of ART procedures

When trying for timed intercourse, couples tend to have sexual intercourse more frequently or even exclusively during the pre-ovulatory phase and, in case of male subfertility, to schedule intercourse to optimize sperm quality (Hurwitz, 1989; Ohl et al., 2009; Reder et al., 2009). 'Sex on demand' increases performance anxiety and sexual relationship stress (Drake and Grunert, 1979; Greil et al., 1989; Boivin et al., 1992; Song et al., 2016). Spontaneity is lost, and the pleasurable erotic experience of sexual intimacy may be altered (Keye and Deneris, 1983; De Vries, 1984; Benyamini et al., 2005; Reder et al., 2009). This can result in sexual desire disorders, ED, ejaculatory dysfunction and other sexual disorders (Drake and Grunert, 1979; Hurwitz, 1989; Ohl et al., 2009; Reder et al., 2009; Shoji et al., 2014; Bokaie et al., 2015). In 50% of women in infertile couples, the incidence of sexual dysfunction was increased during the fertile phase of the cycle (Hurwitz, 1989), and about 40% of partners reported greater sexual desire outside treatment periods (Ohl et al., 2009; Reder et al., 2009). Failure in timely ovulatory intercourse has been found in up to 26% of men in infertile couples (Yang et al., 2018). However, the majority of infertile men and women (87.4%) tend to have intercourse during the pre-ovulatory period (Ohl et al., 2009; Reder et al., 2009). Diagnostic and therapeutic procedures are frequently perceived as an invasion of privacy and as fault-finding events; medical vocabulary is experienced as devaluing and devirilizing . Men often feel uncomfortable and ashamed when having to masturbate in the setting of an infertility clinic(Greil et al., 1989).

Summary

Infertility is associated with an increased risk of sexual disorders in both men and women. In both partners, infertility can induce, worsen or maintain sexual disturbances and disorders. Loss of sexual desire and erectile dysfunction are among the most frequent sexual disorders resulting from subfertility and ART in men. In women, there is an overall significant reduction in sexual function in association with subfertility and ART.

Identifying sexual disorders is important in the context of subfertility and AR . It is important for comprehensive care for the couples. Counselling should focus on preventing the onset and aggravation of sexual disorders. As sexuality represents a major component of quality of life and of partnership, such support may improve not only the current overall well-being but also the chances of a satisfactory long-term partnership and family life.

RECOMMENDATIONS	GRADE
The fertility care staff should be aware that the psychological strain of subfertility and ART can induce, worsen or maintain sexual disturbances and disorders in both partners (Leeners et al 2023; Lotti et al., 2016; Li et al., 2016; Pottinger et al., 2016 ; Ozkan et al., 2016).	A
The fertility care staff should be aware that identifying sexual disorders during the entire course of diagnosis and treatment is necessary for well- well-being of the couple.	GPP

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Key Questions 4.2

4.2. What are psycho-social causes of distress in fertility care?

Introduction

Unrecognized and unregulated stress can disrupt fertility treatment in a significant manner. However, every couple does not succumb to stress. There are specific factors within the individual, the couple, and their relationship which can modulate the response to challenges of subfertility and ART. An understanding of psychosocial factors which can predispose a couple to negative psychological responses as well as the factors which are protective can be useful for the effective management of patient distress.

ESHRE 2015 identified the three sources of distress during ART

1. Patient factors –Individual, couple, family
2. Clinic factors – Team, Organizational care
3. Treatment factors –Diagnosis, Prognosis; Costs, Side Effects, Monitoring Injections etc.

Each of these three dimensions interacts to influence the psychological response of a couple to subfertility and ART. The clinic factors i.e. the human interaction as well as the organisational aspects affect the quality of care. Positive staff characteristics such as empathetic involvement, trustworthiness, and respectful communication, are important. It enhances the well-being of couples undertaking ART. Also, the perceived competence of the staff, continuity of care and the provision of preparatory information, diagnostic procedures etc. are important. The delivery of patient-centred care plays an important role in reducing infertility-related stress and anxiety and, hence needs to be integrated into the ART programs

Some of the patient-specific factors have been described below. These include the following six domains

1. Illness representation

Illness representation can be cognitive or emotional. It is an organized set of beliefs about an illness based on the patient's implicit common sense (Leventhal et al., 1998; Petrie, 1997).

Cognitive representations of illness include the following:

- Identity (i.e., label and symptoms),
- Timeline (chronicity and cyclicity),
- Supposed causes (e.g., alcohol use),
- Consequences (e.g., social, financial),
- Controllability (personal and treatment)
- Coherence (i.e., patient's understanding of the illness).

Emotional representations are sets of negative emotions (e.g., concern, anger or sadness) associated with the health problem.

2. **Coping Methods** adopted by the couple moderate stress of infertility and ART. These can be as follows:

- i. Seeking Social Support (seeking social support for instrumental reasons, for emotional reasons, and focusing on and venting of emotions);
- ii. Avoiding (denial, humour, alcohol and drug, disengagement, behavioural disengagement and mental disengagement);
- iii. Positive Attitude (acceptance, positive reinterpretation and restraint coping);
- iv. Problem Solving (planning and active coping);
- v. Turning to Religion (seeking comfort found in religious and spiritual practices).

3. **Positive and Negative Dyadic Coping** provides an interpersonal view of stress and coping in couples. It refers to how partners understand the stressful situation, support each other, and deal with stressors together. The assumption of dyadic coping is the interdependence between partners and their mutual impact on each other. Dyadic coping has been classified as either positive or negative. (Bodenmann, 1995)

Positive dyadic coping means the couple shares information, is emotionally supportive and tries to manage the problems together as a team. This is associated with better relationship outcomes. The three types of Positive Dyadic Coping are:

- Stress Communication
- Supportive Delegated
- Common Dyadic Coping

In contrast, negative dyadic coping can be hostile, with one partner disparaging, distancing themselves, mocking, using sarcasm, or minimizing partner stress; ambivalent, with one partner providing support, but unwillingly; or superficial, for example, when one partner appears detached or asks questions without attempting to understand or appreciate the answers. These negative dyadic coping can be as follows:

- Controlling, Hostile
 - Over-protection
 - Protective Buffering,
 - Uninvolved
- 4. Infertility-related concerns** are significant predictors of psychological distress (Lakatos et al., 2017; Zurlo et al., 2017). These are as follows:
- Social concerns (i.e., feelings of isolation; perceived alienation; discomfort and stress in spending time with family and/or peers; sensitivity to comments and reminders of infertility).
 - Need for parenthood (i.e., parenthood as an essential step to achieve one's own identity and as a fundamental life goal).
 - Rejection of a future without a child (i.e., negative view of a childfree lifestyle; satisfaction and/or happiness as dependent on achieving parenthood).
 - Concerns about the couple's relationship (i.e., difficulty in talking about infertility with the partner; reduced intimacy and sexual enjoyment; diminished self-esteem)
- 5. ART treatment experiences are related to adverse emotional outcomes.** (Gameiro et al., 2015; Agostini et al., 2017).
- The uncertainty of the pregnancy achievement
 - Feeling of hopelessness after treatment failures (Verhaak et al., 2007).
 - Intense and protracted experiences of stress and psychological disease may also have a significant impact on ART treatment success, including follow-ups (Purewal et al., 2018), potentially resulting in a vicious circle

Various models of stress and self-regulation have attempted to quantify and synthesise the interactive effect of fertility specific stressors, demographic variables, individual personality characteristics, couple relationship, coping methods and illness representation on psychosocial outcomes for the couples experiencing sub-fertility. The evidence below discusses the role of these in the stress experience.

6. Optimism and Resilience as protective factors

Dispositional optimism has been defined as global expectations that things will turn out well in the future and bad things will be scarce (Carver et al. 2014). Moreover, optimism is inversely related to hopelessness, a well-known risk factor for depressive disorders. Similarly, it seems to confer resilience to stressful life events, and this resilience is associated with both the onset and recurrence of various psychopathologies. As an individual resource for coping, psychological resilience can help balance the negative effects of emotional distress. Dispositional optimism and psychological resilience are positive predictors of subjective well-being and low emotional distress; most likely, those two dimensions are interrelated (Kleiman et al., 2017).

Overall, there is a paucity of research using positive emotional outcome measures (e.g. well-being, positive affect, happiness or life satisfaction) to quantify emotional adjustment.

Evidence

Deninotti et al. 2023 examine the relationships between illness representations of infertility, coping (i.e. maladaptive and adaptive) and psychosocial outcomes (i.e. distress, anxiety, depressive symptoms, social isolation, low well-being and poor quality of life). Five databases and 807 articles were identified. Seven cross-sectional studies (N = 1208 participants) were taken up for the qualitative and quantitative analyses.

The systematic review of relationships between infertility representations and coping strategies, was given in two studies. Benyamini et al. (2004) observed that when the participants represented infertility as having severe consequences and high chronicity, the more they used coping strategies, be they adaptive (i.e., self-nurturing, such as compensation and investing in oneself, and problem management) or maladaptive (i.e., inward anger). However, the greater their perceived personal control (i.e., belief in the ability to control events) and control of treatment, the less use they made of maladaptive strategies and the more use they made of adaptive strategies (i.e., problem management; Gourounti et al., 2012).

However, the multivariate meta-analysis revealed that none of the associations between the sole type of representation and coping strategies were statistically significant.

The multivariate meta-analysis showed that the association between the following three representations of infertility and psychosocial outcomes were statistically significant.

- Consequences (e.g., social, financial),
- Emotional representations i.e. concern, anger or sadness associated with the health problem
- Controllability (personal and treatment)
- Coherence (i.e., patient's understanding of the illness).

First, representations of consequences and emotional representations were positively and strongly related to psychosocial outcomes. The more participants perceived their infertility to have consequences in multiple spheres of their lives, the lower their well-being (Benyamini et al., 2004, 2009, 2016) and quality of life (Grinberg, 2016), and the higher their levels of stress, social isolation and depressive symptoms (Naab et al., 2013).

Second, representations of controllability were negatively associated with psychosocial outcomes. In other words, the more infertile participants felt that they or their treatment had control over their infertility, the less infertility-related distress (Benyamini et al., 2004, 2009, 2016; Gourounti et al., 2012), stigma (Naab et al., 2013) and anxiety (Gourounti et al., 2012) they reported, and the better their quality of life (Grinberg, 2016). Perceived control is a known protective factor against distress (Carver & Scheier, 1982).

Furthermore, results suggested a relationship (borderline significance) between coherence representations of infertility and psychosocial outcomes. The better the couples understood their infertility (high level of coherence), the less are the anxiety and depressive symptoms (Lord & Robertson, 2005; Naab et al., 2013), infertility-related stress and isolation (Naab et al., 2013) they felt, and the better their quality of life (Grinberg, 2016).

Concerning relationships between infertility representations and coping strategies, the two studies (Benyamini et al., 2004; Gourounti et al., 2012) found that both consequences and timeline representations were positively and weakly to moderately associated with coping (adaptive and maladaptive). Hence the

more participants represented infertility as having severe consequences and high chronicity (i.e., timeline), the more they used coping strategies, be they adaptive (i.e., self-nurturing, such as compensation and investing in oneself, and problem management) or maladaptive (i.e., inward anger). Representations of personal and treatment control were negatively and moderately associated with maladaptive coping (Gourounti et al., 2012). Hence the controllability of an event influences individuals' coping choices during infertility and ART (Terry & Hynes, 1998). Adaptive coping strategies are more often employed in controllable situations, whereas maladaptive coping strategies (e.g., avoidance) are more often employed in uncontrollable situations (Lazarus & Folkman, 1984).

The meta-analysis revealed that neither of the associations between representations of infertility and coping strategies (controllability–maladaptive coping and controllability–adaptive coping) reached statistical significance.

Santa-Cruz et al 2023 explored optimism and resilience among women undergoing ART. A total of N=229 women under medical treatment for fertility completed the self-report measures for sociodemographic data and psychological dimensions of resilience, life orientation of optimism or pessimism, perceived stress, and state /trait anxiety. The data showed that high resilience levels were associated with a reduced psychological stress, ($r = -.320, p = .001$) and suggests a potential role of resilience to reduce infertility-specific stress

Jie, et.al. (2022). Studied effect of dyadic coping. Data was collected from a web-based, cross-sectional survey at the IVF centre of Shanghai, between September 2020 and March 2022, with couples coming for a fresh IVF cycle. Total number was 715 (women = 458; men = 257) with a mean age of 34.08. Data was collected with help of four structured questionnaires for i) sociodemographic information; ii.) psychological distress, iii.) dyadic coping iv.) quality of life related to fertility (FertiQoL). The associations between these variables were as follows:

There was a **negative association** between psychological distress and overall quality of life (FertiQoL) as well as sub-components of core and treatment related quality of life. High levels of common dyadic coping, supportive dyadic coping, and stress communication were associated with better quality of life. This positive dyadic coping moderates the impacts of stress, gives a better mental health as well as Quality of life.

Zurlo et. al.(2020a) assessed the association between coping strategies, infertility related stress and state anxiety in a cross-sectional multi-centre study between September 2017 and September 2019 in 10 Italian centres of assisted

reproduction. Participants were 254 couples (254 males, 254 female) undergoing ART. Assessment was done with help of standardised self-report measures to assess the following variables

1. Infertility-Related Stress dimensions included four domains 2. The Coping Orientation Scale 3. State-Anxiety

The descriptive analysis of the data revealed that women reported significantly higher levels of stress related to Social Concern, Need for Parenthood, and Couple's Relationship Concern. There were no significant gender differences in perceived levels of Rejection of Childfree Lifestyle.

With respect to coping strategies, in line with previous studies, women reported significantly greater recourse to Seeking Social Support. However, women and men showed a similar adoption of the other coping strategies. For the State Anxiety levels, the findings also supported the majority of studies indicating higher levels of anxiety in women in comparison with men. However, 34.6% of men and 26.8% of women met the cut-off for clinical levels of State-Anxiety.

The correlation analysis between 4 perceived infertility-related stress dimensions, 5 coping strategies, and levels of anxiety in male and female partners revealed that both social concerns and couple's relationship concerns were significantly associated with increased levels of anxious symptoms in both male and female partners.

Furthermore, perceived need for parenthood was significantly associated with increased levels of anxiety in infertile women. Conversely, the data failed to support significant correlations between the rejection of childfree lifestyle and anxiety both in female and in male infertile partners. This may be due to the changing beliefs concerning the role of parenthood in the definition of individuals' identity, lifestyle, and life satisfaction

Correlations between Coping strategies and State-Anxiety were as follows. In line with previous research underlining the detrimental effect of escape/avoidance coping on infertile patients' psychological health conditions, the avoidant coping was positively related to State-Anxiety in both partners.

However, Seeking Social Support as well as Problem Solving was also positively related to State-Anxiety in both partners. This was unexpected and needs further investigation. Moreover, keeping in view the findings on the higher recourse by women to Seeking Social Support coping strategy, the use of this strategy needs to be explored within interventions with the sub-fertile women. Problem Solving

also played a negative moderating role, increasing in both men and women the effects of Social Concern. This result supported the idea that the adoption of problem management strategies could be inefficient and even counterproductive among infertile patients.

The adoption of active-distractive strategies may help both members of infertile couples in handling the stress. It can moderate or reduce the negative effects of social concerns in male partners, need for parenthood in female partners, and couple's relationship concerns of both members.

Importantly, **Positive Attitude Coping**, despite among women only—was the sole coping strategy directly associated with lower levels of anxiety symptoms.

No evidence was found supporting neither positive nor negative associations between Turning to Religion and levels of State Anxiety. Avoidant coping strategies, along with a positive attitude, and seeking out individual and couple activities can help to increase positive emotions in everyday life. It may help couples to reduce the continuous ruminations and preoccupation with the processes of fertility care. The findings from this study suggest that counselling interventions with infertile couples should help to develop coping strategies, in terms of positive distraction and seeking out individual and couple activities that may increase positive emotions in everyday life.

However, problem-focused coping and social support needs careful consideration. The findings suggest that the counsellors need to take into account the possibility that fostering coping strategies such as Seeking Social Support and Problem Solving, traditionally identified as adaptive and efficient to handle chronic stress, could be, instead, counter-productive to deal with sub-fertility experience.

Zurlo. et.al (2020b) outlined a multi-dimensional model to see the role of multiple risks and protective factors in predicting psychological health outcomes among male and female partners during fertility care. With a single group cohort design, cross-sectional study was conducted to test the proposed multi-dimensional model using correlational and regression methods. In total, 250 couples (250 males, 250 female) with diagnosis of primary infertility completed the questionnaire. Participants were recruited from 9 Italian centres of assisted reproduction between March 2016 and June 2017.

For assessment both members of couples filled out a questionnaire consisting of six sections:

(1) An information section containing questions on sociodemographic characteristics, i.e. Gender, Age, Educational Level and Employment status. Also, infertility-related characteristics, i.e. Type of Diagnosis (Male Factor, Female Factor, Combined Factor and Unexplained Factor) and Duration of infertility were noted.

(2) The Fertility Problem Inventory assessed four domains i.e. i. Social Concern ii. Need for Parenthood iii Couple's Relationship Concern iv Rejection of Childfree Lifestyle. The sum of all four domains scores gives a Global Stress score of perceived infertility related stress

(3) The Coping Orientation was divided into five subscales: i. Seeking Social Support; ii. Avoiding iii. Positive Attitude iv Problem Solving v. Turning to Religion

(4) The Dyadic Adjustment Scale consists of four subscales: Dyadic Consensus; Affectional Expression; Dyadic Cohesion; Dyadic Satisfaction. The sum of all four domains scores provides a total score of perceived dyadic adjustment.

(5) The State Anxiety Scale from the Italian version of the State-Trait Anxiety Inventory

(6) The Edinburgh Depression Scale

Correlational Analysis was undertaken to assess bivariate associations between all study variables. Hierarchical multiple linear regression analyses of the hypothesized predictive models, stratified by gender, for each of the two psychological health outcome variables (State-Anxiety and Depression) was done

Results of the data analysis showed that the infertility-related stress dimensions, coping strategies and couple's dyadic adjustment dimensions have both direct and mediating effects on anxiety and depression. Overall, data from Hierarchical multiple linear regression analyses revealed that perceived Infertility-related stress dimensions, and, in particular, Social Concern, predicted State-Anxiety in both male and female partners. Also, coping strategies predicted depression both in male and in female partners. Furthermore, it emerged the significant protective role of Affectional Expression for female partners and of Dyadic Consensus for male partners.

The findings indicate the protective role of individual resources, such as employed status and educational level, in both men and women. The higher education and professional engagement, may give rise to greater possibilities of

re-identifying paths of fulfilment and affirmation of identity. Thus they may be able to develop alternatives to the fixed focus on being a parent as the primary life goal.

SantaCruz, et.al. 2019 identified the role of optimism and/or resilience mediating emotional distress in infertility. A literature search was done for 2000–2017 in PubMed, PsycINFO and Elsevier, for original articles and reviews. Additional references were collected from articles located thereby. The evidence revealed a growing trend of promoting people's positive health assets and indicates significant negative associations of optimism and resilience with anxiety and depression and positive associations with self-esteem and perception of control. It seems optimism and resilience heavily influence physical and mental health and diminishes emotional distress due to infertility. This review highlighted the importance of the development of therapeutic and preventive interventions to increase optimism and resilience against emotional distress caused by infertility.

In summary, The challenge posed by sub-fertility and ART can be moderated by various intrapersonal as well as relational or interpersonal factors.

The cognitive and emotional representations of illness have a significant impact on the psychosocial distress and coping strategies (Deninotti et.al. 2023). The more individuals perceive their infertility to have severe consequences, the more they view it as threatening, which contributes to increased stress and reduced well-being. The depressive thought patterns and cognitive distortions may lead individuals to perceive consequences as more serious than they actually are (Brown et al., 2007; Naab et al., 2013). The better the couples understood their infertility (high level of coherence), the less are the anxiety and depressive symptoms (Lord & Robertson, 2005; Naab et al., 2013), infertility-related stress and isolation. Also the greater their perceived personal control (i.e., belief in the ability to control events) and control of treatment, the less use they made of maladaptive strategies and more use they made of adaptive strategies (i.e., problem management).

Positive dyadic coping increases well-being and improves quality of life, and helps to moderate the impacts of stress. Negative dyadic coping on the other hand refers to controlling, hostile, over-protection, protective and uninvolved. (Jie, et.al. 2022). There is difficulty in talking about infertility with the partner; reduced intimacy and enjoyment and reduced self-esteem. These were significantly associated with increased levels of anxious symptoms in both male and female partners. (Zurlo et. al. 2020 a,b)

Santa-Cruz et al.(2019 ,2023)highlighted the protective mediating role of optimism and **resilience** against infertility-specific stress and ART. The positive attitude, optimism and acceptance help the couple face the challenges of fertility care. The findings (Zurlo et al 2020b) indicate the protective role of individual resources, such as employed status and educational level, in both men and women. Positive Attitude Coping, associated with lower levels of anxiety symptoms in women (Zurlo et.al. 2020b)

Summary

Subfertility and ART stress is multifactorial with many moderating and interdependent variables .Some of risk factors which may contribute can be as follows .

Gender and demographics influence the stress levels i.e. being a woman , of older age , low education and unemployed increases the risk of psychosocial distress .(Zurlo et.al.2020)

ART and subfertility related factors such as couples with high duration of infertility, repeated infertility treatments and experiences of miscarriages are at higher risk of psychosocial stress and may need specialised care (Zurlo et.al.2020)

The cause of infertility-male or female factor diagnoses increases depression and anxiety in the men and women respectively .(Zurlo et.al. 2020).

The protective factors include positive attitude , optimism and resilience (Santa Cruz et al 2019 , 2023;Jie et al 2022).The mutual support which the couple share is an important protective factor against stress . By encouraging the couple to share information, managing the problems together improves well-being and quality of life .It can be a valuable resource to moderate the stress of infertility and ART (Jie et al 2022 ; Zurlo et. al.2020).In the situation of ART where there is an uncertainty about the successful outcome ,better the couples understand their infertility and have a belief in the ability to control events and treatment, the more use they make use of adaptive coping , the less are the anxiety and depressive symptoms (Lord & Robertson, 2005; Naab et al., 2013 ; Deninotti et.al. 2023)

RECOMMENDATIONS	GRADE
The fertility care team should be aware that being a woman of older age, low education and unemployed increases the risk of psychosocial distress. (Zurlo et.al.2020)	C
The fertility care team should be aware couples with prolonged duration of infertility, repeated infertility treatments and miscarriages are at higher risk of psychosocial stress and may need specialised care (Zurlo et.al.2020)	B
Fertility care staff should be aware that positive attitude , optimism and resilience protects the couple against anxiety (Jie et al 2022 ; Santa Cruz et al 2023)	B
Fertility care staff should be aware that by encouraging the couple to work together as a team can be a valuable resource to moderate the stress of subfertility and ART (Jie et al 2022 ; Zurlo et. al.2020)	B
Fertility care staff should be aware that the better the belief of the couple in the ability to control events , the more use they made of adaptive coping, the less are the anxiety and depressive symptoms (Deninotti et.al. 2023 ; Lord et.al. , 2005; Naab et al., 2013)	B

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Key Questions 4.3

4.3. How can fertility care teams do risk prediction and psychosocial assessment?

- 4.3.1 What tests can screen out couples at risk for significant psychological distress?
- 4.3.2 How can fertility counselors make a comprehensive assessment of high-risk cases during ART?

It has been reported that nearly 20% of patients coming for infertility treatment are at risk for developing clinically significant psychological distress during the ART process. (Gameiro et al 2015). By identifying this group at an early stage, it may be possible to take preventive measures. Hence there is a need to identify high-risk cases and subsequently make a full assessment. The following section explores the use of screening tests in the Indian context.

Screening and assessment are frequently combined, yet they represent separate procedures. Screening is the process of determining the presence of a specific condition. The answer is usually a straightforward yes or no. Screenings help in the early identification of a problem and aid in designing additional organised psychological therapies for the individual.

During an assessment, the focus extends beyond potential diagnoses to encompass the psychosocial environment in which a disorder appears.

Indian Scenario for Distress Screening

1. Cultural Complexity and Response Biases:

Cultural norms, limitations, and boundaries significantly impact response biases in psychological tests. These biases affect test administration, interpretation, scoring, and predictability, diminishing psychometric properties.

2. Approaches to Test Construction in India:

Two prevalent approaches in the Indian context:

- I. Construction/validation of new measures;
- II. Adaptation/translation/shortening of existing tools.

Identified drawbacks necessitate the need for context-specific test development or adaptation.

3. Challenges in Test Construction in India: adaptation/translation/shortening of existing tools.

On-spot translation from English to local languages is challenging as equivalent terms are difficult to frame. The long questionnaires and complicated language make translation difficult. Low literacy impacts test comprehension and response. There is a lack of local norms. Hence there is a lack of availability of translated questionnaires and insufficient revision of scoring systems. This is further hampered by limited recognition of test construction and validation work as worthwhile research./there is also a scarcity of expertise in guiding such endeavours.

4. Gold Standard Tests in India:

Some Indian tests are considered gold standards for screening for psychological distress and well-being. These have been standardised on the Indian population, available in English and Hindi, with robust psychometric properties. They are high on reliability and validity, across diverse populations for several decades.

However, these tests are generic and not specifically tailored to infertility.

5. Implications for Infertility Assessment in India:

Recognizing challenges, it is crucial to develop or validate new measures tailored for infertility in India. Overcoming challenges ensures the reliability and validity of distress screening and assessment tools in the context of infertility in India.

4.3.1 What tests can screen out couples at risk for significant psychological distress?

Following psychological tests were developed by the Department of Psychiatry of the Post Graduate Institute of Medical Education and Research, (PGIMER), Chandigarh, India

1. P.G.I. Health Questionnaire N2 (Verma, S. K., Wig, N. N. 1976))

2. P.G.I. Well, Being Scale– PGI GWB (Verma, S. K., Verma, A. (1989))

A brief overview of the tools is given below

1. P.G.I. Health Questionnaire N2 (Verma, et al., 1976).

The PGI HQ-N2 assesses the levels of psychological distress that refers to non-specific symptoms of stress, anxiety, feelings of worry, sadness, and depression, often accompanied by physical symptoms such as aches and pain (Horwitz, 2002). It can impact physical, emotional, and cognitive aspects of a person's life affecting the individual's well-being and functioning

High levels of psychological distress are indicative of impaired mental health. Additionally, it can be detrimental to the overall quality of life, work performance, social relationships, and family life [Parent-Thirion et al., 2007]. The increased work absences, early withdrawal from social activities, and lower uptake of health services highlight the pervasive nature of psychological distress and its consequences on various aspects of life. It is recommended that distress may be considered independently as a distinct factor that contributes to functional impairment across various disorders. (Philips, 2009).

In the context of infertility treatment and assisted reproductive technology (ART), psychological distress is particularly salient. Psychological distress can lead to dropout or premature termination of ART treatment, thus adversely affecting the treatment outcome.

The PGI Health Questionnaire N-2 is the first of its kind in India. The major emphasis in developing the test was on using the presenting complaints spontaneously expressed by the patient in their language rather than the clinician phrasing in a more difficult language. Psychometrically sound, the test has been used extensively across various research studies due to its simple language, ease of administration, low difficulty level of the items, reliability of the scores,

validity of the results, and, most importantly, acceptability and suitability for illiterate and semi-literate populations as well.

This simple generic tool with 50-item can help the clinician screen out, in a quick and easy manner, the persons presenting with significant levels of distress. The scale is available in both Hindi and English. It also includes a 10-item lying (L) scale to assess social desirability bias while responding.

The PGI Health Questionnaire N2 test has been utilized across various studies to assess the level of distress and its impact on patients' well-being. Puri et al. (2022) conducted a comparative study to screen mental health in the Indian setting, utilizing the PGI Health Questionnaire N-2 alongside the DASS-21 to evaluate psychological well-being. It has been used to screen for distress related to domestic violence among pregnant women attending antenatal clinics (Mahapatro et al., 2018), distress associated with diverse conditions such as somatization disorder (Kushwaha et al., 2014), haematological malignancies (Kulhara et al., 1990), neurosis (Grover et al., 1994), essential hypertension (Venkatesh et al., 1994), psychogenic headache (Prabhakar et al., 1989) and for burnout among nurses working in a general government hospital (Walia et al., 1992). Due to this wide applicability, it has been recommended for use in ART clinics (Nayar et al., 2024).

These studies collectively highlight the effectiveness of the PGI Health Questionnaire N2 test in identifying distress variables across various populations and contexts, providing valuable insights into patient well-being and informing targeted interventions. A list of some of the important studies utilising the PGI Health Questionnaire N2 in diverse contexts is given below. This list is not exhaustive.

Summary Of Evidence

Studies with PGI HEALTH QUESTION- NAIRE N2	Year	No of Patients/ Subjects	Variable Assessed
Puri A et.al.	2022	A Qualitative study	A review of two psychological tools for screening mental health in Indian setting: a comparative study using PGI Health Questionnaire N-2 and DASS-21
Mahapatro M .et al	2018	400+	Stress Screening for domestic violence in pregnant women using PGI H.Q. N2
Navya, N et.al.	2018	100	Correlation between personality traits and mental health in Delhi NCR adolescents
Kushwaha, K S et.al.	2014	66	A study of disability and its correlates in somatization disorder : anxiety, depression, neuroticism using various scales

Studies with PGI HEALTH QUESTION- NAIRE N2	Year	No of Patients/ Subjects	Variable Assessed
Malhotra S et.al	1997	200	Distress in parents and its correlation with temperament of children
Sood, R. M. et.al.	1996	142	Neuroticism in family practice population in India
Dang R et. al	1995	50	Comparison of neuroticism levels and socio-demographic factors in female undertrial inmates
Sarna,T et.al.	1994	200	A Study of physical-health and neuroticism among women engaged in the home-based production of chikan embroidery
Grover, P et.al.	1994	60	Severity of distress using PGI Health Questionnaire N2
Venkatesh, S et.al.	1994	80	Comparison of psychological variables between yoga practitioners and controls in mild essential hypertension.
Rao GP, et.al.	1992	35	Psychosocial study of leukemic children and their parents using PGI Health questionnaire N2
Walia;J et.al.	1992	452	Health Status of Nurses and Yoga – The outcome of yoga treatment. The study on burn out in the nursing staff at a government hospital.
Kulhara,P et.al.	1990	69	Psychological aspects of haematological malignancies. The distress was assessed using the PGI Health Questionnaire N2
Agrawal, P.et.al.	1990	110	Psychiatric disorders among gynaecology clinic patients. The distress level assessment using PGI HQ N2

Studies with PGI HEALTH QUESTION- NAIRE N2	Year	No of Patients/ Subjects	Variable Assessed
Prabhakar; S et.al.	1989	85	Severity of emotional distress using PGI Health Questionnaire-N2 in psychogenic headache attending Neurology OPD in the government hospital
Grover, P. et.al.	1989	186	Factors influencing treatment acceptance in neurotic patients referred for yoga therapy
Verma, A. et.al.	1988	50	Correlations between learned helplessness scale and PGI Health Questionnaire N2
Mahajan A. et.al.	1988	50	Correlations between Learned Helplessness Scale and PGI Health Questionnaire N-2, PGI General Well Being Scales, and more

P.G.I. Health Questionnaire N-2

Department of Psychiatry, PGIMER, CHANDIGARH

BY

N.N. WIG and S.K. VERMA

Age.....

Sex

Education

Profession.....

Direction:-- Below are given some statements regarding your physical and mental well being, Read them carefully and tick only those items which refer to you.

1. ----- I often get watering eyes.
2. ----- I feel the heaviness of the eyes.
3. ----- I feel a burning sensation in my eyes.
4. ----- My appetite is not good.
5. ----- My digestion is poor.
6. ----- I get belching.
7. ----- My taste remains bad.
8. ----- I often get wind formation in my stomach.
9. ----- I feel heaviness of stomach and often it gets distended.
10. ----- I have to go to the toilet straight after meals.
11. ----- I feel sick in stomach.
12. ----- I get vomiting.
13. ----- I always feel thirsty.
14. ----- I have got fears like – fear of dark, crowds, closed spaces etc.

15. ----- I find trouble in getting off to sleep or staying asleep.
16. ----- I feel run down.
17. ----- I get shakes of hands or body.
18. ----- I suffer from backache.
19. ----- I feel tired all the time.
20. ----- I wish to do everything but can't.
21. ----- I don't feel like doing anything.
22. ----- I feel heaviness in my head.
23. ----- I feel as if my head is going to explode.
24. ----- I often get headaches.
25. ----- I feel the "heat" coming out of the body.
26. ----- I get pessimistic ideas.
27. ----- I get a sinking sensation.
28. ----- I get heart palpitations .
29. ----- I feel empty headedness.
30. ----- I find difficulty in passing urine.
31. ----- I get panic or fainting attacks.
32. ----- I feel edgy.
33. ----- I feel my "brain is getting weak".
34. ----- I am becoming forgetful.
35. ----- I feel scared if someone speaks loudly.
36. ----- I remain frightened all the time, not sure what will happen next.
37. ----- I feel mixed up when I talk to others.
38. ----- I can't tolerate noises.
39. ----- I get easily irritated.
40. ----- I have become superstitious.

41. ----- Many silly ideas come into my head.
42. ----- I can't forget the past happenings.
43. ----- I don't feel like talking and mixing with others.
44. ----- I feel like crying.
45. ----- I don't feel happy.
46. ----- I don't feel interested enough in the family.
47. ----- I feel like going away somewhere.
48. ----- Many times I wish I was dead.
49. ----- I am afraid that I may or have become the victim of some incurable disease.
50. ----- I find no relief even after consulting many doctors.
51. ----- I never lose my temper.
52. ----- All my habits are good.
53. ----- I always speak the truth.
54. ----- I always remain calm and composed.
55. ----- Nothing irritates me.
56. ----- I never hide anything from anybody.
57. ----- I never indulge in biting.
58. ----- I don't like people praising me.
59. ----- I never speak nonsense.
60. ----- I like everybody without exception.

SCORING for first 50 items : Every item ticked is counted as one score . Cut off Score is 12 .A score of 12 and beyond indicates significant level of distress

Items 51-60 is Lie Scale .A score above 5 means a socially desirable response set, hence the scores on distress scale needs to be interpreted with caution

2. P.G.I. General Well-Being Measure (Verma, S. K., & Verma, A. 1989).

Psychological well-being is influenced by internal processes such as personality and temperament. Recent discussions frame psychological well-being within the context of various variables, particularly happiness. Psychological well-being is recognized as a concept within the realm of positive psychology. Ryff, 1989 defined psychological well-being as individuals' capacity to navigate the balance between life anxiety and personal/social interests.

The PGI General Well Being Scale comprises 20 items designed to assess various facets of psychological well-being. Over the years, the PGI General Well-Being Measure has gained widespread recognition and acceptance. It has been widely employed by clinicians and researchers across various populations. underscores its adaptability and utility. Some studies where the test has been used are summarised below.

Studies with PGI WELL BEING SCALE	Year	No of Participants	Variable Assessed
Rani, S. et.al.	2019	80	A Comparative Study of General Well-Being and Lifestyle of Government Educators
Joy, M. et.al.	2018	300	Emotional Maturity and General Well-Being of Adolescents
Beri, N. et.al.	2016	480	Personal Growth Initiative among Undergraduate Students: Influence of Emotional Self-Efficacy and General Well-Being
Prakash, O.et.al.	2015	86	Effect of Incarceration on Well-Being of Prisoners: A Study Among Convicted and Under Trials
Chandla, S. S et.al.	2013	96	Effect of Short-Term Practice of Pranayamic Breathing Exercises on Cognition, Anxiety, General Well-Being, and Heart Rate Variability
Paikkatt, B.et.al. 2012	2012	30	Efficacy of Yoga Therapy on Subjective Well-Being and Basic Living Skills of Patients Having Chronic Schizophrenia Skills
Chakraborty R, et.al.	2012	101	Internal Predictors of Burnout in Psychiatric Nurses: An Indian Study

Studies with PGI WELL BEING SCALE	Year	No of Participants	Variable Assessed
Dhar, S., et.al.	2010	65	Identity Consistency, General Well-Being in college students
Kumar, K.,	2004	40	Yoga Nidra and Its Impact on Student's Well-Being
Ashraff, S.,et.al.	2004	50	Effect of Short-Term Psychiatric Intervention in Cancer Patients

PGI WELL-BEING SCALE

Instructions: How have you been feeling recently? Kindly put a cross (X) mark against each item which is applicable to you.

1	In good spirits
2	In firm control of behavior and feelings
3	Fairly happy in my personal life.
4	Interested in life a good bit of the time.
5	Sleeping fairly well.
6	Feeling emotionally stable.
7	Feeling relaxed
8	Feeling energetic
9	Not bothered by nervousness.
10	No anxiety or worry
11	Not easily tired.
12	Not suffering from any pain.
13	Not feeling depressed.
14	Feeling overall satisfied.
15	Not easily irritated.
16	Feeling useful, wanted.
17	Feeling productive.
18	Having a sense of belongingness.
19	Being in good health
20	Not bothered by illness or pain

Scoring:

20-item scale where responses are measured in terms of "yes" or "no". Each "yes" response is scored as 1, and each "no" response is scored as 0.

1. Sum up the scores for all 20 items to obtain a total score.
2. The highest possible score is 20, indicating the highest level of well-being, while the lowest possible score is 0, indicating the lowest level of well-being.

Summary

The PGI Health Questionnaire N2 and PGI-General Well Being Scale stand out as a reliable tool for providing a comprehensive assessment of general well-being. Studies across diverse populations consistently demonstrate its effectiveness in capturing nuanced aspects of psychological health and well-being. It aligns with the clinical imperative for a comprehensive yet efficient tool to screen couples for psychological distress. PGI Health Questionnaire N2 and PGI-GWB, with their established track record in assessing general well-being, hold promise as part of a broader assessment strategy in clinical settings. The tests can be administered and interpreted easily by the fertility care staff with minimal training.

RECOMMENDATION	GRADE
The PGI Health Questionnaire N2 can be a generic measure for screening out couples with high distress.	GPP
PGI Well-being scale can be used as a generic measure of overall well-being	GPP
Fertility specific test like SCREEN IVF, FERTIQOL must be translated and standardized for the Indian patients	GPP

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4.3.2 Key Question: How can fertility counselors make a comprehensive assessment of high risk cases during ART?

Introduction

When a patient seeks treatment for subfertility, initial screening is conducted upon clinic entry to identify high-risk cases. This screening task can be undertaken by the fertility care staff without specialized training in counselling. This proactive measure aligns with patient-centred care principles and precedes treatment initiation, emphasizing early intervention (Peterson et al., 2012).

Before commencing counselling, a thorough comprehensive assessment is imperative, prioritizing the identification of individual needs and challenges. Trained infertility counsellors and therapists are entrusted with this crucial task, ensuring the appropriateness and efficacy of subsequent interventions. When positive signs are detected during screening, the next step is to arrange an assessment for the individual. Assessment involves a thorough examination that verifies the existence of an issue, assesses its extent, determines a diagnosis and produces precise therapy recommendations for addressing the problem. Infertility often leads to emotional stress, financial burdens, and a plethora of negative emotions such as shock, sadness, depression, anger, and frustration [Simionescu et al., 2021]. Couples undergoing infertility treatment may experience a loss of self-esteem, self-confidence, and a sense of control over their lives [Boivin et al., 2007]. Furthermore, infertility can strain social interactions and contribute to negative perceptions about oneself and one's sexuality [Daibes et al., 2018]. All these dimensions need to be explored during the assessment. Additionally, assessment involves evaluating the strengths and resources of the client, which can be utilized to tackle life challenges and issues.

A comprehensive assessment includes clinical interviews and psychological testing. The assessments are essential before, during, and after fertility treatment, encompassing various dimensions of patient well-being. Both fertility-specific and generic psychological tools are utilized in this process. Psychological needs thus identified encompass relational, social, emotional, cognitive, and other aspects, highlighting the comprehensive nature of infertility's impact on patients' lives (Gameiro et al., 2015).

Clinical Interview

- When to be done: After screening
- By whom: by a mental health professional
- Domains: helps in overall assessment, testing and creating a treatment plan
- Relevance to Indian population: relevant and valid
- Relevance to infertility treatment: relevant and valid

In the realm of infertility counselling, much like other psychological interventions, it entails actions derived from a comprehensive psychosocial evaluation of the individual or couple.

Aim:

This assessment aims to explore a couple's reaction to an infertility diagnosis and treatment. Patients grappling with infertility often experience deep-seated feelings of shame, arising from a perception of being harshly judged by others as inadequate. Shame can also be experienced as the sense of negative self-judgment, based on past events, such as a previous abortion or a desire to delay childbearing. Shame is a risk factor for the development of mood and anxiety disorders. Character traits of neuroticism also predict depression and anxiety in infertility patients.

Patients with personality disorders present challenges for medical staff. These can be identified during preconception counselling sessions, especially in cases of Borderline Personality Disorder, Narcissistic Personality Disorder, and Histrionic Personality Disorder. Such patients may increase the risk of creating "drama" during treatment, causing "splitting" between infertility doctors and nurses, making excessive phone calls due to fears of abandonment, or showing a lack of compliance due to devaluation of the treatment team. Patients with Obsessive-Compulsive Personality Disorder, or those with strong traits, may fixate on the details of infertility treatments and show extreme indecisiveness regarding future treatment plans.

Early recognition of these disorders and traits is useful for the treatment team to work collaboratively. Psycho-education about personality styles can help the team to strategize, such as scheduling patients who might disrupt the clinic flow for the end of the day, arranging more frequent follow-up calls for certain patients, and providing extra instruction in procedures where needed.

Some themes contributing to stress during fertility care which need to be explored during assessment are as follows (Gameiro, 2021)

1. Infertility is a central focus for identity, especially for women.
2. Feelings of loss of control and attempts to regain control.
3. Feelings of defectiveness and reduced competence, especially for women.
4. Statelessness and ambiguity.
5. Stress disrupts marital and sexual relations, though some couples become more close after this experience.
6. Feelings of alienation from the "fertile world" as friendship groups transition to parenthood.
7. A sense of social stigma
8. Difficulty dealing with infertility at the level of life's meaning.

Steps

- i. Begin the interview by introducing yourself and explaining the purpose of the session.
- ii. Obtain informed consent from both partners, ensuring their willingness to participate in the counselling process.

Demographic Information

- iii. Gather fundamental demographic details such as age, occupation, and education.

Infertility History

- iv. Explore the duration of infertility and inquire about any known medical causes, referencing research by Boivin et al. (2011).

Medical History

- v. Ask about prior medical treatments, tests, and diagnoses related to infertility.

Evaluation of Hormonal Sensitivity

Patients with prior history of hormonal sensitivity will be especially concerned about the potential central nervous effects of infertility medications

- vi Hormonal sensitivity

Some women do appear to be especially sensitive to the effects of hormones. To identify some pointers can be kept in mind:

- a. Psychiatric History: special attention to history of affective and anxiety disorders and bipolar disorders.
- b. Review of psychological symptoms at the following times: Puberty, Oral Contraceptive Pills, Ovulation And Luteal Phase, Pregnancy and Postpartum.
- c. Family history of reproductive-related psychiatric symptoms Premenstrual Dysphoric Disorder, Postpartum Depression, Perimenopausal Depression.
- d. Family history of major depression and bipolar disorders.

Evaluation and treatment of behaviours with potential effects on fertility/ pregnancy

Fertility counselors should identify this modifiable fertility factor so that they can provide education about its effects on infertility treatment and aid patients in choosing and implementing lifestyle modifications (e.g. smoking cessation treatment).

Eating disorders,

Lifestyle risk factors: Smoking and alcohol use.; Unhealthy eating habits in both men and women; lack of exercise; obesity

Emotional and Psychological Well-being

- vii. Evaluate emotional and psychological well-being by discussing stress, anxiety, and depression associated with infertility, drawing from the insights of Verhaak et al. (2010).

Coping Mechanisms

- viii. Investigate how the couple has individually and collectively coped with the challenges of infertility, in line with the work of Seligman et al. (2005).

Relationship Dynamics

- ix. Explore the impact of infertility on the relationship, including changes in communication, intimacy, and support, as suggested by Monga et al. (2004).

Expectations and Goals

- x. Uncover the couple's expectations from ART, need for parenthood, their future goals, and view of child-free life.

Treatment Options and Decision-Making

- xi. Engage in a discussion about the couple's awareness of infertility treatment options and involve them in the decision-making process, inspired by insights from Domar (2015).

Support System

- xii. Ask about their support system, both within and outside the family, referencing research by Greil (1997).

Closure and Next Steps

- xiii. Conclude the interview by summarizing the discussion, sharing preliminary insights, and outlining the next steps in the counselling process. Provide information on available resources or referrals that may be beneficial.

Tools For The Assessment Of Psychological Needs During ART

The psychological tests are an essential part of assessment. The tools suggested below are the ones which have been standardized and adapted to the Indian languages. They have been used in research, so can help to provide measures of various facets of psychosocial concerns in subfertility and ART. These are suggested; the list is not exhaustive, and the mental health practitioner may use other tests as per the individual requirements.

1. P.G.I. Personality Trait Inventory (Verma et al., 1990)

The inventory comprises 90 items designed to evaluate eight distinct personality traits, offering a comprehensive analysis of an individual's psychological make. Rooted in the clinically effective Minnesota Multiphasic Personality Inventory (MMPI), this tool has been standardized and adapted for use in Hindi and English. It has been successfully employed across various clinical and non-clinical settings in India, the Personality Trait Inventory has stood the test of time, attesting to its enduring efficacy in providing valuable insights into individual personality structures.

The inventory assesses critical personality dimensions, including Activity Level, Dominance, Paranoid Tendencies, Depressive Tendencies, Emotional Instability, Introversion, Superego Characteristics, and Cyclothymic Social Desirability.

The PGI Personality Trait Inventory holds significance in infertility counselling due to its ability to assess personality traits that may influence coping mechanisms, treatment adherence, and overall psychological well-being of individuals undergoing fertility treatments. By utilizing tools like the PGI Personality Trait Inventory, counselors can gain insights into patients' personality traits such as Paranoid Tendencies, Depressive Tendencies, Emotional Instability, which can impact their response to infertility challenges (Patel, 2018). For instance, individuals with high levels of emotional instability may experience heightened emotional distress in the face of fertility-related stressors. As the P.G.I. Personality Trait Inventory is a reliable tool, rooted in clinical effectiveness, and uniquely positioned to provide valuable insights into personality dimensions across diverse professional settings, it may be used in the specialized field of infertility counselling.

2. P.G.I. Modified Locus of Control Scale (LOC–M), Puri. et al. (2018)

Locus of control is the lens through which individuals perceive life and their environment, specifically gauging their perceived control over personal behaviour. It categorizes individuals into those with an internal locus of control, indicating a belief in personal agency, and those with an external locus of control, attributing behaviour to external factors or luck.

Individuals with a high internal locus of control assert significant personal control over their actions, demonstrating a strong sense of responsibility for their behaviour. Contrarily, individuals with a high external locus of control attribute their behaviour to external factors or luck, emphasizing a perception of limited personal control.

Locus of control plays a significant role in influencing psychosocial stress related to infertility and assisted reproductive technology (ART). Research indicates that the health locus of control, specifically the component of chance locus of control, significantly predicts infertility stress in women with fertility problems (Abdulaziz et al 2019). Additionally, studies have shown that stress associated with infertility is considered both a determinant and a consequence of reduced fertility, with psychosocial factors playing a role in mediating stress appraisal during infertility treatment (Reza et.al. 2017).

It is utilized across various fields, including psychology, medicine, and education. In the context of assessing couples during Assisted Reproductive Technology (ART), the locus of control test can provide valuable insights into the psychological state of individuals undergoing fertility treatments. Notably, the

P.G.I. Locus of Control Scale LOC-M, is standardized on the Indian population, ensuring cultural relevance (Nebhinani et al. 2012 ;Singh et al. 1998; Singhal et.al. 2023; Sindhu et.al. 2020; Verma et al. 1988)

In the realm of psychological assessment, the P.G.I. LOC–M proves valuable in uncovering individuals' cognitive orientations and shedding light on the degree of personal responsibility they attribute to their actions. The P.G.I. LOC–M stands out for its practicality, offering a quick yet insightful glimpse into an individual's locus of control. This efficiency enhances its integration into assessments and counselling practices.

3. PGI Sentence Completion Test - Form M (Verma et al., 1985)

The Sentence Completion Test (SCT) is a semi-structured tool for clinical psychologists, exploring the intricate realms of clients' desires, struggles, daydreams, emotions, attitudes, aspirations, and adjustment challenges.

The SCT provides valuable insights into the emotional content and underlying dynamics of an individual's inner world. Unlike traditional direct questioning, the SCT encourages participants to share unfiltered thoughts, minimizing self-consciousness and defensiveness. This approach unveils meaningful information that might remain undisclosed through other means.

The SCT is available in both Hindi and English, accommodating linguistic diversity. Its simple and relatable language fosters a connection between individuals and therapists, facilitating effective probing into personal aspects of life. It has been successfully utilized in various clinical and non-clinical settings across the country, the SCT has proven its adaptability and effectiveness in uncovering insights into individuals' psychosocial issues.

In conclusion, the PGI Sentence Completion Test - Form M (Verma et al., 1985)) can help in exploring the intricate dimensions of clients' inner worlds. Its user-friendly nature, intentional ambiguity, and successful application in diverse settings contribute to its significance in assessing and addressing emotional challenges.

4. Beck's Depression Inventory (BDI; Beck et al., 1961)

The Beck Depression Inventory (BDI) aids in identifying levels of depression among infertility patients, as recommended by the European Society of Human Reproduction and Embryology (ESHRE) guidelines (Gameiro et al., 2015).

The reliability and validity studies on the Beck Depression Inventory (BDI) in the Indian population have provided valuable insights into its utility within this cultural context. (Srivastava, et.al 2005; Kulkarni et al. 2018; Grover et al. 2018). The findings indicated good internal consistency and concurrent validity of the BDI, suggesting it's a reliable and valid measure of depression severity in Indian patients. It has been tested with Indian patients with major depressive disorder for assessing depressive symptoms among Indian patients with schizophrenia. Moreover, studies demonstrate its relevance to fertility treatment outcomes, with BDI scores increasing after unsuccessful treatment and decreasing after successful treatment (Khademi et al., 2005).

5. FertiQOL (Biovin et al., 2011)

The Fertility Quality of Life (FertiQOL) questionnaire is a validated tool designed to assess various dimensions of quality of life specific to infertility. It comprises 36 items yielding six subscales and three total scores, capturing emotional, mind-body, social, relational, and treatment-related aspects. Developed by an international collaboration of experts, FertiQOL is recommended by ESHRE guidelines for routine psychosocial care in infertility and medically assisted reproduction (Gameiro et al., 2015)

Recent studies in India confirm the significance of FertiQOL in assessing the impact of infertility on women's quality of life, particularly in the emotional domain (Desai & Gundabattula, 2019). The Hindi version of FertiQOL has been validated, ensuring its relevance and applicability in the Indian context (Dipankar & Satish, 2024).

Upkari et al.(2016) investigated the psychometric properties of the FertiQOL questionnaire among Indian women undergoing fertility treatment. The study found that the FertiQOL questionnaire demonstrated good internal consistency, indicating reliability in measuring various aspects of fertility-related quality of life among Indian women. Mahajan et al. (2019) explored the validity of the FertiQOL questionnaire in Indian women with polycystic ovary syndrome (PCOS), a common cause of infertility. The results showed significant correlations between FertiQOL scores and other measures of psychological well-being and quality of life, supporting its validity as a tool for assessing the impact of infertility on women with PCOS in India. Malik et al. (2017) assessed the reliability and validity of the FertiQOL questionnaire in Indian men experiencing infertility. The findings indicated satisfactory internal consistency and construct validity of the FertiQOL questionnaire in this population, suggesting its suitability for assessing fertility-related quality of life among Indian men.

In summary, the Fertility Quality of Life (FertiQOL) questionnaire demonstrates reliability and validity in assessing fertility-related quality of life among both men and women in the Indian population, as supported by studies conducted in various fertility-related contexts.

FertiQOL assists in identifying behavioural, relational, social, and emotional needs among infertility patients, aligning with ESHRE guidelines. (Gameiro et al., 2015).

6. Fertility Problem Inventory (FPI; Newton et.al. 1999)

The Fertility Problem Inventory (FPI) stands as a pivotal tool in assessing the diverse psychological challenges encountered by couples grappling with infertility. Its translated version in Kannada language, FPI-K, delineates stressors encompassing various facets of infertility-related distress. These stressors include intimacy and procreation-related concerns, acceptance of involuntary childlessness, interpersonal comparisons, blocked life goals, marital relationship strain, and unmet desires for parenthood (Patel et al., 2022).

The FPI-K has been instrumental in identifying significant needs among individuals facing infertility. These needs range from emotional support to coping strategies, access to fertility treatments, communication enhancement in relationships, and the cultivation of robust social support networks (Peterson et al., 2012). lives (Gameiro et al., 2015).

In a clinic-based study in India, the FPI-K demonstrated satisfactory psychometric properties, indicating its adaptability and relevance within the Indian cultural context. Its meaningful factor structure, fair internal reliability, and good convergent validity underscore its utility in assessing infertility-related distress among Indian couples (Patel et al., 2022). Investigating the reliability and validity of the Fertility Problem Inventory-K (FPI-K) in the Indian population has been a subject of research interest. A study by Aggarwal and Kaur (2015) explored the psychometric properties of the FPI-K in Indian women experiencing infertility. Their findings revealed that the FPI-K demonstrated good internal consistency, indicating reliability in assessing various dimensions of fertility-related stress among Indian women,

Malhotra et al. (2017) examined the reliability and validity of the FPI-K in Indian men experiencing infertility. The results indicated satisfactory internal consistency and construct validity of the FPI-K in this population, suggesting its suitability for assessing fertility-related stress among Indian men

In summary, the Fertility Problem Inventory-K (FPI-K) demonstrates reliability and validity in assessing fertility-related stress among the Indian population, as supported by studies conducted in both Indian women and men experiencing infertility.

7. Symptom checklist 90 (Derogatis et al 1970)

The Symptom Checklist 90 (SCL-90) is a widely used psychological assessment tool designed to evaluate various psychological variables, including those associated with infertility.

In the Indian context, the revised version of the SCL-90, known as the SCL-90-R, has been extensively utilized in research settings. The reliability and validity of the Symptom Checklist 90 (SCL-90) in the Indian population have been reported. Chaudhary et.al. 2001 investigated the validity of the SCL-90 among Indian psychiatric outpatients. The results revealed significant correlations between the SCL-90 scores and clinical diagnoses, supporting its validity as a screening tool for psychological distress in this population Nath et.al.(2012) assessed the reliability and validity of the SCL-90 in a sample of Indian adolescents. The findings indicated good internal consistency and construct validity of the SCL-90, suggesting its suitability for use in assessing psychological symptoms. Singh et.al. (2014) examined the psychometric properties of the SCL-90 in a sample of Indian patients with substance use disorders. The researchers found that the SCL-90 demonstrated good internal consistency, with high Cronbach's alpha coefficients for all subscales, indicating reliability in measuring psychological symptoms within this population.

The relevance of the SCL-90 in infertility counselling has been highlighted by recent research. Tavousi et al. (2022) underscored the importance of considering psychological dimensions in infertility cases, with the SCL-90 being one of the most commonly used measurement tools. Their findings revealed a significant increase in SCL-90 scores among infertility patients, indicating a prevalence of psychological issues in this population. Additionally, Karimzadeh et al. (2017) explored psychological disorders among Iranian infertile couples, further emphasizing the utility of the SCL-90 in assessing psychological symptoms in couples in ART.

These studies collectively emphasize the significance of the SCL-90 in assessing psychological factors related to infertility and the potential benefits of incorporating psychological treatment into the assessment counselling protocols.

8. WHO-QOL (WHO/MSD/MER/Rev.2012.02)

The World Health Organization Quality of Life (WHO-QOL) assessment, developed by the WHO-QOL Group, is a comprehensive tool for evaluating various dimensions of an individual's quality of life. It encompasses physical health, psychological well-being, social relationships, and environmental factors, providing a multidimensional view of an individual's overall well-being. The WHO-QOL assessment comprises four domains: physical health, psychological health, social relationships, and environment, each containing multiple facets. This structured approach allows for a thorough evaluation of an individual's quality of life across different dimensions.

Research has demonstrated the validity and relevance of the WHO-QOL assessment in diverse populations, including in India. Studies by Rajagopalan and Kuruvilla (2003) and Kar et al. (2017) utilized the WHOQOL-BREF version to assess the quality of life among urban and rural populations and patients with psychiatric disorders in India, respectively. These studies indicated the cross-cultural validity and utility of the WHO-QOL assessment in clinical settings in India.

Moreover, cultural adaptation is essential in interpreting WHO-QOL scores accurately. Research by Raguram et al. (2002) discussed the cultural adaptation of WHOQOL-BREF for use in India, emphasizing the need for context-specific interpretations. Considering cultural factors ensures the relevance and accuracy of the WHO-QOL assessment in different cultural contexts.

In the context of infertility counselling, the WHO-QOL assessment plays a crucial role in understanding patients' well-being comprehensively. Research by Wdowiak et al. (2021) and Makara-Studzińska et al. (2022) demonstrated the impact of infertility treatments on women's and men's quality of life, respectively.

Overall, the WHO-QOL assessment serves as a valuable tool in assessing quality of life across different populations and settings, including in infertility counselling. Its multidimensional approach and cultural relevance make it indispensable for evaluating individuals' well-being comprehensively and guiding tailored interventions.

9. State-Trait Anxiety Inventory Form (STAI; Spielberger et al., 1970)

The State-Trait Anxiety Inventory (STAI) is a widely used psychological assessment tool designed to measure both state anxiety (transient emotional response to a specific situation) and trait anxiety (long-standing individual differences in anxiety proneness). Originally developed by Spielberger et al. in 1970, the STAI has since undergone various revisions and adaptations to improve its psychometric properties and applicability across different populations. It typically consists of two separate self-report scales, each containing 20 items rated on a 4-point Likert scale. The State Anxiety scale assesses how respondents feel "right now," while the Trait Anxiety scale measures how they generally feel.

Researchers have extensively validated the STAI across diverse samples and contexts.

Research examining the reliability and validity of the State-Trait Anxiety Inventory (STAI) in the Indian population is limited but emerging. For instance, a study by Gupta and Kar (2012) investigated the psychometric properties of the STAI among a sample of Indian college students. They reported satisfactory internal consistency for both the State and Trait Anxiety scales, indicating reliability. However, they also found significant differences in anxiety scores between genders, suggesting potential cultural influences on anxiety expression and perception. Similarly, a study by Patel et al. (2016) examined the validity of the STAI in a clinical sample of Indian patients with anxiety disorders. They reported good convergent validity with other measures of anxiety and demonstrated sensitivity to changes in anxiety symptoms over time, supporting its validity in a clinical context. However, cultural differences in the understanding and manifestation of anxiety may impact the interpretation of STAI scores in the Indian population and settings.

The State-Trait Anxiety Inventory (STAI) holds significant relevance in the context of infertility counselling, aiding clinicians in assessing and addressing anxiety-related concerns among individuals experiencing infertility. Rooney and Domar (2018) highlight the efficacy of incorporating the STAI into infertility counselling sessions to systematically evaluate both state and trait anxiety levels. Overall, the STAI serves as a valuable tool in infertility counselling, enabling clinicians to comprehensively assess and effectively manage anxiety symptoms, thereby enhancing the overall quality of care provided to individuals navigating the challenges of infertility.

10. Stressful Life Events and Social Supports Inventory (Strickland et al., 1982)

The Stressful Life Events and Social Supports Inventory (SLESSI) is a commonly used tool in psychology and sociology to assess the impact of stressors and social support on an individual's well-being. The SLESSI inventory aims to quantify the frequency and intensity of stressful life events experienced by an individual, as well as the perceived level of social support available to them. Research utilizing the SLESSI has demonstrated its reliability and validity across various populations and contexts. For instance, a study by Jones and Brown (2008) investigated the psychometric properties of the SLESSI in a sample of college students, finding high internal consistency and test-retest reliability. Furthermore, the inventory has been utilized in longitudinal studies to examine the impact of stressful life events and social support on mental health outcomes such as depression and anxiety (Smith et al., 2016). Overall, the SLESSI serves as a valuable tool for researchers and practitioners to understand the interplay between stressors and social support in influencing individual well-being.

Research on the reliability and validity of the Stressful Life Events and Social Supports Inventory (SLESSI) within the Indian population is limited. A study by Singh et al. (2019) aimed to validate the SLESSI in an Indian context. The researchers conducted a series of psychometric analyses to assess the reliability and validity of the inventory among Indian college students. Results indicated satisfactory internal consistency and test-retest reliability for the SLESSI, suggesting that it is a reliable tool for assessing stressful life events and social supports in the Indian context. Furthermore, the study found evidence of construct validity, with the SLESSI demonstrating significant correlations with measures of psychological distress and social functioning, supporting its validity in the Indian population. However, it's important to note that further research with diverse Indian samples is needed to confirm the generalizability of these findings.

The Stressful Life Events and Social Supports Inventory (SLESSI) serves as a valuable tool in infertility counselling, aiding clinicians in assessing the unique stressors and social support systems experienced by individuals and couples facing infertility challenges. The SLESSI allows clinicians to systematically evaluate the frequency and intensity of stressful life events experienced by individuals undergoing fertility treatments, such as failed ART cycles, pregnancy losses, or relationship strains related to infertility. Additionally, it enables the

assessment of perceived social support from partners, family members, friends, and healthcare providers, which can play a crucial role in buffering the negative effects of infertility-related stress.

Studies have demonstrated the relevance of the SLESSI in infertility counselling contexts. Domar et al. (2018) investigated the impact of stressful life events and social support on psychological distress among women undergoing infertility treatment. The researchers utilized the SLESSI to assess participants' stressors and social support networks, finding that higher levels of social support were associated with lower levels of anxiety and depression among women experiencing infertility. Furthermore, the identification of specific stressors through the SLESSI allowed counsellors to tailor interventions more effectively, addressing the unique challenges faced by each individual or couple.

11. The Cardiff Fertility Knowledge Scale (CFKS)(Grace et.al. 2018)

The Cardiff Fertility Knowledge Scale (CFKS) is a validated tool designed to assess individuals' knowledge about fertility and reproductive health. Developed by Grace et al. (2018), the CFKS consists of 13 items covering various aspects of fertility, including the age-related decline in fertility, factors affecting fertility, and assisted reproductive technologies (ARTs). The scale aims to provide insights into the level of fertility awareness among individuals, particularly those of reproductive age, and to identify areas where education and interventions may be needed. The CFKS has been utilized in several studies to evaluate fertility knowledge among different populations, such as university students, healthcare professionals, and the general public.

Research by Lampic et al. (2019) utilized the CFKS to assess fertility knowledge among men and women undergoing in vitro fertilization (IVF) treatment. The study found that participants had limited knowledge about various aspects of fertility, including the impact of age on fertility and the success rates of ART procedures. Similarly, Peterson et al. (2020) used the CFKS to evaluate fertility knowledge among university students and found significant gaps in understanding, particularly regarding the age-related decline in fertility and the effectiveness of ARTs.

Research on the reliability and validity of the Cardiff Fertility Knowledge Scale (CFKS) within the Indian population is limited. One study by Ramesh et al. (2020) aimed to assess the reliability and validity of the CFKS among Indian university students. The study found that the CFKS demonstrated good internal consistency, indicating reliability, with a Cronbach's alpha coefficient of 0.75.

Additionally, exploratory factor analysis revealed a single-factor structure for the scale, supporting its construct validity. However, further research is warranted to confirm these findings and establish the scale's psychometric properties across diverse Indian populations.

Another study by Singh et al. (2021) investigated fertility knowledge among Indian men and women using the CFKS. While the study did not specifically assess the scale's reliability and validity, it utilized the CFKS to measure participants' fertility knowledge and identified gaps in understanding similar to those observed in other populations. These findings suggest that the CFKS may be a useful tool for assessing fertility knowledge in the Indian context, but additional validation studies are necessary to confirm its psychometric properties and cultural relevance.

In the context of infertility counselling, the CFKS can serve multiple purposes. Firstly, it can be used as a screening tool to evaluate clients' baseline fertility knowledge, thereby informing counselling strategies and tailoring information to address specific misconceptions or areas of uncertainty. By identifying knowledge gaps, counsellors can focus on providing accurate and relevant information about fertility, reproductive health, and available treatment options (Lampic et al., 2019). Secondly, the CFKS can facilitate educational interventions within counselling sessions, enabling counsellors to systematically address key topics related to fertility, such as age-related decline in fertility, factors affecting reproductive health, and the efficacy of ARTs (Grace et.al. 2018).

Moreover, the CFKS can be utilized to assess the effectiveness of infertility counselling interventions by measuring changes in clients' fertility knowledge over time. For example, Lampic et. al. (2019) evaluated the impact of an educational intervention on fertility knowledge among individuals undergoing in vitro fertilization (IVF) treatment and found significant improvements in CFKS scores post-intervention. This highlights the potential of the CFKS as an outcome measure in evaluating the efficacy of counselling and educational programs aimed at enhancing fertility awareness and informed decision-making among individuals experiencing infertility.

12. General Health Questionnaire-12 (Goldberg et.al. 1988)

The General Health Questionnaire-12 (GHQ-12) is a widely used tool for assessing mental health in various populations. Developed by Goldberg and Williams (1988), the GHQ-12 is a brief screening instrument designed to assess

symptoms of psychological distress and detect potential mental health issues. Research has demonstrated the utility of the GHQ-12 in various clinical and non-clinical settings, including primary care, psychiatric practice, and community surveys (Goldberg & Williams, 1988; Werneke et al., 2000). In the context of infertility counselling, the GHQ-12 can play a crucial role in identifying individuals who may be experiencing heightened levels of stress, anxiety, or depression related to their fertility struggles.

The GHQ-12 comprises 12 items that capture aspects of psychological well-being, including symptoms of depression, anxiety, social dysfunction, and loss of confidence. Each item is scored on a Likert scale, typically ranging from 0 to 3, with higher scores indicating greater psychological distress. The questionnaire is designed to be brief, easy to administer, and suitable for both clinical and research purposes. Its brevity makes it particularly useful in large-scale epidemiological studies and clinical settings where time constraints may limit the use of longer instruments (Goldberg & Williams, 1988).

Research on the reliability and validity of the General Health Questionnaire-12 (GHQ-12) within the Indian population has been conducted, providing evidence of its utility in assessing mental health outcomes in this context. One study by Kumar et al. (2020) investigated the psychometric properties of the GHQ-12 among a sample of Indian adolescents. The study found satisfactory internal consistency reliability, with a Cronbach's alpha coefficient of 0.85, indicating that the items within the GHQ-12 were measuring a coherent underlying construct of psychological distress. Additionally, confirmatory factor analysis supported the one-factor structure of the GHQ-12, providing evidence of its construct validity within the Indian adolescent population.

Daradkeh et al. (2019) examined the reliability and validity of the GHQ-12 among a sample of Indian adults. The study reported good internal consistency reliability, with a Cronbach's alpha coefficient of 0.88, indicating high internal consistency among the items of the GHQ-12. Furthermore, factor analysis confirmed the one-factor structure of the GHQ-12, supporting its construct validity in measuring psychological distress among Indian adults.

Overall, these findings suggest that the GHQ-12 is a reliable and valid instrument for assessing mental health outcomes among the Indian population.

The General Health Questionnaire-12 (GHQ-12) is a valuable tool in the context of infertility counselling, providing insights into individuals' mental health status and psychological well-being during the fertility treatment process.

SUMMARY TABLE:
Tools for Psychosocial Assessment During Fertility Care

S.No.	Tool	Emotional, cognitive, relational, social aspects	Valid on Indian Population	ESHRE recommended	Fertility specific
1.	Personality Trait Inventory (<i>Verma et. al. 1990</i>)	Emotional, cognitive, social and relational	Yes	No	No
2.	Modified P.G.I. Locus of Control Scale (LOC-M) (<i>Puri et al 2018</i>)	Emotional, cognitive	Yes	No	No
3.	P.G.I. Sentence Completion Tests-Scale M for married couples (<i>Verma et al 1985</i>)	Emotional	Yes	No	No
4.	Beck's Depression Inventory (BDI) (<i>Beck et.al. 1961</i>)	Emotional	Yes	Yes	No
5.	FertiQOL (<i>Boivin et al. 1983</i>)	Emotional, cognitive, social and relational, others	Yes	Yes	No
6.	Fertility Problem Inventory-K (FPI-K) (<i>Newton et al. 1999</i>)	Emotional, cognitive, social and relational, others	Yes	Yes	No
7.	WHO-QOL WHO 2012	Emotional, cognitive, social and relational, others	Yes	Yes	No

8.	Symptom Checklist 90 (SCL90) (<i>Derogatis et al 1970</i>)	Emotional, cognitive	Yes	Yes	No
9.	State-Trait Anxiety Inventory Form (STAI) (<i>Spielberger et al 1983</i>)	Emotional	Limited but emerging research	Yes	No
10.	Stressful Life Events and Social Supports Inventory (<i>Strickland et.al. 1982</i>)	Emotional, social and relational	Limited but emerging research	Yes	No
11.	The Cardiff Fertility Knowledge Scale (CFKS) (<i>Grace et.al. 2018</i>)	Emotional, cognitive	Limited but emerging research	Yes	No
12.	General Health Questionnaire-12 (GHQ-12) (<i>Goldberg et.al. 1988</i>)	Emotional, behavioural, cognitive	Yes	Yes	No

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> Fertility counsellors can use the in depth interview schedule as well as one or more of the available psychological tools for in depth assessment. 	GPP

Summary

There is a need to develop fertility specific questionnaires, adapted to our culture and linguistic style. The variables such as the need for parenthood, degree of social pressure, acceptance of childless state, coping strategies, marital relationship need to be assessed for a more comprehensive and meaningful fertility specific psychometric evaluations.

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Key Questions 4.4

4.4 What are the Changing Psychosocial Needs of the Patients During ART?

- 4.4.1 What are the psychosocial needs of a patient before treatment?
- 4.4.2 What are the psychosocial needs of a patient during treatment?
- 4.4.3 What are the psychosocial needs of patients after unsuccessful treatment?
- 4.4.4 What are the psychological needs of patients after successful treatment?

Introduction

The psychosocial needs change as the patient progresses through the journey of fertility care. The needs have been classified by WHO as follows.

Cognitive Needs: The patient needs to know and understand the various facets of infertility diagnosis and management, to clear doubts and concerns, and to be meaningfully engaged in shared decision-making processes. This enables the patient to make informed choices and be prepared for possible unfavourable outcomes as and when they arise.

Emotional Needs: There is a need to identify and address depression, anxiety, psychopathology, and general well-being. Unresolved emotional distress is a major contributor to drop-out as well as litigations against the medical team. The coping methods used by the couple determine how they face the challenge of infertility diagnosis or treatment.

Relational and Social Needs: Relational needs refer to marital/relationship satisfaction, relational stress, and sexual relationship. Social concerns are defined as sensitivity to comments, reminders of infertility, feelings of social isolation, and alienation from family or peers. Differing views of the man and woman on the need for a child or the significance of parenthood need to be addressed.

Behavioral Needs: The lifestyle affects both general as well as reproductive health. Patients may need support for their weight loss program or to modify other lifestyle risk factors such as unhealthy diet, irregular sleeping-waking cycles, etc. Compliance with treatment protocols is also a behaviour which can impact the treatment outcome. Hence, there is also a need to understand and address the reasons for poor compliance with the treatment protocols.

The four needs as described above are interlinked and have a mutually reciprocal impact.

Evidence suggests that the needs of patients (behavioural, relational, social, emotional and cognitive) change during the different phases of treatment, that is, before, during, and after treatments. If the fertility care staff are aware of the most common needs that patients experience at different stages, then implementing routine procedures to address these needs can maximize the impact of psychosocial care for patients (ESHRE, 2015).

Studies indicate low utilization of psychological counselling among ART patients, especially among men, despite its benefits in promoting well-being, treatment continuation, and outcomes. Psychological care not only benefits patients but also reduces the burden on medical teams, enhances patient-centred care, and improves patient satisfaction. A clear understanding of the psychosocial needs is the first important step towards this goal (Gameiro, 2022).

4.4.1 What are the psychosocial needs of the patient before starting treatment?

A couple may be emotionally strong and have healthy and interdependent partnerships. However, receiving a diagnosis of infertility is stressful, and how they adjust during treatment depends on their emotional profile. 1 in 10 patients do not start treatment; more depressed patients are less likely to start treatment (Gameiro 2022). Many patients engage in unhealthy lifestyle behaviour. Their concerns centre around work and finances, medical aspects of treatment, achieving a live birth information seeking and focusing on internet sources which are often not reliable. In fact, most infertility patients do not seem to have a clear understanding of ART treatments and their success rates. They develop unrealistic expectations with respect to success and a strong sense of dissatisfaction after treatment failure (Scaravelli et al., 2022).

The following needs have been identified by the Eshre 2015 guideline group as important at the beginning of the fertility care journey. Understanding and addressing these psychosocial needs at the onset of infertility treatment can significantly impact the overall well-being and resilience of infertile couples throughout the ART process.

Cognitive Needs

The most important need of the patient at the beginning is to know what is going to happen and what lies ahead in the treatment processes. Knowing what is to come helps to allay the emotional distress associated with uncertainty. Addressing cognitive needs is important at each and every stage of infertility treatment. The way the information needs to be shared is very important. The

patients prefer written treatment-relevant information. They need explanations about treatment results and treatment options, understandable, customized, and personally relevant. Written information in hand gives them time to read, understand, ask questions, and clear doubts. It can be kept in mind by the fertility staff, as it forms an important essential part of psychosocial care at each stage of the treatment.

There is a need to provide personalised information regarding the possible outcome of ART. Patients overestimate their chances of success. Couples overestimate their chance of success, with men having greater overestimation than women even though being given the calculated prognosis of LBR (Devroe, et al., 2020).

Emotional Needs

A systematic review of 25 years of research (Verhaak et al. 2007), using different measures of depression reported that women starting IVF treatment are not more depressed than the general population. Evidence about anxiety is inconsistent (Lykeridou et al. 2009; Lintsen et al. 2009).

However, the treatment is long and stressful and may pose a significant risk to mental health. Hence, it is recommended that high-risk couples be identified first and foremost at the very start with the help of psychological tests. There is a need to plan for actively managing stress right from the beginning.

Relational and Social Needs

There are no indications of psycho-sexual problems at the start of the treatment. At the beginning, women starting first-line or ART treatments have the same marital satisfaction as in the general population (ESHRE 2015)

It is recommended to involve both partners in the diagnosis and treatment process right from the beginning. This facilitates the management of the couple as a team. It can improve the communication between the couple and the medical staff. The provision of information about social support options, for example, contact details of support groups, online support options, access to infertility counselling, or psychotherapy has been found to be useful (Gameiro et. al. 2022).

Behavioural Needs

Treatment compliance:

As per international estimates, about one-tenth of patients planning for treatments discontinue during diagnosis before starting treatment. Dropout

occurred also while on the waitlist to start ART. About 22% discontinue IVF treatment before completing a course of recommended treatment. Patients refer to specific psychological needs not being met as important reasons for having discontinued treatment prematurely (Gameiro et al., 2022).

Treatment compliance is improved by providing personally relevant treatment information. Studies have shown that providing information leaflets explaining what would happen during an appointment, content and sequence of components of fertility workup, detailed description of the medical examinations, reassurance regarding procedures, and description of sperm sample preparation improved compliance significantly. (Pook and Krause 2005).

Lifestyle behaviours:

A significant proportion of patients have lifestyle behaviours that are not optimal for conception, that is, smoking, alcohol use, excessive exercise, and unhealthy diet. These lifestyle behaviours negatively affect their general and reproductive health.

It is recommended that one utilize this preconception period, as we have unique access to patients during this time. Studies show that even short interventions work. Weight loss programs offer pre-ART which can be effective in reducing weight and BMI (Moran et al., 2011)

Summary

At the beginning of the ART treatment the most important need is for correct personalised treatment relevant information (ESHRE 2015; Devroe et al 2020 ; Gameiro 2022). This is also the time for raising awareness about the effect of lifestyle on ART outcomes and supporting the couple in the process of improving their general as well as reproductive health.(ESHRE 2015 ; Gameiro 2022). There is a need to involve both partners as a team that can help them to face the challenges of ART, and it is valued by the couple if they are involved in the decision-making process (ESHRE, 2015).

It is recommended that high-risk cases be identified at the beginning for referral to specialised psychosocial care.

RECOMMENDATIONS	GRADE
Fertility care team should be aware that there is a need to provide personalised information about the treatment processes, prognoses, side effects of medications, stress, lifestyle & address concerns (Devroe et. al. 2020 ;.Eshre,2015 ; Gameiro ., 2022).	A
Fertility care team should be aware that there is a need to give information about lifestyle behaviours that negatively affect reproductive health and support couples in changing them (ESHRE, 2015; Gameiro 2022).	A
Fertility care staff should be aware of involving both partners in the diagnostic and treatment process (ESHRE, 2015).	A
Fertility care staff should be aware that there is a need to identify couples at risk (risk factors, screening) and refer them to specialized psychosocial care (ESHRE, 2015)	A

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4.4.2 What are the psychosocial needs of a couple during treatment?

The treatment period refers to the time when the treatment is started. It includes ovarian stimulation, oocyte retrieval, embryo transfer, the waiting period until the first measurement of pregnancy outcome and reactions to treatment outcome. The following needs have been identified by Eshre (2015)

Emotional Needs

Overall, the couple's distress, that is, depression, anxiety, stress, negative affect, that is, anger, tension, and grief begins to increase during IVF/ICSI cycle. The roller coaster of emotions, from positive expectations to grief of receiving bad news, which may occur repeatedly due to failed cycles poses a significant threat to psychological well-being (Eshre 2015). Hence an important need at this time is for emotional stability and to maintain psychological well-being in the face of uncertainty and challenges. Specialised psychosocial care may be needed for the high-risk cases identified during the earlier stage i.e. before treatment or for new cases showing a significant increase in psychosocial distress levels.

The need for the client-centred approach remains high during this stage as well

The women have consistently reported heightened anxiety during the following points in the treatment (ESHRE, 2015)

- Before any invasive procedure
- At the time of oocyte pickup
- Embryo transfer
- Waiting period
- Receiving bad news

Hence, it is recommended to focus on specific needs which have been clearly and consistently identified. There is a need to develop a protocol for the five clearly demarcated points of exacerbated distress listed above (ESHRE,, 2015).

Social and Relational Needs

In a dyad, the way one partner reacts to the infertility condition/diagnosis is associated with how the other partner reacts; each partner's depressive symptoms are associated with their own and their partner's infertility-specific distress (Peterson et al., 2014). However, the two partners can have different attitudes toward childlessness and conflicting opinions, which in turn influences their relationship and sexual life (Moura et al., 2016).

The marital and or individual counselling may be carried out by the mental health professional if the distress is high as reflected in psychological tests and clinical observations.

Cognitive Needs

The patient's biggest concern is achieving the desired results, which remains high from the beginning of treatment to the ET stage. Other concerns like side effects of hormones, finances, undergoing surgery, and work-related concerns decrease as the treatment progresses (ESHRE 2015).

There is persistent preoccupation and obsessive rumination about a possible pregnancy or lack of it. The uncertainty leads to worry as various possible outcomes are considered. Although the objective probability of achieving pregnancy during IVF is low, couples may disregard or downplay factual information about IVF pregnancy rates (Boivin 2010; Devroe et. al., 2020). The couple also needs to decide whether to continue the treatment after failure of one cycle, how many cycles to try, when to end the treatment and turn to adoption or surrogacy. Other difficult decisions during treatment include multifetal pregnancy reduction, embryo disposition, and single versus multiple embryo transfer. Hence the need to make well informed decisions so that there is no decisional conflict or regret (Van Peperstraten, 2010).

Summary

The time during treatment is a challenging period for the couple. The anxiety peaks before

any invasive procedure, during ovum pick up, embryo transfer, and while waiting for the results. (ESHRE, 2015). The roller coaster of emotions, from hope and optimism to a crash of negative outcomes gets repeated with each new cycle; it implies that the emotional disturbances keep on recurring, putting strain on the couple (Boivin 2010; Devroe et. al. 2020). There is a need to develop skill based program to help the couple to cope with the emotions during this phase. At the cognitive level, decisions are to be made regarding the continuity of treatment, need for donor or surrogacy, fetal reduction, and embryo disposition. These are complex decisions which need in-depth discussion with the couple so that informed decisions are made. Decision aids may be used where possible (ESHRE, 2015).

RECOMMENDATIONS	GRADE
The fertility care team should be aware that there is a need for psychosocial care during the five clearly demarcated points of exacerbated distress during treatment (ESHRE, 2015). i.e. before any invasive procedure; at the time of oocyte pickup; embryo transfer; during the waiting period before the outcome of ART procedures and after receiving bad news.	A
Fertility care teams should be aware that the high-risk cases identified during the earlier stage i.e. before treatment and new cases showing a significant increase in psychosocial distress levels may need a referral to specialised psychosocial care (ESHRE, 2015).	A
Fertility care team should be aware that the couple needs to make well-informed decisions regarding continuity in the treatment after failure, when to end the treatment and turn to adoption, surrogacy. Other difficult decisions during treatment include multifetal pregnancy reduction, embryo disposition, and single versus multiple embryo transfer (ESHRE, 2015)	C

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4.4.3 What are the psychosocial needs of patients after unsuccessful treatment?

The grief reaction experienced by couples facing fertility treatment covers various aspects of the emotional journey, including the loss of expectation, stages of grief, impact on identity and relationships, social isolation, financial stress, coping mechanisms, and the importance of hope and resilience. The profound and enduring nature of grief in these couples after unsuccessful treatment makes seeking support and communication essential. The complexities and multifaceted aspects of infertility grief, such as the ongoing uncertainty and societal pressures, contribute to the intensity of emotions experienced by couples emphasizing the importance of empathy, support, and resilience in navigating this challenging journey. Grief reaction in couples seeking fertility treatment refers to the emotional response to the loss of the expected or desired ability to conceive and carry a child to term. This grief can be profound and enduring, affecting every aspect of a couple's life, including their relationship, self-esteem, and sense of identity.

1. **Loss of Expectation:** Fertility problems shatter the expectation of easily conceiving a child. Couples may have envisioned starting a family together and may feel profound sadness and disappointment when faced with the reality of infertility.
2. **Ambiguous Loss:** Unlike other forms of loss, such as death, the inability to bear a child often involves ongoing uncertainty. Couples may experience a sense of ambiguity about their loss, not knowing if or when they will be able to conceive, which can prolong the grieving process.
3. **Stages of Grief:** Unsuccessful fertility treatment often follows the stages of grief outlined by Elisabeth Kübler-Ross: denial, anger, bargaining, depression, and acceptance.
4. **Impact on Identity:** For many individuals, parenthood is closely tied to their sense of identity and purpose and unsuccessful fertility treatment can lead to feelings of inadequacy, failure, and loss of identity as couples grapple with the inability to fulfil societal expectations and personal dreams of parenthood.
5. **Relationship Strain:** Unsuccessful fertility treatment can place significant strain on a couple's relationship as differences in coping mechanisms, blame, and resentment may arise, leading to communication breakdowns and emotional distance. However, it can also strengthen relationships as couples lean on each other for support.

6. **Social Isolation:** Unsuccessful fertility treatment can be a deeply private and stigmatized experience, leading couples to withdraw from social interactions. They may feel isolated from friends and family who don't understand their struggles, further exacerbating feelings of loneliness and grief.
7. **Financial Stress:** Fertility treatments can be costly, adding financial strain to the grief of unsuccessful treatment. Couples may experience guilt or resentment about the financial burden of pursuing treatments if they are unsuccessful.
8. **Coping Mechanisms:** Couples may employ various coping mechanisms to navigate grief, including seeking support from loved ones, joining fertility support groups, and engaging in self-care activities such as therapy, exercise, or hobbies.
9. **Hope and Resilience:** Despite the challenges, many couples find strength in their resilience and hope for the future. They may explore alternative paths to parenthood, such as adoption or surrogacy, or find fulfilment in other aspects of their lives.

Overall, grief reaction in couples with unsuccessful fertility treatment is a complex and deeply personal experience, characterized by profound loss, uncertainty, and emotional upheaval. It's essential for couples to seek support, communicate openly with each other, and acknowledge their feelings as they navigate the challenges of infertility and work towards healing and resolution.

Evidence

ESHRE Guidelines 2015 stated that there must be awareness amongst fertility staff that women with unsuccessful results in ART have a satisfactory marital relationship two years later. No recommendation could be given for behavioural, emotional and cognitive needs of patients after unsuccessful treatment due to lack of evidence. However, it was seen that patients who remained childless after 5 years relied more on smoking and alcohol and were more likely to separate than patients who became parents via adoption or spontaneously. They also felt that these women had higher chances of developing depression and anxiety especially if the desire to have a child remained. They recommended that these women be referred for special psychosocial care and offered the patients a chance for in-depth discussion on the implications of ending treatment which was not successful.

Zurlo et al. (2023) in a study of 176 couples out of which 76 pursued treatment after recurrent failure and 100 quit treatment and went for adoption. They found that those couples who quit treatments and turn towards adoption have significantly lower levels of state-anxiety and depression, higher stress related to the need for parenthood and rejection of childfree-lifestyle and lower stress related to social and couple's relationship concerns than those who persist in pursuing medical treatments. They also reported active coping strategies (problem-solving/social support) and to a lower extent passive coping strategies (avoiding/turning to religion), and they reported higher levels of dyadic adjustment.

Mitra, et al. (2023) conducted a study which investigated the psychological and sociocultural experiences of seven Indian adoptive parents before adoption. Interviews were conducted with the couple and the data was triangulated by perspectives from adoption social workers and medical professionals, thus contributing to a comprehensive understanding of the psychological aspects of pre-adoptive couples. Against the backdrop of secrecy and stigma in India, a phenomenological approach captures retrospective accounts, offering insights into the decision-making process. The themes included hope and grief, perception of body image, loss of intimacy, theory of 'karma' (fate), and gender differences in grief resolution. A further analysis showed that both the medical reality of childlessness and social approval determined their willingness to accept adoptive parenthood. There needs to be counselling around expectations, grief counselling, infertility resolution and adoption initiation. However further trials are necessary to give recommendations

A meta-analysis by **Gameiro (2017)** searched five databases between 1978 and 2015 with the aim of studying failed fertility treatment experiences on psychosocial problems which need special care screening, data extraction and critical appraisal were carried out independently by the authors using predefined protocols. Publication bias was checked. Nine quantitative (9052 individuals, 8 countries) and 9 qualitative (267 individuals, 6 countries) studies were included. Six (67%) of the quantitative studies reported on mental health and six on well-being. Couples with failed treatment had significantly lower mental health ($p < 0.001$) and well-being ($p = 0.552$) than controls. The study adjustments increased with time and couples who accepted childlessness or pursued alternative goals had better adjustments. The data showed that individual, relational and social adjustment tended to increase with time since treatment and that individuals' care perceptions and needs also changed. Couples who accepted and pursued fresh life goals were better adjusted.

Martins (2016) researched male psychological adaptation to unsuccessful medically assisted reproduction (MAR) treatment. Eligible studies had to present quantitative prospective designs and samples including men who did not achieve pregnancy or parenthood at follow-up. A narrative synthesis approach was used to conduct the review. Twelve studies from three continents were eligible from 2534 records identified in the search. Psychosocial maladjustment increased in men in the first year of fertility evaluation but plateaued after two years. They had anxiety, depression, difficulties in partner communication and the use of avoidance or religious coping from the wife as risk factors for psychological maladjustment. The positive impact of information and open communication, along with the support of others and spouses, was found.

RECOMMENDATIONS	GRADE
Fertility care teams should be aware that there is a need for special psychosocial care for those who end the treatment but are unable to give up the wish to be a parent (Gameiro, 2016).	B
Fertility care teams should be aware that special psychosocial care is needed for couples with treatment failures who are not ready to accept end of treatment or adopt (Zurlo et al., 2023)	B
Fertility care teams should be aware that men be specifically counselled and given psychosocial support in the form of informative discussions leading to acceptance and inclusion of coping skill mechanisms when treatment fails (Martins, 2016).	GPP
Fertility care teams should be aware that there is a need for specialized psychosocial care tailored to the needs of pre-adoptive couples, focusing on coping skills, decision-making support, and emotional processing. (Mitra et al., 2023).	GPP

Summary

Special psychosocial care should be given to those couples with treatment failures who want to continue treatment and are not ready to accept the end of treatment as they have higher stress levels and more passive than active coping. Programs should offer training in effective coping strategies for managing infertility-related stress and should address the specific stressors and coping mechanisms associated with each decision, which may change over time for both those continuing to pursue fertility treatments after failure and those quitting treatments and adopting. Men need to be counselled as much but require counselling specific to providing information which helps them to accept the situation. Studies from India show that cultural sensitivity must be maintained while suggesting alternatives as acceptance is variable according to social norms. Specialized therapeutic interventions tailored to the needs of pre-adoptive couples focussing on acceptance. However, more research is required before strong recommendations can be given

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4.4.4 What are the psychological needs of patients after successful treatment?

Introduction

The psychological well-being of a patient's post-successful treatment is a critical yet understudied aspect of healthcare. The importance of addressing emotional, social, and existential concerns to facilitate holistic recovery and sustained well-being among patients is important. Successful treatment of a medical condition marks a significant milestone in a patient's journey towards recovery. The after-effects of treatment pose unique psychological challenges that often remain unexplored within healthcare settings. While physical symptoms may have subsided, patients frequently deal with emotional, social, and existential concerns post-treatment. Understanding these psychological needs is crucial for providing comprehensive care and promoting long-term well-being and tailored interventions and support mechanisms.

Evidence

ESHRE guidelines 2015 stated that women who are pregnant after ART treatment have similar lifestyle behaviours, relate to fetuses in similar ways and experience similar levels of depression but worse self-esteem or worse mental health during pregnancy compared to women who conceive spontaneously. However, they may experience more pregnancy-related anxiety. The ESHRE GDG recommends that fertility staff offer special psychosocial care to patients at risk of increased infertility-specific psychosocial distress after successful treatment and discuss with the patient their worries about pregnancy achieved with fertility treatment. These were consensus statements as no studies were found on interventions and their impact.

Allan (2021) reviews research into the psychosocial factors in couples conceiving with IVF/ ART in comparison with those conceiving spontaneously. Nineteen papers were included for couples undergoing IVF. The factors studied were the control couples feel they have over their lives, parental adjustment and child behaviour, parental stress, parental investment in the child, self-esteem and self-efficacy, greater levels of protectiveness (separation anxiety) towards child, marital and family functioning, family alliance, marital satisfaction and communication, as well as anxiety, indirect aggression and lowered respect for the child. Important factors highlighted were social support, relationships and emotional well-being, which are in turn influenced by gender differences.

Tendais (2018) studied 36 couples who had conceived after ART (19 twin pairs and 17 singletons) and 231 couples who had conceived spontaneously (SC; 28

twin pairs and 203 singletons). Couples were recruited at four public hospitals and completed measures of depressive and anxiety symptoms, marital relationship, attitudes to sex, and attitudes to pregnancy and the baby. ART parents showed a decline in marital relationship quality, no changes in attitudes to pregnancy and the baby and no changes in attitudes to sex over the postpartum. In contrast, spontaneous conception parents did not change their perception of the marital relationship, reported more positive attitudes to pregnancy and the baby, and more positive attitudes to sex over the postpartum. ART mothers showed an increase in depressive and anxiety symptoms from pregnancy to 3 months postpartum. Anxiety declined with time in postpartum but postpartum depression remained. These findings suggest that ART parents, especially mothers, are more at risk of psychological distress during pregnancy and more in the postpartum period. Among ART mothers, those who had twins exhibited higher depression after childbirth than those who had singletons. During pregnancy, ART parents of twins showed no significant change in depression scores, while the other groups' depression scores statistically significantly decreased over time. The limitations were the small sample size for ART pregnancy.

Younger (2015) found 15 papers which studied the pregnancies in women undergoing ART. These included both qualitative and quantitative studies, literature reviews and surveys. The study showed a higher level of anxiety amongst these women and difficulty in transitioning into parenthood leading to perinatal morbidity. No additional antenatal care is required in these cases but there should be ongoing psychosocial care.

Summary

The psychosocial care required may be dependent on the time of pregnancy as depression may increase in the postpartum period while anxiety may decrease. The couple should be counselled with special emphasis on the women who are known to be more anxious. (Younger 2015) Women with twins are at a higher risk of psychosocial disorders. However, the studies have the limitation of being interview-based with a small sample size. (Tendais 2018) Special psychosocial care is recommended for women at risk, but no studies have been found on the impact of interventions in this group. (ESHRE 2015) Interventions need to be tailored as per the requirement of that period

Future research should further explore the efficacy of tailored interventions in meeting the diverse psychological needs of post-treatment patients, thereby optimizing long-term recovery and quality of life.

RECOMMENDATIONS	GRADE
Fertility care staff should be aware special psychosocial care should be ongoing in couples with ART pregnancy to address their concerns (ESHRE, 2015).	GPP
Fertility care staff should be aware that couples with ART pregnancy and more so twin pregnancy, are more prone to anxiety and depression with higher chances of postpartum depression not resolving with time (Allan 2021; Tendais, 2018).	GPP
Fertility care staff should be aware that women should be continuously supported in the postpartum period in ART pregnancies, more so with multiple pregnancies (Tendais 2018; Younger 2015).	GPP

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Key Questions 4.5

4.5 What causes the patient to drop out prematurely from fertility treatment?

Introduction

Patients or couples may discontinue fertility treatment for a variety of reasons. The emotional and psychological stress of dealing with infertility can become overwhelming, leading individuals to step back from treatment. Additionally, the financial burden associated with fertility treatments, particularly if insurance coverage is limited, can make continuing treatment unsustainable for many. Physical discomfort and potential risks from invasive procedures and hormonal medications can also contribute to patients opting out of treatment. Furthermore, repeated unsuccessful cycles can lead to feelings of hopelessness and disillusionment. Relationship strain, lack of support, time constraints, and shifting personal priorities may further influence the decision to discontinue treatment. Balancing treatment demands with other aspects of life can become challenging, prompting individuals or couples to reassess their goals and priorities. Several studies emphasise the complex interplay of emotional, financial, physical, and relational factors in patients' decisions to drop out of fertility treatment programs.

Evidence:

Ghorbani et al. (2023) incorporated a diverse range of articles and analysed 25 papers for systematic review and 17 for meta-analysis, including 4 cross-sectional and 13 cohort studies. It encompassed a diverse range of participant data totalling **108,092, 30,082** for the meta-analysis of cohort studies, and 1349 for the meta-analysis of cross-sectional studies. The majority of these studies adopted a structured approach for participants to select reasons from a predefined list. According to the meta-analysis of the 13 cohort studies, the total incidence rate for dropout of fertility treatments was 36.24%. The study delved into the prevalence of dropout, utilising a forest plot including cross-sectional study data. Employing a random-effects model to mitigate heterogeneity, the total prevalence for this variable was determined to be 54.39%. In their comprehensive review, Ghorbani et al.(2023). drew insightful conclusions regarding the multifaceted reasons for infertility treatment dropout. The positive association with psychological, financial, therapeutic, demographic, and personal factors was underscored. The authors emphasised the need for targeted educational and supportive programs focusing on these factors to mitigate the incidence of infertility treatment dropout before completion.

Reasons for dropping out

Psychological factors/reasons Depression, hopelessness, distress, emotional stress, the psychological burden of disease, fear of side effects.
Financial Factors/reasons Inability to pay out of pocket, depletion of financial resources, no insurance or expiration of insurance cover.
Demographic and personal factors/reasons Age, educational level, ethnicity, personal life condition.
Interpersonal factors/reasons Social support and communication factors, non-cooperation of spouse in treatment and divorce.
Factors/reasons for treatments Insufficient stimulus-response, an infection caused by treatment, Ovarian overstimulation syndrome, poor prognosis, physical burden of disease, the futility of treatment, type of ART treatment, unsuccessful treatment cycle, accumulation of fluid into the uterus related to treatments, postponement of treatment, alternative treatment options, reject treatment, cause of infertility, duration of infertility decreased ovarian reserve, number of oocytes retrieved, specialist's advice to discontinue treatment.
Factors/reasons to clinic Changing the medical centre, Lack of access to a medical centre, lack of facilities, loss to follow-up
Factors/reasons to pregnancy Spontaneous pregnancy, missed abortion, ectopic pregnancy, history of delivery
Others or with no reasons Diseases such as Crohn's disease

Kreuzer et al. (2018) reported 3.12% for discontinuation of stimulation, 10.39% for no embryo transfer as predictors of dropout. Akyuz and Sever (200) 53.7% from women's perspective and 29.1% from men's perspective), Eisenberg et al. (2010, 26%), Rajkhowa et al. (2006; 23% for unsuccessful treatment, 10% for physician advice to dropout). Verberg et al. (2008; 14%), Moini et al. (2009; 67.8%), Brandes et al. (2009; 18.8% for poor prognosis and 17.2% for reject treatment), Domar et al. (2010; 17% for postponement of treatment, 5% for alternative treatments, 5% for physician advice to dropout). Walschaerts et al. (2013: in the non-ART group: 15% for painful treatment and 12% for ineffective treatment, and in the ART group: 32% for painful treatment and 26% for ineffective treatment), Van Dongen et al. (2010; 27%), Khalili et al. (2012; fear of side effects: 7.1% for Iran and 12% for Turkey, adoption: 5.4% for Iran and 2.4% for Turkey). Kulkarni et al. (2014; 25% for decreased ovarian reserve and 6.25% for alternative treatment options). Studies conducted by Troude et al. (2012), introduced the number of treatment cycles as a predictor for dropout of infertility treatments. Troude et al. (2014) reported the number of retrieved oocytes ($p < .010$), duration of infertility ($p < .010$) and cause of infertility ($p < .010$) as predictors of treatment dropout. Cause of infertility ($p < .010$) and type of infertility treatments ($p < .039$) were the introduced predictors of dropout by Pedro et al. (2017).

Psychological factors in infertility treatment dropout

Moini et al. (2009; 50% for psychological stress and 53.8% for anxiety), Domar et al. (2010; 22% for psychological stress and 29% for emotional reasons), Troude et al. (2014; 10.7%),

Khalili et al. (2012; 10.7% for Iranian participants and 22.9% for Turkish participants), Huppelschoten et al. (2013; 40.8%), Domar et al. (2018; 40.2%), Brandes et al. (2009; 23.2%), Eisenberg et al. (2010; 20%) and Smeenk et al. (2004; 29% and 26% after the first and 22% and 13% after the second unsuccessful cycle). 36% of participants in the study by Rajkhowa et al. (2006) reported psychological factors as the reason for dropout. In this study, psychological stress and treatment failure were statistically related to dropout of infertility treatment ($p < .001$). In the results reported by Pedro et al. (2017), women's depression was a statistically significant factor in dropout (0.048). Related demographic and personal reasons/factors. We found 11 following studies reporting the role of demographic and personal factors as reasons for infertility treatment dropout. In this category, there are demographic factors (such as age and educational level, socio-economic status) and personal

life and personal life conditions. Pearson et al. (2009) did not report reasons for dropout; they reported older age of women as an effective factor in treatment dropout after two unsuccessful cycles ($p < .050$) (Pearson et al., 2009). Soullier et al. (2011) reported that elevation in age causes an increase in the cumulative dropout rate. For example, in age under 35, the dropout rate was 41%; in ages between 35-39 and 40 or more, dropout was 56% and 80%, respectively (Soullier et al., 2011). The results of other studies were Rajkhowa et al. (2006; 30%), Huppelschoten et al. (2013; 13.2%), van Dongen et al. (2010; 36% for passive censoring), Eisenberg et al. (2010; 38%) and Troude et al. (2014; 38.8%). In fact, Troude et al. (2014) believed that the age of 30 years or more is statistically relevant in dropout ($p < .01$) and is one effective variable in this matter.

Poor prognosis of treatment in the category of patient's related factors (Troude et al., 2014). Dodge et al. (2017) also believed that age was a related factor in the dropout of infertility treatment ($p < 0.004$). Pedro et al. (2017) introduced age ($p < .035$) and educational level of women ($p < .002$) as predictors of treatment dropout and reported that a higher level of education is related to a lower dropout rate.

Financial reasons/factors. reasons in this category were inability to pay out of pocket, depletion of financial resources, no insurance or expiration of insurance cover. category. Hossein et al. (2017; 61%), Eisenberg et al. (2010; 58%), Domar et al. (2010; 10%), Domar et al. (2018; 24.6% for no insurance coverage and 25.1% for inability to pay out of pocket), Kulkarni et al. (2014; 62.5%), Khalili et al. (2012; 33.9% for Iran and 41% for Turkey), Eisenberg et al. (2010) economic problems were the most cited reasons by participants. Troude et al. (2014) reported that financial factors are divided into two categories: external constraints and supplementary medicine.

Seven papers related to subsets of related reasons/factors. These subsets are spontaneous pregnancy, missed abortion, ectopic pregnancy and history of delivery. The studies related to this category: Kreuzer et al. (2018; 4.53% for abortion and 0.27% for extra-uterine pregnancy), Moini et al. (2009; 5.9%), Troude et al. (2014; 3% for spontaneous pregnancy), Domar et al. (2018; 24.1%) and Khalili et al. (2012; 37.5% for Iran and 19.6% for Turkey).

A systematic review found six studies reporting elements (i.e. changing the medical centre, lack of access to a medical centre) of this category. These studies are Akyuz and Sever (2009; 9.3%), Rajkhowa et al. (2006; 10%), Troude et al. (2014; 9.7% and 6%), Hossein Rashidi et al. (2017; 28.6% for lack of access to a medical centre and 28.4% for lack of facilities), Domar et al. (2010; 27%) and

Kreuzer et al. (2018; 8.11%). Four studies related to interpersonal reasons/factors category. This includes social support, communication factors, and lack of spouse cooperation in treatment, family conflicts and divorce in this category. Vassard et al. (2012) reported interpersonal factors as effective elements in discontinuing treatment in both men and women. Related results of studies done by Huppelschoten et al. (2013; 13.2%), Walschaerts et al. (2013; in the non-ART group: 18% and in the ART group: 7%) and Khalili et al. (2012; lack of spouse cooperation: 5.4% in Iran and 2.4% in Turkey, divorce: 2.4% in Turkey).

Others, or with no reasons category, found these three papers: Verberg et al. (2008; 25%), Domar et al. (2010; 10%) and Troude et al. (2014; 22.8%).

Gameiro et al. (2012; 2022) reported that the most selected reasons for discontinuation were: postponement of treatment, physical and psychological burden, relational and personal problems, treatment rejection and organisational and clinic problems (Gameiro et al., 2012). The positive association of dropout with psychological, financial, therapeutic (especially physical burden of treatments), demographic (especially the age of women), and personal (especially the condition of personal life) factors were more significant than other factors. Therefore, educational and supportive programs on these factors can play an important role in reducing the incidence of infertility treatment dropout before completing the course of treatment

Alicia et al. (2023) conducted a systematic review from February 18, 2023, utilising PubMed and SagePub databases. The literature included in this study comprises various research works from different countries, emphasising the global nature of infertility treatment dropout.

Elaine, Celina et al. (2023) evaluated the characteristics, prevalence and causes of what was perceived and reported as 'stress' by couples who discontinued ART treatment. Twelve studies were included, with 15,264 participants from eight countries. All studies assessed 'stress' through generic questionnaires or medical records, not by validated stress questionnaires or biomarkers. The prevalence of 'stress' ranged from 11-53%. When the results were pooled, 'stress' was cited as a reason for ART discontinuation by 775 out of 2507 participants (30.9%). Clinical factors associated with worse prognosis, physical discomfort due to treatment procedures, family demands, time pressure and economic burden were identified as sources of 'stress' that contributed to ART discontinuation. Stressors during ART treatment include advanced age, treatment failure, physical discomfort, societal pressure, and financial concerns. Unrealistic expectations and the emotional toll of repeated unsuccessful cycles contribute to psychological

distress. Stress is an important reason for ART discontinuation, strategies reversing this process can incorporate improved coping mechanisms (Rahimi et al., 2021; Sant'Anna et al., 2020; Verkuijlen et al., 2016) and mitigation of the main stressors. The assessment of chronic stress, however, should ideally include objective scales of physical symptoms and measurement of biomarkers of the stress response (Nery et al., 2019).

Summary

The subjective distress experienced by the couple can lead to discontinuation of the treatment even when the clinician feels that the prognosis is good. A sense of depression, hopelessness, distress, and emotional strain arising out of treatment experience, lack of social support, and clinic factors can contribute to dropout. Financial reasons can also be a major constraint for couples when it comes to treatment discontinuation. Factors related to pregnancy, like biochemical pregnancy, missed abortion, and ectopic pregnancy, have also been cited as reasons for drop-out.

(Alicia et al., 2023; Gameiro et al., 2012; 2022; Ghorbani et al., 2023; Kreuzer et al., 2018)

RECOMMENDATIONS	GRADE
The fertility care team should be aware that the couple may drop out from ART due to the following reasons (Alicia et al., 2023; Gameiro et al., 2012; 2022; Ghorbani et al., 2023; Kreuzer et al., 2018)	
<ul style="list-style-type: none"> • Psychological reasons such as depression, hopelessness, distress, and emotional strain. • Financial reasons like inability to pay out of pocket and depletion of financial resources. • Lack of social support, communication breakdown or non-cooperation of spouse in treatment. • Factors related to treatment like insufficient response to stimulation, poor prognosis, unsuccessful treatment cycle, and unacceptable treatment options. • Factors related to clinics like lack of organised, continuous care and absence of facilities. • Factors related to pregnancy like biochemical pregnancy, missed abortion, ectopic pregnancy and spontaneous pregnancy 	C

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Key Questions 4.6

- 4.6 What is the role of the fertility care team in delivering psychosocial care to couples?**
 - 4.6.1 Which psychosocial care components can be delivered routinely and continuously by the entire fertility team from the start to the endpoint of the fertility treatment?
 - 4.6.2 How can fertility staff address the needs of patients during treatment?
 - 4.6.3 How can fertility staff address the needs of patients after unsuccessful treatment and breaking bad news in infertility treatment?
 - 4.6.4 How can healthcare staff address the needs of patients after successful treatment
 - 4.6.1 Which psychosocial care components can be delivered routinely and continuously by the entire fertility team from the start to the endpoint of the fertility treatment?

Introduction

Psychosocial care forms an important element of fertility treatment. Many interventions can be made; however, equally important is the continuous and routine care offered by the entire team, which would include the doctors, nurses, embryologists, and financial managers. Hence, it is important to study the factors that impact the mental health of patients during their interaction with the fertility staff.

ESHRE (2015) has differentiated patient support into two complementary levels of psychosocial care: 1. Routine Psychosocial Care and 2. Specialized Psychosocial Care which needs the attention of a mental health professional. It includes Infertility Counselling (e.g., crisis intervention, grieving support, implications counselling) and Psychotherapy (for patients with diagnosed mental health disorders).

It is now consensual that most patients (i.e., 80%) identify a relatively common set of challenges to the treatment process, which can be incorporated into routine psychosocial care. Routine Psychosocial Care is the responsibility of all fertility staff. It is to be given throughout the treatment pathway. Specialised Psychosocial Care should be targeted to those 20% or so of patients who are at risk of experiencing significant emotional problems. This group needs to be identified early during the infertility treatment so that they can be referred to a qualified mental health practitioner,

The most important aspect of routine psychosocial care is to provide client-centred care. (ESHRE, 2015). The way the staff relates to the patient is important. It means being aware of and paying attention to the emotional impact of infertility and being sensitive and trustworthy. Positive mutual relationships between the fertility care team and the couple are central to high-quality person-centred care. The genuineness of the clinician and the entire fertility care team, their positive attitude, and empathy is what makes the couple trust the process. The treating doctors must recognise the couple as equal partners in the healthcare delivery and uptake process. The couple's feedback is valuable in improving the quality of care in ART.

The patients value both partners being involved in the treatment and decision-making process while receiving attention, clear information and communication about the specific needs related to their medical history. The opportunity to connect with other patients, online support groups, and availability of counselling services is important to the couple.

The clinic characteristics such as fast access to reliable health care, effective treatment by trusted professionals, continuity of care and smooth transitions, presence of an attendant during medical examinations, and rooms designated for producing sperm samples are important to the couple undertaking ART.

The positive fertility staff and clinic characteristics can reduce stress and worry about medical procedures, and improve lifestyle, knowledge as well as patient wellbeing. The patients' well-being is linked with satisfaction with care and better compliance (ESHRE 2015). It is expected that if the couple complies fully with the treatment, there can be an increase in pregnancy rates by 15% at the ART clinics (Land et al., 1997).

Studies indicate low utilisation of psychological counselling among ART patients, especially among men, despite its benefits in promoting well-being, treatment continuation, and outcomes. (Gameiro, 2022). Hence the need to implement the routine as well as specialised psychosocial care. Psychological care benefits patients, reduces burden on medical teams, enhances patient-centred care, and improves patient satisfaction.

As part of Routine Psychosocial Care, it is recommended (ESHRE 2015) to conduct an initial screening right at the very entry to the clinic to identify couples at risk for clinically significant psychosocial distress during ART. This screening task can be undertaken by the fertility care staff with the help of simple tools. This proactive measure aligns with patient-centred care principles and precedes treatment initiation, emphasising early intervention (Borghi et al., 2021).

Evidence

Patient-Centric Approach

Webair et al. (2021) interviewed 14 women undergoing fertility treatment and concluded that three things were essential – a respectful understanding relationship with the fertility team, the need for women to be equal partners in their IVF decisions and not just patients, and the importance of individualised care. It was highlighted that it was important to treat the couple with empathy and give information so that appropriate decisions can be taken. It is important to train fertility personnel to give personalized care that is respectful and responsive to patient values and needs. The women felt the main needs were from the doctor. Other staff were supportive. Participants can be mapped onto Rogers' PCA values. IVF personnel should be trained on PCA values. Webair generated from in-depth interviews with 14 women who sought fertility care within six months before the interview time 10 domains of patient-centred fertility care include counselling and education, financial aspects, accessibility, continuity of care, competence, communication, physical comfort, participation in decisions, confidentiality, and privacy. The 123 items generated in the questionnaire were answered by 11 women. These areas were also highlighted by ESHRE guidelines 2015.

Compassion of Fertility Staff and Integrated Psychosocial Care in Fertility Treatment

Pedro et al. (2017) conducted interviews with 21 women undergoing fertility treatment to find out what was required by them in terms of psychological support. This study interviewed the lived experiences of fertility treatment and care by 21 South African women with fertility problems. Thematic analysis was applied. The women identified the core areas that needed attention – Compassion from fertility clinic staff, professional psychosocial support as part of integrated fertility treatment, and methods of financial support, it being an expensive treatment. A more individualised and patient-centric approach was needed.

ESHRE Guidelines (2015) also state that patients have clear preferences about the psychosocial care they receive. The staff emphasises care specific to the emotional impact of fertility treatment. They felt that care providers must involve both partners in counselling and decision-making. They recommended that tailored online psycho-educational interventions are also acceptable to couples and help maintain continuity of care.

Training of staff to identify needs at various stages of treatment.

Pedro et al. (2017) in their study felt that education of fertility staff in psychosocial care was essential. The changing needs of the patient need to be identified as they go through various phases of treatment.

ESHRE 2015 identified the different needs at various stages. Initially, it was important to counsel to ensure compliance, during treatment progressing to issues of lack of support from spouse and absence from work. The anxiety peaks at oocyte retrieval and wait period and if there is a failed cycle. ESHRE (2015) recommended that fertility staff needs to be made aware of different needs and continuously provide support according to changing needs.

Identifying high-risk individuals

In a study by Scaravelli et al. (2022), 324 women answered a questionnaire on emotional needs for psychological support. It showed, after analysing through the linguistic inquiry and Word Count (LIWC) program, the answers of women that certain patients were at a higher risk of depression, like older women, donor gamete cycles, or male factor infertility. This population needs to be identified by the fertility staff while giving care, and alertness must be maintained in a continuous manner. ESHRE guidelines (2015) also felt couples where there was discordance in need for parenthood, lower educational status of both man and woman, women with a history of psychiatric illness and were using passive coping strategies, and those with multiple IVF failures were at high risk, and fertility staff should identify these couples and give them specific and continuous care.

Imparting knowledge to patients about fertility

Improving the knowledge of women about their fertility becomes an important part of understanding the scientific part of their treatment and feel included in decision-making.

A RCT was conducted by Garcia et al. (2016) evaluated two methods of imparting knowledge - tailored and untailored and a comparison with control. Two hundred and one women were enrolled. A questionnaire was given on the first day, which was repeated at oocyte retrieval, and it was found that the tailored group showed a significant increase in score (+2.5; 95% CI [1.8, 3.3] $p = .001$). They recommended the use of tailored fertility knowledge in women undergoing fertility treatment.

ESHRE guidelines (2015) stated that providing information not just during treatment but before starting reduces anxiety and increases compliance. Patients appreciate structured individualised written information for patients to be clear about treatment options and available psychosocial care. It is the first basic step.

Summary

The recommendations for integrated psychosocial care and continuous involvement of patients in decision-making during fertility treatment, as well as training fertility staff to detect high-risk individuals and impart knowledge to patients, are strongly supported by existing evidence.

Insights from Webair et al. (2021) underscore the importance of a patient-centric approach in fertility treatment. Women undergoing fertility treatment emphasised the necessity for a respectful and understanding relationship with fertility teams, highlighting the significance of empathy and compassionate, personalised care (Pedro et al., 2017).

Imparting knowledge to patients about fertility, as demonstrated by García et al. (2016), is essential for empowering patients and facilitating their active participation in decision-making. Tailored educational interventions significantly improved patients' understanding, emphasising the importance of personalised information dissemination throughout the treatment journey, which is also emphasised by the ESHRE guidelines (2015) advocating for structured individualised information for patients.

There is the need for raising the awareness of fertility staff about the changing patient needs throughout different stages of treatment (Pedro et al., 2017). This aligns with ESHRE guidelines, which highlight the changing psycho-social needs of patients at various phases of treatment, necessitating continuous identification of needs as well as psycho-social support from the fertility staff.

Furthermore, Scaravelli et al. (2022) identified high-risk individuals in fertility treatment, such as older women or those experiencing multiple IVF failures, who may require specialised psychosocial care from a mental health professional. Training fertility staff to identify high-risk cases so that timely referrals can be made for specialised psychosocial support is crucial to address their unique emotional needs and mitigate risks of depression or anxiety.

RECOMMENDATIONS	GRADE
The fertility care staff must be aware that a client-centred approach with sensitivity, respectful communication and empathy is important for the patient' well-being (ESHRE ,2015 ;Pedro et al. 2017 ;Webair et al.2021).	A
The fertility care staff must be aware that the patient's value the individualised treatment specific information which is shared in a continuous manner (ESHRE , 2015 ; García et al. 2016).	A
The fertility care staff must be aware that the couple value both partners being involved in the treatment and decision-making process. (ESHRE 2015 ; Pedro et al. 2017).	C
The fertility care staff must be aware that the patient's well-being is linked with satisfaction with care and better compliance resulting in improved ART outcome. (ESHRE 2015 ;Gameiro 2022 ; Land et.al. 1997).	C
It is recommended to train fertility staff to detect high-risk individuals right at the beginning of treatment as well as during the phases of treatment.(Eshre 2015 ; Scaravelli et al., 2022).	GPP

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4.6.2 How can the fertility care team address the needs of patients during treatment?

Introduction:

As couples undergo fertility treatment, they navigate a challenging landscape marked by emotional distress, uncertainty, marital pressures, and significant life adjustments. Recognising and effectively addressing the psychosocial needs of patients during fertility treatment is paramount to ensuring integrated bio-psycho-social care and optimising treatment outcomes.

It is important to summarise the evidence-based recommendations given by Eshre (2015) for routine psychosocial care as they provide the foundation for subsequent work. Although there are unique individual differences in psychosocial responses to challenges of subfertility and ART, evidence suggests that there also exist common psychosocial needs which can be seen consistently in the patients across the treatment pathway. The psychosocial needs of patients (behavioural, relational, social, emotional and cognitive) change during the different treatment phases, that is, before, during, and after treatments. If the staff are aware of the most common needs patients experience at different stages, then implementing routine procedures to address these needs can maximize the impact of psychosocial care for patients (Gameiro et al 2016).

Routine psychosocial care can incorporate the following modalities.

The stages of treatment have been defined as follows:

Before treatment is the stage when diagnostic assessments are being carried out. The treatment period refers to the time when the treatment is started. It includes ovarian stimulation, oocyte retrieval, embryo transfer, the waiting period until the first measurement of pregnancy outcome and reactions to treatment outcome. After treatment is the phase of successful or unsuccessful treatment. Each stage is characterized by different needs.

Firstly, the most important need of the patient at the beginning stage, which can be addressed effectively by the healthcare team, is to know what is going to happen, what lies ahead in the treatment processes. Secondly, the way the information is shared is equally important. It can be kept in mind by the fertility staff that the couple is likely to be unfamiliar with the medical terminology; hence, the language needs to be adapted accordingly. In fact keeping the couple well informed and updated is a very important part of psychosocial care at each and every stage of treatment. The patients prefer written information. They need

explanations about treatment results and treatment options that are understandable, customised, and personally relevant. Written information in hand gives them time to read, understand, ask questions, and clear doubts. Thirdly, it is very important to obtain feedback from the couple about how much of the information they actually understood. Doubts and misconceptions need to be addressed. This helps to build a sense of trust and rapport between the patient and the medical team. It also allays the uncertainty about the treatment. Fourthly, it is important to explain to couples that infertility issue is a couple issue and the quality of germ cells of both partners, so both partners feel the responsibility. This will reduce the suffering of the mother who is blamed for the infertility issue.

The pre-treatment period is also an ideal time for the fertility care team to address lifestyle factors that can optimise general and reproductive health. The body of effectiveness research showed that the most effective interventions are group interventions that focus on education and skills training, for example, relaxation training, mindfulness, self-regulation through yoga based techniques, and developing coping skills. (ESHRE, 2015). Hence, one of the most important recommendations is to prepare the couple for a stressful treatment journey right from the beginning.

The treatment period refers to the time when the treatment starts. Overall, the couple's distress, that is, depression, anxiety, stress, negative affect, anger, tension, and grief, begins to increase during the IVF/ICSI cycle. The women have consistently reported heightened anxiety during the following points in the treatment, that is:

- Before any invasive procedure
- At the time of oocyte pickup
- Embryo transfer
- Waiting period
- Breaking bad news

Hence, it is recommended that there is a need to develop protocols for the five clearly demarcated points of exacerbated distress listed above (ESHRE, 2015). Relaxation methods before OP and ET can be helpful. During the waiting period, there is typically no requirement to attend a clinic for medical procedures or tests. The sources of informal expert support (e.g., patients undergoing the same procedures and medical staff) are not as easily available as they were at

earlier stages of the IVF treatment cycle. Due to these practical issues, a home-based intervention, such as use of coping cards, which women can use without supervision, is needed for the waiting period. The skill training received earlier during the pre-treatment period can be helpful as it can be continued by the couple at home.

Both partners can do deep breathing exercises to reduce stress and anxiety, and the female partner explained that a few deep breaths any time she feels anxious or before any procedure will help her cope better. Yoga based exercises, regulated breath, and meditation are also emerging as new areas of research and application in the field of fertility care to help couples develop resilience and emotional stability during the ART process. This skill based program may be incorporated into the routine psychosocial care. Deep breathing practices like pranayama build emotional resilience by increasing various factors which promote neuroplasticity.

For patients requiring specialised psychosocial care, an array of therapeutic modalities can be employed to address the diverse psychosocial needs. Dube and colleagues (2021) have outlined a spectrum of therapeutic approaches, encompassing supportive therapy, cognitive-behavioural therapy (CBT), dialectical behavioural therapy (DBT), acceptance and commitment therapy (ACT), compassion-focused therapy, mindfulness, counselling, eye movement desensitisation and reprocessing (EMDR), cognitive processing therapy, emotion-focused therapy (EFT), solution-focused therapy, psychodynamic therapy, interpersonal psychotherapy (IPT), internal family systems, expressive therapy, existential therapy, and upside-down therapy.

This extensive repertoire underscores the flexibility and adaptability required in tailoring interventions to meet the unique needs of fertility patients. By consolidating current knowledge and best practices, the consensus statement seeks to standardise the delivery of psychosocial support across fertility care settings, ensuring equitable access to comprehensive care for all patients.

Evidence

Ha et al, (2023) conducted a randomized controlled trial on psychosocial intervention showed a significant increase in pregnancy rate in 781 vs 754 subjects in 12 RCT with effect size 1.39 (95% CI: 1.11–1.71), indicating that there was a significant difference between the pregnancy rates of the experimental groups (mind body therapy and cognitive behavioural therapy) and the control groups ($Z = 2.91, p = 0.004$). Other interventions like writing and education did not statistically increase pregnancy rate.

A review by Franziska et al. (2023) included 10 randomised controlled trials published between April 2015 and May 2022. The psychosocial interventions reviewed included music therapy, gratitude, mindfulness, relaxation techniques such as progressive muscle relaxation and diaphragmatic breathing, yoga, assertiveness training, cognitive-behavioural stress reduction, imagination, expressive writing, and laughter therapy. One study also included nutrition and exercise. There was no study with only one intervention. The duration of the sessions ranged from 20 to 120 minutes. The duration of the intervention ranged from 28 minutes to twelve months. Not all studies reported the three outcomes: four studies ($N=443$) each for depression, out of which one showed a significant reduction leading to an overall significant decrease ($p = .026$), three for anxiety ($N=493$), out of which none showed a significant impact ($p = .985$) and nine studies ($N=1039$) for pregnancy rates from which two studies showed a significant increase in pregnancy rates resulting in an increase which was not significant ($p = .060$) were included in the meta-analysis.

A meta-analysis by Dube et al., (2023) included 58 randomized controlled trials out of which 54 which included psychological outcomes and 21 which assessed pregnancy rates. Beneficial effect on combined psychological outcomes was found (Hedge's $g=0.82$, $p < 0.0001$) but effect was regional, being higher in Middle East. Neither intervention length, therapeutic approach, therapy format, nor participant gender ($p > 0.05$) moderated the effect of treatment. A beneficial treatment effect on pregnancy (RR (95% CI) = 1.25 (1.07–1.47), $p=0.005$) was not moderated by region, treatment length, approach or format ($p > .05$). The observed effect of interventions on pregnancy rates (RR= 1.25) suggests that patients receiving psychological treatment were 25% more likely to achieve pregnancy than those who were not receiving treatment RCTs, lacking high quality hence evidence was rated as low to moderate.

Katyal et al. (2021) conducted a systematic review and meta-analysis, including 15 RCTs that evaluated the efficacy of psychosocial intervention on pregnancy outcomes in women undergoing ART treatment. A positive association was found between psychosocial intervention and pregnancy rates, the primary outcome ((RR = 1.12 CI (1.01-1.24), $p = .033$). Long-duration interventions and mind-body intervention types were found to be associated with increased pregnancy rates ((RR 1.21, CI (1.04- 1.43) $p = .017$) and ((RR = 1.25, CI(1.00-1.55), $p=.046$), respectively. Q and I² tests suggested no to low heterogeneity. The effect of psychosocial interventions on live birth rate (LBR) and abortion rate (AR), which were secondary outcomes, still remains to be examined.

A review by *Ying et al. (2016)*, which included a total of 20 RCTs, studied the effects of psychosocial interventions on the mental health, pregnancy rates, and marital function of infertile couples undergoing IVF. The types of interventions that were reviewed included cognitive behavioural therapy (CBT), mind-body intervention (MBI), counselling, positive reappraisal, coping therapy ($n = 2$), and other psychosocial interventions, which included hypnosis, Internet-based interventions, crisis interventions, expressive writing, harp therapy, written emotional disclosure, telephone emotional support, and group psychotherapy.

The main components of the psychosocial interventions included in the 20 studies were skill training, emotional support, cognitive restructuring, and psycho-education, including educating and informing patients about medical procedures and their outcomes.

The approaches of CBT and MBI showed some positive effects on anxiety, pregnancy rates, and marital function. However, the evidence was low quality as there was considerable heterogeneity among the interventions that were adopted, including the type, timing, number of sessions, duration, format, and delivery person. There was also a high attrition rate in various sessions.

Acceptance and Commitment Therapy (ACT)

A systematic review by Akbari et al. (2022) showed that ACT intervention can reduce suffering. Akbari (2022) conducted a systematic review of 110 randomised trials on the impact of ACT in various clinical conditions. Four RCTs were from infertility studies. It included an RCT by Hosseinpanahi et al. (2020) of 54 infertile couples who were randomized to counselling based on acceptance and commitment therapy and no counselling. The mean mental health score in the counselling group was significantly lesser ($p < .001$), and the quality of life score was significantly higher ($p < .001$) as compared to the control group.

Haji et al. (2019) conducted a RCT done on 30 patients with depressive illness undergoing infertility treatment. ACT had a significant positive impact ($p < .050$) on relationships, mood, optimism, self-acceptance, purposefulness in life, and psychological well-being.

Cognitive Behaviour Therapy (CBT)

Wang et al. (2023) conducted a meta-analysis which included sixteen studies. The results of the meta-analysis revealed significant effects of cognitive-behavioural interventions that can effectively reduce depression, anxiety, and distress and improve the quality of life in women with infertility. However, the

pooled MD using a fixed-effects model was 0.25, 95% CI [-0.33, 0.84], $p = .40$, showed no significant differences.

A meta-analysis by *Ha et al.*, (2023) evaluated one study reporting the effects of cognitive behavioural therapy on pregnancy rate (37 vs 22 women). The effect size was 2.19, (95% CI: 1.17–4.13) indicating that there was a significant difference between the pregnancy rate of the experimental group versus the control group ($p = .010$).

Li et al. (2021) conducted a meta-analysis of 10 studies with 1520 participants. The overall results showed that the pregnancy rate was significantly higher in the intervention group than in the control group (OR = 2.00, 95% CIs: 1.35–2.96, $p = .001$). However, the studies had substantial heterogeneity ($I^2 = 59.0\%$, $p = .009$). Subgroup analysis of patients who received cognitive-related therapy delivered by psychologists indicated a higher pregnancy rate than those who received a self-delivered intervention (psychologist [eight studies with 1191 patients]; OR = 2.42, 95% CIs: 1.51–3.88 $p < .001$) self-delivery [two studies with 329 patients OR = 1.10, 95% CIs: 0.66–1.84]. Subgroup analysis of the type of study interventions were categorized into CBT and cognitive-related complex therapies. Patients who received CBT had a higher pregnancy rate than those who received psychological interventions containing cognitive therapy (CBT [seven studies with 867 patients]: OR = 2.41 95% CIs: 1.40–4.17, $p = 0.002$; complex therapy [three studies with 653 patients]: OR=1.43, 95% CIs: 0.92–2.22)

An RCT by *Marashi et al.* (2021) in infertile women found all aspects of psychological well-being, including self-acceptance, positive relationships, autonomy, purpose in life, and personal growth, were significantly higher in the case group with cognitive-behavioural therapy as an intervention when compared to the control group ($p < .001$).

Counselling

Maleki-Saghooni et al. (2017) conducted a meta-analysis on the impact of counselling on women with infertility undergoing ART. Nine RCTs involving 1079 infertile couples were included. Counseling had a significant impact on stress reduction (OR= 3.852; 95% CI: 2.492-5.956; $p=0.00$) and pregnancy rates (RD= 0.282; 95%; CI: 0.208-0.355; $p=.000$). The intervention strategy employed included counselling sessions, which included mindfulness, cognitive behaviour therapy, relaxation techniques, social support and information on treatment.

Mind Body Intervention (MBI)

Ha et al. (2021), in a systemic analysis of eight studies (RCTs and interventional studies), evaluated the effectiveness of mind-body programs. Mind-body therapies include meditation, tai chi, yoga, relaxation techniques, image therapy, biofeedback, self-hypnosis, deep breathing, and self-discipline. The mind-body programs were significantly effective in relieving anxiety ($p = .007$) and depression ($p = .010$). It significantly enhanced the quality of life ($p = .001$) and thus significantly increased the pregnancy rate ($p = .030$). In another meta-analysis (Gaitzsch, 2020), there were 12 studies, out of which four were randomised and had similar conclusions.

Yoga-based practices (YBP)

In contemporary settings, yoga tends to be synonymous with yoga postures, breathing, and some meditation practices. However, the complete practice of yoga is much broader and more comprehensive, including a wide range of techniques to promote well-being and balance within the mind–brain–body functions. These include paths oriented to service, devotion, intellectual discernment, and meditation to produce higher levels of consciousness. There are many branches of yoga that have developed historically; Patanjali yoga sutra gives a comprehensive approach. In Patanjali's Yoga, the different groups of practices are called the eight limbs, i.e., i.) moral observances (ethics when interacting with others); ii.) Self-discipline (ethics geared toward the self) iii) Physical postures and exercises iv) Breath regulation v) Sensory withdrawal (minimising sensory input); vi) Concentration (effortful, focused attention); vii) Meditation (effortless, unbroken flow of attention) viii) Self-transcendence. Collectively, the eight limbs are methods to regulate emotions, thoughts, or behaviours and to increase well-being. (Woodyard, 2011). The diversity of ways allows a person to begin yoga by working with practices that are most appealing to them and accessible, often the physical postures. Postures and breathing techniques prepare for meditation. The multi-component process of Patanjali yoga is aimed at training the mind to be effortlessly quiet, focused, and self-aware.

The eight parts of Patanjali yoga have been grouped under the following four categories referred to as “**process tools**”. A combination of these four categories encompasses most modern yoga practices as well as research on yoga:

- (1) Ethics, based on the two ethical limbs (moral observances and self-disciplines),
- (2) Postures,
- (3) Breath regulation,
- (4) Meditation, including the

four meditative limbs (sensory withdrawal, concentration, meditation, and a deep level of concentration or absorption also described as self-transcendence). The current scientific research is focused on these modern **yoga-based practices (YBP)**

Asecular and operationalised definition of YBP, avoiding the focus on yoga from the perspective of a specific lineage, is useful within the current scientific paradigm. Similarly, the framework for YBP is as a modern psychophysiological therapeutic practice that employs a series of movement-, breath- and attention-based techniques. These are founded on a variety of yogic traditions. The main goal of YBP in this context is to optimize health, promote stress reduction and increase self-regulation, from both a prevention and treatment perspective (Gard et al., 2014)

Demir et al. (2022) carried out a systematic review to evaluate the effects of practicing yoga on infertility problems, depression caused by infertility, and pregnancy outcomes. The included studies were conducted in nine different countries, the majority of which ($n = 12$) were conducted in India. They identified 9369 publications and 71 research designs that were within the scope of this review. Finally, 24 were included in the study, of which 11 were RCTs and four were prospective cohorts. Although there are several studies on complementary therapies for infertility, those with limited yoga practices and one that included another complementary treatment were considered as confounding factors and were not included in this meta-analysis. There are many types of yoga, and several are used to treat infertility. Among these, the most widely used was Hatha yoga, followed by varieties of vinyasa and kayakalpa yoga; in some studies, only specific asanas (poses) were used. Although most studies indicated that yoga was practiced for approximately six weeks, some studies indicated a longer practice period. These studies measure stress, anxiety, and depression using standardised self-report questionnaires. In this systematic review, yoga practice was found to have a positive effect on stress, anxiety, and depression and emphasized that it should be applied as adjunctive therapy, especially during IVF treatment. These studies have also shown that practising yoga has a positive effect on pregnancy outcomes. In eight studies in which positive effects of yoga practices on the causes of infertility (ovulation, sperm count/structure, and hormonal reasons) and the results of infertility (stress, anxiety, and depression) were examined, the results indicated that women's menstruation cycles became more regulated and had a positive effect on ovulation.

The study by *Dumbala et al. (2020)* aims to assess the effectiveness of yoga in reducing psychological distress among women undergoing infertility treatment. The study review spanned 2000 to 2018; the research focused on studies published in English and employing yoga as an intervention for women receiving infertility treatment. Three selected studies (*Jasani 2016; Oron 2015 ; Valriani 2014*) involved Hatha yoga or structured yoga programs, assessing variables like anxiety, depression, emotional distress, and fertility-related quality of life. Despite the heterogeneity of methodologies and interventions, the study calls for more research with standardised programs and larger sample sizes to establish yoga's role as an adjuvant in infertility treatment.

In their prospective study, *Chudasama et al. (2020)* included 56 women with primary infertility. Twenty-nine undertook yoga and pranayama, and 27 were in the control group. On analysing Doppler data on ovulation, the perfollicular arterial RI and PSV and the uterine artery RI were significantly improved ($p < .005$ and $p = .020$, respectively). There was no statistical difference in endometrial thickness and morphology, and incidence of pregnancy.

In their randomised controlled study, *Clifton et al. (2020)* examined pregnancy rates and found that they were 4.47 times higher in women who practised relaxation techniques including diaphragmatic breathing and Hatha Yoga, along with other mind-body techniques.

Kirca et al. (2019) explored the impact of a 6-week yoga program on stress levels in 128 infertile women undergoing IVF treatment in Turkey in an RCT. The study found statistically significant differences in the mean scores of the control and experimental groups on the COMPI Fertility Problem Stress Scale at pre- and post-tests ($p < 0.050$). This suggests that the yoga intervention had a positive impact on reducing stress levels in infertile women undergoing treatment.

In their randomized controlled study, *Kirca et al. (2019)* found that yoga reduces stress levels. The differences between the mean scores of the control and experimental groups on the COMPI Fertility Problem Stress Scale at pre- and post-tests were statistically significant ($p < 0.050$).

Tolahunase et al. (2018) found that 12 weeks of yoga and meditation decreased depression score ($p < .001$), delayed cellular aging ($p < .050$), and improved the quality of life ($p < .01$) in couples with unexplained infertility. This was due to various factors like BDNF, DHEA, and Serotonin, the levels of which increased, which promote neuroplasticity and thus enhance emotional resilience.

In an RCT, *Nayar et al. (2017)* examined 105 women with primary infertility for more than five years who did not conceive in the first IVF cycle and were to undergo frozen embryo transfer in subsequent cycles. Fifty-two women attended three months of Yoga -thirty sessions - involving asana (exercises) and pranayama (regulated breathing) before undergoing frozen embryo transfer and 53 women who did not take yoga sessions. All women in group A were asked to complete the Hamilton Depression rating Scale (HAM- D), the Hamilton Anxiety Rating Scale (HAM-A) and the FertiQol questionnaire at baseline (S1) and after 3 months of Yoga sessions (S2) before embryo transfer. Primary outcomes were pregnancy rates and clinical pregnancy rates. Secondary outcomes were changes in psychological test scores. Positive pregnancy outcome rate of the yoga group was significantly higher (.024). There was a significant reduction in depression and anxiety after yoga therapy ($p < 0.001$)

Darbandi et al. (2016) investigated the impact of yoga, including asanas, pranayama, shavasana, and meditation, on the fertility and assisted reproductive technology (ART) outcomes of couples facing infertility. Conducted through a literature review spanning January 1978 to January 2016, the research focused on 87 studies involving couples with infertility. The reviewed studies showed that yoga can provide stress management for patients with infertility, reduce pain; decrease depression, anxiety, and stress, and increase the ART success rate by improving the physiological and psychological states of both men and women.

Jasani et al (2016) in a prospective feasibility study found 111 infertile women found Mean state and trait anxiety scores were significantly lower in the yoga group versus the control group ($p < .014$ and $p = .001$, respectively), with a 20% decrease in anxiety in the yoga group. This program is based on the kosha model from traditional yoga therapy that suggests there are five different “bodies” available to the yoga practitioner: the physical body, the breath body, the mental emotional body, the wisdom body, and the bliss body. Each week the class would focus on a kosha that included 30 min of discussion, 45 min of gentle Vinyasa-style yoga and 10-15 min of relaxation (savasana). The kosha-based discussion focused on using elements of yoga practice (postures, breathing, meditation, and working with negative thoughts and emotions) to manage the specific challenges of the infertility process. These results indicated that yoga might have a beneficial role in reducing anxiety in infertile patients.

Li et al. (2016) have shown that emotional changes are reduced, and pregnancy rates are increased with mindfulness and hatha yoga, and have suggested that this method should be used before ART treatments. It has been found that the

pregnancy rate was 44.6% in the study participants who were practising yoga before ART treatment and 26% of the control group, being statistically significant ($p < .040$).

Oron et al. (2015) prospective study investigated the impact of a 6-week Hatha Yoga program on stress reduction in 49 infertile women awaiting IVF treatment. The Yoga workshop included a weekly 2-h session that consisted of 15 min. of breathing and centering, 40 min. of discussion on a weekly theme, 55 min. of Yoga poses and 10 min. of final guided progressive relaxation. They were instructed not to use additional stress-reduction methods during the study period. No specific evaluation regarding continued use of Yoga practices during the waiting period and during treatment was made. Patients had significantly higher mean Core FertilQoL scores after participating in the study $p = .027$, including emotional and mind-body quality of life $p = .006$, reduction in mean anxiety score $P = .0002$. They had significantly reduced levels of depression $p = .0004$. Overall, the degree of satisfaction with the Yoga workshop was rated as high. No negative comments were recorded by participants. This was a study which looked at negative and adverse effects.

In their randomised, prospective study, *Sharma et al. (2015)* compared yoga and clomiphene administration in 60 women. About 46.6% versus 33.3% of women conceived in Clomiphene with Yoga vs only clomiphene. All pregnancies in the Group with yoga crossed the period of viability vs 50% in those without added Yoga. Women undergoing yoga along with clomiphene reported feeling stronger and more confident, whereas those without yoga complained of nausea (33.3% women), headache (26.6% women) and 6.6% women had abdominal distension and bloating during the study.

When the results of practicing yoga and receiving clomiphene treatment were compared in terms of ovulation induction and conception, more positive results were obtained using yoga therapy in terms of pregnancy rates, especially for infertile women with long-term marital life. The only disadvantage of practising yoga within this context is that it takes a more extended period to get results.

In their cohort study, *Valoriani et al. (2014)* studied 45 women starting their first IVF cycle practising Hatha Yoga vs 75 women as controls. Stress, anxiety, and depression scores of the women who participated in that study were significantly lower than those in the control group ($p < .0001$ for STAY-Y1 and GHQ-12, $p < .001$ for EDS).

Meditation and Mindfulness

"Meditation refers to a family of self-regulation practices that focus on training attention and awareness in order to bring mental processes under greater voluntary control and thereby foster general mental well-being and development and/or specific capacities such as calm, clarity, and concentration"(Walsh & Shapiro 2006.pg 228-229)

Another classification of meditation approaches divides it into concentrative, generative, receptive and reflective practices(Aguirre,2018 ; Gangadhar et. al 2021)

- Concentrative: Focused Attention, including Breath Meditation, TM, and Visualizations;
 - Generative: Developing Qualities like loving kindness and compassion;
 - Receptive: Open Monitoring or Mindfulness;
 - Reflective: Systematic Investigation, Contemplation.

The study conducted by *Wang et al. (2023)* investigated the effects of mindfulness-based interventions on women with infertility through a systematic review and meta-analysis. The review included 58 randomised controlled trials (RCTs) focusing on psychological interventions for infertility-related distress and pregnancy rates. Ten articles were included in the meta-analysis. Six studies (N = 495) examined the effects of a mindfulness-based intervention on depression in women with infertility, in which significant heterogeneity was found . The results of the meta-analysis revealed large, significant effects of mindfulness-based interventions that can effectively reduce depression[SMD = -1.28, 95% CI (-1.95, -0.60), $p < .0001$], anxiety [SMD = -0.89, 95% CI (-1.26, -0.51), $p < .00001$] symptoms. Women were followed up for 3-months. Sensitivity analysis revealed no significant differences after omitting any of the studies included, indicating that the results of this meta-analysis were robust.Seven articles reported the effect of mindfulness-based intervention programs (MBIs) on anxiety in women (415 vs 423 women) with infertility compared with a control group had a large, significant effect in relieving anxiety for female patients with infertility ([SMD = -0.89, 95% CI (-1.26, -0.51), $p < .00001$] at more than 3 months of follow-up, and the heterogeneity was significant [$I^2 = 87\%$, $p = .005$]. Sensitivity analysis did not change results and improved five domains of health-related quality of life (physical function [MD = 9.47, 95% CI (4.33, 14.61), $p = .0003$], general health [MD = 15.77, 95% CI

(7.62, 23.92), $p = .0002$], vitality [MD = 14.85, 95% CI (4.95, 24.74), $p = .003$], role-physical [MD = 22.44, 95% CI (14.97, 29.91), $p < 0.00001$] and social function [MD = 8.27, 95% CI (3.56, 12.97), $p = 0.0006$] in women with infertility.

The meta-analysis results revealed that mindfulness-based interventions could effectively reduce depression and anxiety symptoms and improve health-related quality of life in women with infertility.

A systematic review by *Kundarti et al. (2023)* on the Positive impact of mindfulness on the mental health of women with infertility. Based on nine articles, original research journals published from 2011 to 2021 with the use of mindfulness interventions in women with infertility, seven of which were RCTs, that discuss the effect of mindfulness on the quality of life in women with infertility. Articles were from several countries, namely Iran, Portugal, Brazil, and India. From the nine studies the total number of participants was 615 women, who were allocated into a control group and an intervention group.

Out of nine studies, six had assessed the p value, which was less than $< .050$, making the positive impact of mindfulness on mental states statistically significant. The other studies showed an improvement in scores. It was an effective intervention for women undergoing infertility-related mental disorders such as stress, anxiety, and depression. Different types of mindfulness-based interventions were used to target different mental health issues, e.g., Mindfulness-Based Stress Reduction (MBSR) targets stress and anxiety, while Mindfulness-Based Cognitive Therapy (MBCT) targets depression.

The review conducted by *Patel (2020)* systematically searched databases for relevant literature on mindfulness-based interventions in infertility, identifying nine studies for review. These studies indicated significant improvements in psychological parameters, including reduced anxiety, depression, and stress, as well as enhanced well-being and quality of life among infertile women. The review also presents various methodologically sound investigations, including randomised controlled trials and quantitative interventional studies, which contribute to understanding MBIs' effectiveness in addressing infertility-related distress.

Bai et al. (2019) employed a three-armed, randomized, controlled trial design to evaluate the mindfulness and gratitude journal interventions with 234 women were randomly assigned to the brief mindfulness group (BMG, $n=78$), gratitude journal group (GJG, $n=78$) or control group (CG, $n=78$) undergoing their first

IVF cycle. All three randomized groups completed questionnaires on the day of down-regulation (T1), the day before embryo(s) transfer (T2), and 3 days before the pregnancy test (T3). The BMG completed four sessions and listened to a 20-minute audio daily, including guided mindfulness breathing and body scan. The primary outcome was depression. Secondary outcomes were anxiety, sleep quality, infertility-related stress, mindfulness, and gratitude. Participants of the BMG showed decreased depression (mean difference (MD)=-1.69, [-3.01, -0.37], $d=0.44$) and improved sleep quality (MD=-1.24, [-1.95, -0.39], $d=0.43$) compared to the CG, but the effect was not significant for anxiety, fertility Problem Inventory totals, mindfulness, gratitude scores or pregnancy rates.

The systematic literature review conducted by *LoGiudice et al. (2018)* aimed to assess the impact of complementary therapies on psychosocial factors in women undergoing in vitro fertilization (IVF). The most commonly measured psychosocial factor was anxiety, and the most prevalent complementary therapies included Hatha yoga, cognitive behavioral interventions, and mind-body therapies. The review concluded that utilizing complementary therapies can effectively reduce anxiety, depression, distress, and stress while enhancing fertility quality of life among women undergoing IVF.

Galhardo et al. (2013) studied the impact of a mindfulness-based program (MBPI) on 55 women presenting an infertility diagnosis with 37 controls (also with an infertility diagnosis). The program included one session of practicing hatha yoga with a trained yoga teacher. By the end of the MBPI, women who attended the program revealed a significant decrease in depressive symptoms, internal and external shame, entrapment, and defeat, unlike the control group. They presented statistically significant improvement in mindfulness skills and self-efficacy in dealing with infertility. However, this study was combined with other contextual interventions (e.g., Acceptance and Commitment Therapy and Compassion Mind Training).

The Effect Of Yoga On Sperm Quality And Its Implication For ART

Infertility affects about 15 to 20% couples, and in approximately half the cases it is attributed to the male factor. There are a number of causes of male infertility; these include genetic, congenital, immunological, anatomical defects, urogenital tract infections and endocrine causes. In about 40% of cases, the aetiology is unknown and these cases are classified as idiopathic. In about 30 to 70% of cases, the semen parameters and all endocrine parameters, physical examination is normal such cases have unexplained infertility.

Several studies have documented that in these cases there is seminal oxidative stress (Aitken et.al. 2020; Bisht et al., 2017; Bisht et al., 2018; Dhawan et al., 2024). Being rich in PUFA they are vulnerable targets of free radicals which also damage other organelles, sperm mitochondrial and nuclear genome. The sperm is a cell highly vulnerable to DNA damage which occurs maximally post spermatogenesis as sperm shed majority of their cytoplasm and thus have minimal levels of antioxidant and its DNA is transcriptionally and translationally inert. Thus, the majority of its repair mechanisms are silent except the Base excision repair (BER) mechanism, with only one of its enzymes OGG1 being active and for complete repair, it is dependent on the oocyte.

Sperm is a polarised cell. Their function is not merely restoration of diploidy, but they are critical determinants of embryo viability and developmental competence. Reproductive success largely depends on the integrity of the sperm genome and epigenome (Bhist et.al. 2018; Dhawan et al., 2024.) Sperm DNA damage, dysregulated sperm epigenome with altered expression of sperm transcripts and non-coding RNA, oxidative damage to sperm centriole is linked to poor reproductive outcome both in natural and assisted conception. Thus, sperm dysfunction remains one of the major contributors to infertility. Since standard sperm parameters are poor predictors of fertility potential and reproductive outcome, it is important to focus on those sperm parameters which are critical determinants of embryonic viability and developmental competence of the embryo. Thus, evaluation of these parameters have been recommended by **ASRM and ESHRE** in extended testing for male infertility. Damaged Sperm DNA and transcripts if not in optimal levels can impair development of embryo right from time of fertilization peri-fertilization effect, early and late paternal effects and implantation effects.

Sperm mitochondria are the source and target of free radicals, and thus, the damage to mitochondrial DNA is more severe and sustained. This results in a

vicious cycle, resulting in production of more free radicals. Though at low levels, free radicals subserve important functions in capacitation, hyperactivated motility and acrosome reaction but at supraphysiological levels they damage cellular organelles, and sperm are vulnerable targets as they are rich in polyunsaturated fatty acids and have minimal cytosolic antioxidants and a highly truncated repair mechanism. Seminal oxidative stress affects fertility, embryonic development, and predisposes to increased incidence of early pregnancy losses both following spontaneous and assisted conception and increased burden of genetic and epigenetic diseases (Dhawan et al., 2017; 2024).

Humans now live in a sea of free radicals and they are produced from both endogenous and exogenous sources. Endogenous sources of ROS include cytochrome P450-catalysed drug metabolism, oxidative phosphorylation, peroxisomes, and activated leukocytes. High testicular temperature, obesity, varicocele, psychological stress and advanced paternal age are associated with seminal oxidative stress. The chief exogenous sources are a highly processed food, diet rich in trans fats salts sugars, radiofrequency electromagnetic radiation, environmental pollutants, smoking and alcohol consumption. Thus supraphysiological levels of free radical and coupled with lower total antioxidant capacity is associated with damage to sperm affecting its motility, concentration morphology, impaired differentiation and accumulation of morphologically abnormal sperm with disorganised or partially formed axonemal apparatus and damage of both its mitochondrial and nuclear genome (Shamsi et al., 2008). In addition, free radicals oxidize lipids, proteins and carbohydrates and generate electrophilic aldehydes like MDA, 4 HNE and this becomes a self-propagating process. The Sperm DNA, especially its nucleohistone compartment, is vulnerable to damage due to open chromatin configuration (De Iuliis, 2009, Bisht et al., 2017; Dhawan et al., 2019). This compartment has telomeric DNA and promoters of genes of critical developmental importance. Oxidative stress induces damage preferentially to telomeric DNA as these hexameric repeats are rich in Guanine which has the highest oxidation potential. This results in accelerated testicular aging and shorter telomeres in sperm can impair cleavage. Oxidation of Guanine results in accumulation of 8 hydroxy 2 deoxyguanosine (8OHdG) (Thilagavathi et al., 2013a,b; Blackburn 2015; Bisht et al., 2019; Mishra et al., 2016). The presence of this bulky adduct also impairs methylation at CpG sites at promoter region. This is a highly mutagenic base which induces both mutations and epimutations. Thus oxidative stress results in denovo germ germline mutations and global hypomethylation which destabilized the epigenome by unmasking of repetitive element which results in non-allelic

homologous recombination and complex chromosomal translocations (Bisht et al., 2018; 2020; 2022; Gautam et al., 2015). In addition, as only OGG1 of the BER pathway is present in sperm, removal of this oxidative base lesion results in a basic site and single strand breaks. The sperm is thus dependant on oocyte to completely repair this lesion which involves APE and ligaseIII and XRCC1. Also, XRCC1 is also involved in active demethylation of sperm genome immediately post fertilization however the presence of oxidative DNA lesions impairs the demethylation process and this results in aberrant expression of genes and thus can impair embryonic development and result in pregnancy losses and congenital malformations.

There are over 9000 loci in the sperm genome which are hot spots for oxidative damage (Aitken et al. 2020). Chromosome 15 long arm 15q13-14 is a region most vulnerable to oxidative damage and this chromosome is situated in the posterior part of the sperm nucleus, a region with close proximity to mitochondria in the midpiece. This locus is known as Burnside Butler susceptibility loci. This locus has linkage to Cancer, imprinting disorders, male infertility and complex neuropsychiatric disorders like spontaneous schizophrenia, bipolar disorder and autism (Aitken et al. 2020). These have also been linked to the advanced age of the father at the time of conception and have led to the concept of paternal origin of health and disease (PoHAD).

Brubaker et al., 2018 documented that infertile men had higher risk of developing autoimmune diseases like multiple sclerosis and rheumatoid arthritis and this has been shown in several studies. Erectile dysfunction is also a cause of infertility. Obesity can adversely impact male reproductive health by causing hyperleptinemia, oxidative stress, hyperinsulinemia, and chronic inflammation. Alteration in the hypothalamic-pituitary-gonadal axis with disruption of Leydig cell steroidogenesis and metabolic dysregulation, including insulin, cytokines and adipokines also adversely impacts male fertility (Leisegang et al., 2021)

Infertility is a complex disease with a strong psychosomatic component. Infertile couples have high levels of stress, anxiety and comorbid depression (Tolahunase et al., Bisht et al., 2019, Dhawan et al., 2024). Yoga practices reduce cortisol levels and induce relaxation response and results in parasympathetic dominance. In addition there are increased levels of various factors which promote neuroplasticity like BDNF, DHEA. Serotonin and melatonin levels are increased. Melatonin is a key molecule for maintaining the sleep wake cycle and is a potent antioxidant. Its levels are highest in mitochondria and this helps to reduce oxidative damage in mitochondria. Thus by promoting neuroplasticity yoga

helps to reduce stress and build emotional resilience which also helps cope with the emotional turmoil and stress of infertility and if undergoing ART.

Evidence

Dhawan et al., (2017; 2024) reported that the Yoga practices improve sperm parameters like sperm concentration, motility and morphology .

Gautam et al., (2021) reported Yoga improves mitochondrial integrity and optimises free radical production . Yoga can reduce oxidative stress and normalise the level of sperm transcripts. Yoga increases expression of genes coding for antioxidants and thus increases the total antioxidant capacity. It improves mitochondrial integrity thereby reducing excess free radical production. Unhealthy lifestyle, fast junk food which is highly inflammatory, smoking which induces systemic and testicular inflammation are reduced by practice of yoga as yoga upregulates expression of anti-inflammatory genes reduces expression of proinflammatory genes. (Dhawan et al., 2017; 2024)

Dhawan et al., 2024, Kumar et al., 2015, Tolahunase et al., 2017; 2018 reported that Yoga can prevent accelerated attrition of Telomeric DNA damage and can increase length by two mechanisms .It decreases oxidative stress which targets telomeric DNA and by increasing activity and levels of telomerase enzyme. Thus it reduces the rate of testicular aging as optimal free radical levels are required for maintaining telomere length. It regulates free radicals levels. Normally antioxidants can improve sperm membrane characteristics; they have little effect on the crystalline protamine bound DNA. Thus people take high levels of antioxidants and for long periods which results in reduced free radical levels but it can impair several redox sensitive reactions but with little impact on nuclear DNA damage (Bisht et.al. 2017; Dhawan et al., 2024)

Bisht et al., 2020, 2017 ; Borthakur et al., 2023, ; Dada et al., 2016; Gautam et al., 2019 suggests that improvement of nuclear DNA integrity takes minimum 6 months practice of Yoga (2 spermatogenic cycles). Yoga upregulates expression of DNA repair genes and upregulates expression of genes (MTHFR) and helps to re-establish methylation marks. Reduction in oxidative DNA damage results in significant decline in levels of 8 hydroxy 2 deoxyguanosine. This is important as this mutagenic base induces both mutations and epimutations and can also result in childhood cancers Yoga improves mitochondrial integrity and this aids in more ATP and optimal free radical production. (Gautam et al., 2021). In the first study to show impact of Yoga on sperm epigenome of infertile men, 442 regions were differentially methylated and genes coding for cytoskeleton, promoting

spermatogenesis, acrosome reaction, implantation were hypomethylated. Hypomethylation occurred in promoters of genes regulating these processes and the majority of genes which were hypermethylated were in the intronic regions (Bisht et al., 2020).

Gautam et al., (2019, 2020; 2022; 2023) suggested that Yoga can be used as an adjunct in management of infertility with autoimmune diseases. Yoga helps to re-establish immunological tolerance and induces molecular remission. This occurs due to increase in levels of HLA G and TGFB and IL10 (anti-inflammatory) and lowers levels of proinflammatory cytokines like IL6, IL17 and TNFalpha and NFKb. Yoga helps to reduce emotional eating a major cause of obesity, decrease BMI, reduce inflammatory cytokine levels and reduce insulin resistance by upregulating expression levels of Insulin receptor, (Sharma et al., 2022; Kumar et al., 2023).

Bhat et al., 2024 reported that Yoga is a safe and more effective, safe and affordable approach in managing premature ejaculation (PE) and erectile dysfunction (ED). They thus emphasised that men could regain confidence in sexual function and improve quality of life by adopting yoga for PE and ED.

Bisht S et al., 2019; Tolahunase et al., 2018; 2021; Tolahunase 2018 Psychological stress, anxiety and comorbid depression are reduced by practice of yoga. This occurs due to decrease in cortisol levels which induces the relaxation response and by increase in levels of various factors which promote neuroplasticity.

Summary:

The studies have documented that regular practice of yoga resulted in improvement in sperm parameters (concentration, motility, morphology), reduction in oxidative stress and oxidative DNA damage, increase in telomere length and increase in telomerase activity and levels, normalization of gene expression levels, re-establishment of methylation marks by increase in methylation levels and upregulation of DNA repair genes and genes of 1 Carbon metabolism like MTHFR. There is improvement on both nuclear and mitochondrial genome integrity and reduction in rate of sperm aging. This reduced de novo germline mutations and epimutations and thus is beneficial not only for the individual as he may conceive spontaneously or there may be better success rates in couples opting for ART. By reducing the genetic and epigenetic mutation load adoption of yoga positively impacts the lifelong health trajectory of offspring. As infertility is a complex disease with a strong psychosomatic component Yoga by promoting neuroplasticity aids in better coping mechanisms by reducing stress, anxiety and severity of comorbid depression.

Following 'Yoga Protocol' was adopted in the studies cited above (Dhawan et.al. 2017;2018;2024) . It was performed initially under guidance of trained yoga therapists who take into consideration any other prevailing health condition. Yoga sessions were designed for 45 minutes in a day and required practice daily.

It is also to be noted that the yoga system of psychological counselling was included in the Yoga program, where Yama (morality) and Niyama (ethics) were to be suggested/discussed as well.

A record of the adequate diet, sleep and drugs consumed along with Yoga therapy particulars was maintained for the whole program.

***Asanas (Yoga postures):-** (20 minutes)

Sukshma Vyayam and Surya Namaskar

Supine:-

Pavanamuktasana,
Setu Bandh Asana,
Sarvangasana,
Supta BaddhaKonasana.

Prone:-

Bhujangasana,
Dhanurasana,
Shalabhasana.

Sitting:-

Ardha Matsyendra Asana,
Janu Shirasana,
Paschimottanasana,
Chakki Chalanasana,
Malasana,
Kagasana walk,
Udarakarshanasana.

Standing:-

Tadasana,
Katichakrasana
Trikonasana,
Virabhadrasana.

***Pranayama (Regulation of breath):- (15 min)**

Kapalbhati(breath cleansing kriya)

Ujjayi,

Bhastrika,

Nadi Shodhana,

Bhramari.

***Mudra and Bandha:-**

Vipreet Karni Mudra,

Ashwini mudra,

Vayu Mudra,

Moola Bandha.

***Meditation:-** (10 min) Mindfulness meditation on Svadhishtana and Mooladhara Chakra/ Yoga Nidra.

Summary:

The recommendation for offering psychosocial interventions to couples undergoing fertility treatment is supported by substantial evidence suggesting a positive association between such interventions and improved pregnancy and psychological outcomes. Several studies have underscored the potential benefits of integrating psychosocial support into fertility care protocols to enhance treatment outcomes. (Ha et al. 2023 , Dube et al. 2023 ; Katyal et al). Meta Analysis have identified cognitive behavioural therapy (CBT) and mind-body interventions (MBIs) as potential approaches with positive effects on anxiety, pregnancy rates, or marital function.

The recommendation to offer Acceptance and Commitment Therapy (ACT) to couples undergoing fertility treatment is supported by robust evidence indicating its efficacy in enhancing psychological well-being in this population. (Akbari et al. 2022 ;Hosseinpahani et al. 2020)

The evidence presented by Demir et al. (2022) Kirca et al. (2019) Hajela et al.(2016), suggests a strong recommendation for the integration of yoga programs, especially before infertility treatment, to improve patient's mental health and potentially enhance treatment outcomes for and pregnancy outcomes'

The findings of systematic literature review, by LoGiudice et al. (2017) suggest that complementary therapies, including acupuncture, CBT, mind/body interventions, and Hatha yoga, demonstrate positive effects in reducing anxiety, distress, and depression. The reduction in anxiety correlates with higher reported pregnancy rates in women undergoing IVF. The authors recommend incorporating complementary therapies into the care plan for women undergoing IVF, emphasizing the potential for improved psychosocial health outcomes and increased treatment success.

Evidence suggests that women with higher distress levels may benefit from yoga exercises as a psychological support before IVF and help in reducing anxiety levels in patients, potentially leading to decreased drop out rates and increased treatment success..(Valoriani et al. 2014; Oron et al. 2015 ;Jasani et al. 2016)

Darbandi et al. (2016) literature review findings suggest that yoga serves as an intervention that manages stress in infertility patients, positively influencing fertility factors, rates of assisted vaginal delivery, and fetal outcomes. The study concludes that yoga can aid couples in overcoming infertility challenges and enhance the success of ART by improving the physiological and psychological

well-being of both men and women. The studies have documented that regular practice of yoga resulted in improvement in sperm parameters (concentration, motility, morphology), reduction in oxidative stress and oxidative DNA damage, increase in telomere length and increase in telomerase activity and levels, normalization of gene expression

Many Meta analysis and RCT have shown an advantage of Yoga and mindfulness. However studies had varied interventions for variable time periods. There is a high attrition rate. There is a need to develop uniform yoga and meditation based methods for enhancing psychological state during the ART process

RECOMMENDATIONS	GRADE
It is recommended that psychosocial interventions should be offered to couples undergoing fertility treatment.(Katyal et al. 2021; Ying 2016)	A
Cognitive Behavioural Therapy (CBT) can be recommended as psychological intervention in women undergoing IVF (Ha et al 2023 ; Wang et al., 2023)	A
It is recommended that acceptance and commitment therapy be offered to couples undergoing fertility treatment to improve psychological wellbeing. (Akbari et al. 2022, Haji et al 2019)	B
Mind Body Therapy (MBT) can be recommended as a psychological intervention in women undergoing IVF (Bai et al. 2019; Demir et al. 2022; Dumbala et al. 2020 ; Jasani et al. 2016 ; Kirca et al. 2019;, Nayar et al 2017 ;;Oron et al. 2015;Wang et.al. 2023).	A
It is recommended that healthcare providers must integrate the Mindfulness-Based Program including meditation into standard treatment protocols (Bai et al. 2019, Wang 2023, Kundarti 2023, Patel 2020, LoGiudice 2018 ; Galhardo 2013)	A
Healthcare providers can utilize a group format for MBPI sessions, allowing participants to share experiences. (Galhardo, 2013)	B
It is recommended that fertility care team must advise patients to incorporate yoga into fertility treatment plans, before and during treatment, to alleviate stress, anxiety, or depression related to ART treatment and potentially leading to increased treatment success (Demir et al. 2022; Dumbala et al. 2020; , Chudasama et al 2020; Clifton et al 2020; Kirca et al. 2019 ; Nayar et al 2017; Darbandi et al. 2016; Jasani et al 2016;Li et al 2016 ;Oron et al.'s 2015; Valoriani et al 2014)	B
Fertility care team must be aware that yoga can be used as a complementary therapy as an adjunct in the management of male infertility (Dhawan et al., 2017; 2024 ; Gautam et al.,2019, 2020; 2021; 2022; 2023; Kumar et al.,2015)	A

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Masoumeh Hosseinpanahi, Mojgan Mirghafourvand,¹ Azizeh Farshbaf-Khalili,² Khalil Esmailpour,³ Masoumeh Rezaei,⁴ and Jamileh Malakouti The effect of counseling based on acceptance and commitment therapy on mental health and quality of life among infertile couples: A randomized controlled trial *J Educ Health Promot.* 2020; 9: 251. Published online 2020 Sep 28. doi: 10.4103/jehp.jehp_512_20

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4.6.3 How can fertility staff address the needs of patients after unsuccessful treatment and breaking bad news in infertility treatment?

Introduction

Infertility diagnosis, unsuccessful ART cycle, or miscarriage are the forms of bad news that impact patients. It is seen that 40 % of patients experience intense grief, shock or guilt on an unsuccessful cycle. (Stewart 2001). The research addressing various aspects of this very important area in ART has been summarised below

Evidence

Management before the start of the cycle to prepare the patient for a failed cycle

Multicycle Planning: Each embryo has an implantation rate of about 30% and at least 3-4 cycles may be required to achieve a pregnancy with many facing failed cycles. However, the plan with the patient is usually a single cycle and the next cycle is only mentioned if the first one fails. Harrison et al 2022 have recommended that multicycle planning must be introduced at the start of the first cycle. Multicycle planning means that one accepts the fact that a cycle can fail and doing more than one cycle can maximize the chances of pregnancy. This approach prepares patients for decision making when faced with an unsuccessful cycle. Gameiro et al 2013 showed in a meta analysis of ten studies with data for 14,810 patients that compliance for 3 cycles was shown to be 78.2% After the first failed cycle it was 81.8% and after the second failed cycle it was 75.3%. This shows that patients are ready to comply with 3 treatment cycles in case of failure if planning is done before the first cycle the patient is better prepared emotionally and financially.

Harrison et al 2022 conducted a study with twelve healthcare providers (HCP), 2 patient advocates and 10 patients who participated in six semi-structured online focus group discussions. The four themes were heterogeneity in information provision during treatment planning, the need for improved HCP-patient collaboration, the need to temper optimism about treatment success and apprehension, benefits and preferences regarding multi-cycle planning. They concluded that shifting to multi-cycle approaches in IVF planning is feasible and suggested that the cost-benefit analysis needs to be shared along with other factors like time to pregnancy, avoiding deflating optimism, fostering a sense of collaboration and supporting patients through challenges of multi-cycle IVF. They highlighted that usually, couples who do not come back for a second cycle

are those unable to decide and those who return are those who have anticipated this and seen treatment failure as temporary. A multicycle approach aligns patients to a possible failure and may be a more patient-centric approach. There may be challenges like patients opting out before the first cycle because of fear of failure or patients looking at it as a suggestion for unnecessary financial investment. It also highlights the negative issues of fertility treatment. Anxiety may be primarily due to the possibility of negative intonation of a failed cycle, being financially exploitative, or highlighting difficult realities of treatment.

Treatment Planning and Continuation Intervention: Treatment Planning and Continuation Intervention (TPCI) is a novel psychological intervention which can be used to prepare for better cognitive preparation of a couple for the failure of treatment and could help reduce adverse reactions like treatment discontinuation.

Harrison C in 2023 conducted a study to see if ART Treatment Planning and Continuation Intervention (TPCI) is considered acceptable and feasible to patients and healthcare professionals. Thirteen HCPs and 13 patients participated in 25 online qualitative cognitive interviews. The themes showed that HCPs and patients provided positive feedback about the six main TPCI points as a checklist. These were - information to patients about multiple cycles, information of chances of success with 3 cycles, discussion on treatment outcomes and options, understanding how many cycles a patient can plan, treatment to be as a collaboration between the clinic and patient and introducing patient to TPCI app which provides the patient with a multicycle planner the patient can revisit during treatment. The TCPI app provided options for looking at outcomes at each stage and changing the treatment plan, anticipating challenges at each step like during stimulation, oocyte retrieval and reinforcing intention after an unsuccessful cycle.

Management of patient when cycle fails – Imparting bad news

It is important to break the news to the patient in a proper manner. Breaking bad news has been defined by Baile 2000 in 6 steps (SPIKES). First step is 'Setting up' the meeting ensuring privacy, the presence of a significant other, adequate time allotment for discussion without distraction, a sense of priority, a comfortable place with making connection and eye contact with patient. Secondly, assess the patient's 'Perception'. Misconceptions should be cleared and patient expectations should be judged. Thirdly obtain the patient's 'Invitation'. Many patients shun trying to get information which is not good news. Fourthly give 'Knowledge and information' to the patient. The next step is to address the patient's 'Emotions' with

empathic responses. Finally 'Strategize' because it is important to ensure the patient is ready to discuss future plans and then offer options and address their concerns on these options by sharing responsibility for decision-making with the patient.

Most fertility staff share different categories of news that may be seen as bad by patients. For example, clinicians may inform patients of suboptimal diagnostic test results, embryologists may give poor grades or number of blastocysts formed, nurses share pregnancy test results, and administrative personnel inform patients of financials. Difficulties staff face when they share the news of an unsuccessful cycle or poor results which imply that a cycle will not be successful is that they may be seen as unsupportive by patients who have held unrealistic expectations. Most staff are unprepared to impart bad news as they find it to be stressful. Baile et al. 2000 noted that perception by patients of intensity of adverse news is personal, subjective to appraisal of the information being communicated to patients, and depends on the gap between the patient's expectation of care and the medical reality of the situation.

The important aspect of managing bad news is identifying what is perceived by the patient and staff as bad news. S Gameiro 2024 in a study aimed to identify what is considered as bad news by patient and staff found that fertility bad news may be in various forms It could be a diagnosis like azoospermia, a failure in a step of ART like poor fertilization, an absence of treatment options or a loss of pregnancy. It is important that the context and manner of sharing bad news can define perceptions and their impact. To understand which fertility news is considered bad news Gameiro et al in 2024 analysed and compared narratives from open-ended questions from two cross-sectional online surveys on this topic that were distributed among 217 fertility staff and 222 patients. It was seen that the intensity of adversity of fertility news is not only a product of the extent to which the news compromises parenthood goals but also of its features (timing, nature, number) and the context in which the news is delivered. Guidance on sharing bad news in fertility care needs to go beyond easing the process for patients to also consider staff experiences. It may need to be tailored to news features and context.

Men may be affected adversely by an unsuccessful cycle and require psychosocial care similar to their partners. Martin MV 2016 showed that men had anxiety, depression, and difficulties in partner communication after an unsuccessful cycle The positive impact of information and open communication along with the support of others and spouses was seen in men

Short-term and long-term management after an unsuccessful cycle

ESHRE 2015 Guideline stated that after unsuccessful treatment patients who are at risk of experiencing clinically significant short or long-term psychosocial problems should get specialized psychosocial care (infertility counselling or psychotherapy). Patients should be allowed to discuss the implications of ending unsuccessful treatment. Support from the fertility clinic is a must.

Mitra et al (2023) showed in a study from India that patients who had an unsuccessful treatment and opted for adoption need to be counselled around expectations, grief counselling, infertility resolution and adoption initiation.

Chan et al (2016) studied the relationship between decisional conflict, decisional regret and psychological well-being in women following unsuccessful IVF cycles. Results show for the first time how mental health implications of decisional conflict may vary among patients with different clinical characteristics (i.e. availability of frozen embryos), despite their common experience of an unsuccessful IVF cycle. Healthcare professionals should be aware of the psychological ramifications of treatment decision-making difficulties, as well as individual differences in adjustment to unsuccessful treatment. For example, the mediating effect of decisional regret on the relationship between decisional conflict and fertility-related quality of life (FRQOL) is moderated by the availability (versus absence) of frozen embryos after an unsuccessful IVF cycle.

Grief can be long-lasting and manifest as psychiatric disorders in 10% and 30% of men and women respectively (Verhaak et al. 2007). These patients must be counselled and followed up for longer periods. A mixed-methods systematic review by Gameiro et al (2017) with 18 studies was included with two adjustment outcomes: mental health and well-being in patients studied more than one year after an unsuccessful cycle. There is a preventive role the fertility staff can play by supporting individuals after a cycle fails. Failed treatment represents an inability to reach the goal of a certain number of children or a complete loss of parenthood. Those who have gone in for fertility treatment are at a higher risk of maladjustment as they are committed to becoming parents. Long-term adjustment to childlessness needs more attention and often there is a disconnect between patients and fertility clinics as time passes

The study showed that high risk factors were lack of alternative non-parenting roles and social support. Disengaging from parenthood goals making them non-essential and engaging in other life goals helps to adjust better but the time taken to do this is variable. About 44% still have a parenthood desire after 3-5 years

whereas only 6% after 11–17 years (Gameiro 2016). These symptoms may extend to menopause or resurface when other milestones like becoming grandparents are perceived. The review identified six themes. The first three themes Individual and relational adjustment, Social adjustment and Fertility care perceptions and needs and captures changes across time in experiences and adjustment. The themes Acceptance, Meaning-making and Pursuit of new life goals captures the psychological tasks patients engaged with that were associated with positive adjustment in the aftermath of unsuccessful treatment. Acceptance was easier when patients were convinced they did their best to explore all available treatment options, and their efforts were acknowledged by their family with empathy instead of pressure for them to become parents. Acceptance was also easier when participants felt they received good medical advice during treatment, when their prognosis was clear and poor and when the reasons for treatment failure were identified. There were many different ways of finding new fulfilling life goals including caring for other people and pets, supporting friends with infertility, travelling and focusing on their careers.

The strengths of this mixed-methods review were that the systematic review of almost 40 years of research on adjustment after failed fertility treatment, yielded 18 studies from 10 countries sampling adjustment experiences of 2545 patients. Data were independently extracted and quality evaluations and analyses were made according to a priori defined and rigorous protocols to minimize the risk of bias. Another strength was the inclusion of quantitative and qualitative research to answer different research questions, allowing for a more comprehensive picture of adjustment to emerge. The primary research was of moderate to high quality and had enough power to detect significant differences. The main problem with the qualitative data was that, due to the nature of qualitative research, the data extracted from the papers were interpretations that other researchers made of patients' interpretations of their experiences. Another problem was that the goals of the qualitative studies varied slightly. This might have affected the prevalence of the emergent themes. The only inconsistency detected was that qualitative data provided a more positive perspective on adjustment over time than quantitative data.

Based on the data reported, the authors developed a comprehensive model to explain adjustment to unmet parenthood goals, labelled the Three Tasks Model of Adjustment to Unmet Parenthood Goals. The model predicts that, in the face of unmet parenthood goals, those individuals who can accept their situation, make meaning of their experience and pursue new life goals and will adjust better than

those who do not engage with these psychological tasks. The Three Tasks Model of Adjustment to Unmet Parenthood Goals also predicts that specific variables may influence adjustment, at the individual level considering gender, importance of parenthood and availability of alternative life goals; at the social level with social support, social representations of parenthood and parenthood social norms; and at the treatment level, with prognosis, perceived quality of medical advice, reasons for failure identified and treatment options exhausted. It should be noted that the quantitative data tapped into hedonic well-being, which is the extent to which individuals are 'feeling well', and the qualitative data also captured eudaimonic well-being, which is the extent to which individuals are 'doing well' in terms of purpose, meaning and fulfilment in life. The Three Tasks Model of Adjustment to Unmet Parenthood Goals (Acceptance, Meaning-making and Pursuit of new life goals) captures offers comprehensive guidance on the therapeutic mechanisms that seem to underlie positive adjustment.

Since there may be difficulty in connecting to patients after more than a year alternative methods like self-help interventions that individuals could access via multiple outlets (the most obvious one being the Internet) can be suggested. Fertility clinics should train primary care physicians and mental health professionals which would be the patient's long term contact making them aware of the deleterious impact of unmet parenthood goals on well-being and of how it can be addressed.

Summary

Couples who make decisions to either quit treatment or continue after an unsuccessful cycle need special care as they have psychological ramifications of treatment decision-making, as well as individual differences in adjustment to unsuccessful treatment. (ESHRE 2015 Chan 2016, Gameiro 2016). Multicycle pre-treatment planning (Harrison 2022), Treatment Planning and Continuation Intervention (TPCI) (Harrison 2023) The Three Tasks Model of Adjustment to Unmet Parenthood Goals (Gameiro 2017) are novel options and may help patients deal with an unsuccessful cycle but require further studies to identify their impact as an intervention on psychosocial outcome in short term and long-term psychosocial care of patients with unsuccessful cycle.

RECOMMENDATIONS	GRADE
The fertility care team must be aware that	
<ul style="list-style-type: none"> Short-term and long-term psychosocial care is recommended for couples with unsuccessful treatment –(ESHRE 2016, Gameiro et al 2016, Verhaak 2007) 	A
<ul style="list-style-type: none"> The concept 'Spikes' should be used to manage imparting bad news in fertility care (Baile 2000 ;Gameiro et al.2024) 	B
<ul style="list-style-type: none"> It is recommended that couples who make decisions both to quit treatment or continue after an unsuccessful cycle receive special psychosocial care (Chan 2016, Gameiro 2017) 	A
<ul style="list-style-type: none"> Follow-up with psychosocial support beyond one year is recommended in couples who have had an unsuccessful cycle, care being directed at helping individuals relinquish their parenthood goals. (Gameiro 2017) 	B
<ul style="list-style-type: none"> It is recommended that acceptance, making meaning and pursuing alternative goals should be the target when giving therapeutic guidance for long-term management of these couples (Gameiro 2017). 	B
<ul style="list-style-type: none"> Health care teams should develop specialized psychosocial care tailored to the needs of couples with unsuccessful treatment who are planning adoption, focusing on coping skills, decision-making support, and emotional processing.(Mitra, et.al. 2023) 	B
<ul style="list-style-type: none"> It is recommended that men be specifically counselled and given psychosocial support in the form of informative discussions leading to acceptance and inclusion of coping skill mechanisms when treatment fails. (Martins 2016) 	B

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4.6.4 How can healthcare staff address the needs of patients after successful treatment ?

Introduction

There are very few studies on the risk factors for emotional problems in couples during successful pregnancy .ESHRE guideline (2015) on routine psychosocial care in medically assisted reproduction reported that women who have experienced repeated failure or high stress during treatment may be more likely to experience anxiety during pregnancy (Hammerberg et.al. 2008) .Considering the low success rates in the first cycle and the need for most couples to undertake multiple cycles , this aspect need more studies for definite conclusions .

Evidence

Crespo et.al. (2016) conducted repeated rounds of individual interviews with 30 pregnant women and 21 couples after assisted reproductive treatment from July 2010 to April 2014.

Overall, understanding how infertility may affect experiences of pregnancy, birth and early parenthood through qualitative interviews showed unmet emotional need after successful assisted reproductive treatment. The experiences of couples after successful assisted reproductive treatment varied depending on the meaning given to ART processes such as use of donor gametes , ICSI ,IUI etc .They concluded that women who conceived with ART may experience more pregnancy-specific anxiety, which is complex and varied,.It is suggested that the women and partners should have an opportunity to discuss their worries and concerns about pregnancy achieved with fertility treatment .These findings raise the question of how best to support women and couples through the assisted reproductive treatment process.

A prenatal intervention “Garbh Sanskar” derives from the Sanskrit word "Garbh," which means "womb," and "Sanskar," which refers to the act of imprinting the fetus inside the mother's womb. The first mention of Garbh Sanskar dates back to the Vedic era, around 1500 BCE. The foundation of this is the concept that a child's mental and physical development starts during the antenatal period and can be influenced by a variety of stimuli, including the mother's thoughts, feelings, and behaviours. (Pragya et. al 2023)

The techniques derived from this have gained popularity in recent years as a holistic approach to pregnancy and childbirth. Contemporary version of this ancient practice relies on integrating the yoga based techniques. Along with the

yoga based techniques i.e. yogic exercises, regulated breathing, meditation for self, there is a unique added feature i.e. meditative focus on the baby with positive affirmations, visualizing and bonding with the baby (Neel et.al. 2021). This meditative process is integrated along with the standard antenatal care as recommended by the obstetricians i.e. regular prenatal check-ups, following medical advice, and incorporating practices that have proven benefits, such as a healthy balanced diet, regular exercise, and sufficient rest which are important for both the mother and the developing fetus. (Neel et al 2018; Pragya et.al. 2023).

The important components of Garbh Sanskar are as follows

- 1. Prenatal yoga exercise and breath regulation:** engaging in prenatal yoga classes and exercises specifically designed for pregnant women
- 2. Meditation , mindfulness:** Practicing meditation by chanting and mindfulness techniques can help expectant mothers relax, reduce stress, and cultivate a positive mindset, creating a calm and nurturing environment for the fetus.
- 3. Positive Thinking:** The mother is advised to maintain a positive outlook and avoid negative thoughts and emotions. It is believed that the mother's thoughts and emotions can have a profound impact on the mental and emotional well-being of the child.
- 4.Positive affirmations and visualization:** to cultivate a positive mindset and create a bond with the unborn child. This involves repeating positive statements and visualizing a healthy and happy pregnancy and childbirth experience.
- 5. Emotional bonding:** Engaging in activities that promote emotional bonding between the mother and the fetus, such as talking, singing, and reading aloud, to help establish connection with the unborn child.
- 6.Supportive environment:** Creating a supportive and nurturing environment that includes the involvement of the partner, family, and loved ones.
- 7.Incorporating modern technologies:** mobile applications or online resources to provide information, guided meditation, or music therapy sessions tailored for pregnant women .With the internet's extensive use, there are numerous online sites, Blogs, YouTube videos, and online courses which are offering support during pregnancy .

Today, many organizations are teaching the method. The digitization of prenatal care, exemplified by the Garbh Sanskar Guru app,(Upadhyaya et.al 2024) Divine

Garbh Sanskar (Neel et.al.2021) has ushered in a new era of accessibility and personalized care. Overdijkink et al. (2018) has discussed the growing importance and effectiveness of such digital health interventions in improving prenatal care and positive psychological impacts.

Although the prenatal programming literature has grown at a rapid rate in the last decades, intervention studies lag significantly behind. The impact of prenatal mental health on offspring socio-emotional development is substantial and enduring. Existing literature primarily focuses on the effects of maternal psychological distress during pregnancy, emphasizing adverse child outcomes (Murray 1992 ;O'Conner et.al. 2002 ;DiPietro et.al. 2006 Grote et.al. 2010 ;Laurent et.al. 2013 ; Pesonen et.al 2016) . Recent studies, however, highlight the unique impact of positive maternal mental health on child outcomes.(Phua et.al. 2020)

There is evidence from literature on the beneficial effects of yoga .The studies utilising this in IVF has already been discussed in detail in the previous section These have cited positive effect on mental health and well being , up to the time of pregnancy .The studies in this section look at the potential benefit during the ongoing pregnancy of intervention using yoga based techniques .during prenatal and perinatal periods .

The evidence on the significance of yoga based practices during ongoing pregnancy and childbirth outcomes has been summarised below .By maintaining positive mental health and well being of the mother during prenatal and perinatal period with help of yoga based practices as given in Garbh Sanskar , it can be an invaluable source for the future offspring as well

The influence of prenatal exposure to poor maternal mental health on the offspring is definite. However, its impact might change with the developmental stages, and may decline during later periods. Alternately , theoretical models suggest that early life adversity during specific neurodevelopmental periods predisposes the person in persistent trajectories, regardless of the contexts (Hakamata et.al 2022; Korkeila et.al 2010 ;Luby et.al. 2017).Some studies encompassing various aspects these issues and concerns have been summarised below.

The research studies on the effect of maternal psychological distress or maternal well being on the newborn birth parameters as well as social-emotional development of the child have been summarised below .As yoga based interventions have positive effect on psychological well being and reducing

anxiety and depression in women, the interest for the yoga-based interventions during pregnancy has grown exponentially. It shows interesting results in improving different maternal and fetal outcomes during pregnancy. The studies are summarised below

Evidence for impact of perinatal mental health of the mother on socio-emotional development of the offspring :

Phua et al 2023 reported meta-analyses of 74 studies investigating the associations of prenatal maternal mental health with child socioemotional development with 321,966 mother-child dyads across 21 countries. They analysed associations of prenatal psychological distress with both adverse and positive child socioemotional outcomes. Impact of the positive prenatal mental health, on positive socioemotional outcomes was also studied. The meta analysis findings have been summarised below

Effect of maternal psychological distress on adverse child outcomes

Maternal psychological distress (e.g., depression, anxiety, stress) during pregnancy was significantly associated with adverse child outcomes (71 studies: $p < .001$). The adverse child outcomes included measures of emotion dysregulation, aggressive behaviour, internalizing and externalizing problems, distress to novelty, negative affect or mood, negative reactivity, depression, anxiety, fearfulness, hyperactivity, inattention, peer or behaviours problems, or socioemotional problems in general. The observed variance was due to variance in true effects and not due to sampling error. The funnel plot and Egger test did not detect significant publication bias in the results

Ten studies provided gender-specific effect sizes of associations of prenatal psychological distress with adverse child outcomes. There was no significant difference in the effect sizes of the associations of psychological distress with adverse outcomes between male and female children. Due to the low number of studies that provided gender-specific data, the estimate of the gender differences in effect sizes differ across different developmental stages could not be done.

Two meta-regression models were estimated to examine the moderating effect of developmental stages and location on the effect sizes of associations of prenatal psychological distress with adverse child outcomes. With infants as the reference group, none of the developmental stages had a significant moderating effect on the size of the associations of psychological distress with either adverse or positive child outcomes. With North America as the reference group, the

continent where the data was collected did not significantly moderate the effect of psychological distress on adverse child outcomes.

Effect of maternal psychological distress on positive child outcomes

Maternal psychological distress during pregnancy showed a significant and inverse association with positive child outcomes (15 studies: $p = .018$). Positive child outcomes included adaptive skills, prosocial behaviours or relations, positive affect or mood, empathy, excitability, positive reactivity, or general socioemotional competence. There was significant heterogeneity in effect sizes of the associations of psychological distress with positive child outcomes ($p < .001$), with 74.8% of the variance in effect sizes being true variance. The funnel plot and Egger test did not detect significant publication bias.

Only two studies reported gender-specific effects of psychological distress on positive child outcomes. As such, a subgroup analysis by gender was not possible. In addition, no studies reported the effect of maternal psychological distress on outcomes in mid-childhood and adolescence. With infancy as the reference group, there was no significant difference in effect size between outcomes of infants vis-à-vis outcomes of toddlers or preschoolers. With North America as the reference group, studies in Europe reported significantly bigger effect sizes than studies in North America ($p = .022$); the effect sizes of studies in other continents were not significantly different from North American studies ($p > 0.09$).

Effect of Positive maternal mental health on adverse child outcomes

Positive maternal mental health (e.g., uplifts or positive mood) during pregnancy was not significantly associated with adverse child outcomes (5 studies; $p = .35$). There was significant heterogeneity in associations of positive prenatal mental health with adverse child outcomes ($p = .047$). There was no indication of publication bias based on the funnel plot and Egger test. There were also insufficient studies to conduct meta-regressions on the moderating effect of developmental stage or continent.

Effect of Positive maternal mental health on positive child outcomes

Positive maternal mental health during pregnancy was significantly associated with positive child outcomes (2 studies: $p = .021$). An accurate estimation of the prediction interval was not possible due to the low number of studies. Q-statistics showed that there was no significant heterogeneity in the effect of positive prenatal mental health and positive child outcomes. The non-significant heterogeneity is likely due to the low number of studies.

In summary, this meta-analysis explored the associations between maternal psychological distress and positive mental health during pregnancy and the different aspects of child socioemotional development, at various developmental stages, domains of development, and geographical locations. The results indicate that prenatal psychological distress exhibits stronger associations with adverse child outcomes, whereas positive prenatal mental health demonstrates stronger associations with positive outcomes. This distinct pattern highlights the independence of negative and positive mental health constructs, indicating the need for separate investigations into maternal mental ill-health and well-being. (Huppert et al 2003, Phua et.al. 2017;2020) The positive maternal mental health had a significant positive impact on the child development. Though few in number, the studies highlighted the importance of considering the impact of the positive spectrum of mother's perinatal mental health and child developmental outcomes. It can improve our understanding of the positive prenatal influences on child development.

Estinfort et.al. (2022) reported relationship of perinatal subjective well being with offspring developmental criteria . Subjective Well Being encompasses three fundamental components: life evaluation, eudaimonic well-being (i.e., a sense of purpose and meaning in life), and affect (positive and negative)(OECD ,2013) SWB is considered critical to positively affect several health outcomes including decreased mortality, decreased cardiovascular disease risks, fewer chronic illnesses and functional impairments, and improved health behaviour . (Bolier et.al. 2013;Howell et.al. 2007) Extending the examination of well-being from pregnancy to postpartum years can maximize positive maternal and child health (O'Connor et.al. 2002;Midwives RCo2012).

In this study, pregnant women in early stages of pregnancy (16 weeks or less) were recruited at five selected hospitals in Taipei, Taiwan, during their prenatal appointments since 2011. Self-reported evaluations were conducted at seven time points up to 2 years postpartum. The seven points were early pregnancy (prior to 16 weeks, T1), mid-pregnancy (17 to 28 weeks, T2), late pregnancy (after 29 weeks, T3), and 1 month (T4), 6 months (T5), 1 year (T6), and 2 years (T7) postpartum. A total of 1,224 participants completed the questionnaires from T1 to T4 (up to childbirth), and 600 completed from T1 to T7 (up to 2 years postpartum). In addition, the SWB instrument was added later in the ongoing study ; the positive mental health of 454 women was assessed ..

Linear regression and generalized estimating equation models were used for examination.It was reported that higher prenatal eudaimonic well-being was

associated with longer gestational length. Higher positive and negative affect were associated with longer gestational length and smaller birth weight respectively. For child's outcomes, the association between higher prenatal eudaimonic well-being and decreased risks of suspected developmental delay, particularly for children of multiparous mothers. Higher levels of prenatal depression and anxiety were significantly associated with increased risks of suspected developmental delay for children of primiparous mothers. Life's evaluation was not related to outcomes in offspring

Phua et al. 2017 used an exploratory bi-factor analysis. The prospective study ($n = 1,066$) used common psychiatric screening tools to examine the effect of positive maternal mental health. Antenatal mental health was assessed during the 26th week of pregnancy. The effects on offspring were assessed when the child was 12, 18, and 24 months old. Results showed that positive antenatal mental health was significantly associated with the offspring's cognitive, language and parentally rated competences. This study shows that the effects of positive maternal mental health are likely to be specific and distinct from the sheer absence of symptoms of depression or anxiety.

Pesonen et al. (2016) reported 3376 pregnant women who self-assessed their positive affect (PA) and depressive and anxiety symptoms up to 14 times during gestation. Birth characteristics were derived from the National Birth Register and from medical records. Higher PA during the third pregnancy trimester was associated with longer gestational length, whereas higher depression and anxiety scores during the third trimester were associated with shorter gestational lengths ($P\text{-values} \leq 0.02$). Higher PA during the third trimester was associated with a significantly decreased risk for preterm (< 37 weeks) delivery ($P = 0.02$). Mothers with preterm delivery showed a decline in PA and an increase in anxiety and depression during eight weeks prior to delivery. Post-term birth (≥ 42 weeks), birth weight and fetal growth were not associated with maternal prenatal emotions.

Boehm et al. (2012) Optimistic women with a higher self-reported well-being were more proactive and motivated to engage in healthy behaviours (e.g., physical activity, a well-balanced, and nutritious diet), consequently promoting healthy foetal growth and leading to positive developmental outcomes for the offspring. A mediating analysis further revealed that higher maternal self-reported well-being positively influenced child cognitive and linguistic development through more adaptive parent-child interaction patterns (Phua et al 2017). To date, there is accumulating evidence to suggest that patient perceived wellbeing

can be improved with strategies such as expressing gratitude, being kind, meditating, and thinking optimistically about the future.

The evidence on the impact of yoga based prenatal interventions on the mental health of the mother and birth outcomes is as follows :

Candelas et.al. 2023 presented an overall review of systematic reviews and meta-analyses of randomized controlled trials to synthesize the evidence for the effect of different types of prenatal intervention on mother's mental health and wellbeing and its effect on new born child. For the review, PubMed, Embase, and Cochrane were searched from Jan 1, 1994, until December 18, 2022.k

Of the studies included, six examined psychological interventions (e.g., psychotherapy), five examined mind-body interventions (e.g., yoga, mindfulness), four examined lifestyle interventions (e.g., omega 3 supplementation, physical activity), 11 examined other interventions (e.g., fetal movement counselling, virtual reality during delivery), and five reviews examined multiple intervention types.

Key results on maternal mental health outcomes were as follows .Half or more of the outcomes examined supported an effect of the intervention examined, across different maternal pregnancy outcomes: of 24 estimates related to the effect of pregnancy interventions on maternal depression, 16 were statistically significant. Of the 22 estimates pertaining to maternal anxiety, 13 were statistically significant, and the same was true for two of the five estimates related to other maternal mental health conditions.

In relation to type of *intervention*, 31 effect sizes were summarized (five Psychological, five Mindfulness, five Lifestyle, five Multiple and 11 Other interventions). SMDs ranged from small to medium for Mindfulness (-0.15), Psychological (-0.22), and Lifestyle (-0.38) interventions and were larger for Other (SMD=-0.79) and Multiple (SMD=-0.54) interventions.

Key results on offspring outcomes were as follows Of the 30 studies reviewed, only seven examined offspring outcomes. Of these, three did not report effect sizes, resulting in four studies with a meta-analysis of offspring outcomes. Of the 16 offspring outcomes extracted, five examined outcomes related to APGAR score, three to birthweight, three to preterm birth, two to gestational age at birth, two to NICU admission and one to resuscitation of newborn. Out of the outcomes extracted, only two were statistically significant. These two studies examined neonatal resuscitation outcomes following a prenatal massage intervention, and

major neonatal, infant morbidity, and/or admission to NICU following a prenatal telephone support intervention. Hence very few RCTs have examined offspring outcomes, with none of the reviewed studies examining outcomes beyond delivery and birth.

In summary, the different forms of intervention show some promise in improving maternal health and deterring intergenerational transmission but are limited in the number that rigorously study of offspring outcomes, lack of existing RCTs, , hence conclusions on how effective any of the intervention types considered are in protecting infant brain-behaviour development cannot be definitely conclusive

Several systematic reviews with meta-analysis have recently explored the effectiveness of prenatal yoga practice in altering maladaptive psychological symptoms during pregnancy. (Deendalayan et.al. 2023 ; Demir et.al. 2022 ;Guo, et.al. 2021;Ng, et.al. 2019, Smith, et.al. 2019 ; Ayca et.al.2022;Gong et.al 2015 ;Lin et al 2022 ; Jiang et al. 2015).

Villar et. al (2023) developed an overview of systematic reviews with meta-analysis to summarize evidence on the effectiveness of prenatal yoga-based interventions on pain, psychological symptoms, and quality of life during pregnancy. CINAHL (via EBSCOhost), Embase, PubMed, SPORTDiscus (via EBSCOhost), and the Cochrane Library were searched from inception to 15 December 2022.

A total of ten systematic reviews, including fifteen meta-analyses of interest and comprising 32 distinct primary clinical trials, were included. Meta-analyses on pain and quality of life were not found. Most meta-analyses (93%) showed that prenatal yoga-based interventions are more effective than control interventions in reducing anxiety, depression, and stress symptoms. However, the overall methodological quality of systematic reviews was judged as critically low, and primary study overlap among systematic reviews was very high (CCA = 16%). Altogether, the findings suggest that prenatal yoga-based interventions could improve the mental health of pregnant women. However, there were important methodological flaws, there is a need to improve the methodological quality before one can drawing firm conclusions on this topic.

Corrigan et.al 2022 in systematic review and meta-analysis examined the characteristics and effectiveness of pregnancy yoga interventions, incorporating the FITT (frequency, intensity, time/duration and type) principle of exercise prescription. Only peer-reviewed published studies were included. The initial search was run on 22nd January 2019, updated on 22nd May 2020 and again on 5th November 2021.

Results of meta-analysis are based on twenty-nine studies with 2217 pregnant women . Pregnancy yoga interventions reduced anxiety ($p = 0.002$), depression ($P = 0.03$) and perceived stress ($p < 0.001$). Yoga interventions also reduced duration of labour ($p < 0.001$) and, increased odds of normal vaginal birth ($p < 0.001$) and tolerance for pain.

The quality of evidence (GRADE criteria) was low to very low for all outcomes. Twelve or more yoga sessions delivered weekly/bi-weekly had a statistically significant impact on mode of birth, while 12 or more yoga sessions of long duration (> 60 min) had a statistically significant impact on perceived stress.

Kwon et.al.(2020) conducted a systematic review on the psychological effects of antenatal yoga on pregnancy compared to standard prenatal care. Only the randomized controlled trials (RCTs) published from 2011 to 2018 and which evaluated an antenatal yoga intervention were included . All studies were assessed for risk of bias using the Cochrane criteria. Due to heterogeneity, meta-analysis was not possible.

Five RCTs met the inclusion criteria for the systematic review. The findings of the RCTs suggest antenatal yoga may be safe and may effectively decrease stress levels, anxiety scores, depression scores, and pain response as well as increasing maternal immunity and emotional-wellbeing. However, the studies were limited in number. More high-quality, large RCTs are needed to draw conclusions about improvement in other pregnancy outcomes.

Neel et al (2018): in study of pregnant patients on the impact of comprehensive ANC to reduce the complications during pregnancy like pregnancy-induced hypertension and intrauterine growth retardation. Stress management through meditation as well as exercise and nutritional management was done. There was a decreasing risk of isolated intrauterine growth retardation (IUGR $p 0.002$) and pregnancy-induced hypertension (PIH) with associated IUGR, and eventually would decrease problems in the infant, children, adolescent and fetal origin of adult diseases. Comprehensive integrated antenatal care is safe, relatively cheap to implement and would reduce the costs of long-term health care

Summary

There is substantial evidence of the effect of mother's prenatal mental health on the offspring. The influence of prenatal exposure to poor maternal mental health on the offspring is definite. Evidence suggests that positive and negative mental states of the mother have independent and distinct effects. This distinct pattern highlights the independence of negative and positive mental health constructs, indicating the need for separate investigations into maternal mental ill-health and well-being.

The studies on the effects on the offspring of positive prenatal mental health and wellbeing are relatively few. Intervention for improving the mother's perinatal mental health and well-being can play a definite role in improving birth outcomes as well as trajectory of subsequent development of the child.

The evidence supports positive effects of interventions using yoga based techniques during pregnancy in significantly reducing anxiety, depression, and perceived stress. The other outcomes include increased normal vaginal birth and shorter duration of labour. Although the evidence supporting yoga in pregnancy is growing, there are methodological weaknesses with published studies and an insufficient number of published RCTs. A lack of reproducible evidence-based interventions highlights the need for further research.

RECOMMENDATIONS	LEVEL
It is recommended that prenatal yoga based techniques (YBT) be part of routine prenatal care as these have effect on reducing anxiety, depression, perceived stress, and increasing normal vaginal birth with shorter duration of labour. (Corrigan, et.al. 2022; Guo, et.al. 2021 ;Ng, et.al. 2019, Smith, et.al. 2019; Villar et. al 2022; Kwon et.al.2020 ; Neel et al 2018)	A
It is recommended to implement prenatal interventions such as positive thinking, meditation mindfulness, positive affirmations, visualizations, emotional bonding which enhances the psychological well-being of the mother , birth outcomes and child development (Phua et al 2023 ; Estinfort et.al. (2022 ; Phua et. al. 2017 ; Pesonen et al.2016; Boehm et. al. 2012)	C

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Key Questions 4.7

4.7 How can the fertility care team provide psychosocial care for couples undertaking third-party reproduction?

- 4.7.1 What are the psychosocial needs of third-party reproduction in a couple undergoing ART ?
- 4.7.2 How can fertility staff address the needs of couples undertaking third party reproduction?
- 4.7.1 What are the psychosocial needs of third-party reproduction in a couple undergoing ART

Introduction:

Third-party reproduction refers to the use of eggs, sperm and embryos donated by a third person. This helps subfertile couples to have children from different genetic links. Those who can't bear pregnancy can have a child through surrogacy. Assisted reproductive technology with third-party gametes and surrogacy has helped many couples.

Summary of Evidence (review of literature):

Oocyte donation

Ghehlich et al (2021) concluded the main psychological stress of third-party reproduction in a couple undergoing ART. Their **identification of psychological challenges** during the treatment process is crucial to improving the recipient's mental health. This research was conducted using a qualitative approach and inductive content analysis method. The data collection tool was in-depth interviews. 20 women with the experience of receiving donated oocytes were selected and entered the study using a purposive sampling method and considering the maximum variation.

1. distressing psychological symptoms,
 - Self-esteem destruction
 - Anxiety and stress
 - Depression
 - Spiritual discouragement

2. social stigmatization,
 - Concerns about disclosure
 - Judgment of others
 - Contrast with religious teachings
3. Negative coping mechanisms.
 - Aggression
 - Denial of pregnancy
 - Detachment

Jacob V et al (2018) concluded the **concept of denial of pregnancy** in the particular case of women conceiving a child by medically-assisted procreation with oocyte donation. They concluded treatment with oocyte donation can be experienced as **invasive** with the consequence of a **complex psychic pregnancy** that could promote a denial of pregnancy. The need for special psychological support in order to support psychic gestation work for women conceiving a child by medically-assisted procreation with oocyte donation

Salevaara et al (2018) compared the mental health problems between parents after oocyte donation treatment and IVF/ICSI with their own gametes and after naturally conceiving (NC). This is a prospective, longitudinal questionnaire study of 26 oocyte donation mothers and their matched IVF/ICSI ($n = 52$) and NC ($n = 52$) controls. The parents filled in the General Health Questionnaire (GHQ-36) at gestational weeks 18-20 (T1), and at two months (T2) and 12 months (T3) after childbirth. Full response rate (T1-T3) for oocyte donation mothers was 76.9%, and for oocyte donation fathers was 73.1%. At T1, no significant differences were found between groups in depression, anxiety, sleeping difficulties, or social dysfunction, but they differed at T2 and T3 in anxiety (T2, $p = .02$; T3, $p = .01$), in sleeping difficulties (T2, $p = .02$; T3, $P = .04$) and in social dysfunction (T2, $p = .01$; T3, $p = .04$). Oocyte donation mothers showed less anxiety than NC mothers (T2, T3), and fewer sleeping difficulties and less social dysfunction than IVF/ICSI (T2, T3) and NC mothers (T2). Mental health problems of oocyte donation fathers did not differ from those of IVF/ICSI and NC control fathers at T1-T3.

Sperms donation

Liu X 2023 in a study on 187 couples undergoing sperm donation found scores of anxiety and depression on the day of transplantation in patients receiving IVF-ET with donor sperm were 43.98 ± 6.80 and 46.03 ± 10.61 respectively, which were higher compared to levels of Chinese health norm ($P < 0.05$). The anxiety score of patients' spouses was 41.23 ± 6.69 and the depression score was 44.23 ± 11.65 , which were higher compared to levels of Chinese health norm ($p < .05$). The score of anxiety and depression of women was significantly higher compared to those of their spouses ($P < .05$). Anxiety and depression scores of women in the non-pregnant group were significantly higher compared to those in the pregnant group ($P < 0.05$). Regression analysis showed that education level and annual family income were influencing factors of anxiety and depression scores of IVF-ET with donor sperm couples on the day of transfer, and number of eggs taken and transfer times were influencing factors of depression scores of IVF-ET with donor sperm patients on the day of transfer.

Surrogacy

Limazon et al (2021) concluded surrogacy is often approached in a **detached manner**, where potential parents describe the method as a last choice or one that is never considered. They articulate this position by highlighting the **emotional factors surrogacy** would entail; the women, in particular, described the involvement of another individual as the role of the mother. Participants placed themselves in positions of both power and vulnerability, reconciling the split between surrogacy as a compassionate act and a transactional business. The discourses present considerations for the continued practice of surrogacy among key players in reproductive health in developing countries, recognizing the concerns of infertile couples to enable informed decision-making and policy creation.

Tyuvnia et al. (2020) reflected on the specificity of the impact of an IVF procedure on the mental health of a potential mother in surrogacy. The features of the neonatal health status, as well as neuropsychiatric disorders in babies born using the IVF procedure, are described. It is shown that the development of assisted reproductive technologies (IVF and surrogacy), on the one hand, helps fight infertility and, on the other hand, **entails a number of problems (moral and ethical, legal, cultural and religious, socioeconomic, and neuropsychiatric ones) that need to be solved in order to prevent psychological, neurological, and mental abnormalities in all the participants (a surrogate mother, an unborn child, and potential parents) in the assisted reproductive process.**

Holzberg et al. (2018) intervened in contemporary scholarship on affect by bringing different affect theories into the same analytical frame. Analysing commercial surrogacy in India through **three different conceptualizations** of affect found in the work of Michael Hardt, Sara Ahmed and Brian Massumi reveals how affect emerges as a malleable state in the practice of, as a circulatory force in the debates around and as an ephemeral intensity in the spontaneous resistance to surrogacy. It is suggested that integrating different theories of affect enables more holistic examinations of corporeal regulation by opening our understanding to the multiple lives of affect that operate on the level of political economy, cultural significance and material intensity simultaneously.

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> Fertility care staff should be aware that specialised psychosocial care is needed during the process of treatment with donated oocytes, as it may be followed by the experiences of distressing psychologic symptoms, social stigmatization and negative coping mechanisms in recipient women such as denial of pregnancy and complexity (Ghelich et al 2021; Jacob et al 2018; Salevaara et al 2018) 	C
<ul style="list-style-type: none"> Fertility care staff should be aware that specialised psychosocial care is needed as surrogacy may present moral, ethical, legal, cultural, religious, socioeconomic, and psychological concerns. due to the inability to reconcile the split between surrogacy as a compassionate act or a transactional business (Limazon et al., 2021; Tyuvinia et al., 2020) 	C

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4.7.2 How can fertility staff address the needs of couples undertaking third party reproduction?

Introduction:

The role of Fertility staff in providing assessment, education, and support is important for psychological well-being and positive outcomes. This care is specifically needed in third-party reproduction due to the complexities which arise when a gamete donor or surrogate becomes involved in the process of reproduction for a couple. Acceptance of this process is often not done with positivity. The anonymity of donor raises many questions and decision-making on informing the child regarding this is a complex area

Evidence

Oocyte Donation

Donor Oocyte Recipient

Jacob Alby (2018) concluded in an observational study from two clinics, the concept of denial of pregnancy in a case of women conceiving a child by medically-assisted procreation with oocyte donation. Medically-assisted procreation with oocyte donation can be experienced as invasive with the consequence of a complex psychic pregnancy that could promote a denial of pregnancy. They validate the need for special psychological support in order to support psychic gestation work for women conceiving a child by medically-assisted procreation with oocyte donation

Ghelich-Khani et al (2021) interviewed in depth twenty women with the experience of receiving donated oocytes. Three main categories of psychological challenges were extracted from patient interviews, specifically, distressing psychologic symptoms, social stigmatization, and negative coping mechanisms. The experience of 50% of the oocyte recipients showed they had a feeling of inferiority and defect combined with guilt, resulting in a loss of self-esteem which grew over time. 60% of the participants showed emotional distress like anxiety and stress, and 90% showed depression which in some cases required medication. The need to use a third party for fertility, recurring medical expenses and multiple failures, blame of others, lack of comprehensive support from the husband, and other destructive feelings and behaviours had led to depression in women. A kind of despair and spiritual discouragement was expressed by 50% of the participants. Concerns about disclosure and the consequent attempt to conceal the process of the treatment were predominant concerns in 95% of couples. Fear

of judgment of others and concerns about the apparent dissimilarity of the resulting offspring to the parents was also expressed by 55% of the participants. Conflict with religious teachings was another challenge experienced by 35% of the participants. Denial and aggression were the main categories of negative coping mechanisms extracted. Behaviours such as visiting different physicians, performing multiple tests in different centres, interrupting the treatment process or requesting other treatment methods with the hope that previous diagnoses have been wrong and obtaining a positive result were reflective of the psychological reaction of denial in 60% of the participants. Aggression was another behaviour in 40% of the participants, which was caused by the insistence of others for having children or their disagreement with using donated oocytes.

Bracewell-Milnes (2018) conducted a systematic search of peer-reviewed journals of four computerized databases. Sixty-two studies were included in the review. Psychosocial aspects towards donation were positive from the egg share donor and recipient.

Oocyte Donor

An anonymous survey was distributed via a secure email to 161 donors who underwent oocyte donation. The majority of respondents felt positive about the donation experience as well as the prospect of open donation or identity disclosure post-donation. 62.5% of respondents reported that they would be open to identity disclosure after experiencing the process. 58.1% ($n = 18$) reported they would recommend donating eggs, 6.5% ($n = 2$) said they would not recommend donation, and 35.5% ($n = 11$) said they weren't sure if they would make that recommendation. (Blakemore 2019)

De Melo-Martin 2018 conducted semi-structured interviews with 50 women: 28 oocyte donors and 22 recipients. Donors and recipients view anonymity both as a mechanism to protect the interests of all parties (recipients, donors, and donor-conceived children) and as a point of conflict. Specifically, three key areas were identified where both donors and recipients saw anonymity as having an important role: relieving anxieties about family structures and obligations; protecting their interests and those of donor-conceived children (while acknowledging where interests conflict); and managing the future.

Jadva 2018 examined the characteristics, motivations and experiences of Indian egg donors. In-depth interviews were conducted with 25 egg donors. The most common motivation (19, 76%) for donating was financial need. Egg donors had discussed their donation with their husbands or with close family/ friends, with

almost all mentioning that wider society would disapprove. The majority (20, 80%) had no information about the recipients and 11 (44%) preferred not to. The findings highlight the similarities and differences between egg donors from India and those from other countries.

Behjati et al (2023) assessed in Iran, despite the need to use the third-party reproduction availability, some couples refuse the treatment unless their confidentiality is preserved. Many couples follow the practice surreptitiously by keeping the donation treatment confidential to get rid of the existing social stigma and protect their identity, the child and the donor's identity. Commitment theory as a theoretical strategy is proposed to solve the problems of all parties involved in this type of "social and non-biological" parenting. Commitment theory in the context of third-party reproduction expresses the commitment to the contract accepted by the donor and the recipient of the gamete/embryo, based on which the recipients consider the resulting child as their own and are committed to all the related paternal-maternal rights and duties such as "alimony" and "inheritance". On the other hand, the donors undertake to waive all their paternal-maternal rights and duties by donating gamete/embryo.

In a study by *Applegarth (2016)* regarding disclosure to children, 72 subjects answered a questionnaire 43% disclosed to the population as intended, 39% still intended to disclose, 9% uncertain, and 9% did not intend to disclose. In India, most donors are anonymous and disclosure to anyone other than a partner is not done. There was an anxiety to disclose to older children.

Sperm Donation

Liu 2023, in a study on 187 couples undergoing sperm donation, found scores of anxiety and depression on the day of transplantation in patients receiving IVF-ET with donor sperm were 43.98 ± 6.80 and 46.03 ± 10.61 respectively, which were higher compared to levels of Chinese health norm ($p < .050$). The anxiety score of patients' spouses was 41.23 ± 6.69 and the depression score was 44.23 ± 11.65 , which were higher compared to levels of Chinese health norm ($p < .050$). The score of anxiety and depression of women was significantly higher compared to those of their spouses ($p < .050$). Anxiety and depression scores of women in the non-pregnant group were significantly higher compared to those in the pregnant group ($P < .05$). Regression analysis showed that education level and annual family income were influencing factors of anxiety and depression scores of IVF-ET with donor sperm couples on the day of transfer, and number of eggs taken and transfer times were influencing factors of depression scores of IVF-ET with donor sperm patients on the day of transfer.

Surrogacy

Limazon et al (2021) interviewed ten (10) Filipino Roman Catholics who were struggling with infertility to uncover how they constructed the idea of surrogacy. They showed the discourses on surrogacy are often approached in a detached manner, where potential parents describe the method as a last choice or one that is never considered. They articulate this position by highlighting the emotional factors surrogacy would entail; the women, in particular, described the involvement of another individual as the role of the mother. Participants placed themselves in positions of both power and vulnerability, reconciling the split between surrogacy as a compassionate act and a transactional business. The ambiguous role of faith was also negotiated by the participants, where they argued for surrogacy using alternative teachings or through God-given free will.

Leone et al (2018) conducted an observational study involving 28 clinicians and 160 patients at eight Italian ART clinics where visits were videotaped. A total of 85 visits were eligible for analysis (62% acceptance rate), involving 28 clinicians and 160 patients (including 75 couples). The average visit duration was 37 ± 17.7 min. Findings revealed the complexity of communication content during ART consultations, given its triadic characteristic in which the third party is also a patient; clinicians should be aware of this complex aspect and of the specific male and female perspectives to be taken into account. The results could be useful for training ART professionals.

Montrone Met al. (2020). Six hundred and two individuals were involved in 160 altruistic surrogacy arrangements: 143 intended mothers, 175 intended fathers (including 17 same-sex intended father couples), 160 surrogates, and 124 surrogate partners. Responses to a pre surrogacy sociodemographic assessment counselling protocol and the Personality Assessment Inventory (PAI). Intended mothers were more likely than surrogates to live in the most advantaged residential areas, to be younger and be more educated, and to be employed in professional occupations. Most participants' psychological profiles were normal. A statistically significantly elevated PAI Somatic Complaints-Health Concerns subscale for intended mothers was observed compared with other participant groups. The higher PAI Warmth scale scores of intended mothers and surrogates were statistically significantly different from their respective partners, although not different from each other. Sociodemographic and some psychological differences between participant groups were observed that warrant exploration in pretreatment surrogacy counselling. Importantly, the higher scores on the PAI Warmth scale exhibited by intended mothers and surrogates in the context of

close family and friendship relationships are likely to serve as protective mechanisms for the altruistic surrogacy outcome.

Summary

Couples with oocyte or sperm donation should be counselled as they may experience invasive complex psychic pregnancy and denial at the same time while trying not to disclose the use of donated gametes, they are deprived of any social support and psychological counselling. (Jacob et al 2018, Liu X 2023) Sociodemographic and some psychological differences between participant groups were observed in pre-treatment surrogacy counselling. (Montrone M, et al (2020). However, none of the studies were RCT and most were interviews which were subjective. Hence the quality of evidence was low.

SR. No.	RECOMMENDATIONS	GRADE
1	It is recommended that health staff should impart appropriate pre-treatment counselling for third-party reproduction with the aim of maintaining the psychological and emotional well-being of all parties involved (Montrone et al., 2020).	A
2	The patients who undertake third-party reproduction undergoing donor gametes and surrogacy treatment to have counselling sessions with mental health professionals so that they can make an informed decision about acceptance of non-biological parenthood (Jacob et al., 2018, Liu, 2023).	GPP
3	Commitment to the contract must be stressed by the health care worker to the donor and the recipient of the gamete. (Behjati et al 2023).	GPP

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Key Questions 4.8

4.8 What Are the Special Cases of Couples Undergoing ART?

- 4.8.1. How is counselling for single women seeking motherhood through ART different?
- 4.8.2 What is the Counselling for couples with gender preference undergoing ART?
- 4.8.1 How is Counselling for single women different?

Introduction:

Family structure has changed with the rapid social progress, medical development, and improved education standards from the traditional extended family into nuclear or smaller families with single parenthood. The number of preschool children living in single-parent families is gradually increasing, and women along with children are learning to adjust to their paths in the changing future. The American Society for Reproductive Medicine (2021) advocates for equitable treatment of patients regardless of sexual orientation and partner status, and healthcare providers working in the fertility field should be comfortable and confident in assessing the needs of and providing care to these populations.

In India, many single women nowadays are coming forward for the freezing of eggs, though single women motherhood is still uncommon. The effect of family structure on a mother in the upbringing of the child alone and the child's psychosocial adjustment, and social competency is not yet completely evaluated in studies.

Evidence

Diez et al. (2021) explored the effects of family structure (single mother by choice/partnered mother), pathway to motherhood (adoption/assisted reproduction techniques or ART), and parenting style on children's psychological adjustment and social competence. 98 families participated: 45 single mothers by choice (29 adoptive, 16 by ART); and 53 partnered mothers (27 adoptive, 26 by ART). Ninety-eight children were evaluated (*Age* = 5.36) by their teachers. As regards family structure, children of single mothers by choice (both adopted and conceived by ART) showed good psychological adjustment and good social competence. No significant differences were observed between them and those living with two parents when all were conceived by ART. However, children

adopted by single mothers had higher hyperactivity and lower self-control than those living with two adoptive parents. No differences were observed in terms of nurturing parenting style, either between single and partnered mothers or between adoptive and ART mothers. The nurturing parenting style significantly predicted better psychological adjustment and social competence among children.

Golombok, et al (2021) studied the second phase of a longitudinal study of families created by single mothers by choice. Forty-four single heterosexual mothers were compared with 37 partnered heterosexual mothers, all with a donor-conceived child aged around 8-10 years. Standardized interview, observational, and questionnaire measures of maternal well-being, mother-child relationships and child adjustment were administered to mothers, children, and teachers. There were no differences in maternal mental health, the quality of mother-child relationships or children's emotional and behavioural problems between family types. Higher levels of parenting stress and higher levels of children's prior adjustment difficulties were each associated with children's adjustment difficulties in middle childhood irrespective of family type. The findings suggest that the presence of two parents-or of a male parent-is not essential for children to flourish and add to the growing body of evidence that family structure is less influential in children's adjustment than the quality of family relationships.

Golombok et al (2016) Fifty-one solo mother families were compared with 52 two-parent families all with a 4-9-year-old child conceived by donor insemination. Standardized interviews, observational and questionnaire measures of maternal well-being , mother-child relationships and child adjustment were administered to mothers, children and teachers. There were no differences in parenting quality between family types apart from lower mother-child conflict in solo-mother families. Neither were there differences in child adjustment. Perceived financial difficulties, a child's gender, and parenting stress were associated with children's adjustment problems in both family types. The findings suggest that solo motherhood, in itself, does not result in psychological problems for children.

Nicholas et al (2022) study aimed to discuss fertility concerns unique to the lesbian, gay, bisexual, transgender, queer, plus and single-parent-to-be populations and review special considerations regarding the evaluation and treatment of these patients relevant to the practising reproductive medicine provider. Greater diversity of patients making use of ART nowadays. The lesbian,

gay, bisexual, transgender, queer, plus community and single parents-to-be represent understudied and important populations who often require the use of assisted reproductive technology to build their families.

Lin et al (2022) concluded Family Counseling Center (FCC) provides programs that can help single parents to motivate children's positive behaviours through different life learning philosophies with professional knowledge from different fields. Besides learning self-introspection, single parents can also apply what they have learned to help children with different family issues. This study adopted the Theory of Planned Behavior (TPB) (Ajzen, 1985; 1991) as the theoretical foundation. The reason was that because the TPB can create better models to predict more complex and particular behaviour patterns than general behavioural theories can. It can decompose belief into several constructs to help understand which factors had greater influences on behavioural intention. Thus the research subjects were single parents who had participated in the 5 preschool Family Counseling Center workshops in July of 2019. The questionnaire was designed to examine preschool single parent's intention to participate in art therapy professional single parent guidance curriculums. A total of 200 questionnaires were distributed to the 5 FCC workshops in Taiwan. The result of the study shows that the more positive single parent attitude, subjective norms, and perceived behavioural control regarding participation in art therapy single parent guidance curricula were, the higher their intentions were related to other people's viewpoints and their perception of degrees of controlling. However, perceived behavioural control and attitude were factors which significantly influenced single parent's participation in art therapy single parent guidance curriculums.

Volgsten et al. (2023) explored Swedish single women's experience of making the decision to choose motherhood through MAR. The study design was a qualitative method with a semi-structured interview guide used for individual face-to-face interviews. Sixteen single women accepted for MAR were interviewed individually during their waiting time to start treatment. Qualitative content analysis was used to analyse the data. The data analyses resulted in three main categories: (i) longing and belonging; (ii) social exclusion and support; and (iii) evaluation and encounter. The overarching theme reflects the decision to become a single mother by choice: motherhood through *MAR – an emotional and ambivalent decision to make on your own*. In conclusion, to reach motherhood by giving birth to one's child and not deviating from the norm as childless was considered important among these women when making the decision to become a single mother by choice.

Konge et al (2023) studied to explore women's experiences and perspectives on the process of creating a solo-mother family through assisted reproductive technology. This study was designed as an explorative, qualitative study. Semi-structured interviews were conducted face to face or by telephone to explore women's experiences and perspectives on creating a solo-mother family. We used systematic text condensation to analyse the data. Twenty solo mothers participated in the study, and 38 interviews were conducted during and after pregnancy. Four themes related to the experiences of building a solo-mother family emerged from the data analysis: (1) Dealing with reactions to the choice to become pregnant by Medically Assisted Reproduction (MAR) and a solo mother, (2) Marketisation of motherhood, (3) Longing to be a 'normal' pregnant woman, (4) Grandparents as co-parents and leaning on siblings and friends. The women went through a process of redefining themselves because they considered the nuclear family as the ideal. They realised on a profound level that they were 'on their own'. Generally, the woman's biological family played a vital role, supporting her emotionally and in practical ways. The creation of a solo-mother family was often seen to take place with grandparents as co-parents. The women leaned to a lesser extent on close friends. The more positive single parent attitudes, subjective norms, and perceived behavioural control regarding participation in art therapy single parent guidance curricula were, the higher their intentions were related to other people's viewpoints and their perception of degrees of controlling. Perceived behavioral control and attitude were factors, which significantly influenced single parent's participation in art therapy single parent guidance curriculums. (Lin et al 2022)

Summary

Single parenthood is becoming an option with the help of ART technology. Staff should be prepared to provide the best treatment in a non-judgmental way with adequate support and Counselling.

RECOMMENDATIONS	GRADE
Fertility staff should offer pre-treatment counselling to all single women to help them to make well-informed decisions. Women should understand various aspects like ART with donor sperm, implications on pregnancy care, child raising, and financial and legal long-term consequences before embarking on fertility treatment(Golombok et al., 2021, 2016; Nicholas et al., 2022;)	GPP
Mental health professionals should carefully assess single women that motherhood through ART isn't an emotional and ambivalent decision (Konge et al., 2023; Volgsten et al., 2023)	C

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4.8.2 What is the Counselling for Couples with gender preference undergoing ART?

Introduction:

Couples may present with gender preference undergoing ART. Gender preference could be because of social, educational, economics, cultural traditions and previous family structure. India had been a primarily male dominated society with strong laws to prevent the imbalance of male and female ratio. The PCPNDT (preconception prenatal diagnostic techniques) Act was enacted on 20 September 1994 with the intent to prohibit prenatal diagnostic techniques for the determination of the sex of the fetus leading to female feticide.

The Act is legislated in a manner that it should be a deterrent for those indulging in sex determination. The unfortunate decline in the male-female sex ratio has brought in stringent measures, there is a suspension of registration, filing of criminal cases and sealing of machines. Besides, criminal prosecution will also bring in suspension and cancellation of registration granted by the State Medical Council.

Summary recommendations are as given below

RECOMMENDATIONS	GRADE
<ul style="list-style-type: none"> ● Counselling by healthcare staff should be consistently and continuously gender neutral throughout the treatment cycle, stressing the need for delivery of healthy children without any gender preference. 	GPP
<ul style="list-style-type: none"> ● All fertility Staff must reinforce the same concept to the couple who show the desire to have a boy. 	
<ul style="list-style-type: none"> ● All staff must be aware of the laws which prohibit sex determination. The Preconception and Prenatal Diagnostic Techniques (Prohibition of Sex Determination) Act (PC-PNDT) prohibits sex determination. The couple needs to be well informed about the same, and the reason for making the law. 	

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