



Clinical Trial Details (PDF Generation Date :- Thu, 28 Oct 2021 03:36:15 GMT)

CTRI Number	CTRI/2015/07/005973 [Registered on: 06/07/2015] - Trial Registered Retrospectively	
Last Modified On	27/01/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Behavioral	
Study Design	Randomized, Parallel Group, Active Controlled Trial	
Public Title of Study	The study is a clinical trial to study the effectiveness of psychotherapy in reducing emotional distress in infertility couples, while they undergo infertility treatment (IUI) and face unsuccessful outcomes in such treatment cycles.	
Scientific Title of Study	Effectiveness of modified mindfulness based cognitive therapy in distressed couples with infertility, undergoing intra-uterine insemination.	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> nil			
Primary Sponsor	Primary Sponsor Details			
	Name	Selfsponsored		
	Address	Department of Psychiatry Self sponsored Ms. Ansha Patel Kasturba Medical College, Manipal university Manipal		
	Type of Sponsor	Other [self sponsored]		
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr Pratap Kumar Professor and Head Division of reproductive medicine Dept of OBG	DEPT OF OBSTETRICS AND GYNAECOLOGY, DIVISION OF REPRODUCTIVE MEDICINE, MARC	DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY, DIVISION OF REPRODUCTIVE MEDICINE, MANIPAL ASSISTED REPRODUCTION CENTRE, KASTURBA MEDICAL COLLEGE (KMC), MANIPAL UNIVERSITY MANIPAL Udupi KARNATAKA	08202922162 pratap.kumar@manipal.edu
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Doctoral Accreditation Committee	Approved	05/08/2015	No
	Kasturba Medical College, Institutional Ethics Committee	Approved	14/05/2014	No
Regulatory Clearance Status from DCGI	Status	Date		
	Not Applicable	No Date Specified		
Health Condition / Problems Studied	Health Type	Condition		
	Patients	Primary Infertility		
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	INTERVENTION TYPE: Behavioural Intervention, namely PSYCHOTHERAPY TYPE OF PSYCHOTHERAPY IN THIS STUDY: Mindfulness based cognitive therapy (MBCT) MODIFIED MBCT SESSION CONTENT , FREQUENCY, DURATION & FORMAT : The experimental group in this study	CONCEPTUAL DEFINITION OF PSYCHOTHERAPY: Psychotherapy is a form of psychological intervention modality offered by mental health clinicians, for patients with significant emotional morbidity. PSYCHOTHERAPY is defined as a 'treatment by psychological means of	



	<p>consists of infertility couples , in which both wife and husband receive 6-DAILY-1.5HOUR-SESSIONS OF MBCT, in couple format, along with IUI (Treatment-as-usual at MARC)</p>	<p>problems of emotional nature, in which a trained person, deliberately establishes a professional relationship with the patient with the object of (1) Removing, modifying, or retarding existing symptoms, (2) Mediating disturbed patterns of behavior, and (3) Promoting positive personality growth and development.' BRIEF DESCRIPTION OF MBCT IN THIS STUDY: Mindfulness Based Cognitive Therapy is a multi-component evidence based psychotherapy that involves "training the mind in observing, describing, accepting whatever one is experiencing at present-moment, with the attitudinal qualities of acceptance, fearlessness, enlightenment, courage, truth and compassion ". MODIFIED MBCT SESSION CONTENT : Prescribes several MBCT based cognitive-behavioural-emotional self-regulatory skills to help patients deal and cope with painful aspects of infertility. It aims to create a mindful acceptance of their life situations, self and relations. THE MODIFIED MBCT SESSION STRUCTURE : With permission from original authorities, in this study, the original format of MBCT has been altered and dovetailed to fit within the schedule of the routine assisted reproductive treatments and procedures offered at MARC.</p>
Comparator Agent	<p>THE WAITLISTED CONTROL GROUP: Does not receive any psychological intervention. They receive the routine IUI treatment at MARC.</p>	<p>The routine IUI treatment at MARC- Treatment-as-usual consists of detailed infertility evaluation, medical and lab investigations, for both wife & the husband.</p>

Inclusion Criteria

Inclusion Criteria	
Age From	20.00 Year(s)
Age To	35.00 Year(s)
Gender	Female
Details	<p>Inclusion Criteria-

 • Persons who give consent for the study, with female partner of couple of Age 20 years to 35 years , Educated at least up to 10th standard and should be able to read and write Kannada.
 • Couples who are coming as new cases to MARC , with p/h/o diagnosis of primary infertility
 • Patients who have 5-10 years of p/h/o undergoing Assisted Reproductive</p>



	Treatments • Couples with PCOD in female partner and /or oligospermia and varicocele in male partner • Suitable for intra-uterine insemination • Neither partner of the couple meets any diagnostic criteria on Mini International Neuropsychiatric Interview (English version 5.0). • Having a significant infertility specific stress score , in either partner of the couple ,(i.e. raw score of 167 or above as assessed in females and of 147 or above as assessed in males) as measured on Fertility Problem Inventory.	
Exclusion Criteria	Exclusion Criteria	
	Details	<ul style="list-style-type: none"> • Couples with >10 years of diagnosis of primary infertility and p/h/o undergoing Assisted Reproductive Treatments. • Couples who have undergone surgery in the last 3 months . • Couples who are going to under surgeries in the coming 3 months • Couples suitable for IVF • Couples suitable for donor egg/ donor insemination • Couples in which female partner has a diagnosis of recent cyst/ fibroids/ endometrioses and /or males with a diagnosis of azoospermia/aspermia. • Couples in which either partner with diagnosed with any psychiatric disorder or on Rx for psychiatric comorbidities ,or meets the diagnostic criteria on Mini International Neuropsychiatric Interview (English version 5.0). • Having an insignificant infertility specific stress score in both the partner of the couple (raw score of or less than 167 as assessed in females and equal/less than 147 as assessed in males) as measured on Fertility Problem Inventory.
Method of Generating Random Sequence	Permuted block randomization, fixed	
Method of Concealment	Sequentially numbered, sealed, opaque envelopes	
Blinding/Masking	Not Applicable	
Primary Outcome	Outcome	Timepoints
	Infertility Specific Stress assessed by Fertility Problem Inventory	Pre to Post Intervention, 1 month
Secondary Outcome	Outcome	Timepoints
	ii. Mindfulness skills : Assessed by Kentucky Inventory for Mindfulness Skills	Pre to Post intervention, 1 months
	iii. Anxiety and Depression: Assessed by Hamilton anxiety and depression scale.	Pre to Post Intervention, 1 month
	v. Fertility related Quality of life : Assessed by Ferti QOL	Pre to post intervention, 1 month
Target Sample Size	Total Sample Size=30 Sample Size from India=30 Final Enrollment numbers achieved (Total)=0 Final Enrollment numbers achieved (India)=192	
Phase of Trial	Phase 2	
Date of First Enrollment (India)	30/05/2014	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=2 Months=6 Days=0	



Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	nil
Brief Summary	<p>This study was a randomized controlled single centre trail, with a 2 group design, to test the effectiveness of modified Mindfulness Based Cognitive Therapy for distressed couples with infertility undergoing unsuccessful outcomes on Intra Uterine Insemination (Experimental group) , in comparison to those distressed couples with infertility undergoing unsuccessful outcomes on Intra Uterine Insemination, who are in treatment as usual (The waitlisted control group).</p> <p>The primary outcome is the change in scores on mean infertility specific stress experienced by each of the partners in the couple, after 2 months (from pre-post intervention), among the two study groups.</p> <p>The secondary outcome was changes in scores on mean mindfulness skills, symptoms of depression, symptoms of anxiety, marital distress and Fertility related quality of life in the couples after 2 months (from pre-post intervention), among the two study groups.</p> <p>Results: The modified MBCT was reasonably accepted by infertile couples. The total attrition was below 30%. Mean Compliance during sessions was above 70%. At follow-up, the mean compliance was 53% in women and 33% in men. Factors associated with the take-up of therapy, compliance and attrition were identified. There were no adverse effects from practice of MBCT.</p> <p>In women, between-group differences obtained on ISS,</p>



Anxiety, Depression, FertiQol and Coping were found to be statistically significant.

In men between-group differences obtained on ISS, FertiQol and Mindfulness coping were found to be statistically significant.

This study also provides a limited evidence for enhanced fertility outcomes in MBCT group. Superior outcomes were also observed in couples who underwent booster MBCT sessions and in those who conceived as well as continued MBCT practice during their early gestational period.