BMJ Open

Effectiveness of psychological interventions on mental health, quality of life and relationship satisfaction for individuals and/or couples undergoing fertility treatment: a systematic review and meta-analysis protocol

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ABSTRACT

Introduction Infertility is a global public health problem affecting men, women and couples worldwide. The medical implications of infertility are often of primary focus in healthcare settings, but the experience of infertility also has a considerable social, emotional and psychological impact. Interventions aimed at alleviating psychological symptoms in individual and/or couples undergoing fertility treatment requires a systematic and comprehensive review of the literature to determine the efficacy of psychological interventions. The objective of this review is to evaluate the effectiveness, feasibility and acceptability of psychological interventions for individuals and/or couples seeking fertility to treat anxiety, depression, distress, quality of life and relationship satisfaction, as well as improve pregnancy rates.

Methods and analysis The search strategy will involve 11 databases, including MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily (Ovid), EMBASE (Ovid), PsycINFO (Ovid), Cochrane Central Register of Controlled Trials (OVID), The Cumulative Index to Nursing and Allied Health Literature (CINAHL) with Full Text (EBSCO), Social Work Abstracts (EBSCO), SocINDEX with Full Text (EBSCO), Academic Search Complete (EBSCO), Family & Society Studies Worldwide (EBSCO), Family Studies Abstracts (EBSCO) and Scopus. These databases will be searched from their inception to September 2019. Independent reviewers will search peer-reviewed published studies through electronic databases and additional sources, will extract the data and assess the methodological quality. Random-effects meta-analysis will be carried out by calculating effect sizes as Cohen's d indices. Heterogeneity will be examined by the I^2 and the Q statistics.

Ethics and dissemination The current review does not require ethics approval. The results will be disseminated through publications in peer-reviewed journals.

PROSPERO registration number CRD42019133757.

Strengths and limitations of this study

► Search strategy was developed and run by a senior research librarian.
► Study selection and data extraction will be performed by two independent reviewers.
► If heterogeneity is found, subgroup analyses will be conducted for studies.
► This study does not assess the mental health status and psychological intervention needs of couples struggling with infertility who choose not to undertake fertility treatment.
► Another limitation might be that some studies do not report data for recruitment and retention or authors do not provide them on request.

INTRODUCTION

Infertility affects 48.5 million people worldwide,[1] including 15% of reproductive-aged couples.[2] Though the medical aspects of infertility are generally the primary focus of health professionals who treat the condition, enormous psychological impact of infertility is also well-established.[3] Indeed, rates of depression and anxiety among women struggling with infertility have been estimated to be as high as 30%–40% in tertiary care settings.[4–6] Couple relationships are also often negatively impacted.[7]

In light of the significant psychological burden associated with infertility, a number of studies have aimed to test the efficacy of various psychological interventions in improving mental health and relationship quality in this population, with mixed findings. Two systematic reviews of this literature have been conducted in the last 5 years, however, each coming to fairly disparate conclusions.[8 9] The first,[8] conducted in 2014,

included 39 eligible controlled and uncontrolled trials and concluded that psychological interventions—cognitive behavioural interventions, in particular—showed clear benefits in this population. The second,[9] conducted in 2016, narrowed their search to randomised controlled trials and identified 20 eligible studies. Based on these more narrow inclusion criteria, the authors concluded that currently available treatments are largely ineffective and recommended that a new, infertility-specific intervention be developed. There is, therefore, a lack of clarity and agreement on whether currently available treatments are sufficient.

The current systematic review aims to clarify this issue, with a careful examination of potential explanations for the vastly different conclusions of the two above-mentioned reviews. Furthermore, we aim to provide an updated review that incorporates the numerous trials of online interventions that have been published since the above-mentioned systematic reviews were conducted.[8 9] We aim to be more inclusive, reviewing both controlled and uncontrolled trials, interventions targeting individuals and/or couples (heterosexual or same-sex), and including studies examining a range of outcomes related to efficacy and acceptability. By being more inclusive, we hope to be better positioned to explore the existence of multiple predictors, mediators and moderators of treatment efficacy. The specific questions guiding this systematic review and meta-analysis are as follows:

1. What is the effectiveness of psychological interventions for individuals and/or couples seeking fertility treatments in reducing anxious and depressive symptoms, and increasing quality of life, relationship satisfaction and psychological well-being?
2. What is the effectiveness of psychological interventions for individuals and/or couples seeking fertility treatments in improving pregnancy rates?
3. What is the acceptability of psychological interventions for individuals and/or couples undergoing fertility treatment?
4. What are the mediators and moderators of treatment efficacy for individuals and/or couples undergoing fertility treatment?

METHODS AND ANALYSIS

Studies of all sizes will be included, though sensitivity analyses excluding studies with <20 participants in the treatment condition will be performed.

Protocol and registration

The protocol for this systematic review was developed according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols[10] (see online supplementary file 1). Any amendments to the protocol will be documented with a rationale and will be reported in the final publication.

Eligibility criteria

Study characteristics

The review will consider studies evaluating the feasibility, acceptability, effectiveness and/or efficacy of psychological interventions for individuals and/or couples (heterosexual and same-sex) seeking and/or undergoing fertility treatment. Experimental studies including randomised control/clinical trials (RCTs), quasi-experimental studies and single group prepost studies will be included in the review. In cases of duplication (ie, publications of the same sample), we will include the publication with the largest sample size. If sample sizes reported in two manuscripts are the same, the first published study will be included in the review. Qualitative studies that explore the acceptability of the intervention will also be included. Conference papers, dissertations, reviews and non-English publications will be excluded. All identified articles will be screened despite their publication dates and setting of interventions.

Participants

Individuals and/or couples seeking or undergoing assisted reproductive technologies, which include in vitro fertilisation, intrauterine insemination, intrafallopian transfer, intracytoplasmic sperm injection and monitored use of exogenous gonadotropins and medications to regulate or induce ovulation will be considered eligible.

Interventions

Psychological interventions will be defined as any non-pharmacological intervention whose purpose is to reduce psychological distress and improve mental well-being. The intervention must be tailored to individuals and/or couples while seeking or undergoing fertility treatment(s). Eligible interventions will include unstructured counselling or psychotherapy, cognitive–behavioural therapy, behavioural psychotherapy, interpersonal psychotherapy, acceptance and commitment therapy, acceptance-based therapy, dialectical behaviour therapy, cognitive behavioural analysis system of psychotherapy, functional analytic psychotherapy, couples therapy, marital therapy, couples or marital counselling, grief therapy, metacognitive therapy, rational emotive psychotherapy, mindfulness-based therapy and/or well-being therapy. Therapist-guided interventions will be included, as well as blended interventions that combine technology with face-to-face-based treatment. Couples-based, group-based and one-on-one interventions will be included.

Outcomes, mediators and moderators

For aim 1, primary outcomes will include anxiety, depressive mood, infertility distress and a combined outcome variable averaging effect sizes from all psychological outcomes. Secondary outcomes will include quality of life and relationship satisfaction/quality. For aim 2, the primary outcome will be rates of successful pregnancy and, if available, live birth rates. For aim 3, outcomes will include indicators of acceptability, such as participant

attendance and retention. For aim 4, the primary outcomes will be the combined psychological outcome variable, pregnancy rates and participant retention rates, assuming that a sufficient number of studies exist for each outcome (k≥3). Potential moderators investigated will include length of intervention, therapeutic approach, study design (eg, randomised vs non-randomised), and study quality rating. Change in anxiety and depressive mood will be considered as potential mediators in the effect of interventions on pregnancy rates.

Informational sources and search strategy

The search strategy will focus on three main concepts: infertility, psychological interventions and outcomes as identified above. Keywords will be the same for all databases but the subject headings will be adjusted to reflect the controlled vocabulary of each specific database. The search strategy will be conducted in the following databases: MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily (Ovid), EMBASE (Ovid), PsycINFO (Ovid), Cochrane Central Register of Controlled Trials (OVID), CINAHL with Full Text (EBSCO), Social Work Abstracts (EBSCO), SocINDEX with Full Text (EBSCO), Academic Search Complete (EBSCO), Family & Society Studies Worldwide (EBSCO), Family Studies Abstracts (EBSCO) and Scopus. Databases will be searched from inception to September 2019. These searches will be re-run prior to the final analysis to retrieve any additional recently published article for inclusion. In addition, citation searching in Google Scholar, searches of the reference lists of included studies, and experts will be asked to identify further studies for inclusion. The search strategy was developed in collaboration with an expert health sciences librarian (KAH). The MEDLINE (R) search strategy is shown in table 1.

The search filter "humans only" will be used. No study design search filters will be used. Study language will be restricted to English. Covidence will be used to manage the records, remove duplicates and manage full texts. Searches will be re-run prior to the final analyses to retrieve any additional recently published articles for inclusion. Studies of all sizes will be included, though sensitivity analyses excluding studies with <20 participants in the treatment condition will be performed.

Selection process

Prior to screening titles and abstracts, we will conduct training and an inter-relater calibration exercise of 10% of the studies with the review team. An agreement level of 90% or greater will be reached prior to moving on to reviewing the remaining records. In the case where the agreement level is less than 90%, the inclusion/exclusion criteria will be refined. The calibration exercise will be completed a second time and if the agreement level is greater than 90% the team will move forward with reviewing the remaining records. These two reviewers (KSB and LD), who are experts in the area of infertility-related mental health, will then independently screen the remaining studies for eligibility in two steps. The first step will consist of reviewing all records' titles/abstracts to identify studies that meet the eligibility criteria. The second step will consist of reviewing the provisionally included studies' full text to ensure that the studies meet all the inclusion criteria. Any disagreements will be resolved by a third expert reviewer (JG). The total number of studies retrieved, reviewed, included and excluded as well as reasons for exclusion will be reported at the full-text stage.

Data extraction and management

Table 2 details the data items to be extracted from the studies.

These items are informed by the Template for Intervention Description and Replication[11] and Transparent Reporting of Evaluations with Nonrandomized Designs checklists.[12] Extracted data will include study characteristics, participants, intervention characteristics (including type, length, timing, mode of delivery and intensity), participant flow, assignment methods, recruitment methods and retention methods. We will use a templated Microsoft Excel data extraction tool. The tool will be piloted on 10% of the studies. Adjustments to this form will be based on a consensus of the research team. After the research team completes an inter-rater exercise with the extraction tool, two reviewers (KSB and LD) will extract all the study data independently. Any discrepancies in extracted data will be resolved through discussion.

Assessment of risk of bias

Studies will be included regardless of methodological quality and two reviewers (KSB and LD) will assess the risk of bias. The Effective Public Health Practice Project (EPHPP) will be used to assess the quality of quantitative studies.[13] The EPHPP tool will be used to assess selection bias, study design, confounders, blinding, data collection methods, withdrawals and drop-outs, intervention integrity, analysis and result in a global rating for study as strong, moderate or weak. The Critical Appraisal Skills Programme (CASP) Qualitative Research Checklist will be used to assess the quality of qualitative studies.[14] The CASP tool will be used to assess the clarity of the aims of the research, appropriateness of the research design, recruitment strategy, data collection method, relationship between the researcher and the participant, ethical considerations, the rigour of data analysis, clarity of the statement of findings and value of the research.

Data synthesis

Synthesis of data will be conducted according to the Cochrane guidance.[15] Data permitting, a meta-analysis will be conducted using Comprehensive Meta-Analysis software, V.3.0.[16] Additionally, should the data permit, a meta-synthesis will be conducted on the qualitative studies.

Table 1 Search Strategy (Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily)

#	Searches	Results
1	exp *Infertility/	46 199
2	exp Fertilisation in vitro/	34 638
3	exp Sperm injections, intracytoplasmic/	6349
4	exp Reproductive techniques, assisted/	67 142
5	exp Insemination, artificial/	11 491
6	exp Fertility agents, female/	19 780
7	exp Fertility agents/	29 087
8	exp Clomiphene/	5211
9	exp Infertility, male/	27 064
10	exp Infertility, female/	27 867
11	(Infertility or infertile).tw,kf.	59 471
12	((Infertility or fertility) adj2 treatment).tw,kf.	5924
13	(Assisted reproducti* adj2 (treatment or technique* or technolog*)).tw,kf.	10 700
14	("iIn vitro fertilisation" or invitro fertilisation).tw,kf.	21 160
15	Intracytoplasmic sperm injection*.tw,kf.	6976
16	((Intrauterine or intra-uterine or intra uterine) adj2 inseminat*).tw,kf.	2689
17	(Clomid* or clomiphene* or clomifene).tw,kf.	5280
18	(Fertility adj2 (drug* or medication* or agent*)).tw,kf.	716
19	(Reproducti* adj2 (drug* or medication* or agent*)).tw,kf.	1409
20	(Ovulation adj2 induc*).tw,kf.	7331
21	(Ivf or icsi or iui).tw,kf.	27 929
22	Or/1-21	171 919
23	exp Counseling/	42 278
24	exp Psychotherapy/	189 227
25	exp Cognitive therapy/	26 436
26	exp Behaviour therapy/	71 379
27	exp Couples therapy/	2098
28	exp Marital therapy/	1521
29	exp Psychotherapy, rational-emotive/	193
30	exp "Imagery (psychotherapy)"/	1696
31	exp Mindfulness/	2633
32	exp Relaxation therapy/	8753
33	(Counsel* or psychotherap*).tw,kf.	146 789
34	(Cognitive adj2 (behavior* or behaviour* or therap* or psychotherap*)).tw,kf.	40 864
35	((Behavior* or behaviour* or interpersonal) adj2 (therap* or psychotherap*)).tw,kf.	25 456
36	(Acceptance adj2 commitment therap*).tw,kf.	835
37	(Acceptance-based adj2 therap*).tw,kf.	70
38	(Dialectical adj2 (behavior* or behaviour* or therap* or psychotherap*)).tw,kf.	789
39	Functional analytic psychotherap*.tw,kf.	39
40	Integrative behavio* couple therap*.tw,kf.	27
41	((Couple* or marital) adj2 (therap* or counsel*)).tw,kf.	2235
42	((Metacognitive or meta-cognitive) adj3 (therap* or counsel*)).tw,kf.	191
43	(Rational adj2 (emotive* or psychotherap*)).tw,kf.	232
44	Guided imagery.tw,kf.	696
45	(Mindfulness or mindfulness-based or mind body or hypnosis).tw,kf.	16 887

Continued

#	Searches	Results
	Table 1 Continued	
46	(Psychological adj2 (intervention* or program* or education* or support* or group* or therap*)).tw,kf.	13 916
47	(Stress adj2 (intervention* or program* or education* or support* or group* or therap*)).tw,kf.	8885
48	(Emotional adj2 (intervention* or program* or education* or support* or group* or therap*)).tw,kf.	7840
49	(Psychosocial adj2 (intervention* or program* or education* or support* or group* or therap*)).tw,kf.	10 743
50	((Well being or wellbeing) adj2 (intervention* or program* or education* or support or group* or therap*)).tw,kf.	1817
51	Or/23-50	380 254
52	exp "Quality of life"/	181 255
53	exp Happiness/	4050
54	exp Depression/	111 527
55	exp Emotions/	229 292
56	exp Stress, psychological/	124 580
57	exp Anxiety/	80 197
58	exp Mental health/	34 924
59	exp Adaptation, psychological/	122 920
60	exp Self concept/	105 367
61	exp Personal satisfaction/	17 474
62	exp Interpersonal relations/	316 737
63	exp Guilt/	6141
64	exp Pregnancy outcome/	70 796
65	exp Pregnancy rate/	18 717
66	(Stress or anxiety or depression or depressed or distress*).tw,kf.	1 207 522
67	("quality of life" or QoL).tw,kf.	261 799
68	(Well being or wellbeing or wellness or mental health).tw,kf.	219 745
69	(Happiness or coping or hardiness or self-esteem or self-compassion).tw,kf.	77 513
70	(Optimism or mood or guilt or sadness).tw,kf.	88 718
71	(Psychological adj2 (health or wellness)).tw,kf.	6701
72	(Marital adj2 (relationship* or satisfaction)).tw,kf.	2919
73	(Relationship adj2 satisfaction).tw,kf.	1828
74	(Pregnancy adj4 (outcome* or rate*)).tw,kf.	53 233
75	(Birth adj4 (outcome* or rate*)).tw,kf.	25 079
76	Or/52-75	2 312 767
77	22 and 51 and 76	2088
78	Limit 77 to english language	1961
79	Limit 78 to "humans only (removes records about animals)"	1940

A narrative synthesis of the findings from the included studies will be structured to describe the studies according to the following characteristics:

1. The target population characteristics, for example, age, ethnicity, socioeconomic status, and/or education level, low/middle/high-income country setting (as classified by the World Bank list of economies[17]).
2. The recruitment and retention strategies used.
3. The type of intervention.
4. The intervention content—features of the intervention employed, intervention components such as peer support, intensity, duration, personalisation and theoretical basis (if stated).
5. The type of outcome, for example, reduction of psychological distress, as well as the acceptability, efficacy and effectiveness of the intervention.

Additionally, summaries of intervention effects for each study will be provided by calculating the risk ratios (for

Table 2 Information extracted for the primary studies and coding procedure[22]

Information extracted	Coding
Title of the paper	Full title of the paper
First author name	First author's last name
Publication date	Publication date of the paper
Country where the paper was conducted	Name of the country
Study type	'Qualitative' or 'quantitative'
Research design	Design of the study
Participants' inclusion criteria	Quote the inclusion criteria reported in the study paper
Participants' exclusion criteria	Quote the exclusion criteria reported in the study paper
Participants in the study	No of participants in the study
Participants receiving treatment	No of participants receiving the intervention
Control participants	No of control participants
Matched controls	'yes' 'no' If yes, specify if match was made on age or gender or both
Age	Total study mean age and SD. If the study does not report these data, they will be requested from the corresponding author. If this is not the case, mean and SD will be estimated from the median and IQRs through the formula proposed by Wan and Colleagues *. Otherwise, the study will excluded from the analysis involving data on age.
Recruitment	Overall recruitment rate
Strategies for recruitment	Quote the strategies reported in the study paper
Retention	Overall retention rate
Strategies for retention	Quote the strategies reported in the study paper
Setting where participants were recruited	Quote the setting where participants were recruited
Women	Total percentage of women in the study
Men	Total percentage of men in the study
Infertility diagnosis	Diagnostic criteria and established diagnosis
Fertility treatment	'in vitro fertilisation', 'intrauterine insemination', 'intrafallopian transfer', 'intracytoplasmic sperm injection', 'exogenous gonadotropins' and 'medications to regulate or induce ovulation'
Psychological intervention"	'CBT', 'behavioural psychotherapy', 'IPT', 'ACT', 'DBT', 'CBASP', 'FAP', 'couples/marital therapy', 'grief therapy', 'metacognitive therapy', 'rational emotive psychotherapy', 'mindfulness-based therapy' and 'well-being therapy'
Timing of psychological intervention	Timing of when the psychological intervention is delivered during the fertility treatment process
Completion rates	Overall completion rates
Method of administration	'Individual', 'couples' or 'group'
Mode of administration	'Face-to-face', 'online' or 'phone'
Number of sessions	No of sessions in the psychological intervention
Type of intervention	'Prevention', 'treatment'
Acceptability of intervention	Attendance and retention
Instrument used to evaluate depressive symptoms	Acronym of the instrument(s)

Continued

Table 2 Continued

Information extracted	Coding
Type of instrument to assess depressive symptoms	'Clinician-administered interview' and 'Self-Report Questionnaire'
Instrument used to evaluate symptoms of stress	Acronym of the instrument(s)
Type of instrument to assess symptoms of stress	'Clinician-administered interview' and 'Self-Report Questionnaire'
Instrument used to evaluate symptoms of anxiety	Acronym of the instrument(s)
Type of instrument to assess symptoms of anxiety	'Clinician-administered interview' and 'Self-Report Questionnaire'
Instrument used to evaluate symptoms of quality of life	Acronym of the instrument(s)
Type of instrument to assess quality of life	'Clinician-administered interview' and 'Self-Report Questionnaire'
Instrument used to evaluate symptoms of relationship quality	Acronym of the instrument(s)
Type of instrument to assess relationship quality	'Clinician-administered interview' and 'Self-Report Questionnaire'
Instrument used to evaluate symptoms of social support	Acronym of the instrument(s)
Type of instrument to assess social support	'Clinician-administered interview' and 'Self-Report Questionnaire'
Instrument used to evaluate symptoms of psychological well being	Acronym of the instrument(s)
Type of instrument to assess well being	'Clinician-administered interview' and 'Self-Report Questionnaire'
Pregnancy rate	Quote reported pregnancy rates from the study

ACT, acceptance-based therapy; CBASP, cognitive behavioural analysis system of psychotherapy; CBT, cognitive–behavioural therapy; DBT, dialectical behaviour therapy; FAP, functional analytic psychotherapy; IPT, interpersonal psychotherapy.

dicotomous outcomes) or standardised mean differences (for continuous outcomes) from the data presented in the studies.

Statistical analysis and meta-analysis of bias

We will use Stata V.11.0 to pool the results of the RCTs using a random-effect meta-analysis with standard mean differences for continuous outcomes and risk ratios for binary outcomes and calculate 95% CI with two-sided p values for each outcome.

Heterogeneity of the studies will be assessed by the non-parametric Cochrane Q test, which assessed the variance between studies and study populations. The I^2 index will be calculated to evaluate the proportion of heterogeneity between studies. If it is determined that heterogeneity is presented, random-effect models will be used because these models are more appropriate computational approach under conditions of heterogeneity as they are less likely to reject the null hypothesis. Additionally, random-effect models are more robust to accommodate variations in sample sizes.[18]

If heterogeneity is detected, and the number of studies is sufficient (k≥3), mixed effect meta-ANOVAs (Analysis of Variance) and meta-regressions will be conducted to test possible moderators of intervention efficacy,

including the following variables: gender composition of participants (men, women or combined), therapeutic approach, intervention format (online, individual or group), study design (randomised vs non-randomised), length of intervention and methodological quality of the study. Meta-regression will be used to examine intervention adherence as a potential mediator of intervention success on psychological outcomes and to examine the change in a depressive and anxious mood as mediators of intervention success on pregnancy outcomes. Publication bias and selection of variables in publications will be assessed through visual inspection of a funnel plot as well as statistical tests (eg, Egger's regression intercept, Begg and Mazumdar's rank correlation and Orwin's fail-safe N).[19–21]

Ethics and dissemination

The results of this systematic review and meta-analysis will be presented at scientific conferences and published in a peer-reviewed journal.

Findings from this review will clarify the extent to which currently available treatments are effective in reducing infertility-related distress and the extent to which a new infertility-specific intervention is needed. If the need for a new intervention is established, identifying key components of successful psychological interventions will facilitate the design and adaptation of interventions to increase the likelihood that individuals and couples seeking fertility treatment will engage in, complete, and benefit for these interventions. Researchers will also be able to use this review to inform future research aimed at addressing evidence gaps of psychological interventions for individuals and/or couples undergoing fertility treatment.

Methodological strengths of the review include the search being developed and conducted by a senior research librarian. Additionally, the review is based on a study selection and a data extraction performed by two independent reviewers where the inter-rater agreement will be evaluated and consultation with an additional reviewer will be carried out to resolve any disagreements. Another strength is the evaluation of each on the included study's methodological quality through a specific tool. Limitations to the review may include limited data that could impede the ability to run meta-analyses on all potential sub-groups of participant and study characteristics. Additionally, there may be limited descriptions of recruitment and retention strategies as well as the timing of the intervention in the articles under review. Further limitations are related to the inclusion/exclusion criteria of reviewing only English-language articles, which may reduce generalisability to non-English speaking populations. Similarly, the inclusion of only peer-reviewed literature excludes government reports, dissertations, conference papers and reviews. Additionally, this review will not examine the mental health status and psychological intervention needs of couples struggling with infertility who choose not to undertake fertility treatment.

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