Literature Review & Empirical Study

An exploratory and feasibility study: Does a psycho-educational workshop give added value to couples waiting for IVF treatment within NHS organisational systems?

by

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ABSTRACT

The aim of the study was to review psychosocial interventions, assess the feasibility of a compassion-focussed cognitive therapy stress management workshop with couples waiting for in-vitro fertilisation and analyse couples experiences of being on the UK National Health Service waiting list before accessing a fertility clinic.

The method was to invite all 122 clients on one district's waiting list and then to analyse the characteristics of responders. The workshop was piloted with a sample assigned at random and a multiple case study approach was then used to explore the experience of couples who were waiting for IVF.

Results showed that 22% responded to the opportunity to access the workshop. Well-being scores on anxiety were in the mild category and similar to those in the literature. A higher percentage had raised scores for depression. The cohort was from a mixed heritage and educational background. The pilot suggested low feasibility for a generic intervention at this point on the NHS pathway. The case studies gave insight into the psychosocial process of waiting and generated new theories. It suggested that interventions should be related to medical reason for reduced fertility rather than the medical procedure that participants are waiting to access.

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OVERVIEW

This thesis is submitted to the University of Birmingham in fulfilment of the requirement for the CPD top up degree of Doctor of Clinical Psychology. It comprises a literature review, an empirical study and a public domain paper. The review and the empirical study have been prepared as if for submission to the journal Human Fertility.

The first paper is a review of the literature looking at psycho-educational packages for improving coping skills and outcomes related to resilience and tolerance of the procedure in-vitro fertilisation for couples with reduced fertility. The review considered peer-reviewed journal articles and other literature reviews published between 1966 and 2012 which included psychosocial interventions and infertility and included randomised controlled trials (RCT's) and less well controlled studies. Methodological quality and evidence of efficacy were considered using quality criteria checklists, which were devised to assess and evaluate the reviews and papers. Although the assessment of psychological interventions has been influenced by methodological problems and poor descriptors of the intervention content, the results are still promising.

They suggest that psychosocial interventions could reduce negative affect and that group interventions that used a psycho-educational model emphasising skills and education were most promising. Additionally a meta-analysis published in 2005 suggested a possible increase in conception rates. The current review expanded on previous reviews and identified some of the characteristics of psycho-educational interventions and their contexts.

The second paper presents an empirical study exploring the experience of couples on the NHS waiting list for IVF and uses a conceptual framework and exploratory multiple case study design to investigate the feasibility of a psycho-educational intervention in this context. The main findings are that the UK context probably provides some unique stressors. The

results point to low feasibility for a generic psycho-educational intervention at this specific point of the NHS care pathway. They propose hypotheses for research into more focussed, specific, preparatory and remediative interventions during the waiting period before participant's access fertility clinics. It is suggested that interventions be related to medical reason for reduced fertility rather than the medical procedure that participants are waiting to access.

The third paper is a public domain briefing document which summarises the main findings of the literature review and empirical study and is written for commissioners of research in UK Health Service.

LITERATURE REVIEW

What is the evidence that there are effective psycho-educational interventions for improving coping with infertility procedures in particular the clinical procedure In-vitro fertilisation?

ABSTRACT

This literature review considers the efficacy of psycho-educational approaches that may improve resilience and coping with the procedure of in-vitro fertilisation for couples undergoing this clinical intervention for infertility. It considers the effect of these approaches on emotional consequences such as anxiety and depression, and considers the influence of the type and content of the intervention and the level of expertise of the trainer. Peer reviewed journal articles and literature reviews published between 1966 and 2012 were identified as well as books that expanded on course content of interventions. Direct contact was also made with some authors. The search identified 18 studies, including randomised controlled trials and less well controlled trials, and four reviews. A set of criteria was developed to evaluate the papers and these indicated that the quality of the papers varied.

The four reviews concluded overall that group interventions emphasising education and skills training were effective in reducing distress associated with infertility. Individual and couple therapy also had positive effects.

The review of individual published papers allowed some identification of themes in stress coping interventions which could inform psycho-educational programmes to be used with couples awaiting IVF treatment. Research suggested that training include cognitive reframing, relaxation and stress management, and communication skills; and that it be provided by skilled psychological professionals who may be supported by graduates. This review also confirmed the need to situate and focus future research more specifically in its context in the care pathway.

Keywords; IVF, psycho-education, psychosocial interventions, CBT, group, infertility

INTRODUCTION

Most sub-fertile patients especially women consider the assessment, evaluation and treatment of fertility to be the most upsetting experience of their lives (Freeman, Boxer & Rickels, 1985). In this context, finding methods to reduce psychological distress and potentially improve outcomes becomes crucial. Psychological interventions have shown promise in improving coping mechanisms and are the primary focus of this review.

The review begins with some general information about infertility rates, treatments and their associations with psychological distress, before moving on to describe a systematic search, followed by critical evaluation of relevant reviews and papers. It concludes with a summary of the body of evidence and recommendations for clinical practice and further research.

Sub fertility currently occurs in one in seven couples in Great Britain (HFEA, 2012). For those with unexplained infertility (idiopathic), non-correctable organic reasons or correctable organic reasons that have not resulted in conception after medical intervention, the care pathway is to be offered access to In Vitro Fertilisation (IVF). The success rate historically is low for this procedure.

The Human Fertilisation and Embryology Authority (HFEA) 'Patients' Guide to Treatment 2012' includes UK national treatment and success data based on IVF treatments carried out between 1 January 2009 and 31 December 2009. This shows variability, and variation with type of implant and age of recipient. The average success rate for IVF treatment using fresh eggs in the UK, in 2009, was 32% for women under 35, 27% for women aged 35-37, 19% for women aged 38-39, and 12% for women aged 40-42. The average success rate for Donor Insemination treatment in the UK was lower ranging from 15% for women under 35 to 6% for women aged 40-42.

One factor that may contribute to either poor tolerance of the procedures or reduced resilience in the face of treatment is the effect of stress. Eugster & Vingerhoets (1999) found most patients state that IVF treatment is primarily a psychological stressor rather than a physical stressor. The most common reason that patients drop out of IVF treatment, even when covered by medical insurance, is psychological distress. Hammarberg, Astbury, & Baker (2001) found that the dropout rate of non-pregnant patients was 40% after first cycle IVF. Research indicates it may be possible to identify those who will drop out after only one cycle by ascertaining pre-treatment levels of depression, as these were found to be highly predictive of poor tolerance (Smeenk, 2004).

In a study that compared infertile and fertile women undergoing routine gynaecological care (Cwikel, Gidron, & Sheiner, 2004) 11% of the infertile women met the criteria for a current major depressive episode compared with 3.9% for the fertile women. Domar, Zuttermeister, & Friedman (1993) compared sub fertile women's scores on measures of depression, anxiety and hostility to those of women with cancer, hypertension, myocardial infarction and HIV-positive status and their scores were indistinguishable.

The significance of the psychological consequences of sub fertility should not be underestimated in the process of IVF treatment. It has been reported that as many as 13% of women experience suicidal ideation after an unsuccessful IVF attempt (Baram, & Tourtelot, 1988). Improving resilience to the process is therefore significant.

It has been shown that there is value in acute psychological treatment for other medical procedures. Acute psychological treatment for conditions such as cancer seems effective in improving tolerance and preventing depression and anxiety and it can also help to minimise adverse physiological and psychological side effects of invasive medical procedures (Horne, Vatmanidis, & Careri, 1994; Jacobsen et al, 2002).

The overall aim of the current paper was to review research evidence regarding the impact of psycho-educational approaches on resilience and coping with IVF in couples undergoing this medical intervention for infertility. This was achieved through the following set of more discrete aims:

1. To review and evaluate the conclusions from published reviews on interventions to assist the emotional consequences of coping with IVF and consider the influence of the type and content of the intervention on the outcomes.

2. To review relevant studies not included in previous reviews or published since the earlier reviews.

METHOD

Search Strategy.

An initial scan of the literature identified one systematic review on the impact of psychosocial interventions for those with infertility covering research up to the year 2001 (Boivin, 2003). From an initial set of 380 published and unpublished papers on psychological interventions for infertility patients, Boivin (2003) identified 25 studies worthy of review based on their methodological strengths. Studies were excluded if they did not include evaluation of a psycho-social intervention, if they evaluated non-specific patient-centred care or if there was poor statistical or methodological detail. Of these 25 studies, a subset of 13 papers was identified by Boivin as evaluating psycho-educational psychosocial interventions. This subset was drawn out from Boivin's review. It was updated to include further papers evaluating psycho-educational psychosocial interventions and all were critiqued in the current review.

A systematic search was undertaken using a variety of electronic databases to identify all literature relating to the evaluation of psychosocial interventions for infertility published

between 2001 and 2012. The databases Medline, PsycINFO and EMBASE were accessed (Appendix 3). Combinations of search terms were used based on variations of terms around psychosocial interventions (e.g. *psychosocial interventions, group, CBT),* terms around infertility *(e.g. infertility, IVF)* and terms around stress (e.g. *stress,).* The reference sections within identified papers were also searched.

Inclusion and Exclusion Criteria.

The following criteria were used in deciding whether to include papers:

1. As a systematic review up to 2001 had been published in 2003, the subset of thirteen papers within that review that involved focussed (including self-help CBT) or comprehensive educational programmes were included within the current review if they met the further criteria below.

2. In addition other papers published between 2001 and 2012 were included if they studied:

- Group or 1:1 psychosocial or psycho-educational or stress management or CBT self-help psychological intervention regardless of degree of control which included participants who were undergoing fertility treatment procedures of any type.
- Any further reviews of such interventions published in English.

3. Psychosocial interventions that reflected an educational/training model and coping skills approach were the main characteristics sought so other approaches to intervention such as counselling, or psychoanalytic approaches were excluded.

The papers therefore related to interventions that were predominantly focussed on a cognitive psycho-educational approach whether delivered individually or to a group.

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Quality and Efficacy of Reviews and Individual Studies.

In order to evaluate the overall research quality of published papers a set of quality criteria was used from the guidance published by the NHS Centre for Reviews and Dissemination (Khan, Riet, Popay, Nixon, & Kleijnen, 2001). In addition, further classification criteria were developed around the specific questions to be addressed by this current literature review.

Reviews

In order to evaluate the quality of the review papers and assess the validity of their conclusions, the following eight criteria, drawn from Khan et al's (2001) criteria, were used with each of the four identified reviews:

- Is the review systematic as opposed to descriptive?
- Were inclusion/exclusion criteria identified?
- Did the review state defined search terms?
- Did the review state databases and dates searched?
- Did the review classify model (e.g. autogenic training), type (e.g. 1-1 or group) or content (e.g. relaxation/assertiveness skills/cognitive restructuring) of intervention?
- Did the review create a framework for classification of impact on mood (e.g. use a standardised measure of depression)?
- Did the review draw clear and useful conclusions linked to a classification framework?
- Did the review classify level of trainer/therapist?

Studies

In order to know whether the published studies were carried out to a high standard that could allow trust to be based in their results, each was evaluated to establish the quality of the design, to look at whether the intervention was described in sufficient detail to allow replication, to consider whether the sample was sufficiently specific to allow conclusions to

be drawn about participants and to look at whether the training provided to the therapists was described. In addition, the outcome variables were surveyed and the measures used to establish change were considered.

In order to evaluate the overall quality of the individual studies, the following evaluative criteria were used.

Quality of Design

A definition of good quality was given if studies used a control group (i.e. routine care, waiting list or support only controls) and used either random assignment and/or pre- post design to account for the influence of uncontrolled factors on intervention effects. This was rated with a score of two. If there were issues of concern for example how the control group was selected. This was rated with a score of one. If the study was developmental such as a feasibility trial then this was labelled "D".

Intervention Description

Where there was no description of the psychological content of the intervention this study was rated with a score of zero. With some description of psychological content (e.g. model) the rated score was one. If there was a detailed description of psychological content the allocated score was two.

Outcomes/Effects Shown

In studies where no outcome was described the allocated score was zero. If there was a general description of outcome this was rated with a score of one but if there were specific outcome measures given in the paper the rated score was two.

Specifying a Focus on the IVF Procedure

Where the study focussed on fertility investigation only the allocated score was zero. If the study involved preparation for or coping with mixed medical procedures including IVF it was

rated with a score of one. Finally, if the study involved specifically preparing for and coping with IVF then this was allocated a score of two.

Description of Psycho-Educational Trainer

In studies with no description of the professional who provided the intervention these were allocated zero. If the trainer was described this study was allocated a score of one.

RESULTS

There are two parts to the results section. Part one covers reviews, and then part two considers critiques and draws conclusions from individual studies. In part one, the quality and conclusions of four reviews are analysed to set the scene for the later critical review of individual studies. Part two includes an evaluative systematic review of 13 studies from the review papers and a further five studies published between 2002 and 2012 all of which met the inclusion criteria, making 18 individual studies in all for this current review.

Part One: Summary of Reviews

A general description of the four reviews is set out in Table 1. Each of the reviews is evaluated for quality and the results set out in Table 2 with their overall quality rating. The reviews are then summarised individually. Of particular note were the two reviews using similar cohorts of studies (Boivin, 2003; De Liz, 2005) and these are analysed in more detail in Tables 3 and Table 4.

Table 1 Description of Four Literature Reviews

Author and Year	Title	Design	Aim	Conclusions
Griel (1997) (USA)	Infertility and Psychological Distress: A Critical Review of the Literature	Systematic Review 1980-1995	To summarise the state of knowledge about the infertility experience and critically review the quality of research on the social psychological dimension of infertility.	Both partners experience distress irrespective of reproductive impairment but there is a gender difference. No personality trait differences from norms A significant difference in measures of stress and self-esteem.
Boivin (2003) (UK)	A Review of Psychosocial Interventions in Infertility	Systematic Review 1966-2002	To determine whether psychosocial interventions improved well-being and pregnancy rates and to identify the kinds of interventions that are most effective.	Pregnancy rates unlikely to be affected/ Group psychosocial interventions which emphasised education and skills were significantly more effective in improving well being than counselling emphasising emotional expression and support
De Liz (2005) (Germany)	Differential Efficacy of Group and Individual/ Couple Psychotherapy with Infertile Patients	Meta-Analytic Review 1979-2003	To perform a meta-analytic review on available statistical evidence for the efficacy of psychotherapy on infertile patients.	Group, couple and individual psychotherapy improved wellbeing and there was a possible increase in conception rates.
Cousineau (2007) (USA)	The Psychological Impact of Infertility	Descriptive Review (USA context)	To describe best practice and summarise the research in psychosocial interventions	Psychological interventions emphasising stress management and coping skills training have shown beneficial effects on wellbeing and pregnancy outcomes.

Table 2 Summary of Quality Ratings of the Four Reviews

	Overall Quality Rating	Meta-analytic systematic or descriptive	Inclusion/ Exclusion criteria	Defined search terms	Data base and dates	Intervention Classified	Outcomes Classified	Trainers level	Conclusion linked to classification
Griel (1997)	3/7	Systematic	No	No	No	Yes	Yes	No	Yes
Boivin (2003)	6/7	Systematic	Yes	Yes	Yes	Yes	Yes	No	Yes
TM de Liz(2005)	6/7	Meta-analytic	Yes	Yes	Yes	Yes	Yes	No	Yes
Cousineau (2007)	1/7	Descriptive	No	No	No	No	No	No	Yes

Although– Griel's (1997) review was systematic it only achieved 3/7 in the quality rating because few details were given of the search method. As such it is hard to have confidence that Griel located all available studies. It concentrated on studies addressing the experience of infertility (1980 to 1995) and looked at quantitative (94) as well as qualitative studies (26). Its aim was to review the social and psychological aspects of infertility and profile individual characteristics and gender differences. It included no data on intervention approaches. It did however identify the country where the studies were set and this showed two thirds were in the USA health system.

The overall conclusions of this review were:

1. Infertility is a socially constructed life crisis and is not related to individual traits
2. The experience affects women more than men irrespective of reproductive impairment
3. Studies which employ measures of stress and self esteem have found significant differences between the infertile and others but have not found differences in other psychological individual traits.

The main recommendations for future research were that it should be guided by theoretical considerations and avoid the psychological trait approach, concentrating more on the experience of infertility in context. In essence research should aim to consider and influence the experience at specific points across the whole pathway of care.

Boivin's (2003) review achieved a high rating (6/7) on the specified quality criteria (see table 2). The review was attempting to answer the stated questions: "Do psychosocial interventions improve well-being?" "Do psychosocial interventions increase pregnancy rates?" and "Are some interventions more effective than others?"

1957 articles were initially identified between 1966 and 2001 which was narrowed to 380 papers on psychological interventions. Out of these, 25 independent evaluation studies

were identified by specific quality/methodological criteria. The country and health system were not identified. The review was systematic and comprehensive. Thirteen out of 25 articles were identified as pertinent to the current review as they were classified as "focused or comprehensive psycho-educational programmes "or self-help CBT approaches (Table 4).

In summary the overall conclusion of the review was that:

1. Psychosocial interventions could reduce negative affect and distress specifically associated with infertility.
2. Group interventions that emphasized education and skills training were effective in producing positive changes and were more effective than counselling which emphasised emotional expression and support.

The author proposed that future research should concentrate on "who" benefits from "what interventions" and "when" these should be delivered, and that this structure would produce more effective research than is currently available.

The De Liz (2005) review was rated 6/7 within the classification framework (Table 2). This review of 66 studies from 1979 to 2003 used meta-analysis in order to evaluate the efficacy of group versus individual/couple interventions for infertility and their impact on the reduction of negative emotions as well as pregnancy promotion. It used the description "group psychotherapy" to refer to interventions that were described as "psycho-educational" in other literature. The categorisation of studies is set out in Table 4 to allow comparison with Boivin's review and this issue is covered in the discussion section. The country in which each study was set was not identified

The aim was to provide a meta-analysis of the available statistical evidence for the efficacy of psychotherapy with infertile patients. It excluded 44 of the 66 papers from the meta-analysis including only those with sufficient statistical information to permit

calculations of effect size. The remaining 22 papers were deemed statistically suitable for meta-analytic computation and comparison purposes.

The authors mentioned that they used a similar cohort of studies as Boivin (2003) but included papers published up to 2003. The inclusion criteria of this review and Boivin's are compared in Table 3.

Table 3 Search Methods for Boivin (2003) and DeLiz (2005) Reviews

	Boivin	**De Liz**
Dates of search	1966-2001	1979-2003
Dates of papers	1979-2001	1985-2001
Studies identified	380 studies	66 studies
Studies included	25 independent evaluations	22 with statistical data (means/SD)
Search terms	"Psychology and infertility"	"Psychotherapy and infertility"
Other terms	Interventions/group/therapy/ counselling	Infertile couples and infertility
Selection criteria and sample description	One one psychosocial intervention and one outcome measure/sample couples and women	Pregnancy and affect data/ sample Caucasian upper middle class couples and women

However, when comparing the two sets of references, it was noted that there were 17 in common between De Liz's 22 and Boivin's 25 studies. The degree of overlap is set out in Table 4 and commented upon further in the discussion section.

Table 4 Categorisation of Studies in Boivin and DeLiz Reviews

Unique to De Liz review (n=5)	Common to both reviews (n=17)	Unique to Boivin review (n=9)
Psychotherapy Individual and couple		*Counselling*
	Bents 1991	Bresnick 1979
	Brandt 1991	Ellenberg 1982
	Christie 2000 *	Emery 2001
	Connolly 1993	Kemeter 1999
Hoelze 2001b	Hoelze 2001a	Liswood 1995
Sarrel 1985b	Sarrel 1985	Pengally 1995
	Straus 2001	
	Wischman 1998	
Group Psychotherapy		*Focussed /Comprehensive Educational Programmes*
	Clarke 1995 # ☑	
	Clarke 1998 # ☑	
	Domar 1990 ☑	
Domar 1999	Domar 1992 ☑	
Galletley 1996a	Domar 2000a/b ☑ ☑	
Galletley 1996b	McNaughton-Cassil 2000 ☑	McQueeny 1997 ☑
	Stewart 1992 ☑	O'Moore 1983 ☑
	Takefman 1990 * ☑	Wallace 1984 ☑
	Tuschen-Caffier 1999 * ☑	

**placed in different sections by De Liz/Boivin*
 # treated as one by Boivin
☑ Studies included as part of current review
NB. Galletley, 1996 a, 1996b, were not included as they were reporting the same studies as Clarke (1998) and concentrated on the relationship between obesity, wellbeing and infertility.

Overall the De Liz's review concluded that

1. Both individual and group psychotherapy interventions positively impact on emotional well-being (anxiety and depression).
2. There was possible evidence for the enhancement of conception success.

3. Statistically both group and individual interventions are similarly effective

It was proposed in this paper that future research studies should adhere to strict methodological principles and should be larger scale evaluations involving only randomised methodologies before a more precise relationship between interventions and outcomes can be understood.

The paper by Cousineau (2007) did not meet the quality criteria for a systematic review though it did provide a descriptive qualitative review of 79 international papers. It scored a rating of 1/7 within the classification framework (Table 2).

No information on search procedure was found but the research was classified into broad areas covering a) Psychological Effects of Infertility, b) Social, Cultural and Gender Issues in Infertility, c) Marital Issues, d) Treatment Issues, e) Patient Distress and Pregnancy Rate, and f) Psychological Support/Interventions. Cousineau attempted to summarise the evidence and develop points for future research into infertility related distress, fertility outcome, drop-out rate from fertility treatment and pregnancy rate. Occasionally the country where the study was set was mentioned but the majority of statistics quoted were about USA. Cousineau also made a case for psychosocial interventions to be available in the USA health system.

The overall conclusion of this descriptive review (p304) was that;

1. Psychological impact of infertility is often overlooked.
2. Women may experience depressive symptoms and more distress than their spouses throughout treatment
3. Men may suffer silently in efforts to support their wives
4. The rigours of treatment can temporarily tax a marriage and disrupt sexual satisfaction

5. Level of distress in infertility patients tends to increase as treatment intensifies and as duration of treatment continues
6. The most common reason that patients drop out of IVF treatment, even when it is covered by medical insurance is psychological distress
7. Pre-treatment levels of depression are predictive of patient drop-out behaviour after only one IVF cycle
8. The stress of fertility treatment contributes to patients' psychological distress, which in turn may contribute to higher drop-out and lower pregnancy rates
9. Patient preparation and psychological counselling are needed to help patients manage the demands of treatment
10. Most of the information available to couples focuses on the medical and technical aspects of fertility treatment
11. Psychological interventions appear to reduce infertility-related distress
12. Group interventions that emphasize education and skills training appear to be the most effective

It was proposed that future research should focus on the impact of psychological interventions on biological markers for male and female infertility and the value of psychological intervention in improving patients' persistence (tolerance) with fertility treatment, reducing drop-out rate and potentially enhancing pregnancy rates.

In summary these four disparate reviews include two of lower rigour (Griel, 1997; Cousineau, 2007) and two that were more systematic and of higher quality (Boivin, 2003; De Liz, 2005). Those with lower quality help to provide a context for understanding the other reviews, and they seem to suggest that reduced fertility is a life crisis and is not related to psychological characteristics such as personality. The more rigorous reviews, suggest that

there is a body of evidence to show that individual and group interventions focused on enhancing coping with stress produce beneficial outcomes that are more effective than counselling, but that there are limitations to current research. Future studies need to be structured, contextualised and focussed.

Part Two: Summary of Studies

The 18 studies identified were individually reviewed. Their characteristics are set out in the following six tables, and each aspect is evaluated in relation to each of the quality criteria described earlier.

Overall Description of Studies

From Table 5 which summarises the overall description of studies it seems that most are not set in the UK, demonstrating that couples' experience of infertility and its care pathway are not often reported within the UK National Health Service.

Table 5: SUMMARY OF STUDIES

Authors	Country	Title	Aim	Sample	Design	Measures	Outcome
O'Moore et al (1983)	Ireland	Psychosomatic Aspects in Idiopathic Infertility: Effects of treatment with Autogenic training	To assess stress levels before and after autogenic training	15couples 10 control	Matched control	Cortisol Plasma prolactin STAI Cattell EPI	Decreased anxiety scores after training Pre measures of prolactin higher than control and reduced after training
Wallace (1984)	UK	Psychological Preparation as a Method of Reducing the Stress of Surgery	To assess the effectiveness of preparation on stress response to medical procedure laparoscopy	17 women and 20 women in 2 experimental groups 26 control	Routine care plus booklet. Routine care plus booklet with special information. Routine control	STAI POMS BP Pain scales	Patients in special preparation group showed lower stress response pre and post medical procedure with less pain and faster recovery
Takefman et al (1990)	Canada	Sexual and Emotional Adjustment of |Couples undergoing Infertility Investigation and the Effectiveness of Preparatory Information.	To compare 3 types of information programmes and psychological adjustment in relation to the investigative procedure	26couples 13control	Group comparison with routine care control	FAI/BDI/STAI	Descriptive information superior to information about emotional and sexual reactions with baseline levels on measures predictive of poorer adaptation as well as pregnancy at 6 months
Stewart et al (1992)	Canada	A Prospective Study of the Effectiveness of Brief Professionally-led Support Groups for Infertility Patients	To evaluate the effectiveness and acceptability of support groups	25 couples 14 women 35 waiting list control	Waiting list control Experimental participants had self referred to support group	BDI BSI MOOS	Support groups are acceptable and effective for improving wellbeing
McQueeny et al (1997)	USA	Efficacy of Emotion-Focused and Problem – focused Group therapies for Women with Fertility Problems	To test the relative effectiveness of training in emotion focused versus problem focused coping skills	29 women 26 complete data	2 interventions (10+10) Control participants (9) chosen from those with difficulty attending	COPE MHI BDI Birth rate	At treatment termination both groups reported significantly less global distress and at 18 months problem focussed more likely to have conceived
Tuschen-Caffier (1999)	Germany	Cognitive-Behavioural Therapy for Idiopathic Infertile Couples.	To examine the impact of a 6 month CBT intervention on sperm quality/birth rate and cognitions	17 couples	2 matched controls 1) for sperm quality/clinic data 2) 12 couples /birth rate & thoughts	KINT Birth rate Semen analysis	Improved sperm concentration ;reduced thoughts of helplessness; birth rate higher

Table 5: SUMMARY OF STUDIES

Authors	Country	Title	Aim	Sample	Design	Measures	Outcome
Domar et al (1990)	USA	The Mind/Body Programme for Infertility: a new behavioural treatment approach for women with infertility	To evaluate a new programmes and its effects	54 women	No control	STAI POMS Pregnancy rate	Significant decreases in anxiety and depression with 34% pregnancy within 6 months
Domar et al (1992)	USA	Psychological Improvement in Infertile Women after Behavioural treatment: a replication	To replicate previous reported study	41(out of 52) women	No control	STAI POMS	Behavioural treatments are associated with decreases in negative emotional symptoms
Domar et al (2000a)	USA	The Impact of Group Psychological Interventions on Distress in Infertile Women	To investigate whether intervention prevents peaking of distress(2-3Years) in infertile women	184 women 3 groups: 56 CBT/ 65 Support/ 56 control but 38 dropped from control	Routine care control	STAI BDI HADS POMS	Both groups benefitted in comparison to control but CBT overall superior Substantial attrition due to assignment to control
Domar et al (2000b)	USA	Impact of Group Psychological Interventions on Pregnancy Rates in Infertile Women	To determine the efficacy of 2 group intervention on pregnancy rate in women with < 2years infertility	184 women 3 groups: 56 CBT/ 65Support/ 56control but 63 dropped out overall	Randomised Prospective controlled (age/duration/ medical intervention) Routine care control	Viable pregnancy	Group interventions appear to significantly improve pregnancy rates and no difference between 2 intervention groups
Clarke et al (1995)	Australia	Weight Loss Results in Significant Improvement in Pregnancy and Ovulation Rates in Anovulatory Obese	Evaluate a behavioural programme to improve weight loss and record its effects on mood and pregnancy	13 women 5 control	Prospective study Control used drop-outs	HAD GHQ Insulin and testosterone levels	Weight loss results in ovulation ,improved well being and pregnancy-weight loss should be tried before infertility treatment

Table 5: SUMMARY OF STUDIES

Authors	Country	Title	Aim	Sample	Design	Measures	Outcome
Clarke et al (1998)	Australia	Weight Loss in Obese Infertile women Results in Improvement in Reproductive Outcome for All Forms of Fertility Treatment	To repeat 1995 programme with higher numbers	67 women	Prospective study Control used drop-outs	HAD GHQ Insulin and testosterone levels Cost of treatment	Weight loss behavioural programme is effective and less costly than medical fertility treatment
McNaughton et al (2000)	USA	Development of Brief Stress Management Support Groups for Couples undergoing In Vitro Fertilisation Treatment	To develop and assess efficacy of couple stress management offered concurrently with IVF treatment	17 couples Group size 4-7 couples	No comparison group	Ratings	Self reports that CBT focussed group therapy helped them deal with stress
Cousineau & Lord (2004)	USA	A Multimedia Psychosocial support programme for Couples	To develop and test the feasibility of CD ROM prototype	feasibility study with 12	No comparison group	Content analysis Usability tasks Acceptance and satisfaction ratings	90% rated good or excellent so multimedia support tools may help
Lemmens et al (2004)	Belgium	Coping with Infertility :a Body-Mind group Intervention Programme for Infertile Couples	To assess feasibility of a modified Body-Mind Marital Programme	6 couples in group (3failed medical procedures)	No comparison group	Clinical vignettes	One group of 6 couples described The frequency of cognitions about the "Child wish" was 50%
Schmidt et al (2005)	Denmark	Evaluation of a Communication and Stress management Training Programme for Infertile Couples	To evaluate the training programme	37 couples attended 5 courses (9% of 500 invited)	Prospective comparison with 2250 sent same questionnaire and 61 replied	Questionnaires about communication	Marital communication improved but reduced with others and no effect on infertility related distress
Lancastle & Boivin (2010)	UK	A Feasibility Study of a Brief Coping Intervention for the Waiting Period before Pregnancy Test	To determine the acceptability of a brief cognitive intervention over 14 days to redefine the waiting period more positively	55 women in 2 groups (28/27)	Group comparison but no control	Acceptability	Positive reappraisal coping intervention was feasible and more helpful than positive mood intervention

Table 5: SUMMARY OF STUDIES

Authors	Country	Title	Aim	Sample	Design	Measures	Outcome
Domar et al 2011	USA	Impact of a group mind/body intervention on pregnancy rates in IVF	To determine if women who were randomised to a mind/body programme before starting IVF had higher pregnancy rates than control group	143 women but only 6 attended 50% course before cycle 1of IVF	Randomised prospective controlled study	Pregnancy rate	Only 9% attended half programme and no difference in cycle 1 pregnancy rate but 76% attended half programme before cycle 2 and pregnancy rate better than control (52% to20%)

STAI	*Speilberger State Trait Anxiety Scale*	GHQ	*General Health Questionnaire*
KINT	*Kognitionen bei Infertilitat*	MOOS	*Coping Response Inventory*
HAD	*Hospital Anxiety and Depression Scale*	BSI	*Brief Symptom Inventory*
BDI	*Beck Depression Inventory*	EPI	*Eysenck Personality Questionnaire*
FAI	*Feelings about Infertility Questionnaire*	Cattell	*Cattell Personality Questionnaire*
POMS	*Profile of Mood Scale*		

Study Design

Design was identified as good quality if the study used a control group, either routine care waiting list or support only controls and used either random assignment and/or pre- to post design to account for the influence of uncontrolled factors on intervention effects.

It was also noted that the aim of some studies was developmental research rather than effectiveness research and this is labelled.

The overall quality of the design of the studies is not very strong in terms of control (see table 6) with six being feasibility or qualitative development studies. However of the 18 papers reviewed seven did use a control group design of either routine care, waiting list or support only controls (Tuschen-Caffier, 1998; Stewart, 1992; Takefman, 1990; Wallace, 1984; Domar, 2000a; Domar, 2000b; Domar, 2011). Sample sizes were often small ranging from 5-63 individuals in a control group and from 13 to 56 individuals in the intervention groups which is problematic as analysis would lack statistical power. Also some control groups were comprised of drop- outs from intervention increasing the risk of evidence for effectiveness being biased.

In reviewing the table below and considering the combination of both control and sample size, Domar's studies come out best in this domain as they not only have an appropriate control group but also larger numbers in the sample size than most but they only used women participants.

Table 6: QUALITY OF DESIGN OF STUDIES

Authors	Sample size	Type of control	Rating
O'Moore et al (1983)	15couples/10control	Matched control (small number)	1
Wallace (1984)	20women/17women (2 groups)26 control	Routine care control	2
Takefman et al (1990)	26couples/13control	Routine care control	2
Stewart et al (1992)	25couples 14women /control 35 women	Waiting list control	2
McQueeny et al (1997)	18 women 8 control	Control group (from those unable to attend)	1
Tuschen-Caffer et al (1999)	17couples	Matched comparison with clinic data	2
Domar et al (1990)	54 women	Feasibility study with no control	D
Domar et al (1992)	41 women	Replication study with no control	D
Domar et al (2000a)	63control/65support / 56 CBT all women	Routine care control	2
Domar et al (2000b)	63control/65support / 56 CBT all women	Routine care control	2
Clarke et al (1995)	13 women/5control	Control but used drop outs	1
Clarke et al (1998)	67 women/20control	Control but used drop outs	1
McNaughton-Cassill et al (2000)	17 couples	Feasibility study with no comparison group	D
Cousineau & Lord (2004)	12 individuals/ unspecified mixture of couples and women	Qualitative developmental study with no control	D
Lemmens et al (2004)	6 couples	Feasibility study with no comparison group	D
Schmidt et al (2005)	37 couples/61 control	Prospective comparison with others on clinic data base	2
Lancastle & Boivin (2010)	2 groups 55 women(27/28)	Comparison of intervention groups but no control	D
Domar et al (2011)	143 women randomised to control/ intervention	Comparison with control	2

Rating values
0= poor design quality
1=good design but issues
2=good quality
D= developmental study

Intervention Description

The description of the intervention and the context is crucial to allow research replication. The interventions are summarised in Table 7. In the papers reviewed 16 out of 18 described some of the content of the interventions employed. Seven of the studies described only the general model that had been adopted. This was CBT Stress Management or Stress Reduction or a CBT programme (Tuschen-Caffer 1999; Stewart 1992; McNaughton 2000). Moore et al (1983) specified "Autogenic Training". Cousineau and Lord (2004) just specified practical stress management and communications skills.

The description of course content in the other eight papers was more comprehensive but not specific enough to allow exact replication. This may be a reflection of the commercial nature of the contexts and interventions, since much IVF treatment, and consequently IVF research, is done in health care systems that are privately funded and in which commercial secrecy and competition may be strong influences. It was however possible to identify the following themes from the descriptions:

- problem solving *cognitive* skills
- pleasurable activity/behavioural activation/exercise
- relaxation and physiological stress response knowledge
- *cognitive* challenging and *cognitive* restructuring
- communication and or assertiveness skills
- mindfulness/forgiveness (compassion)
- positive reappraisal *cognitive* practice

Some papers described interventions which provided information specifically on infertility and also gave nutritional advice. As this literature review has excluded some

psychological models it is not surprising that the strongest recurring theme of interventions was cognitive strategies such as: problem solving, challenging assumptions/beliefs, cognitive restructuring, and positive re-appraisal. The Body/Mind programme is worth specific mention as the product of research by Domar (1990; 1992; 2000a; 2000b; 2011.). This approach is summarised in the book "Healing Mind, Healthy Woman" (Domar, 1996) and includes education about the effects of stress, relaxation response, cognitive restructuring, self nurturance, social support, mindfulness, and emotional expression.

There was enormous variability around timescales and 'dosage' of interventions which ranged from 6 weekly sessions to 6 months. Some interventions were very time intensive e.g. 4-12 sessions of 45min-90mins (McQueeney et al, 1997: McNaughton et al, 2000).

Others comprised independent self-help using access to a CD Rom or videos (e.g.Cousineau & Lord, 2004). As the latter would be more economical to introduce on a large-scale basis, it may be that future studies focusing on this area would be particularly worthwhile. Further variation between studies derives from whether they focus on a broad or narrow part of the care pathway. Some targeted a specific and narrow part of the care pathway e.g. the 14 day wait for the results of IVF with no personal contact, just using a card provided with self-statements (positive re-appraisal cognitive practice; Lancastle 2010). Concentration on a narrow portion of the pathway may be more informative than broad studies as it would allow more accurate replication of research and understanding of contextual issues.

Table 7: INTERVENTIONS USED: DESCRIPTION AND QUALITY

Authors	Intervention	Duration of course	Rating
O'Moore et al (1983)	Autogenic training	8 week course	1
Wallace (1984)	Preparatory information booklet	1 week	0
Takefman et al (1990)	Preparatory info for diagnostic tests /video and booklet	1 session as couple and monthly phone calls(3)	0
Stewart et al (1992)	Support and stress reduction	8 weeks group	1
McQueeny et al (1997)	Problem solving/emotional expression /pleasurable activity / relaxation /challenge beliefs / assertiveness /information on infertility	6 weekly group sessions 90mins	2
Tuschen-Caffer et al (1999)	Psycho-bio/CBT programme for couples in group	6 months	1
Domar et al (1990)	As above plus self empathy /mindfulness/anger control/forgiveness	10 weeks group	2
Domar et al (1992)	Replicated above (1990) plus buddy support	10 weeks group	2
Domar et al (2000a)	Relaxation/cognitive restructuring/ emotional expression/nutrition/ exercise	10 weeks 3 groups	2
Domar et al (2000b)	As above(mind/body programme)	10weeks group	2
Clarke et al (1995)	Behavioural advice/diet/exercise	24 weeks group	1
Clarke et al (1998)	Behavioural advice/diet/exercise	24 weeks group	1
McNaughton et al(2000)	Support & CBT stress management	twice a week during IVF	1
Cousineau & Lord(2004)	Multimedia stress management educational programme	Access to internet/ CD Rom	1
Lemmens et al (2004)	Detailed sessional extended Body/Mind programme	6 group sessions	2
Schmidt et al (2005)	Stress management/ communication skills	6 group seminars	2
Lancastle &Boivin (2010)	Positive reappraisal coping self talk versus positive mood intervention	Given a card	2
Domar et al (2011)	Mind/Body Programme	10weekly group sessions	2

Rating values
0=No description
1=Some description(e.g. model)
2=Description of content

Measurements Used and Outcomes

A summary of the outcomes reported in each paper, and the measures used are given in Table 8. Of the 18 papers, 12 mentioned the use of validated measures of outcome and examples are described in Appendix 2. The most common for depression was the Beck Depression Inventory (Beck, 1961). Both the Spielberger State Trait Anxiety Test (Spielberger, 1970) and Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983) were used for anxiety ratings, which were also the most common outcome assessed.

There was no clear specific coping questionnaire linked to fertility in the current cohort of studies. The Feelings about Infertility Questionnaire was used once and not referenced. The Kognitionen bei Infertilitat questionnaire (Pook et al, 1999) was used to track thoughts around infertility helplessness and self reports were used to follow the frequency of cognitions about the "child wish".

There were other measures used to assess other outcomes. Some studies used physiological changes such as levels of prolactin (O'Moore, 1983) or semen analysis (Tuschen-Caffier, 1999) or self reported acceptability of interventions.

The impact on reducing distress was beneficial in all studies except for Schmidt (2005) which reported no effect on fertility distress even though the intervention had an effect on the targeted behaviour (communication).

Six studies reported improvement in pregnancy rates but it is still not possible to draw firm conclusions, as only three of the studies fell into the good quality design category (Takefman, 1990; Domar, 2000; Domar 2011.) and pregnancy rate was measured at variable times (e.g. McQueeny, 1997 at 18 months; Takefman, 1990 at 6 months). Domar (2000b) reported improved pregnancy rate at one year but a similar study by Domar (2011) showed no comparable improved rate for IVF cycle 1. The attendance rate for the educational programme was very low but pregnancy rate improved for cycle 2 with higher attendance.

Table 8: MEASURES USED AND OUTCOMES

Authors	Outcome	Measure	Rating
O'Moore et al (1983)	Training reduced anxiety/positive physiological effects	STAI/ EPI	2
Wallace (1984)	Improved post operation anxiety with preparation and less pain with faster recovery	STAI/POMS/ pain scales	2
Takefman et al (1990)	Descriptive information superior to information about emotional and sexual reactions. Baseline levels on measures predictive of poorer adaptation as well as *pregnancy at 6 months*	FAI/BDI/ STAI	2
Stewart et al (1992)	No pregnancy effect /support group improved well-being	BDI/ HAD	2
McQueeny et al (1997)	Reduction in infertility distress/depression at one month and problem focused group higher *pregnancy rate at 18months*	COPE /MHI BDI	2
Tuschen-Caffer et al (1999)	Positive effects on; marital functioning / *pregnancy rate*/sperm concentration /helpless thoughts over 1 year	KINT	1
Domar et al (1990)	Reduced anxiety and depression/ 34% pregnancy rate	STAI/ POMS	2
Domar et al (1992)	Reduced anxiety and depression	STAI/ POMS	2
Domar et al (2000a)	Reduced anxiety/improved marital functioning and stress coping	STAI/POMS BDI/ HAD/	2
Domar et al (2000b)	Reduced anxiety/improved marital functioning and *improved pregnancy*	STAI/POMS/ HADS/BDI	2
Clarke et al (1995)	Course improve depression ,ovulation and weight loss	HAD/ GHQ	2
Clarke et al (1998)	Course improve depression, ovulation and weight loss *reduced miscarriage*	HAD/ GHQ	2
McNaughton et al(2000)	12/17 provided satisfaction rating		1
Cousineau &Lord(2004)	Media/CD ROM acceptability		0
Lemmens et al (2004)	Clinical impression and frequency of child wish cognitions		0
Schmidt et al (2005)	Improved communication/no effect on infertility distress/no standardised measures		1
Lancastre & Boivin (2010)	Acceptability of intervention with opinion it improved coping but no change in cognitive appraisal		1
Domar et al (2011)	Clinical *pregnancy* rate		2
0=no outcome described 1=general description of outcome or non-validated measures 2=specific validated outcome			

Participants in Studies

The descriptions of the target populations revealed that most of the research was undertaken with mixed samples (see table 9).The majority of studies included participants who were in various medical infertility diagnosis, procedures and treatments stages. Only three papers described an intervention that was aimed at a cohort undergoing specifically IVF. All other research had been conducted with clients in mixed fertility treatment contexts and mixed medical problems some with "unexplained" infertility .Indeed some were not involved in any medical pathway. The studies by Clarke (1998) concentrated on the issue of obesity and its relationship to infertility.

Although the average length of time participants had had reduced fertility is often recorded the range in most studies is broad .For example Tuschen-Caffier (1999) reported participants had a range of 12 months to 120 months. The Domar study (2000) had participants with a range but some with only one year of reduced fertility.

It is known that the woman's age is significant in terms of both natural and assisted conception yet participants in studies came from a range of age categories as shown by Domar (1992) whose study was with women in the range 28 to 43 years of age. The quality of study is significant to this area to ensure that there is no significant difference in characteristics between experimental and control groups.

As previously mentioned and can be seen in table 9 sample sizes varied and ranged from 5-63 in control groups and 13-56 in intervention groups though Domar (2011) found that initially only 6(9%) attended the pre-IVF cycle 1 psycho-education course and that was for only half of the sessions. Of those who proceeded to a second cycle however 76% attended the course.

Table 9: PARTICIPANTS IN STUDIES

Authors	Sample size	Target Participants	Rating
O'Moore et al (1983)	15couples 10 in control	Mean 6.7yr of infertility / average age 32/range 27-41yr Mixed ART*	1
Wallace (1984)	20 and 17 women experimental and 26 control	women having laparoscopy	0
Takefman et al (1990)	26couples 13 control	Average age 30 with 2.3 years infertility ± 1.7 years investigations for infertility	0
Stewart et al (1992)	25couples and14women control 35women	couples awaiting a variety treatments no information on age/duration of infertility	1
McQueeny et al (1997)	18(9+9) women experimental 8 in control	Infertility 21-73m range/mixed diagnosis and treatment	1
Tuschen-Caffer et al (1999)	17couples	idiopathic infertility/mixed treatment/ Infertility range12m-120m /average 36m	1
Domar et al (1990)	54 women	infertility of 3.3 yrs(mean) mixed med treatment/no med treatment	1
Domar et al (1992)	41 women	3.1 years average /age average 34 range 28/43)/mixed issues	1
Domar et al (2000a)	3 groups/63 women in control 65support/56CBT	average age 34 with18mnths of infertility and range 1-2 years Mixed ART*	1
Domar et al (2000b)	As above	As above	1
Clarke et al (1995)	13 women 5control	obese/infertile/ anovulatory	1
Clarke et al (1998)	67 women 20control	obese/infertile/anovulatory	1
McNaughton et al (2000)	17 couples	IVF Procedure	2
Cousineau & Lord (2004)	12 individuals	mixed ART*	1
Lemmens et al (2004)	6 couples	mixed ART*	1
Schmidt et al (2005)	37 couples	mixed ART *1/3 undertaking IVF	1
Lancastle & Boivin (2010)	55 women(27/28)	IVF only with some 2nd time/ average age 35	2
Domar et al (2011)	143 women across experimental and randomised control	IVF cycle 1 and 2 age < 40	2
Rating Values 0= Reduced Fertility Investigation 1=Variety of ART 2=Preparing Specifically for IVF			

**ART Assisted Reproductive Treatment*

Psycho-educational Trainer/Intervention Lead

Sixteen of the papers identified the professional identity of the trainer or intervention leader, all being clinical/applied psychologists except four. All included trained mental health professionals except for Schmidt's (2005) project which used a communications expert and a gynaecologist. Two of the projects required no direct contact from the research lead to instigate or support the intervention as it involved using CD ROMs and self-talk cards with written instructions.

Table 10: LEVEL OF TRAINER OR INTERVENTION LEAD

Authors	Level of trainer	Rating
O'Moore et al (1983)	Not specified/ clinical psychology authors	0
Wallace (1984)	Post-doctoral clinical psychologist	1
Takefman et al (1990)	PhD Psychologist	1
Stewart et al (1992)	Psychiatrist	1
McQueeny et al (1997)	Post-doctorate in clinical psychology and trained graduate	1
Tuschen-Caffer et al (1999)	No information	0
Domar et al (1990)	Two clinical psychologists shared group work	1
Domar et al (1992)	As above	1
Domar et al (2000a)	As above	1
Domar et al (2000b)	As above	1
Clarke et al(1995)	Psychiatrist/ dietician/physiotherapist	1
Clarke et al(1998)	as above	1
McNaughton et al (2000)	Psychiatrist and psychologist	1
Cousineau & Lord (2004)	Post-doctorate psychologist /CD ROM	NA
Lemmens et al (2004)	Clinical psychologist/ body oriented therapist/ nurse family therapist	1
Schmidt et al (2005)	Communications expert and gynaecologist	1
Lancastle & Boivin(2010)	PhD Psychologist/card	N/A
Domar et al (2011)	Clinical Psychologists	1
0= No description 1=Description Provided		

DISCUSSION

The four reviews allowed a broad perspective on the current state of research as well as pointers to areas of future research and how to raise the quality of future research. Of particular interest are the two reviews which used the same cohort of studies with 17 studies in common. Although the systematic review by Boivin (2003) and the meta-analytic review by De Liz (2005) reached differing conclusions, it was possible to understand the reasons for this. Categorisation of the papers reviewed had been different, in particular what was deemed psycho-education by one author had been labelled as group psychotherapy by the other, but more significantly the statistical meta-analytic review used data from less well controlled studies than the systematic review. It is possible to conclude that group interventions taking a psycho-educational approach appear either equivalent (De Liz 2005) or superior (Boivin 2003) to individual and couple therapy, and would therefore provide a good foundation for further investigation.

Overall the reviews suggest that future research should be more focused and contextualised (Griel 1997; Boivin 2003) and concentrate on a specific population (i.e. 'who'), a specific well described intervention (what), at a particular point in the care pathway for infertility (when), since it is not possible to understand what is most helpful when highly mixed samples are included. This indicates to the current author that goals of future research should be more specific, targeted and boundaried. The aim of any intervention to improve tolerance of and resilience to invasive clinical procedures would thus be to reduce distress at a particular point along the care pathway and therefore minimise iatrogenic effects. The paper by Lancastre (2008), for example, focuses appropriately narrowly on the 14-day waiting period between implantation of the embryo and pregnancy test on the care pathway of treatment. There are also other significant points on the pathway for research, such as: the first investigation point (Wallace 1984); waiting for specific medical procedures; preparing for

immediate medical procedures; waiting for pregnancy results; second cycle contact where Domar (2011)found participation increased and so on.

Differing world-wide health care and cultural systems in themselves may embody differing stressors and the importance of these factors in shaping the experience is highlighted by Griel (1997) .Griel suggests infertility is a process with an uncertain trajectory and this temporal element i.e. duration of infertility and duration of treatment will be influenced by different world wide medical funding systems. Cultural influences also impact on the experience (Baluch et al, 1993; Domar, & Gordon, 2012). Indeed Griel (1997) emphasises that most research has been done on white affluent participants who have already accessed fertility clinics. The majority of published papers in this current review were set in the USA. Indeed the review paper by Cousineau (2007) could be interpreted as a marketing strategy, set in the USA context of profit-making clinics.

In terms of the individual studies reviewed, lack of specificity continues to be an issue but there are also signs that there is emerging replication of findings, and also more developmental studies are being published.

Pregnancy rate improvement has been commented on but has not been specifically analysed here. The possible promotion of pregnancy would be an outcome that could be measured in the future, but ethically only when interventions are replicable, in multi-centred trials that would allow the robust statistical analyses necessary to draw such significant and politically sensitive conclusion. The outcome of this research could impact on health insurance funding policy or a government's funded care. High success rates are sought after by couples whose very strong wish to conceive may make them vulnerable to exploitation by commercially orientated companies who may not use evidenced based interventions. De Liz (2005) review did conclude that both individual and group therapy "possibly enhances conception success" (p1331). De Liz points out that there is a discrepancy between this

conclusion and that from Boivin's review but that this could be due to the use of evaluation instruments. Boivin's study compared treatment versus control groups in measuring pregnancy whereas De Liz included a greater number of treatment only studies in the statistical analysis.

If a more structured and focused approach of who/what/when /is to be applied in the next stages of research in this area then this could be helped by looking at the evidence from the 18 individual studies. Indeed looking firstly at the design of these studies as previously mentioned there is a move towards developmental papers looking at replication/feasibility and acceptability of specific interventions which have the potential to be taken forward into randomised controlled trials.

There is now a body of evidence about interventions that enable coping with stress which shows that these produce beneficial outcomes, in terms of reducing anxiety and depression, across a range of stages in the fertility experience. The evidence from several studies indicates that a focus on attitude or belief that includes challenging assumptions, problem solving, cognitive restructuring and reappraisal is effective. Although interventions varied significantly in timescales the most recent developmental studies are concentrating on brief interventions such as use of statements on cards or CD media provision. This suggests that effective interventions need not be time consuming or costly.

In the studies reviewed interventions were delivered by qualified psychological /mental health practitioners but future research could look at skill mix issues in the area of delivery, in order to establish whether low cost delivery via less trained or unqualified practitioners can produce equally effective outcomes.

In the 18 studies the samples often included participants with mixed medical problems and from across the range of stages of the experience which reduces the potential for replication of results and reduces the strength of the research. There was some consistency in

the use of mood outcomes measures which is helpful for future research. The measures BDI / STAI / HADs /POMS (appendix 2) were the most frequently used and are recommended for future studies since this will allow comparison across trials. However one possible bias in some studies may arise when research is undertaken in contexts where participants may feel their eligibility for treatment funding depends on them producing socially desirable scores.

This current review of individual papers has limitations; it did not search for self-esteem outcome data as suggested by Griel (1997) and it focussed on psycho-educational and self help cognitive approaches rather than counselling or emotion-expressive models of psychotherapy. A review which includes the latter could allow broader comparative conclusions to be drawn.

The overall criticism of the research is that the lack of specificity continues but there are also signs that replication and more focussed developmental papers are being published.

CONCLUSION

The overall aim of this review was to consider evidence that explores the efficacy of psychosocial approaches for improving resilience and coping with in-vitro fertilisation for couples undergoing this medical intervention for infertility. There are some key conclusions which can be drawn and which are listed below with implications for clinical practice and clinical research.

The reviews, placing emphasis on those that were most rigorous, suggest that:

1. There is potentially significant distress in managing the demands of and the experience of infertility for both partners.
2. Individual/couple and group interventions can assist with the emotional consequences of coping with infertility treatment in comparison to routine care.

3 Focussed or comprehensive educational programmes are superior to interventions that just emphasise emotional expression and support or counselling.

The current review of individual studies shows that:

4 Interventions which focus on themes of cognitive restructuring / reappraisal / challenging assumptions and problem solving show promise.

5 To date effective interventions were usually provided by a mental health professional, most frequently an applied psychologist. Thus at present it is not possible to say whether less qualified staff could successfully deliver interventions, and this is yet to be tested.

6 Individual studies used mixed populations reducing the ability to generalise to specific populations and identify who in particular would benefit from which interventions. This area needs further research.

7 Individual studies also used participants who were at differing points in the infertility experience so reducing the ability to establish more specifically who would benefit from what intervention provided and when.

The majority of studies are set in the USA health care system in which patients either need to have health insurance or the means to pay for treatment, and where companies are potentially focused on profit. This may influence the populations served, the samples in research and the responses to questionnaires. It may limit the extent to which such results can be generalised to the UK context.

Some developmental studies are now narrowing the focus of interventions to a specific point on a care pathway. These have better potential to inform practice than those which are more general.

Future research should aim for randomised controlled studies following on from the qualitative development of standardised intervention programmes. Such studies will yield

clinically useful information if they are set within particular points along identified care pathways. Larger studies carried out in a multi-centre research context would enhance statistical power and lead to more reliable and valid conclusions.

References

Baram, D., Tourtelot, E., Muechler, E., & Huang, K. (1988). Psychological adjustment following unsuccessful in vitro fertilization. *Journal Psychosomatic Obstetrics Gynaecology, 8,181-186.*

Beck, A. T. (1961). An Inventory for Measuring Depression. *Arch.Gen.Psychiatr.* 4,561-571.

Baluch, B., Manyande, A., Aghssa, M., & Jafari, R. (1993).Failing to conceive with in vitro fertilization: the middle eastern experience. *Psychological Reports.*72, 1107-1110.

Boivin, J. (2003).A review of psychosocial interventions in infertility. *Social Science & Medicine*,57,2325-2341

Clarke, A.M., Ledger, W., Galletley, C., Tomlinson, L., Blaney, F., Wang, X., & Norman, R.J. (1995). Weight loss results in significant improvement in pregnancy and ovulation rates in anovulatory obese women. *Human Reproduction*,10,2705-2712

Clarke, A.M., Thornley, B., Tomlinson, L., Galletley, C., & Norman, R.J.(1998).Weight loss in obese infertile women results in improvement in reproductive outcome for all forms of fertility treatment. Human *Reproduction*,13,1502-1505

Cousineau, T.M., & Domar, A.D. (2007). Psychological impact of infertility. *Best Practice & Research in Clinical Obstetrics and Gynaecology*,21(2),293-308

Cousineau,T. M ., Lord,S.E. Seibring,A.R., Corsini,E.A.,Viders, J.C.,& Lakhani,S.R. (2004). A multimedia psychosocial support programme for couples receiving infertility treatment: a feasibility study. *Fertility and Sterility*, 81 (3), 532-538.

Cwikel, J., Gidron, Y., & Sheiner, E. (2004).Psychological interactions with infertility among women. *European Journal Obstetric Gynaecology Reproduction Biology*,117,126-131

De Liz, T.M. & Strauss, B. (2005). Differential efficacy of group and individual /couple psychotherapy with infertile patients. *Human Reproduction*, 20(5),1324-1332

Domar, A. D., Clapp, D., Slawsby, E.A., Dusek, J., Kessel, B., & Freizinger, M. (2000a). Impact of group psychological interventions on pregnancy rates in infertile women. *Fertility and Sterility*,73,805-811

Domar, A.D. & Dreher, H. (1996). Healing Mind Healthy Woman. Caledonia International Publishing.

Domar, A.D., Clapp, D., Slawsby, E.A., Kessel, B., Orav, J., & Freizinger, M. (2000b).The impact of group psychological interventions on distress in infertile women. *Health Psychology*, 19,568-575.

Domar,A.D.,Gordon,K.,Garcia-Velasco,J.,La Marca,A.,Barriere,P., & Beligotti,F. (2012).Understanding the perceptions of and emotional barriers to infertility treatment: a survey in four European countries. *Human Reproduction,* 27 (4), 1073-1079.

Domar,A.D., Rooney,K.L., Weigand,B., Orav,E.J., Alper,M.M.,Berger,B.M.,& Nikolovski,J.,(2011).Impact of a group mind/body intervention on pregnancy rates in IVF patients. *Fertility and Sterility*, 95 (7), 2269-73.

Domar, A.D., Seibel, M., & Benson, H. (1990). The mind/body programme for infertility: a new behavioural treatment approach for women with infertility. *Fertility and Sterility*, 53,246-249.

Domar, A.D., Zuttermeister, P.C., & Freidman, R. (1993). The psychological impact of infertility: a comparison with patients with other medical conditions. *Journal of Psychosomatic Obstetrics Gynaecology*, 14, 45-52.

Domar, A.D., Zuttermeister, P.C., Seibel, M., & Benson, H.(1992). Psychological improvement in infertile women after behavioural treatment: A replication. *Fertility and Sterility*, 58,144-147.

Eugster, A., & Vingerhoets, A.J. (1999). Psychological aspects of in vitro fertilization: a review. *Social Science medicine*, 48,575-589.

Freeman, E.W., Boxer, A.S. & Rickels, K. (1985). Psychological evaluation and support in a programme of in vitro fertilization and embryo transfer. *Fertility Sterility*, 43(1), 48-53.

Goldberg, D.P. & Williams, P. (1988).A Users Guide to the General Health Questionnaire. Nfer-Nelson, Windsor, Uk.

Griel, A.L. (1997). Infertility and psychological distress: A critical review of the literature. *Social Science Medicine*, 45(11), 1679-1704.

Hammarberg, K., Astbury, J., & Baker, H. (2001). Women's experience of IVF: a follow-up study. *Human Reproduction*, 16,374-383.

Jacobsen, P. B., Meade, C. D., Stein, K. D., Chirikos, T. N., Small, B. J& Ruckdeschel, J. C. (2002). Efficacy and costs of two forms of stress management training for cancer patients undergoing chemotherapy. *Journal of Clinical Oncology*, 20 (12), 2851-2862.

Khan, K.S., Riet, G., Popay, J. (2001). Study Quality Assessment. In (Eds) Khan, K.S., Riet, G., Glanville, J., Snowden, A.J., and Kleijnen, J. Undertaking Systematic Reviews of Research on Effectiveness; CRD Report no 4 (2nd Edit). NHS Centre for Reviews and Dissemination.

Lancastle,D.& Boivin,J. (2008) A feasibility study of a brief coping intervention(PRCI)for the waiting period before a pregnancy test during fertility treatment. *Human Reproduction*,23(10) 2299-2307.

Lemmens, G.M.D.,Vervaeke,M.,Enzlin,P., Bakelants, E.,Vanderschueren,D., Hooghe,T.D.,& Demyttenaere,K. (2004).Coping with infertility: a body-mind group intervention programme for infertile couples. *Human Reproduction*,19(8),1917-1923
McNair, D.M. (1971). Manual for the Profile of Mood States. San Diego, C.A.Educational Testing Service.

McNaughton –Cassil, M.E., Bostwick, M.,Vanscoy, S.E., Arthur, N.J., Hickman, T.N., Robinson, R.D.,& Neal,G.S.(2000).Development of brief stress management support groups for couples undergoing in vitro fertilization treatment . *Fertility and Sterility*, 74, 87-93.

McQueeny, D., Stanton, A., & Sihmon, S. (1997). Efficacy of emotion-focused and problem-focused group therapies for women with fertility problems. *Journal of Behavioural Medicine*, 2(4), 313-331.

O'Moore, A.M., O'Moore, R.R., Harrison, R.F., Murphy, G., & Carruthers, M.E. (1983).Psychosomatic aspects in idiopathic infertility: Effects of treatment with autogenic training. *Journal of Psychosomatic Research*, 27,145-151.

Pook,M., Tuschen-Caffier ,B.,Snapper,U., Speiger,K., Krause.W., & Florin, I. (1999).Cognitions in Infertility: Development and validation of a questionnaire (KINT).*Diagnostica ,*45,2,104-113.

Schmidt, L., Tjornhoj-Thomsen, T., Boivin, J., & Anderson, A.N. (2005).Evaluation of a communication and stress management training programme for infertile couples. *Patient Education and Counselling*, 59,252-262.

Smeenk, J.M., Verhaak, C.M., & Stolwijk, A.M. (2004). Reasons for dropout in an in vitro fertilization/intracytoplasmic sperm injection programme. *Fertility Sterility*, 81,262-268.

Spielberger, C.D. (1970). Manual for the Stait-Trait Anxiety Inventory. Palo Alto, California: Consulting Psychologist Press.

Stewart, D., Boydell, K., McCarthy, K., Swerdlyk, S., Redmind, C., & Cohrs, W. (1992) .A prospective study of the effectiveness of brief professionally-led support groups for infertility patients. *International Journal of Psychiatry in Medicine*, 22(2), 173-182.

Takefman, J.E., Brender, W., Boivin, J., & Tulandi, T. (1990). Sexual and emotional adjustment of couples undergoing infertility investigation and the effectiveness of preparatory information. *Journal of Psychosomatic Obstetrics and Gynaecology*, 11,275-290

The Human Fertilisation and Embryology Authority (2012). Patients Guide to Treatment.www.hfea.gov.uk

Tuschen-Caffer, B., Florin, I., Krause, W., & Pook, M. (1999). Cognitive-behavioural therapy for idiopathic infertile couples. *Psychotherapy and Psychosomatics*, 68, 15-21

Wallace, L.M. (1984). Psychological preparation as a method of reducing the stress of surgery. *Journal of Human Stress*, 10, 62-67.

Zigmond, A.S. & Snaith, R.P. (1983) .The Hospital Anxiety and Depression Scale. *Acta Psychiatr.Scand*.67, 361-370.

Empirical Study

An Empirical Enquiry Investigating the Experience of Couples Waiting for IVF within the Context of the UK National Health Service and a Feasibility Study of a Psycho-Educational Workshop Preparing for this Clinical Procedure.

ABSTRACT

The aim of this study was to use psychological models to better understand the experience of waiting for the clinical procedure In Vitro Fertilisation (IVF) and to explore whether a group psycho-educational workshop could give added value at this time. It is set specifically within the context of UK National Health Service (NHS) organisational systems. In particular, the aim was to describe some of the characteristics of those on the waiting list, to improve understanding of the experience of couples waiting for and attending IVF treatment, and to test the feasibility of a Compassion focused Cognitive Behaviour Therapy (CBT) based psycho-educational workshop designed to meet the specific needs of those waiting and undergoing IVF. A multiple/exploratory case study research design was used to provide detailed comparison of six cases against psychological models using an action research method and case study structure.

The main findings were that the UK context probably provides some unique stressors to be considered and that interventions should be related to reason for infertility rather than preparation for IVF. The targeted population should be split into specific sub-categories on the waiting list for the purpose of future research. It is proposed that, to investigate who could benefit from what intervention future research studies the effects of cognitive models on couples specifically with "Unexplained Reduced Fertility"; that future research investigate the relationship between provision of "Information on Donor Sperm" during the waiting period with the ability to engage in anticipatory coping; finally that to facilitate sustained coping over extended periods of unknown waiting time, research should look at the effectiveness of improving information systems at this specific point on the pathway.

INTRODUCTION

Context of Fertility Treatment in UK National Health Service (NHS)

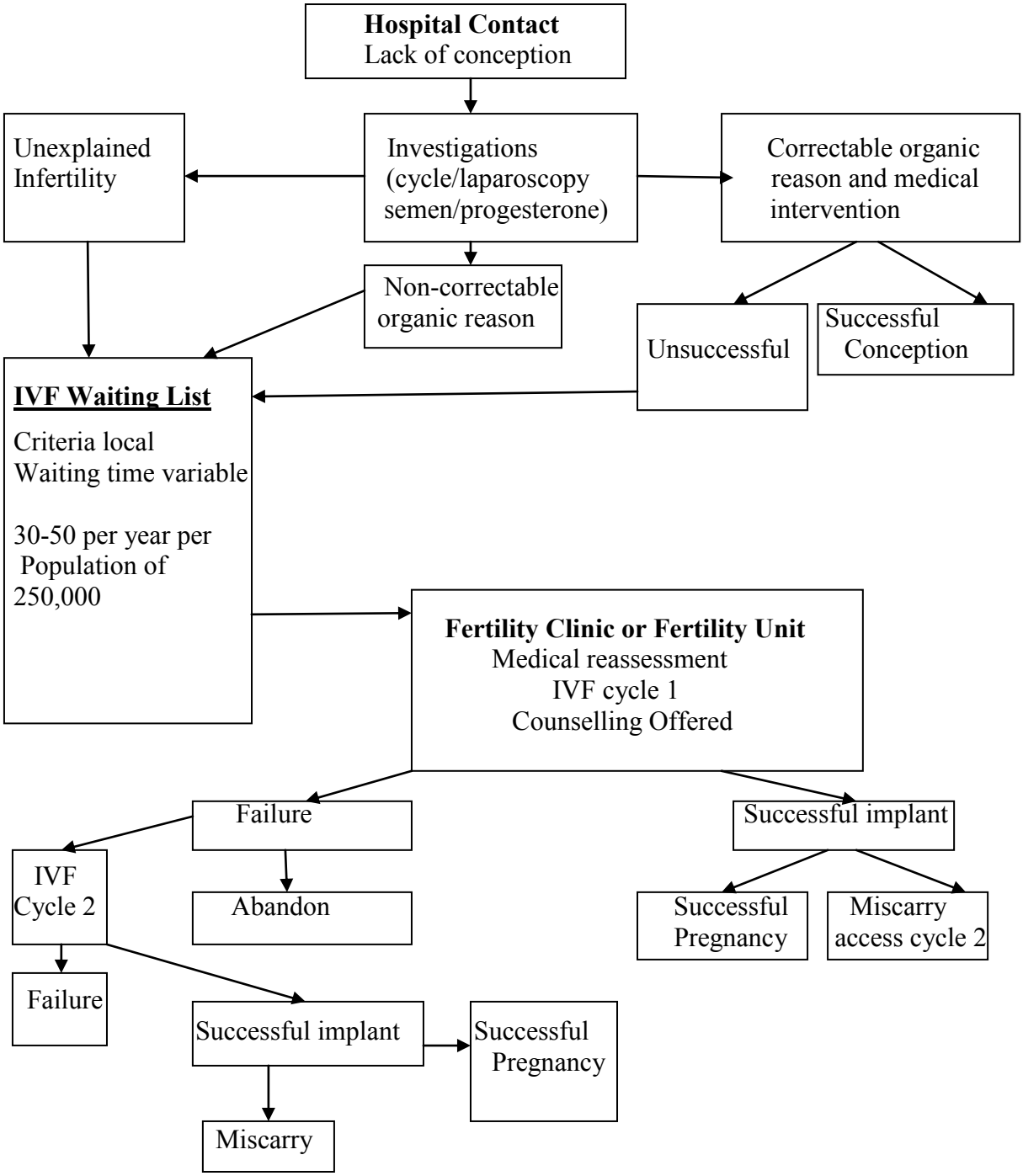
Sub-fertility currently occurs in one in seven couples in Great Britain. For those with unexplained infertility, non-correctable organic reasons, or correctable organic reasons that have not resulted in conception after medical intervention, the way forward for them is to be offered In Vitro Fertilisation (IVF). The success rate historically is low for this procedure. The National Average success rate (2007) is 29% overall per cycle but reduces significantly with age.

The majority of couples in the UK self-fund their own IVF treatment (60%) with 40% using the NHS care pathway. The current National Clinical Guidelines (2004) recommend access to three cycles of IVF treatment. The Department of Health (DOH) advises its NHS commissioning organisations, Primary Care Trusts (PCTs), that at least one cycle should be funded by the NHS. Districts throughout the UK vary in the number of cycles funded and in their eligibility criteria. The NHS care pathway is shown in Figure 1.

Because of the poor success rates most centres providing IVF use multiple embryo implants. However, new guidelines now discourage this as the effects of multiple births are to increase risk of miscarriage; cerebral palsy is three times more common; perinatal mortality is five times more likely and the mother is more prone to suffer hyper emesis (i.e. extreme morning sickness) pre-eclampsia and premature labour. In 2003 126 IVF babies died who probably would have survived a single birth (HFEA, 2007). National data shows 10% of couples have just one embryo transferred (HFEA 2007). The clinical guidelines recommend that no more than two embryos should be transferred during any one cycle. The national goal

is that 50% of couples should have one embryo transferred but this creates a dilemma as clinics wish to maintain success rates and more importantly couples may choose the risk of a twin birth versus no family.

Figure 1: Operational Framework: NHS Care Pathway



Psychological and Counselling Interventions

In this context of low success rates, unknown waiting times and decisions about embryo implantation, it is important to seek methods to reduce psychological distress during the experience and to improve well-being outcomes. In addition, one factor that may possibly contribute to lack of conception is stress (Boivin & Shoog-Svanberg, 1998). Counselling interventions are routinely employed within IVF clinics but this usually only occurs once clients have been taken off the NHS waiting list and have access to the IVF clinic. Studies using survey methodologies were cited within the National Institute for Clinical Excellence (NICE) guidelines (Daniluk, 1988; Baram, 1988; Sundby, 1994) as evidence for the inclusion of counselling in the care pathway. These surveys indicated that most patients felt that access to a support group and counselling would be beneficial to them. This was translated into continued support for the HFEA Code of Practice in Counselling. However, Connolly et al., (1993) in a randomised controlled trial (RCT) comparing the provision of information against information combined with counselling for couples undergoing IVF treatment, showed no significant difference between these two interventions.

Other psychological interventions that address stress responses, and which may complement or be in addition to counselling have shown promise both in the fertility research literature as well as other literature on preparation for invasive medical interventions. A systematic review of psychosocial interventions for infertility, published by Boivin in 2003 indicated that interventions emphasising education and skills were significantly more effective than counselling interventions which emphasised emotional expression and support. The 2004 NICE clinical guidelines cite two RCTs as showing that group psychological interventions using a Cognitive Behavioural Therapy model (CBT) prevented distress (Domar & Clapp, 2000a) and improved pregnancy rates (Domar & Clapp, 2000b). The CBT

intervention group pregnancy rate was 55% and routine care group was 20%. The NICE guidelines rated this research as being at the highest level of evidence but surprisingly these findings were not translated into their recommendations, probably because the research was conducted on women with less than two years infertility who would not have met the UK criteria for infertility treatment.

This current study planned to investigate the experience of couples before accessing the fertility clinic and explore the feasibility of an additional psychological intervention.

Literature Review and Conceptual Framework

Infertility causes ***stress***. Infertility treatments cause stress. However stress may also be a primary or secondary cause of infertility in some couples.

Levels of stress/distress

Most sub-fertile patients especially women consider the evaluation and treatment of fertility to be the most upsetting experience of their lives (Freeman, Boxer, & Rickels, 1999). The most common reason that patients drop out of IVF treatment, even when covered by medical insurance, is psychological distress (Hammarberg, Astbury, & Baker, 2001). Eugster and Vingerhoets (1999) found most patients stated that IVF treatment was primarily a psychological stressor rather than a physical stressor. Research indicates that pre-treatment levels of depression are highly predictive of those with less ***resilience*** who would drop out after only one cycle (Smeenk, 2004).

In a study that compared infertile and fertile women undergoing routine gynaecological care (Cwikel, Gidron, & Sheiner, 2004) 11% of the infertile women met the criteria for a current major depressive episode compared with 3.9% for the fertile women. Domar, Zuttermeister and Friedman (1993) compared sub-fertile women's scores on measures

of depression, anxiety and hostility to those of women with cancer, hypertension, myocardial infarction and HIV-positive status and their scores were indistinguishable.

The significance of the psychological consequences of sub-fertility should not be underestimated in the process of IVF treatment. Lukse (1999) reported that women experienced measurable levels of ***grief*** and depression before, during, and after IVF treatment. In some cultures the status of infertility can have significant consequences. It has been reported that as many as 13% of women experience suicidal ideation after an unsuccessful IVF attempt (Baram & Tourtelot, 1988).

Depression may not only be a predictor of treatment drop-out. A study looking at 98 women undergoing IVF (Demyttenaere, Bonte et al., 1998) showed that increased pre-IVF measures of depression were associated with lower pregnancy rates.

Studies have shown that many women experience ***guilt and self-blame*** as a result of reduced fertility (Domar & Seibel, 1997; Abbey&Halman, 1995). In addition, a number of studies reported by Eugster (1999) profiling psychological status before the IVF procedure show gender differences in coping. Women's scores on state and trait anxiety were significantly elevated during this time in comparison to their partners.

This brief review of research suggests that psychological models around stress, grieving, guilt and self-blame and maintenance of resilience maybe particularly relevant to understanding the emotional impact of the infertility experience.

Psychological Interventions for Stress

How a person responds to a stressful situation depends on their coping style. That is their ability to use strategies to master, reduce or tolerate the stressful situation. There have now been 20 years of valuable research into the efficacy of cognitive behavioural approaches to improve coping styles in the face of stress. The original Folkman and Lazarus model (1984)

evolved through research into the transactional model of stress *appraisal* (Lazarus & Folkman, 1984; Lazarus, 1999; Folkman, 2000). Also Meichenbaum (1996, 2007) has summarised the applications of stress inoculation, again over a 20year period. Stress management and stress inoculation have been used successfully to reduce clinical distress, strengthen resilience and facilitate adjustment across a range of health contexts (Horne, Vatmanidis, & Careri, 1994).

Advanced effective CBT models have also been developed to address trauma and blame, such as compassion focussed CBT (Gilbert, 2006; 2009) and mindfulness based CBT to reduce vulnerability to repeated episodes of depression (Teasdale, Segal, & Williams, 2000). Acceptance and commitment therapy has received growing attention in recent years and has proven effective for people with chronic health problems and mental health concerns (McCracken, & Eccleston, 2006). All of these provide additional evidence–based models that can effectively be applied to stress reduction, and to building resilience and increasing tolerance. The specific area of resilience is also increasing in its evidence base (Neenan, 2009), research guidelines (Luthar & Cicchetti, 2000) and models (Wagnild, 2009).

There has been much work done in the area of cancer diagnosis and treatment as well as in psychological preparation for invasive medical techniques. Indeed Cruess et al. (2000) showed that cognitive behavioural stress management reduces serum cortisol among women with early stage breast cancer. Horne, Vatmanidis and Careri (1994) provide evidence that psychological preparation for invasive treatment has positive long-term emotional effects(less anxiety, depression) and physical benefits (shorter stay in hospital and less pain relief medication). There is also a growing body of evidence in the area of developing resilience psychologically (Strauss & Brix 2007). It would appear from the literature that stress

preparation/facilitation of coping, resilience and increasing tolerance may add value to fertility treatment pathways.

In the area of cognitive coping styles a prospective study (Klonoff-Cohen & Natarajan, 2004) with 151 women who completed questionnaires at their initial clinic visit and then at the time of their IVF or gamete intrafallopian transfer (GIFT) procedure, showed that those who were more concerned about the medical aspects of the procedure had 20% fewer eggs retrieved and 19% fewer eggs fertilized than women who worried less.

Fertility and Psychological Interventions

In relation specifically to IVF and infertility there was a major review by Boivin in 2003 of psychosocial interventions for infertility looking at 25 independent evaluation studies. Due to the variability of interventions the studies were categorised into three types of intervention to allow comparison. These were a) counselling b) focused educational programmes c) comprehensive educational programmes. It was found that group interventions with an emphasis on education and coping skills training were significantly more effective in producing positive change across a range of outcomes than counselling interventions which emphasised emotional expression about infertility. In terms of improvement in pregnancy rate however Boivin expressed caution. Of the 25 evaluation studies only eight were considered good quality research, and of these, only three showed higher pregnancy rates in the group receiving psychosocial interventions compared to the group receiving routine care. The need for more research in this area was emphasised.

A more recent review (De Liz, 2005) looked at 22 evaluation studies across Spain/Turkey and the USA and came to similar conclusions. Although this author was more positive about pregnancy rate improvement, once again the author emphasised the need for studies to be focussed and replicated.

Domar has been cited in both the above reviews and in the NICE guidelines and she calls the CBT interventions she developed and researched the "Mind/Body" infertility programme. She describes this as including relaxation techniques, stress management and emotional expression, coping skills training such as cognitive restructuring; self nurturance and family and group support. The programme is described in "Healing Mind Healthy Woman" (1996). Unfortunately it is difficult to generalise from her work because the inclusion criteria in Domar's studies (2000a; 2000b) specify six months to one year of infertility while the NHS UK criterion is two. Indeed the literature review revealed that most research has been done outside the UK in very different contexts/health systems.

Research indicates that CBT interventions need not necessarily be complex. Brown and Cochrane (2000), for example, showed that it was possible to apply a CBT model of stress coping training equally as effectively to large numbers of participants in a single workshop format (Brown & Cochrane, 2000) in comparison with groups run over a period of time. Cousineau (2004) has developed an online eHealth programme which suggested that a web-based patient education intervention could give effective outcomes for women with fertility problems who spent less than 6o minutes online. On the measures she used, decreased global stress and increased self efficacy were found. Indeed Lancastle (2008) within her feasibility study provided participants with cards containing self statements to read twice daily while awaiting IVF results over the two week period between embryo implantation and testing for pregnancy. The women found the intervention feasible and reappraisal coping statements were reported to be more helpful than statements about positive mood.

In summary there is a small body of evidence to show that psychological interventions produce beneficial effect in fertility treatment outcomes. Cognitive models are potentially transferable to a range of contexts and pathway points and may include self-help

orientated approaches or protocol-driven short-term interventions through to complex cognitive individual therapy. However, there has been no consistency or standardisation of interventions except for the broad principles set out by Boivin's categories previously mentioned. Additionally the majority of fertility specific psycho-social research has concentrated on couples undergoing mixed medical fertility treatments and mixed cohorts of participants who were volunteers i.e. treatment seekers with reduced fertility who were on different points on a pathway to conception.

Complementary and Alternative Medicine (CAM)

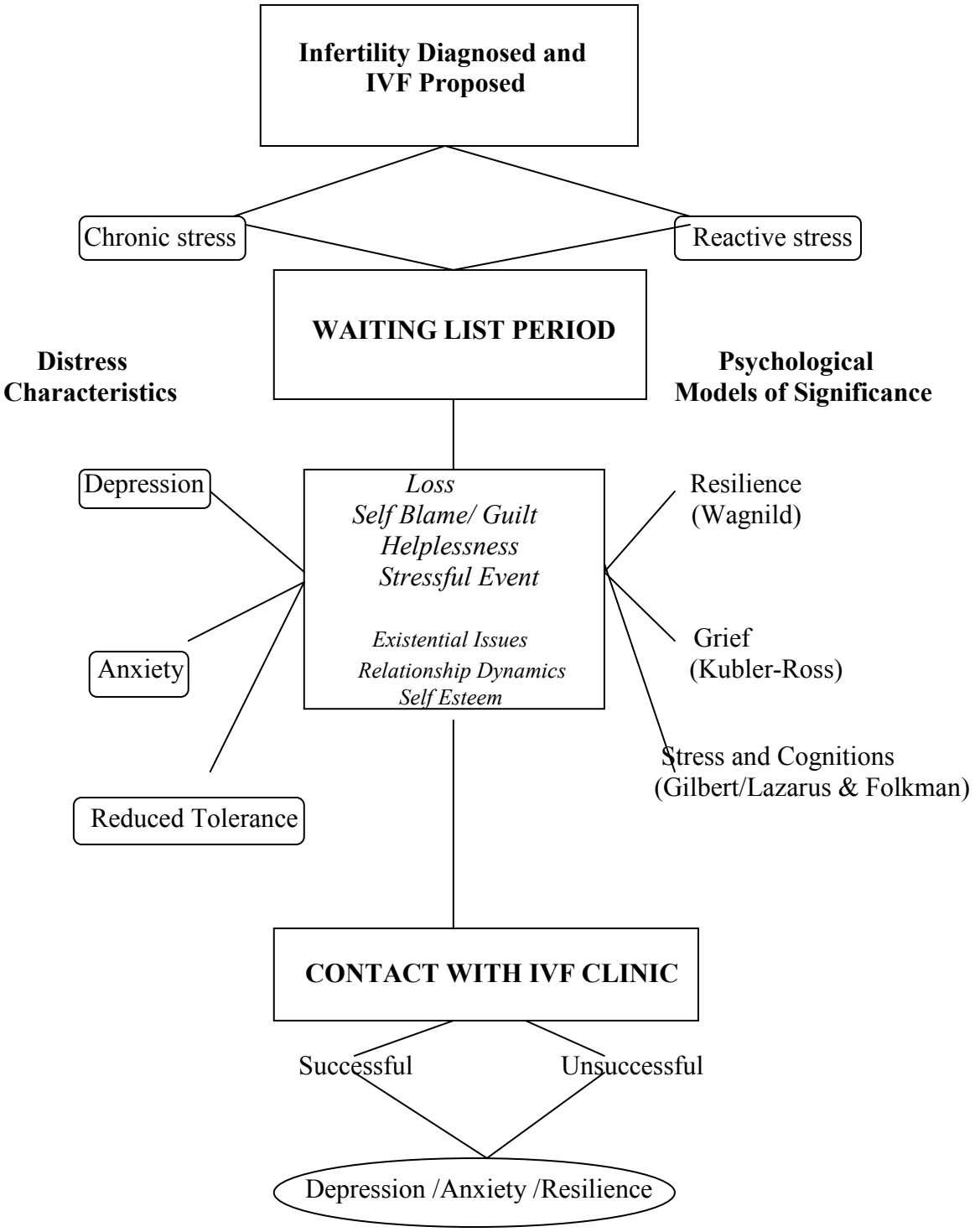
Boivin and Schmidt (2009) in a prospective observational cohort study found that concurrent use of CAM during the assisted reproductive treatment period was associated with 30% lower pregnancy rates suggesting that CAM use may **interfere** with the process of implantation and pregnancy. This is significant and needs further research so that couples can be guided on the issue of self-help. It is totally understandable that many women would try and employ health promotion strategies at this time and on their own as a way to reduce feelings of ***helplessness*** during the infertility treatment experience.

Physiological mechanisms behind stress interventions

There is a growing body of evidence linking stress to biological dysregulation. When an individual experiences a stressor the adrenal cortex secretes the glucocorticoid cortisol. The biological model proposes that the stress hormone cortisol affects ovulation and sperm production and quality (Boivin & Shoog-Svanberg, 1998). Increased distress prior to, or during in vitro fertilisation has been associated with a poorer biological response and/or a reduced pregnancy rate (Smeenk et al., 2001; Boivin & Takefman, 1995). It therefore seems possible that any beneficial effect of psychological interventions may be due to their impact on this biological pathway.

Finally the question of how different national and cultural contexts might influence the experience of reduced fertility is rarely reported (Griel, 1997).

Figure 3: Conceptual/Theoretical Framework from Literature Review



A conceptual framework for the feasibility and case study was developed (Figure 3) to place the enquiry within the UK NHS context and at a particular point on the care pathway i.e. when a couple are on the waiting list before accessing the host fertility clinic. The framework also draws in four relevant psychological models that may help in understanding of the position of those waiting for IVF and cites a key author in each field. It was used to guide the development of the template of the four psychological models (Table 5) to be used in the study. The concepts of loss, self-blame, guilt, helplessness and stress were identified from the literature review as key relevant constructs. Dominant psychological models reflecting these areas that were epistemologically compatible were then characterised and are set out in the template described in Table 5. The first model covers grief which is the process of adapting to loss or abandonment (Kubler-Ross, 2005). The second model covers resilience, the process of maintaining competence and tolerance despite adversity (Wagnild, 2009). The third is the stress transactional model (Lazarus & Folkman, 1984) linking cognitive appraisal and coping and the fourth the compassion-focussed cognitive model (Gilbert, 2009) linking reducing thoughts of blame with kindness, knowledge and self-soothing.

The UK Medical Research Council (MRC) has set a framework to guide design and evaluation of complex interventions to improve health which is particularly relevant to community settings (Campbell et al., 2000). See also Appendix 4. This sets out a process requiring qualitative and quantitative evidence. This current study was developed within that framework and was situated in the following phases:

a) Pre-clinical Theoretical Phase

   Evidence was identified through a literature review combined with clinical experience and was used to develop the conceptual framework.

b) Phase 1 Defining Components of the Intervention and Population

The population on the waiting list was described and an evidence-based intervention was piloted to test the theoretical and operational framework.

c) Phase 2 Intervention Development

A Multiple-Case Study approach was implemented within the feasibility trial using Yin's (1994; 1999; 2002) methodology to explore the relationships between who/what/why for intervention development.

Overall aim of the study

The phenomenon that was the subject of this study was the psychological experience of waiting for and accessing the medical procedure IVF in a UK NHS context, focussing on an exploration of who could benefit from what intervention.

The aim was to describe the population on NHS waiting lists that were more likely to take up the option of attending a psycho-educational workshop and then, by piloting a brief CBT-based tailored intervention, use this process, to explore the specific psychological experiences of couples through case study research.

The ultimate aim was to test the conceptual /theoretical and operating framework by using action research to explore the feasibility of the intervention, and develop a conceptually-based research proposal for intervention development. By providing an evidence-based intervention; describing the characteristics of couples on the waiting list for NHS funded IVF and tracking their experience of waiting and accessing the IVF clinic this would generate new hypotheses for developing preparatory and remediative interventions. The method and results for each phase of the overall study are set out in Phase 1 and Phase 2.

PHASE 1: THE DESCRIPTIVE STUDY

The aim of this study was to profile the characteristics of those on the waiting list who were willing to undertake the intervention prior to undergoing IVF treatment. It is known from

research that less than 25% (Boivin, Scanlon,& Walker, 1999) take up the offer of psycho-social counselling or stress management training (Schmidt et al.,2005), and in a recent study by Domar (2011) only 9% of the couples embarking on IVF cycle 1 attended the psycho-educational programme provided.

METHOD

Recruitment Procedure

122 (61 couples) were contacted by introductory letter from the Medical Director of the local hospital. These were all on the waiting list held at an acute hospital for patients waiting funding from the Primary Care Trust for referral on to a private IVF clinic. They were expected to be on the waiting list for no longer than 18 weeks. Those replying to the introductory letter (Appendix 8) were offered individual appointments with the researcher.

Participants and Inclusion criteria to be on the IVF waiting list

- At least two years of attempting to conceive.
- Within a stable relationship for a minimum of two years
- Both partners non-smokers
- No living children for either partner
- Female BMI (Body Mass Index) less than 30
- Female age range 25yrs to 40yrs
- Male age under 55 yrs
- No previous IVF treatment

Each couple was offered an interview at a suitable time. The overall aims of the project were described and the possibility of being assigned at random to an evening psycho-educational workshop or treatment as usual was explained. Following consent, a semi-structured interview was undertaken and questionnaires were taken away by participants to be completed within four weeks and returned to the researcher. The couple would then be invited to the workshop or allocated to routine care.

Measures

Questionnaires consistent with previous research and the conceptual framework were used to establish a profile of those interested in the workshop. Levels of anxiety were assessed using the Spielberger State-Trait Anxiety Scale (Spielberger, 1970); levels of depression using the Beck Depression Inventory II (Beck, 1996) and resilience using the Wagnild Resilience Questionnaire (Wagnild, 2009). Each is described more comprehensively in Appendix 2.

Also used were opinion and feedback forms (Appendix 4).These forms asked for postal reports about the effectiveness of the workshop and attitude changes as well as any comments on the experience and outcomes from it.

Ethical Considerations

Any possible side effects were likely to be positive even if there was no significant effect on IVF success rate. The burden of the questionnaires was not great, therefore there were no identifiable ethical dilemmas. Informed consent was obtained by explaining the content of the Information Sheet (Appendix 9) and responding to questions.

The research proposal was submitted to the District Research Governance Committee and the National Research and Ethics Service and approval was granted in August 2010 (Appendix 7)

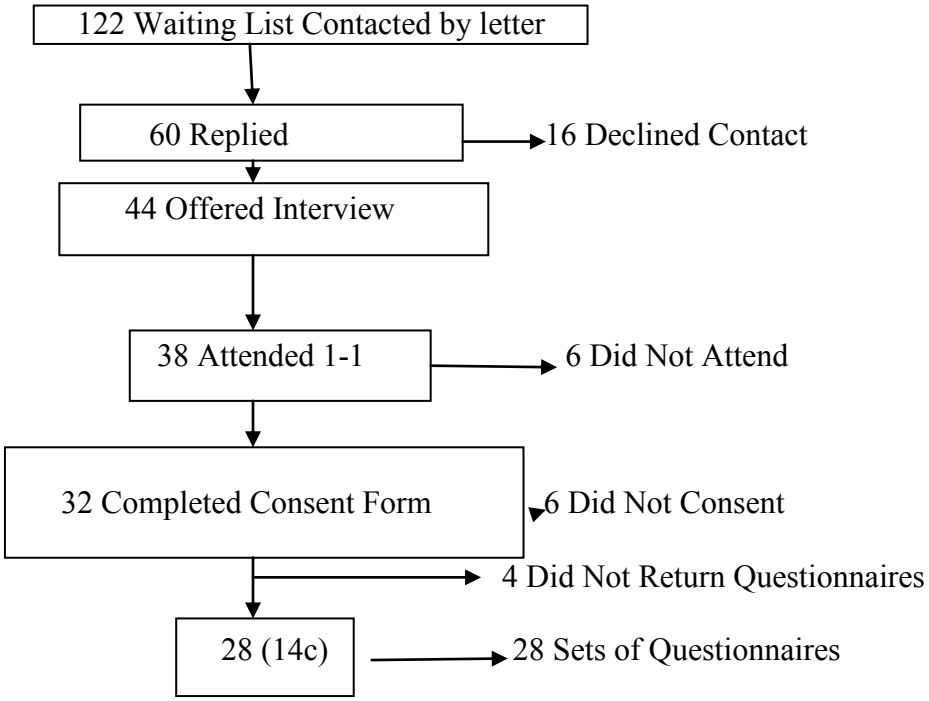
RESULTS

Forty-four responses were received to the 122 invitation letters and, of these, 38 attended for a one-to-one meeting. Of these, 32 consented to take part, but only 28 participants (14 couples; 22%) completed and returned the pre-intervention questionnaires. This low rate is addressed in the discussion.

During the 1:1 interviews it was noted that a significant change to the care pathway waiting time had occurred. It had changed from 18 weeks to an indefinite period. The participants' disappointment at not being told their timescale for accessing IVF by the researcher was a common theme during interviews and this may have contributed to the

dropout rate, especially as some participants expressed disappointment that contributing to the research would not reduce their waiting time. It was also noted that this would potentially limit post IVF data for this study.

Figure 4: **Flow Chart 1**



For a description of characteristics of the 28 participants who completed the 1:1 interview and all pre-intervention measures, see Table 1 and Table 2.

Table 1: ***Characteristics of Cohort***

		Male(n=14)	**Female(n=14)**	**All (n=28)**
AGE	Mean	33.2	29.5	31.4
	Range	22(28-50)	13(25-38)	25(25-50)
ETHNICITY	White British	7 (50%)	7 (50%)	14 (50%)
	Mixed Heritage	7 (50%)	7 (50%)	7 (50%)
MARITAL STATUS	Married Co-Habiting	- -	- -	64% 36%
HIGHER EDUCATION	Yes No Not Available	5(36%) 5(36%) 4(28%)	5(36%) 6(42%) 3(22%)	10(36%) 11(39%) 7(25%)

This shows a range of ages for the male and female cohorts with the men slightly older and with a broader range. It also reflects the mixed heritage and educational levels of the local urban population.

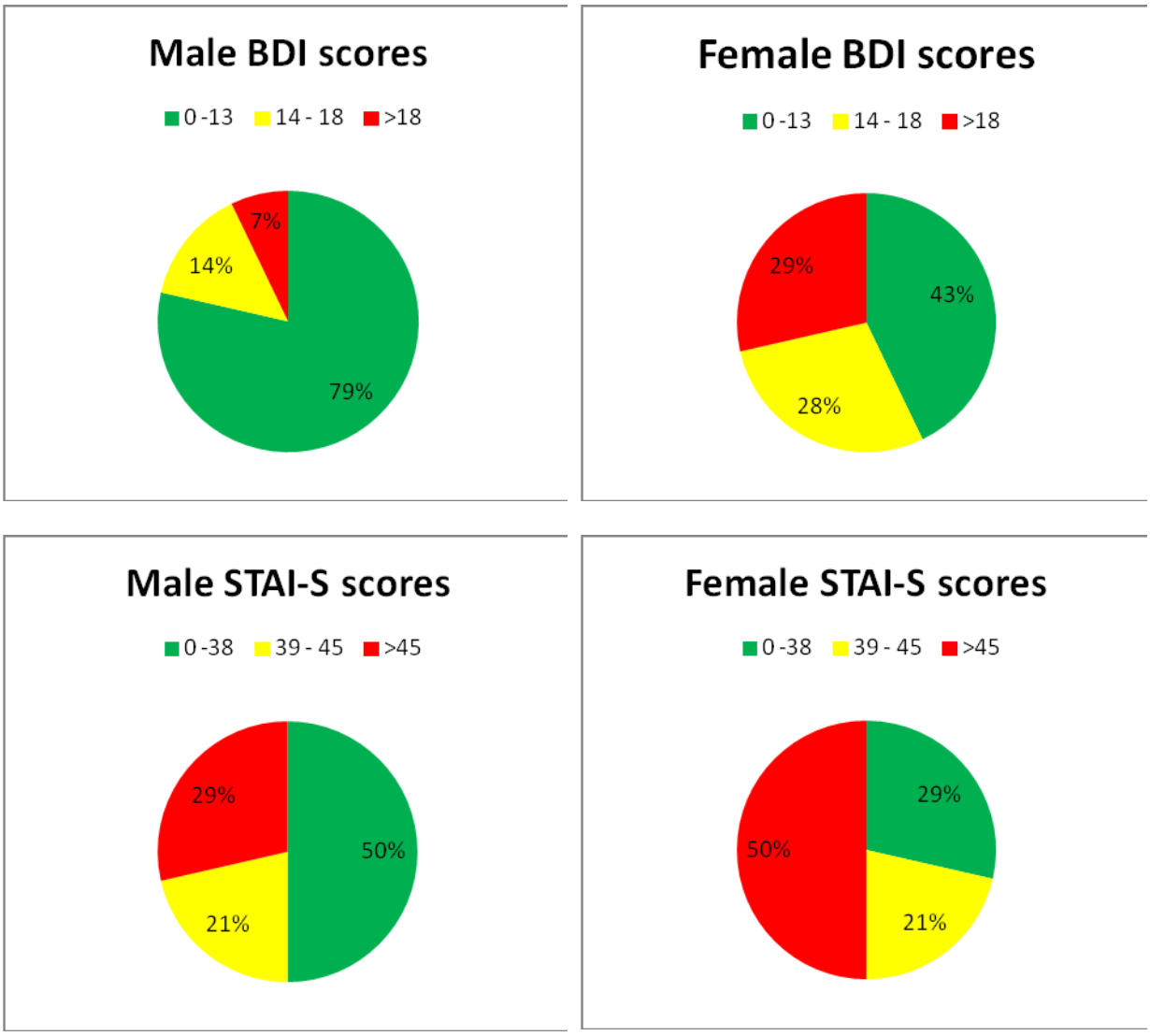
Table 2: ***Descriptive Statistics of Cohort on Waiting List.***

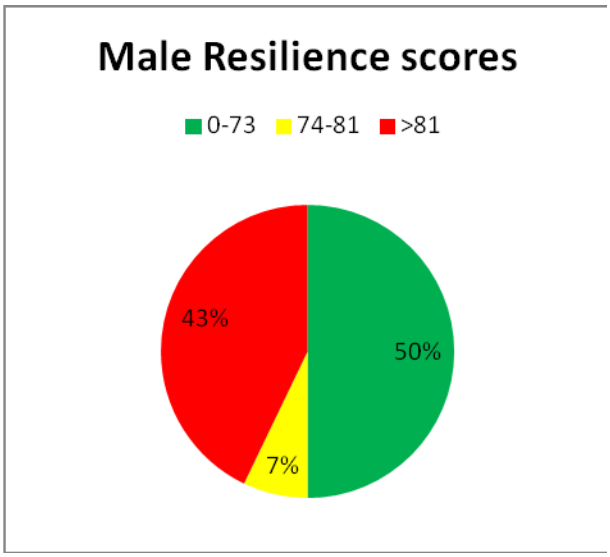
		Male (N=14)	Female (N=14)	All (N=28)	Normative data
Beck Depression Inventory	Mean Median SD Range	8.9 8 6.58 26 (0-26)	14.4 14 9.24 30(1-31)	11.7 10 8.48 31(0-31)	0-13 (minimum) 14-18 (mild/moderate) 19 above (moderate/severe)
Spielberger Trait Anxiety Inventory	Mean Median SD Range	39.1 38.5 10.42 37(24-61)	44.7 46 8.18 27(30-57)	41.9 44.5 9.62 37(24-61)	Mean 36
Spielberger State Anxiety Inventory	Mean Median SD Range	40.7 40.5 11.68 47(20-67)	45.3 46 10.97 36(27-63)	43 43.5 11.56 47(20-67)	39-45 (Mild) 46-63 (moderate)
Wagnild Resilience Scale 14	Mean Median SD Range	75.2 75.5 10.88 31(60-91)	75.8 75.5 9.38 31(60-91)	75.5 75.5 10.16 31(60-91)	82-90 (strong) 74-81 (moderate) 65-73 (Low)

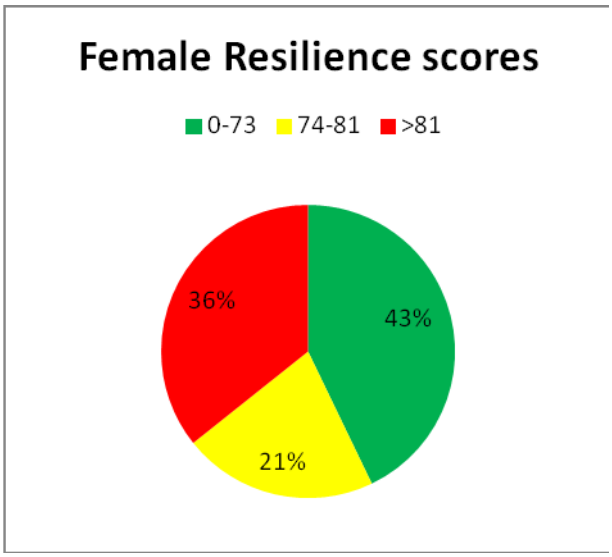
As shown in the descriptive statistics in Table 2, the female participants on average were in the clinical category for mild/moderate depression while the male cohort was in the minimal category. On average however both groups had mild levels of trait anxiety and both male and female participants described themselves as equivalently resilient.

Overall 39% (11/28) had moderate anxiety (STAI score above 46) and 43% (12/28) reported lower than average resilience while 39% (11/28) said they felt strongly resilient at this time. 18% (5/28) had clinically significant scores on depression (BDI score 19 and above) with women participants at 29% in comparison to 11% in the research.7% of men also had significant scores for depression. In Table 4, the pie chart by gender suggests some differences that maybe detected if statistical power was increased.

Table 3: ***Individual participant's scores by gender***







PHASE 2 INTERVENTION AND MULTIPLE CASE STUDIES

A case study approach can be described as a research strategy that investigates phenomena in a real life context (Yin 2003).

The aim was to test the feasibility and impact of delivering a psycho-educational workshop to gain insight and explore the experience of couples waiting for and accessing the IVF clinic. The outcome data would help to generate hypotheses and contribute to future research and intervention design.

The current research questions were;

a) What can psychological models add to understanding the process occurring in the NHS infertility experience and to understanding the feasibility of the piloted intervention?

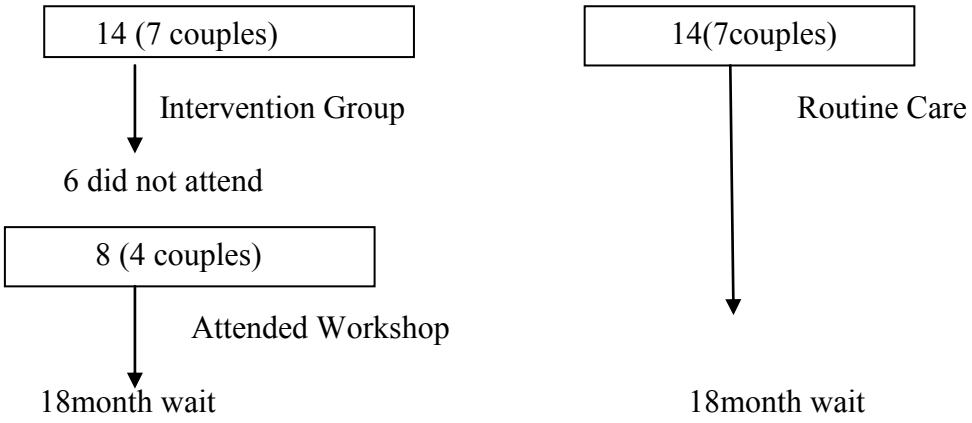
b) What can psychological models contribute to generating hypotheses about who could benefit and what interventions should be further developed and researched?

METHOD

Participants

Of the 14 couples who consented seven couples were invited to attend the workshop and seven matched couples had routine care (see flow chart 2 in Figure 5). Six participants failed to attend the workshop i.e. 57% attendance rate of those invited but this is only 6% of those on the waiting list.

Figure 5: **Flow Chart 2**



Six cases from the original cohort gave permission for ongoing data collection and contact. The cases consisted of two couples (four cases) who attended the workshop; one couple who did not and had routine care (two cases). Two of the couples (one in the workshop and one in the routine care) had the same medical cause of infertility (reduced sperm quality) while the third couple had "unexplained infertility". One couple was of mixed heritage.

The Intervention

The procedure is described next.

Workshop Group

- "Routine" medical consultant support/information/prior to allocation to waiting list then no contact from hospital.
- Introduction to the project via letter and following consent a one-to-one interview. An appropriate battery of psychometric questionnaires taken away to complete within 4 weeks. Invitation by post to the workshop.
- Attendance at workshop and given post-IVF questionnaires to take away.
- Call to undertake IVF procedure (expected between 4-18 weeks depending on position on waiting list) with routine pre-medical intervention and potential access to counselling service.
- Post IVF cycle 1 repeated measures plus pregnancy outcome.
- Questionnaire to ask for patient's views on what they would have liked to help them cope with the experience from both the workshop and the fertility clinic

Routine Care Group

- "Routine" medical consultant support/information/prior to allocation to IVF waiting list then no contact from hospital.
- Introduction to the project and following consent a one-to-one interview. An appropriate battery of psychometrics taken away to complete within 4 weeks while on the waiting list.
- Sent standard health promotion advice on "Healthy Living" by post with post-IVF questionnaires and instructions.
- Call to undertake IVF procedure (expected between 4-18 weeks depending on position on waiting list) with routine pre-medical intervention and potential access to counselling service
- Post IVF cycle 1 repeated measures plus pregnancy rate.
- Questionnaire to ask for patient's views on what they would have liked to help them cope with the experience

Workshop Content

Education about stress and coping were provided using a modified Mind/Body programme (Domar 2000a; Domar 2000b) updated with elements of compassion-focused CBT (Gilbert, 2009). The workshop met Boivin's (2003) criteria for a "Comprehensive Educational Programme" to allow comparability across studies. Similar components were used in the workshop as those previously identified as effective from research and the final content was based on the outcome of an extensive literature review.

- Educational/Information Component

  Overview of research on fertility and stress (psychological and physiological)

  Primary Care Trust funding, fertility clinic systems and success rates

- Compassion Focussed CBT Model

  Old brain/new brain emotional effects

  Old brain /new brain physical effects and benefits of relaxation and exercise.

  Cognitive restructuring, including kindness and self soothing.

  Cognitive options exercise.

The Case Study Protocol

Some qualitative research such as Grounded Theory is open-ended, investigative and uses data to generate concepts. The emphasis in this qualitative approach was to use the existing research in a conceptual framework. A multiple case study design was used to explore the phenomenon of interest (participant's experience) and to test the theoretical/conceptual framework within the NHS. The method proposed by Yin (1984, 1994, 2002) was deemed suitable for a variety of reasons. It allowed the principles of action research (Hughes, 2008) (including reflection, boundaried systems in a changing environment, being cyclical and practical) to be combined with a phenomenological approach (Willig, 2008) (using stories,

lived experiences and meaning).Yin's method provides a research structure which allows previous theory to be applied in a situation of flux. The conceptual framework anchors the study and by defining and testing rival interpretations can help explore why and how things happen.

The principles recommended by Yin (2003) were followed

- Existing theoretical models can be used. *A template of characteristics from four models was developed.*

- The analysis relied on all the evidence. Five sources were taken into account collected, structured and analysed. These were: *interviews, direct observation, physical artefacts (psychometric instruments), participant observation (feedback forms) and questionnaires.*
- All rival interpretations were included. *Summary tables of data collected and word tables were used to aid interpretation of the results and explore all rival interpretations using triangulation against a variety of specific models.*
- The most significant aspect of the case study was addressed. *There is a narrative for each case with a common format and the most significant aspect for each case is analysed against current psychological models drawn from literature and clinically based conceptual framework.*

In addition Yin (1994) suggests a number of ways in which the method can be used to generate and demonstrate validity. Internal validity is strengthened by using multiple sources of evidence for convergence. Construct validity is strengthened by using appropriate measures for the concepts. External validity is strengthened by using rival theories and replication logic. Finally reliability is strengthened through stability, accuracy and precision of measurement supported by reflexivity and peer supervision.

Procedure

The approach was to **bind** the six cases sampled by using previous selection criteria and the experience of the participant was set on the same pathway or **operating framework**. In addition each case was part of a couple and the medical diagnosis was known. Cases were followed over two years for a longitudinal approach to events.

A systematic way of observing the event was used (interviews/postal comments / standardised scales and questionnaires).

A common format was used to analyse information and data and to allow reporting on process and outcome of the experience (Appendices 5&6). Finally, data was **triangulated** against four **psychological models** using a **proforma** (Appendix 5). The models used are drawn from the literature and directly linked to the **conceptual framework**. Their characteristics are set out in the template described in Table 5. Evidence was sort from the data to both support and contradict potential formulations of each case from the perspective of each of the four models.

In the results section the data is reported as multiple case reports, each presented individually before being summarised together.

Table 4: The Characteristics of Four Psychological Models (Template)

Major Characteristics of	Psychological Models
Lazarus & Folkman **Transactional Stress Cognitive Model** *Coping is seen as an individualised experiment with a range of emotions* *It is influenced by state and trait.* *It is influenced by cognitive appraisal and individual attribution of causality and significance.* *It is thinking and doing in a specific context with Affect/Behaviour/Cognitions Structure.* **COGNITIVE Model of Stress Management** **Evidenced by changes in cognitive appraisal and coping**	**Kubler-Ross** **Stages Model of Grief** *Coping is seen as a Process.* *The context is personal loss.* *It can be operationalised under Stages* *Emotional reactions described through Stages* • *Denial* • *Anger* • *Bargaining* • *Depression* • *Acceptance* **A PROCESS model of adaptation to loss over time which is evidenced by emotional changes in stages**
Gilbert **Compassion Focussed Cognitive Model** *Cognitive appraisal is linked to Old Brain /New Brain(autonomic nervous system)* *The Brain has evolved for survival & reproduction with evolutionary factors (fight/flight-High Anxiety / Anger).* *Emotional reaction is normal when there is a loss or threat* *The stress response and context distort thinking style.* *It highlights self-criticism and low level self soothing.* **COGNITIVE Model of Stress Management** **Compassion –focussed CBT which emphasises changes in self-soothing evidenced by active development of self kindness and mindful awareness**	**Wagnild** **Resilience Concepts Model** *The Process of Adapting to the Emotional and Physical Stress Response is itself Strengthening.* *It is Context Specific.* *It is influenced by state and trait and operationalised under concepts of* • *Self Reliance* • *Meaning* • *Equanimity* • *Perseverance* • *Existential Aloneness* **A PROCESS model of competence despite adversity and is evidenced by resilience becoming strengthened by experience**

RESULTS

Case Study Data

Each case is described in a vignette using the same structure. For each, a formulation was produced against all four of the psychological models and evidence to support or contradict the model for that case was sought from all the data. The evidence was analysed and triangulated against each formulation using the proforma (Appendix 5). This allowed exploration of the model and how well it formulated the experience in each case. Finally these themes and the relative strengths of the various models are drawn together. The case study raw data and word charts are in Appendix 6.

Case Study 1

Background

Ann was happily married and had been trying to conceive for three years. Medical investigations at the local hospital for reduced fertility had been inconclusive and a diagnosis of "Unexplained Infertility" was given.

First Interview and Data Collection

Ann said as no reason was found this created mixed feelings. Having no medical problem and being placed on a waiting list for NHS funding for IVF was a relief but also depressing, particularly because the timescale for the funding allocation was unknown. At first interview Ann had been on the waiting list for five months and her BDI score for depression was 18 (Table 1.1 mild / moderate).

Ann also expressed concern about the unknown waiting period in view of her age which was 30 years. She felt this made her more vulnerable as her fertility would be reducing naturally. There was a difference in her reporting of trait anxiety (49, moderate) compared to state (55, table 1.1) reflecting her current anxiety with the situation. Ann saw herself as being

strongly resilient (RS score 79) and was behaving proactively by telephoning the NHS Primary Care Trust main office in an attempt to gain further funding and timescale information. She queried whether contributing to the research project would increase access to the IVF funding but was still happy to participate as it may help others.

Intervention

Ann attended the "Preparation for IVF" workshop with her husband and on her evaluation form (Appendix 4) indicated she found it helpful (5/6); suitable (6/6) and it changed her cognitive style from overly optimistic to realistic and comforting (verbally reported during workshop) and that she saw the situation in a different light (7/7).

Postal Report/Opinion Questionnaire

The funding became available after 12 months and Ann attended the IVF clinic's three hour evening induction session. Feeling unwell at this meeting staff at the clinic performed a scan and Ann discovered she was already two weeks pregnant.

Final Interview and Data Collection

Ann did not return to the IVF clinic and gave birth naturally to a healthy baby. During interview Ann explained the workshop had helped her cope with the waiting period by her understanding the fight /flight reaction of the "Old "brain. She had taken up swimming and yoga to add to the kinder thinking style. Although the wait was a dilemma, in her set of circumstances she felt it allowed her body to conceive naturally.

Repeated BDI score for depression showed a reduction and the reliable change index (Table 1.1) showed this was significant .The STAI-s Anxiety score was no longer in the clinically significant range of moderate anxiety reducing to mild (43) but the change was not statistically significant. Her score on Resilience remained unchanged.

Table 1.1: Case 1 Scores on Pre and Post Measures with Reliable Change Index

Measure	Pre	Post	Comment	Reliable Change Index
Beck Depression Inventory	**18**	**2**	Level of depression initially clinically mild/mod range then significantly improved	#SEM 2.12 S Diff 2.99 RCI -5.34 **Achieved** <-1.96 p<.05
Spielberger Trait Anxiety Inventory	**49**	**47**	Trait anxiety above average with little change	#SEM 3.43 S Diff 4.84 RCI -0.41 **Not Achieved** (p> .05)
Spielberger State Anxiety Inventory	**55**	**43**	State anxiety improved from moderate to mild clinically but change below statistical significance	#SEM 4.55 S Diff 6.43 RCI -1.87 **Not Achieved** (p> .05)
Wagnild Resilience Scale 14	**79**	**79**	Resilience Quotient remains same but self reliance subset improves	#SEM 2.55 S Diff 3.61 RCI 0.0 **Not Achieved** (p> .05)

Triangulation of evidence to link information from case 1 to theoretical models

Relevant data was collated from all sources, i.e. the interviews, postal report and items endorsed on the questionnaires, and is set out in the Table 1.2 (Appendix 6). This evidence was used to both support and contradict each psychological model in addition to the information in the vignette. The principal that the most significant aspect of the case should be addressed was used to ascertain whether current psychological models can formulate the situation and outcome.

Formulations with outcomes based on the models and evidence

Applying Wagnild's Model of Resilience to Case one suggested the following formulation; *Ann has the characteristics of strong resilience so will report responding to stressors well/will find ways to adapt and the outcome of the experience will be improved resilience.*

Evidence to support this model included Ann's report that she used knowledge and skills from the workshop adding to her strong resilience (1st item of evidence in favour). There was a change in reported self-reliance after coping with the experience (2nd item of evidence in favour). She said she had had difficult experiences before (3rd item of evidence in favour). However several pieces of information were found which refuted this model. Having strong resilience would not explain the consistently high trait anxiety Ann described and state anxiety plus mild/moderate depression in the situation (1st item of evidence against the model) nor why the overall resilience scores before and after were not improved by the experience (2nd item of evidence against) Her subsequent reported loss of confidence was also contradictory (3rd item of evidence against).

The formulation using Folkman and Lazarus Transactional Stress Model was;

Ann is cognitively appraising the experience which has strong significance and she has developed a situational stress reaction reflected in increased anxiety from her trait level and reactive mild/moderate depression, a situation that will improve with awareness of and changes to cognitive style and positive changes to the situation.

Evidence to support this model included consistent levels of high trait anxiety yet she reported changes in cognitive appraisal immediately so that her attempt at an unrealistically optimistic cognitive style was replaced after the workshop which improved her ability to cope during the waiting period (1st in favour). She also tried using/experimenting with other new coping strategies suggested by the course such as exercise (2nd in favour). Her state anxiety and depression scores reduced at the end of the experience (3rd in favour).However against this the final outcome of a live birth could explain the reduction in state anxiety and depression score irrespective of the variety of other contributing transactional factors such as

cognitive "style" influencing appraisal(1st against). No other items of evidence were found to refute the model.

The Kubler-Ross Model of Loss and Grief gave the following formulation; *Emotional changes experienced are a grief reaction due to loss of normal fertility and potential loss of an anticipated future as a parent and will resolve on acceptance of the situation irrespective of outcome.*

The range of emotions initially described; anger at the funding organisation; the original bargaining position in the first interview with the researcher; significant depression scores on completing the questionnaires after the first interview would fit with this model (1st in favour).The grieving process was terminated with the natural pregnancy (2nd in favour). There are reported changes in cognitive style accepting the situation directly after the course before continuing on the waiting list and before successful pregnancy (3rd in favour). However in challenging this theory the reported changes in cognitive style rather than reflecting acceptance could simply be linked to attending the workshop as Ann claims (1st against).There are improvements in scores describing emotions but these could just be a function of successful pregnancy not the process of developing acceptance(2nd against).

Gilbert's Compassion –focussed CBT model was also used to formulate; *Ann's emotional response is created by insufficient self-soothing in a painful situation and reported cognitions about disappointment in self combined with old brain fight and flight stress reaction and will improve with awareness of cognitive style and improved self-soothing plus physical management of the bodies stress reaction.*

Evidence supporting this includes the reported change in thinking style which allowed more productive self-soothing and self kindness while on the waiting list so counteracting the autonomic nervous system response (1st in favour), plus physical activity and relaxation

helped influence the fight/flight response to a threat (2nd in favour). Anxiety and depression scores became below clinically significant levels as Ann reported continuing to self-sooth after the birth of her child (3rd in favour). Contradictory evidence was that a pre-workshop questionnaire indicated that she felt that she did not criticise herself more than usual (1st against).

Summary and implications

All models had something to contribute. In spite of high trait anxiety Ann's resilient responsiveness meant she was able to use the cognitive and behavioural changes from the workshop .The issue of loss and grief reactions contributed some understanding but only with part of the experience. The two cognitive models had stronger evidence.

The most significant issue was that Ann reported coping well while on the waiting list and became pregnant naturally. She had" unexplained infertility". The significance of this and its implication for further research is dealt with further in the discussion section.

Case Study 2

Background

Andrew was aged 29 and happily married. He and his wife had been trying to conceive for three years. Medical investigations at the local hospital for reduced fertility had been inconclusive and a diagnosis of "Unexplained Infertility" was given.

First Interview and Data Collection

As no clinical reason was found he reported mixed feelings. Having no medical problem was a relief but waiting for access to the IVF clinic created a dilemma in particular as the timescale for the funding allocation was unknown and he was concerned that if they decided to self fund one cycle themselves it would mean one cycle rather than two would be available on the NHS.

At first interview Andrew and his wife had been on the waiting list for five months and his BDI score for depression was 10 (table 2.1 minimal). There was a difference in his reporting of state anxiety compared to trait (45 and 52) indicating his current anxiety as moderately high with the situation. Andrew saw himself as low on resilience (RS score 61) but was phoning the NHS Primary Care Trust main office in an unsuccessful attempt to get further funding and timescale information. He queried whether contributing to the research project would increase access to the IVF funding but was still happy to if not as he agreed with his wife that it may help others.

Intervention

Andrew attended the" Preparation for IVF "workshop with his wife and on his evaluation form indicated he found it somewhat helpful (4/6); suitable (6/6) and it changed his cognitive style so that he saw the situation in a different light (7/7).

Postal Report/Opinion Questionnaire

The funding became available after 12 months on the waiting list but the NHS locally which had funded two cycles was changing to funding only one in the next financial year so the clinic organised a large group three hour induction meeting for some of those already on the waiting list. Andrew attended with his wife who was feeling unwell at the time so staff at the clinic performed a scan and to his delight discovered she was two weeks pregnant already naturally.

Final Interview and Data Collection

Andrew and his wife did not return to the IVF clinic and she gave birth naturally to a healthy baby. During interview Andrew explained he had used the waiting time after the course to keep fit. Although the wait was a dilemma, he felt it allowed them to conceive naturally as there had been nothing wrong medically with them both.

Repeated BDI score for Depression showed no change (both scores clinically minimal table 2.1).The state Anxiety score was lower (52/46) but still in the significant range of clinically moderately high. His Resilience score had reduced (61/56) rather than improved and but was still in the lower than average range. No scores showed significant change with the reliable change index (table 2.1).

Table 2.1 Case 2 Scores on Pre and Post Measures with Reliable Change Index

Measures	Pre	Post	Comment	Reliable Change Index
Beck Depression Inventory	**10**	**11**	Level of depression initially minimal and no change clinically	#SEM 2.12 S Diff 2.99 RCI 0.33 **Not Achieved** RCI(>1.96)
Spielberger Trait Anxiety Inventory	**45**	**50**	Trait anxiety above average then increased to moderately high clinically but not statistically significant	#SEM 3.43 S Diff 4.84 RCI 1.03 **Not Achieved** (p> .05)
Spielberger State Anxiety Inventory	**52**	**46**	State anxiety remains clinically moderately high no significant improvement	#SEM 4.55 S Diff 6.43 RCI -0.93 **Not Achieved** (p> .05)
Wagnild Resilience Scale 14	**61**	**56**	Resilience Quotient remains low and drops after event but not statistically significant	#SEM 2.55 S Diff 3.61 RCI -1.39 **Not Achieved** (p> .05)

#Standard Error of Measurement

Triangulation of evidence to link information from case 2 to theoretical models

As in case 1 relevant data from all sources (Table 2.2 Appendix 6) and the vignette was used to support and contradict each psychological model.

Formulations with outcomes based on the models and evidence

Applying Wagnilds Model of Resilience to case 2 suggested the following formulation;

Andrew has the characteristics of low resilience so will not respond to stressors well initially but the outcome of the experience will be improved resilience.

Evidence to support this model included that Andrew described his trait anxiety as moderately high (1st in favour) and state anxiety moderately high (2nd) before and after the experience reflecting ongoing low resilience. His view was that he was not reliable (3rd). However Andrew said he used knowledge and skills from the workshop yet the overall resilience scores before and after were not improved by the experience and it's positive outcome (1st against) nor reflected in his reported confidence (2nd).He still viewed himself as not reliable (3rd).

The formulation using Folkman and Lazarus Transactional Stress Model was; *Andrew is appraising the experience and has developed a situational stress reaction which will improve with better coping strategies; positive changes to the situation or continue after the event if he maintains his self critical cognitive style.*

Evidence to support this model included his cognitive style of self-criticism and worry which remained unchanged and so his state anxiety remained high in spite of a positive outcome(1st) and he had altered his reported trait score up to synchronise with the previous state score(cognitive dissonance)(2nd). The situation had changed and it had a very positive outcome i.e. natural conception but this in itself made no difference to the final stress reaction while his self appraisal remained unchanged (3rd).However against this the situation had a positive outcome but this change made no difference to final levels of stress reaction (1st against).He reported thinking more positively after the course (2nd) and reported doing more exercise to cope (3rd) yet there was no reduction in anxiety.

The Kubler-Ross Model of Loss and Grief gave the following formulation; *Emotional changes experienced are a grief reaction due to loss of normal fertility and potential loss of*

an anticipated future as a parent and will resolve on acceptance of the situation irrespective of outcome.

The only evidence for this model is that Andrew demonstrated bargaining at first interview (1st in favour).Against this model the range of emotions did not include reported depression or anger over the experience (1st).There were no clinical improvement in anxiety scores even though the loss issue was resolved (2nd) and he reported positive cognitive appraisal of situation (3rd).

Gilberts Compassion –focussed CBT model was also used to formulate; *His emotional response is created by insufficient self-soothing in a painful situation shown by reported cognitions about disappointment in"self"combined with old brain fight and flight stress reaction to a threat and will improve with awareness of cognitive style and improved self-soothing plus physical management of the bodies stress reaction.*

Evidence supporting this includes his reported change in thinking style to positive rather than self-soothing as advised which is reflected in anxiety remaining high even after the event (1st in favour).There is an ongoing reported emphasis on personal failure (2nd) and a reported reduction in confidence and ongoing low reliability (3rd). No evidence could be found to refute this model.

Summary and implications

All models had something to contribute but grief reactions the least. Cognitive appraisals about self and low self soothing were the most relevant factors. There appeared low characteristics of resilience throughout the experience with no improvement and constant self criticism; in particular the view of not being dependable which meant that in spite of the reported use of cognitive and behavioural changes from the workshop his opinion of himself did not change.

The most significant issue was that Andrew reported coping well while on the waiting list by thinking positively rather than self soothing. His wife became pregnant naturally but his opinion of himself appeared unchanged and he still had clinically significant levels of anxiety. Cognitive dissonance seems also to have aligned his trait anxiety higher to the clinical state level. The significance of this and its implication for further research is dealt with in the discussion section.

Case Study 3

Background

Beverly was 30 yrs old and happily married. She had been trying to conceive for three to four years. Medical investigations at the local hospital for reduced fertility had indicated problems with her husband's sperm quality.

First Interview and Data Collection

Having a firm place on a waiting list for NHS IVF was a relief in particular as the timescale for the funding allocation was unknown. At first interview Beverly had been on the waiting list for 12 months already and her BDI score for depression was 2 (table 3.1 clinically minimal).

Beverly also expressed concern about the unknown waiting period in view of her age which was 30years.She felt this made her more vulnerable as naturally her fertility may be reducing though medically she had no problem. There was a slight difference clinically in her trait anxiety score of 40 compared to state of 35 (table 3.1 above average/below average) reflecting her current low anxiety with the situation, as it was her husband who needed medical help not her. She was pleased that IVF was an option. Beverly saw herself as having strong resilience (RS score 87). She queried whether contributing to the research project would increase access to the IVF funding but was still happy to if not as she said it may help

others. She commented that while she is on the waiting list she feels abandoned and they don't know what is happening.

Intervention

Beverly attended the" Preparation for IVF "workshop with her husband and on her evaluation form indicated she found it only somewhat helpful (2/6); suitable (4/6) but it changed her cognitive style (reported) to seeing the situation actually more negatively. The information on clinic success rates contributed to this as the hospital had not given her this information.

Postal Report/Opinion Questionnaire

The funding became available after a further 12 months and Beverly attended the IVF clinic with her husband. She was told that IVF would not work with the current quality of her husband's sperm. She was not medically approved to undertake the IVF procedure.

Final Interview and Data Collection.

During interview Beverly explained the clinic had suggested donor sperm which surprised her but then that baby would not have been her husband's child which he wouldn't accept. She found this distressing as not conceiving was not her fault and she was encouraging her husband to consider paying and trying different clinics with her as well as taking medication from the GP to try and improve the quality of his sperm.

Although initially the workshop had not helped, she said she had been initially unrealistically optimistic, and looking back she had now changed her opinion. She commented that the workshop had been helpful in preparing her (5/6) and helped her look at the situation in a more constructive different light as she was still problem solving (5/7).She was relieved her husband's family couldn't blame her for the infertility.

Repeated BDI scores for depression remained the same (2) at minimal levels (table 3.1) though both trait (49) and state (46) anxiety scores increased to clinically moderately

high when she was discharged from the clinic. She was now in a dilemma about her marriage. State anxiety scores increased from 35 to 46 (table 3.1 below average to moderately high).Beverly continued to see herself as strongly resilient both before and after the experience (87/81).Although the mood scores moved to clinically significant categories the reliable change index did not show significance.

Table 3.1: Case 3 Scores on Pre and Post Measures with Reliable Change Index

Measure	**Pre**	**Post**	Comment	**Reliable Change Index**
Beck Depression Inventory	**2**	**2**	Level of depression initially clinically minimal and no change	#SEM 2.12 S Diff 2.99 RCI 0.0 **Not Achieved** RCI(>1.96)
Spielberger Trait Anxiety Inventory	**40**	**49**	Trait anxiety above average and increased to clinically moderately high not statistically significant	#SEM 3.43 S Diff 4.84 RCI 1.86 **Not Achieved** (p> .05)
Spielberger State Anxiety Inventory	**35**	**46**	State anxiety clinically below average increased to moderately high but not statistically significant	#SEM 4.55 S Diff 6.43 RCI 1.71 **Not Achieved** (p> .05)
Wagnild Resilience Scale 14	**87**	**81**	Resilience Quotient remains strong with no significant change	#SEM 2.55 S Diff 3.61 RCI -1.66 **Not Achieved** (p> .05)

Standard Error of Measurement

Triangulation of evidence to link information from case 3 to theoretical models

As in the previous cases relevant data from all sources (Table 3.2 Appendix 6) and the vignette was used to support and contradict each psychological model.

Formulations with outcomes based on the models and evidence

Applying Wagnilds Model of Resilience to case 3 suggested the following formulation;

Beverly has the characteristics of strong resilience and so will report responding to stressors well/will find ways to adapt and even if there is bad news of not being suitable for IVF treatment the outcome of the experience will be improved resilience.

Evidence to support this model included the following .Her depression score was not changed by bad news (1st in favour) and although the stress was ongoing the resilience score remained the same and as she wanted to keep trying and exploring further options (2nd). She reported using coping strategies from previous difficult situations initially then some from the workshop when there was further bad news (3rd).However pieces of information were found which refuted this model. In spite of strong scores for resilience continuing both state and trait anxiety scores had increased (1st against model) and she had more mixed opinions i.e. feeling both satisfied with self but also inadequate and self critical (2nd).

The formulation using Folkman and Lazarus Transactional Stress Model was;

Beverly's appraisal of the situation at the beginning of the pathway is that there is a problem that can be solved but she has no responsibility for it so she will not experience strong situational stress however if the situation changes and there is a poor prognosis and marital dilemma this will create a stress reaction as her cognitive appraisal becomes more critical of the situation and self.

Evidence to support this model included her original score on state anxiety. This was below average then increased to clinically moderately high as the significance of not having a solution to the problem became apparent and her appraisal changed (1st in favour). Previous successful coping was used and some advice from the preparation course as the situation became more challenging (2nd). She reported that cognitions at the end of the care pathway were more mixed with her opinion of herself being satisfied but also feeling inadequate and

being more self critical (3rd).This fits with the ongoing experience and mixed issues .No evidence for contradictions to the model were found.

The Kubler-Ross Model of Loss and Grief gave the following formulation; *Beverley does not initially perceive a loss just a problem that is solvable but if the solution is blocked by both clinic and her husband this will create a grief reaction due to the potential loss of her marriage and an anticipated future as a parent.*

Beverley showed no significant anxiety or depression initially as she thought IVF was the solution (1st in favour) then as the situation evolved and her losses became a stronger possibility, the stage of denial began and was reflected in her insistence that clinics abroad would be more successful in spite of strong medical evidence to the contrary (2nd).The anger at her husband and the clinical changes in anxiety scores showed the stages of grief developing (3rd).No evidence to contradict this model could be found.

Gilberts compassion –focussed CBT model was also used to formulate the experience; *Beverley had sufficient self-soothing initially with consequent low emotional reaction to the stressful situation but with some of her cognitions based on optimism rather than perspective and kindness if the problem becomes unsolvable then the painful situation will become more challenging, with stronger emotional reactions should self soothing not be maintained.*

Evidence supporting this was that Beverley's initial thinking style was optimistic with some self-soothing which is reflected in initial low depression scores (1st in favour) .Then anxiety increased after the realistic prognosis was received at the clinic but self soothing also continued with questionnaire responses such as" I am friends with myself"(2nd).As self soothing continued depression scores remained unchanged "It's not my fault"(3rd).For this model there was also contradictory evidence in that there was reported self-criticism at the final contact yet no change in scores for depression(1st against).

Summary and implications

All models had something to contribute to understanding the complexity of the experience and processes. Beverley's behaviour reflected persistence and strong resilience. Her appraisal of the situation changed as the significance to her became clearer with information on donor sperm and she started to realise she had a potential loss of both parenthood and her marriage. She showed the stages of denial and bargaining. Her ability to self –sooth helped her cope emotionally throughout the pathway.

The most significant issue was that Beverly reported coping while on the waiting list but lacked information about the likely outcome and the options .The course alerted her to the low success rates generally but she had had no opportunity to think through future possibilities with her husband in particular those that she and her husband would disagree on such as donor sperm. The significance of this and its implication for research is dealt with further in the discussion section.

Case Study 4

Background

Brian was aged 34, happily married and living with his wife and parents. He and his wife had been trying to conceive for three to four years and were distressed that all their friends had become pregnant. Investigations for reduced fertility had identified sperm quality as the medical issue.

First Interview and Data Collection

Brian felt they were helpless and in the dark waiting for access to the IVF clinic as the timescale for the funding allocation was unknown, they had no contact with the hospital and they wondered if the researcher could speed up access or give them information. At first interview Brian was relieved to have a referral for IVF but had been on the waiting list for a

year already. His BDI score for depression was 7 (Table 4.1 minimal). There was no difference in his state anxiety compared to trait (30 and 31) both of which were below the clinical cut off point (39). Brian saw himself as low on resilience characteristics (RS 68).

Intervention

Brian attended the" Preparation for IVF "workshop with his wife and on his evaluation form initially indicated he found it somewhat helpful (3/6); somewhat suitable (3/6); but was not at all confident it would help before or after or during IVF procedure (1/7) and it made no difference to whether he saw the situation in a different light (3/7).

Postal Report/Opinion Questionnaire

His main concern was the lack of communication and not being in the loop of information about waiting times. The funding became available after another 12 months on the waiting list. His opinion of the course had changed slightly over the waiting period in that he now felt it had helped him somewhat (3/6) during the distressing clinic appointment.

Final Interview and Data Collection

Brian explained that the clinic had said all his sperm were dead so they would be unable to perform IVF and his options were donor sperm or adoption. He had felt neither option was acceptable as the child would not be his. The clinic had discharged him without support. He said his original reaction was devastation and anger and that he couldn't have coped without the support of his parents. He was very critical of the level of information given about semen levels and his options. His GP was reluctantly trying some medication to see if it improved sperm quality so he was still trying but was not willing to pay and go to another clinic. He felt all clinics had the same success rate and that having had a life threatening experience a few years before, his perspective was that he was lucky to have his own life even if he doesn't have children.

This had created a strain within his marriage as he didn't want donor sperm nor to adopt someone else's child. He said if his wife couldn't accept the situation she should divorce him and he would understand.

Final repeated BDI for Depression showed no change (Table 4.1 both scores minimal).The trait and state Anxiety scores had increased with the state score now above average clinically. The Resilience score had improved but was still low (68/73).

Table 4.1: Case 4 Scores on Pre and Post Measures with Reliable Change Index

Measure	Pre	Post	Comment	Reliable Change Index
Beck Depression Inventory	**7**	**8**	Level of depression clinically minimal and no change	#SEM 2.12 S Diff 2.99 RCI 0.33 **Not Achieved** RCI(>1.96)
Spielberger Trait Anxiety Inventory	**30**	**35**	Trait anxiety no change both below average	#SEM 3.43 S Diff 4.84 RCI 1.03 **Not Achieved** (p> .05)
Spielberger State Anxiety Inventory	**31**	**41**	State anxiety initially below average increased to clinically mild but not statistically significant	#SEM 4.55 S Diff 6.43 RCI 1.56 **Not Achieved** (p> .05)
Wagnild Resilience Scale 14	**68**	**73**	Resilience Quotient no change remains below average	#SEM 2.55 S Diff 3.61 RCI 1.39 **Not Achieved** (p> .05)

Standard Error of Measurement

Triangulation of evidence to link information from case 4 to theoretical models.

As in the previous cases relevant data from all sources (Table 4.2 Appendix 6) and the vignette was used to support and contradict each psychological model.

Formulations with outcomes based on the models and evidence.

Applying Wagnilds Model of Resilience to case 4 suggested the following formulation;

Brian has the characteristics of below average resilience but has had previous near death experience which could give him perspective and meaning, if so he will cope with the painful situation about his fertility and the outcome of this experience will be improved resilience.

Evidence to support this model was that depression score was not changed by bad news (1st item in favour) and he has below average trait anxiety. His state anxiety increased only slightly to above average because he said his life had meaning without children (2nd) and previous challenging experiences had given him perspective (3rd). However several pieces of information were found which refuted this model. In spite of scoring below average on resilience he did not show a significant stress reaction initially to the situation with both state and trait anxiety scores and depression being low (1st evidence against) and scores only slightly raised after the disappointing experience (2nd). In spite of previous significant stressors this was not reflected in a strong resilience score (3rd).

The formulation using Folkman and Lazarus Transactional Stress Model was;

Brian's appraisal of the significance of the situation at the beginning of the pathway is that there is a problem that could be solved /that his own health is more important than having children and that his family support him irrespective of the outcome so this would help him with coping strategies throughout the experience but if the final prognosis is poor with a lack of options the changing situation with his wife would be reflected in a reappraisal and increased anxiety about his future.

Evidence to support this model included Brian's initial cognitive appraisal of the situation and ongoing support which was reflected in clinically insignificant scores in anxiety (1st item).After the experience at the clinic there was an increase in level of anxiety from below

average to clinically mild (2nd). There was no change in depression as a stress reaction throughout the process reflecting his ongoing family support (3rd).No items were found to refute this model.

The Kubler-Ross Model of Loss and Grief gave the following formulation;

Brian initially perceived no loss just a problem that was solvable but if the outcome is that all solutions are blocked this will create a delayed grief reaction due to potential loss of an anticipated future as a parent or as a husband.

In favour of this model was the absence of significant depression (1st item) or anxiety (2nd)then as the experience evolved and his potential loss became clearer he denied the significance and expressed anger by suggesting his wife divorce him if she can't adapt(3rd) . His previous health experience and current close family support could mitigate against the significance of any loss to him which contradicts this model (1st against).

Gilberts Compassion –focussed CBT model was also used to formulate;

Brian has sufficient self-soothing initially with consequent low emotional reaction to the situation but if the problem becomes unsolvable the painful situation will become more challenging but his ongoing self-soothing which is reinforced by significant others supports a lower emotional reaction.

The reported initial thinking style from Brian was optimistic with some self-soothing which was reflected in a mild increase in anxiety after the realistic prognosis was received (1st in favour) but depression scores remained the same as self soothing continued with his parents active encouragement (2nd).Depression score didn't change in spite of acknowledging concerns about his future and appreciating his wife's differing views (3rd).No evidence was found to refute the model.

Summary and implications.

All models had something to contribute to understanding the complexity of the processes though the two cognitive models and early stages of grief were more helpful.

The most significant issue was that Brian's wait on the list was a waste of time and how the clinic gave him options that had been unknown and unacceptable to him. This created a marital dilemma. The significance of this and its implication for research is dealt with further in the discussion section.

Case Study 5

Background

Carol was 31 yrs old and had been living with her partner for many years. She had been trying to conceive for three to four years. Medical investigations at the local hospital for reduced fertility had indicated problems with her partners' sperm quality.

First Interview and Data Collection

Being placed on a waiting list for NHS funding for IVF was a relief but also worrying in particular as the timescale for the funding allocation was unknown. At first interview Carol had been on the waiting list for 10 months already and her BDI score for depression was clinically minimal (table 5.1;score7). Carol also expressed concern about the unknown waiting period in view of her age which was 31yrs but also because of her partners age as he was 50 yrs. She felt this made them both more vulnerable as naturally fertility may be reducing though medically she had no problem at the moment. There was no difference in her state anxiety compared to trait (Table 5.1;scores 50 and 49) but the score indicated her current moderately high clinical anxiety with the situation as it was her partner who needed medical help not her but she was pleased that IVF was an option. Carol did not see herself with strong

characteristics of resilience (RS60). She commented that no-one informed them of what was happening while they were on the waiting list and she had felt abandoned.

Intervention

Carol was not randomly allocated a place on the preparation workshop so was sent educational leaflets on healthy lifestyle including alcohol and dietary advice.

Postal Report/Opinion Questionnaire

The funding became available after a further 12 months and Carol attended the clinic with her partner. One successful embryo was created at the clinic only and though Carol was pleased she said she was hoping for two. Unexpectedly she was told by the clinic that IVF was too risky to perform at that moment as a scan had shown she had a polyp which would interfere with implantation so the embryo was frozen (though funding for this needed clarifying first) while she was referred back to the NHS hospital to wait for treatment.

Final Interview and Data Collection

During interview Carol was still waiting for medical help with the polyp and felt in limbo as even after this procedure she would have to allow a recovery period before returning to the fertility clinic. She felt she was unable to think through other options such as donor sperm nor prepare herself. The clinic had offered access to a counsellor which she hadn't taken up. The experience she said had brought her and her partner closer and she commented that he had been extremely supportive.

Repeated BDI scores for depression showed clinical change from minimal to moderately high and reliable change index showed significance (Table 5.1 increased 7 to 22). Both the trait and state anxiety scores increased and again reliable change index showed significance. State anxiety scores increased from 49(moderately high) to 64(high) and trait similarly from 50 to 62.Trait and state became aligned. Carol saw herself as less resilient at the final data

collection point with both scores before and after the experience remaining below average (RS 60 and 48).

Table 5.1: Case 5 Scores on Pre and Post Measures with Reliable Change Index

Measures	Pre	Post	Comment	Reliable Change Index
Beck Depression Inventory	**7**	**22**	Level of depression clinically minimal then increases significantly to moderately high	#SEM 2.12 S Diff 2.99 RCI 5.01 **Achieved** RCI(>1.96) P <.05
Spielberger Trait Anxiety Inventory	**50**	**62**	Trait anxiety moderately high and increased to high statistically significant	#SEM 3.43 S Diff 4.84 RCI 2.47 **Achieved** RCI(>1.96) P <.05
Spielberger State Anxiety Inventory	**49**	**64**	State anxiety moderately high increased to high Statistically significant	#SEM 4.55 S Diff 6.43 RCI 2.33 **Achieved** RCI(>1.96) P <.05
Wagnild Resilience Scale 14	**60**	**48**	Resilience Quotient remains low and falls statistically significantly	#SEM 2.55 S Diff 3.61 RCI -3.32 **Achieved** RCI(< -1.96) P <.05

Standard Error of Measurement

Triangulation of evidence to link information from case 5 to theoretical models.

As in the previous cases relevant data from all sources (Table 5.2 Appendix 6) and the vignette was used to support and contradict each psychological model.

Formulations with outcomes based on the models and evidence

Applying Wagnilds Model of Resilience to case 5 suggested the following formulation;

Carol has the characteristics of low resilience so will not respond to stressors well initially but the outcome of the experience will be improved resilience.

Evidence to support this model included Carols moderately high trait and state anxiety at the beginning of the experience (Table 5.1) reflecting low scores on resilience (1st in favour) but at final data point both state and trait anxiety were further increased reflecting ongoing low resilience as the experience was continuing (2nd). Her depression score significantly increased as she saw the experience as only part way through with further waiting (3rd). In contradiction to this model Carol repeatedly reported that her previous experience of difficult times had not proved to her that she could cope well (1st against) as she didn't experience improved resilience as an outcome. She attributed coping to the support of her partner (2nd).

The formulation using Folkman and Lazarus Transactional Stress Model was; *Carol's appraisal of the situation at the beginning of the pathway was that there was a problem that could be solved and it was her partners but as she depended on him to cope herself this relationship influenced her appraisal and she also experienced situational stress with him then as the situation became more challenging to her personally her stress reaction increased as she reappraised the unresolved situation.*

Carol initially had above average scores on both trait and state anxiety due to the significance of the situation which would support the model (1st item in favour) but she also appraised the problem as solvable through IVF and other options so depression level was clinically minimal (2nd). There was a significant rise in all these scores when the challenges in the situation became prolonged and the medical problem became hers (3rd). There was no evidence to contradict the model.

The Kubler-Ross Model of Loss and Grief gave the following formulation; *Initially no loss was perceived by Carol just a problem that was solvable then the experience of delay and additional medical issues created a grief reaction due to the potential loss of an anticipated future as a parent.*

The raised anxiety and depression scores could be stages of grief and evidence to support this model (1st in favour) but against this there was no evidence of denial or anger (1st against). Carol sees the experience as still ongoing and has already considered other options for a family should IVF not be successful.

Gilberts Compassion –focussed CBT model was also used to formulate; *Carols emotional response was created by insufficient personal self-soothing in a stressful situation and when the medical problem became hers and prolonged, the experience became more challenging and without self soothing the stress response became stronger*.

Carol reported her initial thinking style was dominated by worrying thoughts with little self-soothing (1st evidence in favour) which is reflected in both initial trait and state anxiety levels (2nd). She showed increases in worrying thoughts and significant changes in her depression score(Table 5.1) during the additional personal medical complications(3rd). There was no evidence to contradict the model.

Summary and implications

All models except for the "Stages of Grief" had something to contribute to understanding the complexity of the process. Carol did not have advice on self-soothing cognitive coping styles or stress management strategies. She was also reliant on her partner to cope and support her. The most significant issue was that Carol's pathway was prolonged and had additional challenges compounded by funding worries and new waiting lists. The significance of this and its implication for research is dealt with further in the discussion section.

Case Study 6

Background

Colin was 50 yrs old and had been living with his partner for many years. They had been trying to conceive for three to four years. Medical investigations at the local hospital for reduced fertility had indicated problems with his sperm quality.

First Interview and Data Collection

Being placed on a waiting list for NHS funding for IVF was a relief but the timescale for the funding allocation was unknown. At first interview Colin had been on the waiting list for 10 months already and his BDI score for depression was 7(Table 6.1 clinically minimal). Colin also expressed concern about the unknown waiting period in view of both their ages. He felt this made them both more vulnerable as naturally fertility may be reducing though medically his partner had no problem. There was no difference in his reported score of state anxiety compared to trait (Table 6.1; 47 and 51) but both scores reflected his current moderately high anxiety with the situation. Colin did not see himself with strong characteristics of resilience (RS 60) at this point. He commented that no-one informs them of what is happening while they are on the waiting list and he felt abandoned.

Intervention

Colin was not randomly allocated a place on the preparation workshop so was sent educational leaflets on healthy lifestyle including alcohol and dietary advice.

Postal Report/Opinion Questionnaire

The funding became available after a further 12 months and Colin attended the IVF clinic with his partner. One embryo was created successfully at the clinic with his sperm and though Colin was very pleased, his partner was hoping for two embryos. Colin reported he would have appreciated information on donor sperm. His partner was then told by the clinic that

IVF was too risky to perform as a scan had shown she had a polyp which would interfere with implantation so the embryo was frozen while she was referred back to the hospital for treatment. They did not undertake the IVF procedure and are on a waiting list for medical treatment of the polyp having already waited three months.

Final Interview/ Data Collection.

Colin was pleased that an embryo had been created and frozen for future IVF.

Repeated BDI scores for depression showed no change (Table 6.1; scores 7 and 6). Both trait and state anxiety scores had decreased significantly. State anxiety scores decreased to below average from 51 to 30 and trait from 47 to 32.Trait and state became aligned (cognitive dissonance). Colin saw himself as now having very strong characteristics of resilience at the final data collection point with significant change in scores from RS 60 to RS 94.

Table 6.1: Case 6 Scores on Pre and Post Measures with Reliable Change Index

Measures	Pre	Post	Comment	Reliable Change Index
BDI	**7**	**6**	Levels of depression both clinically minimal	#SEM 2.12 S Diff 2.99 RCI -0.33 **Not Achieved** RCI(>1.96)
STAI-t	**47**	**32**	Trait anxiety moderately high and decreased below average statistically significant	#SEM 3.43 S Diff 4.84 RCI -3.09 **Achieved** RCI(< -1.96) P <.05
STAI-s	**51**	**31**	State anxiety clinically moderately high then significantly decreased to below average	#SEM 4.55 S Diff 6.43 RCI -3.27 **Achieved** RCI(< -1.96) P <.05
RS14	**60**	**94**	Resilience Quotient low and significantly increases to very high	#SEM 2.55 S Diff 3.61 RCI 9.4 **Achieved** RCI(>1.96) P<.05

Triangulation of evidence to link information from case 6 to theoretical models.

As in the previous cases relevant data from all sources (Table 6.2 Appendix 6) and the vignette was used to support and contradict each psychological model.

Formulations with outcomes based on the models and evidence

Applying Wagnilds Model of Resilience to Case 6 suggested the following formulation:

Colin had the characteristics of low resilience so will not respond to stressors well initially but the outcome of the experience will be improved resilience.

Evidence to support this model included Colin's initial description of himself (table 6.1) as having low resilience and high trait and state anxiety (1st item of evidence in favour) with worrying thoughts and feelings of inadequacy (2nd) then after coping with the part of the pathway that involved him medically his score on resilience changed to very strong (table 6.1; RS 64 to 94 achieved RCI). The experience had been strengthening for him and his emotional state was improved in spite of the outcome still being unknown (anxiety significantly reduced table 6.1 RCI) and in spite of the challenge that still remained (3rd in favour). There were no items to refute the model.

The formulation using Folkman and Lazarus Transactional Stress Model was;

Colin's appraisal of the situation at the beginning of the pathway involved thoughts of inadequacy and failure and his stress reaction was initially a reflection of *this but he was able to contribute physically to a positive outcome of the IVF experience so the significance to him changed as well as his self appraisal and was reflected in an improved ability to cope with situational stress and an improved emotional state.*

Evidence to support this model was Colin's initial self critical and worrying comments (1st in favour) and his moderately high clinical scores (Table 6.1) on trait and state anxiety (2nd item of evidence). There was a reliable significant reduction in these scores (Table 6.1

RCI), as well as trait aligning to state as his challenges in the situation were overcome and reappraised in spite of further complications and prolongation of the experience (3rd)**.** No items were found to refute this model.

The Kubler-Ross Model of Loss and Grief gave the following formulation; *initially no personal loss was perceived just a problem that might be solvable with IVF then with the experience of delay and his partner's additional medical issues, a grief reaction was triggered for the potential loss of an anticipated future as a parent.*

No evidence was found to support this model. There was evidence to contradict as his significantly improved emotional scores developed in spite of increased risk of loss with additional medical problems and only one embryo being produced. (1st against).

Gilberts Compassion –focussed CBT model was used to formulate;*Colin's emotional response was created by insufficient self-soothing in a painful situation with reported cognitions about self-blame combined with strong expectations of support from his partner in the stressful situation but when the problem becomes prolonged and also less painful as his medical procedure was successful, the situation becomes less personally challenging and allows the development of self soothing cognitions and his stress reaction to reduce.*

Colin's reported initial thinking style was dominated by worrying, self criticism and with little self-soothing (1st item of evidence in favour) which was reflected in initial trait and state moderately high anxiety scores (Table 6.1 2nd item of evidence). After the successful procedure complimentary self talk increased (Appendix 6), opinion on resilience changed and emotional well-being significantly improved (Table 6.1 RCI achieved) in spite of prolongation of the experience and overall unknown outcome (3rd item). To contradict this model anxiety and resilience significantly improved even though there was evidence of ongoing self-criticism (1st against).

Summary and implications

All models except the "Stages of Grief" had something to contribute to understanding the complexity of the processes. Colin did not have advice on cognitive coping/self soothing or stress management strategies nor information on the medical option involving donor sperm. Some of his self talk changed throughout the experience

The most significant issue is that Colin's personal medical pathway was shortened when there was an embryo produced and the additional medical challenges became his partners. His opinion of his own resilience increased greatly as he continued to support his partner. The significance of this and its implication for research is dealt with further in the discussion section.

Overall Summary of All Cases

The relative strengths of the models are summarised in Table 6. The transactional and compassion-focussed cognitive models were the strongest and were more generalisable across cases.

Table 5: **Summary of evidence for psychological models per case**

		1	2	3	4	5	6
Resilience Model (RS)	+	3/3	3/3	3/3	3/3	3/3	3/3
	-	3/3	3/3	2/3	3/3	2/3	0/3
Transactional Stress Model (TSM)	+	3/3	3/3	3/3	3/3	3/3	3/3
	-	1/3	3/3	0/3	0/3	0/3	0/3
Stages of Grief Model (GF)	+	3/3	1/3	3/3	3/3	0/3	0/3
	-	2/3	3/3	0/3	1/3	1/3	0/3
Compassion Focus CBT Model (CFCBT)	+	3/3	3/3	3/3	3/3	3/3	3/3
	-	1/3	0/3	1/3	0/3	0/3	1/3
Strongest		TSM CFCBT	CFCBT	TSM CFCBT GF	TSM CFCBT GF	TSM CFCBT	RS TSM CFCBT
Weakest			GF			GF	GF

DISCUSSION

The research literature though international is largely set in the USA health context and has predominantly focussed on women, those already attending fertility clinics and affluent participants (De Liz & Strauss, 2005). It does suggest the effectiveness of psychosocial interventions for infertility on well-being and possibly pregnancy rates but it also describes only a 10-15% uptake of some interventions such as counselling (Boivin et al, 1999).

This study described a cohort of participants in a UK context, who were on the NHS IVF waiting list and who expressed a wish to access information about a psycho-educational workshop at this time on the pathway. It then used conceptually based psychological models to explore this experience of waiting, ascertaining the fit of each model to the characteristics

of each of a series of cases. In this section, the analysis of the experience against models was used to explore implications for research and generate hypotheses around what is the best choice of intervention at this time, for whom and why.

Description of Responders

Describing those in the state-funded UK context in phase 1 gave the following information. Patients in this study were self-selecting. Indeed of 122 invited, only 28 completed initial questionnaires (22%). Although this raises questions about whether there were differences between those who participated and those who did not participate, it is useful information about those who were more motivated. It profiles those who are willing to seek further information about the intervention and /or consider the learning of new coping skills as being important for helping to manage distress before accessing a clinic. This is important when attempting to assess the feasibility and acceptability of an intervention.

Contrary to most of the literature the profile describes a cohort with a mixed range of educational levels and the mixed heritage of an UK urban population. On average the female responders scored higher clinically on distressed mood scores than the male participants as might be expected from the existing research on gender differences in the reporting of distress (Griel, 1997) although this difference was not statistically significant. Also within the cohort 18% overall had clinically significant scores for depression with female 29% (BDI score 19 and above) in comparison to the literature describing 11%; 39% had moderate state anxiety (STAI score above 46); and 43 % reported lower than average resilience while 39% said they felt strongly resilient at this time.

Contextual Issues

During the period of the study a number of significant UK national health policy changes took place. Some health districts stopped funding IVF totally and the waiting times in others

increased considerably, including in the location for the current research. There were also proposals to reduce the number of cycles funded and to implement changes in eligibility criteria, creating additional strain.

Case Studies

The data using the reliable change index and clinical significance criteria provided information useful for aiding clinical analysis against the psychological models identified by the conceptual framework. This was used to point to possible components of interventions for future investigation.

Summarising the usefulness of the psychological models for formulation, the analysis indicates that the cognitive models, both the transactional stress model and compassion-focussed CBT, had best fit and this points to the suggestion that future research should concentrate on evaluating a range of ways to alter appraisals, and enhance cognitive coping rehearsal and self-soothing.

This range of ways could be tailored to specific categories of patients with specific reasons for infertility as highlighted by the "issues of significance for each case". Participants, with sperm quality issues commented for example on the need for pre-clinic information on donor sperm and, looking at their experience against the models, the consequences of not understanding the issues are an additional stressor.

Other significant issues highlighted in the experience of waiting were the potential ability to conceive naturally while on the waiting list, the importance of using self-soothing strategies when self-criticism was strong, the effect of the lack of information on options when semen quality was the main stressor and its potential for marital conflict/marital support, and the additional burden of unknown waiting times.

From the analysis firstly it is proposed that those couples who have unexplained infertility are treated as unique at this point on the care pathway and that an intervention for this group could have either the components of a Compassion-Focussed CBT model intervention or Transactional Stress CBT Model.

Secondly to allow anticipatory coping and within-couple discussion of the significance of donor sperm, information on this option could be provided before attending the fertility clinic and could be evaluated in terms of improving resilience/well-being and marital communication.

Thirdly it is proposed there is low feasibility and acceptability of a generic preparatory workshop as an intervention in this context with such a mixed group of medical problems in spite of being on the pathway to the same medical procedure.

Additionally in considering issues raised previously by the literature review this study also highlights the following.

Levels of distress

One of the key strengths of the present research was its focus on participants before they accessed the IVF clinic and it suggests that they have similar or higher levels of distress to that reported in the literature (Cwikel et al, 2004).

Psychological Interventions for Stress

Infertility may be viewed as a psychosocially constructed life crisis and in this study both cognitive models for coping with stress (Lazarus & Folkman, 1984; Gilbert, 2009) gave insight into the experience and pointed to new hypotheses.

Infertility and Psychological Interventions

In spite of the mixed research literature there is a small body of evidence to show that psychological interventions produce beneficial effects (Boivin, 2003).This study points to the

next stage in developing more specific complex interventions in community settings(Campbell, 2000)

Complementary and Alternative Medicine

This study did not directly address this issue but once the further research suggested is piloted then more evidence-based guidance on self-help may be possible.

Physiological mechanisms behind stress interventions

Research proposed by this study (Table 8) would allow the biological pathway to be investigated further.

Problems with case studies and limitations of this study

This study had limitations. Conceptually it concentrated on self-reliance in a specific context not personal existential concepts or self esteem.

Despite their valuable qualities, there can be problems with single case studies. These include the fact that exploratory case studies (such as the current series) may lead to premature conclusions because of inadequate representations of diversity of the phenomenon studied.

Yin (1984; 1994) refutes this criticism by explaining the difference between analytic generalisation and statistical generalisation. In statistical generalisation, an inference is made about a population on the basis of empirical data collected from a sample. In analytic generalisation, a previously developed theory is used as a template with which to compare the empirical results of the case study (Yin, 2002). Furthermore, to ensure trustworthiness of the analysis, he suggests the use of multiple sources of evidence within a framework and this evidence be used to analyse different and contradictory perspectives. Case studies (as opposed to efficacy studies/RCTs) can be important for generating rather than testing new hypotheses.

RECOMMENDED FUTURE RESEARCH

It is proposed that a variety of interventions are considered for research while couples are awaiting access to the fertility clinic as it is suggested that one intervention may have low feasibility and may not meet the needs of all on the waiting list. These are set out in Table 8 below

Table 8: **Research Proposed**

Who	**Unexplained Infertility (25%)**	**Semen Quality (30%)**	**Other**
What	**Transactional stress or compassion-focussed CBT model workshop**	**Information on a)success rates b)donor sperm c)couple problem solving**	**Information on waiting time**
Why	**To sustain coping To reduce physiological effects of stress To increase pregnancy rate before IVF**	**To increase anticipatory coping To improve resilience To develop options awareness jointly by the couple**	**To increase resilience and sustained coping**
How	**Pre-intervention well-being assessed Intervention provided Multi-centre or extended time period for numbers**	**Specific psycho-educational paper literature which includes information on donor sperm option and success rates / CD ROMs**	**Phone or electronic system**
Hypothesis	**Pregnancy outcomes before and after IVF are improved if the psychological and physiological stress reactions are reduced in both partners**	**Additional information improves anticipatory coping and transactional cognitive reappraisal resulting in improved resilience / well-being and marital agreement or understanding**	**Information on waiting time reduces feeling helpless or abandoned and resilience and sustained coping is increased**

Participants should be selected for research studies in terms of medical reason for reduced fertility rather than the medical procedure they are waiting for. The specific point on the pathway (**when**) should be immediately following placement on the waiting list.

Results from the case studies suggest that three interventions could be investigated, piloted and evaluated. For those with unexplained infertility it is proposed that there is an investigation looking at reduction in distress and self-soothing during the waiting period and how this may contribute to physiological improvement and reduction in biological stress markers. Secondly information about donor sperm could be piloted with couples. Assessment would then look for any subsequent changes in the meaning of the situation for couples and if it facilitates anticipatory coping by helping them prepare for their range of options. Thirdly systems that would help sustain the coping process over significant timescales warrant evaluation.

The context of the NHS and issues such as mixed populations accessing private fertility clinics plus variability of funding makes previous world-wide research less generalisable to specific contexts which this study seeks to direct.

REFERENCES

Abbey, A., & Halman, L.J. (1995).The role of perceived control, attributions and meaning in members of infertile couple's well-being. *Journal of Social and Clinical Psychology,* 14,271-296.

Baram, D., Tourtelot, E., Muechler, E., & Huang, K. (1988). Psychological adjustment following unsuccessful in vitro fertilization. *Journal Psychosomatic Obstetrics Gynaecology*, 8,181-186.1988.

Beck, A. T. (1961). An Inventory for Measuring Depression. *Arch.Gen.Psychiatr*, 4,561-571.

Beck, A.T., Steer, R.A., & Brown, G.K. (1996). Manual for the Beck Depression Inventory-II. San Antonio, TX: Psychological Corporation.

Boivin, J., & Takefman, J.E. (1995).Stress levels across stages of in vitro fertilisation in subsequently pregnant and nonpregnant women. *Fertility and Sterility,* 64,802-810.

Boivin, J. (2003).A review of psychosocial interventions in infertility. *Social Science & Medicine*, 57, 2325-2341.

Boivin, J., Shoog-Svanberg, A., Andersson, L., Hjelmstedt, A., Bergh, T., & Collins, A. (1998). Stress level in men undergoing intracytoplasmic sperm injection (ICSI) versus in vitro fertilization (IVF). *Human Reproduction,* 13, 1403-1406.

Boivin, J., & Schmidt, L. (2009).Use of complementary and alternative medicines associated with a 30% lower ongoing pregnancy/live birth rate during 12 months of fertility treatment. *Human Reproduction,* 1(1), 1-6.

Boivin, J., Scanlon, L.C., & Walker, S.M.(1999).Why are infertile patients not using psychosocial counselling? *Human Reproduction*, 14, 1384-1391.

Brown, J., Cochrane, R., & Hancox, T. (2000).Large scale health promotion stress workshops for the general public: A controlled evaluation. Behavioural and *Cognitive Psychotherapy*, 28(2), 139-151.

Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A.L., Sandercock, P., Spielgelhalter, D., & Tyrer, P. (2000). Framework for design and evaluation of complex interventions to improve health. *British Medical Journal*, 16 (321), 694-696.

Connolly, K. J., Edelman, R. J., Bartlett, H., Cooke, I. D., Lenton, E., & Pike, S. (1993). An Evaluation of counselling for couples undergoing treatment for in-vitro fertilization. *Human Reproduction*, 8, 1332-1338.

Cousineau, T. M., Lord, S.E., Seibring, A.R., Corsini, E.A., Viders, J.C., & Lakhani, S.R. (2004). A multimedia psychosocial support programme for couples receiving infertility treatment: a feasibility study. *Fertility and Sterility*, 81 (3), 532-538.

Cruess, D. G., Antoni, M. H., McGregor, B. A., Kilburn, K. M., Boyers, A. E., Alferi, S. M., & Kumar, M. (2000). Cognitive-behavioural stress management reduces serum cortisol by enhancing benefit finding among women being treated for early stage breast cancer, *Psychosomatic Medicine*, 62(3), 304-308.

Cwikel, J., Gidron, Y., & Sheiner, E. (2004).Psychological interactions with infertility among women. *European Journal Obstetric Gynaecology Reproduction Biology*, 117,126-131.

Daniluk, J.C. (1988). Infertility: intrapersonal and interpersonal impact. *Fertility and Sterility*, 49,982-990.

De Liz, T.M. & Strauss, B. (2005). Differential efficacy of group and individual /couple psychotherapy with infertile patients. *Human Reproduction*, 20(5), 1324-1332.

Demyttenaere, K., Bonte, L., Gheldof, M., Vervaeke, M., Meuleman, C., Vanderschuerem, D., & D'Hooghe, T.(1998).Coping style and depression level influence outcome in in-vitro fertilization. *Fertility and Sterility*, 69, 1026-1033.

Domar, A.D., & Dreher, H. (1996). Healing Mind Healthy Woman. New York: Henry Holt.

Domar, A.D., Rooney, K.L., Weigand, B., Oray, E.J., Alper, M. M., Berger, B.M., & Nikolovski, J. (2011).Impact of a group mind/body intervention on pregnancy rates in IVF patients. *Fertility and Sterility*, 95(7), 2269-2273.

Domar, A.D., Clapp, D., Slawsby, E.A., Dusek, J., Kessel, B., & Freizinger, M. (2000a).Impact of group psychological interventions on pregnancy rates in infertile women. *Fertility and Sterility*, 73,805-811.

Domar, A.D., Clapp, D., Slawsby, E.A., Kessel, B., Orav, J., & Freizinger, M. (2000b).The impact of group psychological interventions on distress in infertile women. *Health Psychology*, 19,568-575.

Domar, A.D., Zuttermeister, P.C., & Freidman, R. (1993). The psychological impact of infertility: a comparison with patients with other medical conditions. *Journal of Psychosomatic Obstetrics Gynaecology*, 14, 45-52.

Domar, A. D., & Seibel, M.M. (1997). Emotional aspects of infertility. In Seibel, M.M. (Ed.) Infertility: A comprehensive text. Stamford: Appleton &Large.

Eugster, A., & Vingerhoets, A.J. (1999). Psychological aspects of in vitro fertilization: a review. *Social Science Medicine*, 48,575-589.

Folkman, S. (2000).Positive affect and the other side of coping. *American Psychologist*, 55(6), 647-654.

Freeman, E.W., Boxer, A.S., & Rickels, K. (1985). Psychological evaluation and support in a programme of in vitro fertilization and embryo transfer. *Fertility Sterility*, 43(1), 48-53.

Gilbert, P. & Procter, S. (2006). Compassionate mind training for people with high shame and self-criticism: Overview and pilot study of a group therapy approach. *Clinical Psychology and Psychotherapy*, 13, 353–379.

Gilbert, P. (2009).The compassionate mind: A new approach to life's challenges. London: Constable and Robinson.

Griel, A.(1997).Infertility and psychological distress: A critical review of the literature. *Social Science and Medicine*, 45, 1679-1704.

Hammarberg, K., Astbury, J., & Baker, H. (2001). Women's experience of IVF: a follow-up study. *Human Reproduction*, 16,374-383.

Horne, D.J., Vatmanidis, P., & Careri, A. (1994). Preparing patients for invasive medical and surgical procedures. 1: Adding behavioural and cognitive interventions. *Behavioural Medicine*, 20(1), 5-13.

Hughes, I. (2008). Action research in healthcare. In P. Reason & H. Bradbury (Eds.) Handbook for action research. London: Sage.

Klonoff-Cohen, H., & Natarajan, L. (2004). The concerns during assisted reproductive technologies (CART) scale and pregnancy outcomes. *Fertility Sterility*, 81(4):982-8.

Kubler-Ross, E., & Kessler, D. (2005). On grief and grieving: Finding the meaning of grief through the five stages of loss. London: Simon and Schuster.

Lancastle, D., & Boivin, J. (2008). A feasibility study of a brief coping intervention (PRCI) for the waiting period before a pregnancy test during fertility treatment. *Human Reproduction*, 23(10), 2299-2307.

Lazarus, R.S., & Folkman, S. (1984).Stress, appraisal and coping. New York: Springer.

Lazarus, R.S. (1999).Stress and emotion: A new synthesis. New York: Springer.

Lukse, M.P., &Vacc, N.A. (1999).Grief, depression and coping in women undergoing infertility treatment. *Obstetrics and Gynaecology*, 93(2), 245-251.

Luthar, S., & Cicchetti, D. (2000).The construct of resilience: A critical evaluation and guidelines for future work. *Child Development*, 71,543-562.

McCracken, L. M., & Eccleston, C. (2006). A comparison of the relative utility of coping and acceptance-based measures in a sample of chronic pain sufferers. *European Journal of Pain,* 10(1), 23-29.

Meichenbaum, D. (1996). Stress inoculation training for coping with stressors. *The Clinical Psychologist, 49,* 4-7.

Meichenbaum, D. (2007).Stress inoculation training: A preventative and treatment approach. In P. M. Lehrer, R. L. Woolfolk & W. S. Sime, (Eds.) Principles and practice of stress management (3rd Edition pp 497-518). New York: Guildford Press.

National Clinical Guidelines UK (2004) Fertility Guide CG11. http://publications.nice.org.uk/fertility-cg11.

Neenan, M. (2009).Developing resilience: A cognitive-behavioural approach. New York: Routledge.

Noor, K.B.M. (2008) Case study: A strategic research methodology. *American Journal Applied Science*, 5 (11), 1602-1604.

Schmidt, L., Tjornhoj-Thomsen, T., Boivin, J., & Nyboe Anderson, A. (2005). Evaluation of a stress management training programme for infertile couples. *Patient Education and Counselling*, 59,252-262.

Smeenk, J.M., Verhaak, C.M., & Stolwijk, A.M. (2004). Reasons for dropout in an in-vitro fertilization/intracytoplasmic sperm injection programme. *Fertility Sterility*, 81,262-268.

Spielberger, C.D. (1970). Manual for the State-Trait Anxiety Inventory. Palo Alto, California: Consulting Psychologist Press.

Strauss, B., & Brix, C.(2007).The influence of resilience on fatigue in cancer patients undergoing radiation therapy. *Journal of Cancer and Research in Clinical Oncology*, 133(8), 511-518.

Sundby, J., Olsen, A., & Schei, B. (1994).Quality of Care for infertility patients. An evaluation of a plan for a hospital investigation. *Scandinavian Journal of Social Medicine*, 22, 139-144.

Teasdale, J.D., Segal, Z.V., & Williams, J.M.G. (2000).Prevention of relapse/recurrence in major depression by Mindfulness-Based Cognitive Therapy. *Journal of Consulting and Clinical Psychology*, 68 (4), 615-623.

The UK Human Fertilisation and Embryology Authority (2007) Code of Practice and Implantation Guidance (2007). http://www.hfea.gov.uk/401.html

The UK Human Fertilisation and Embryology Authority (2007). Patients Guide to Treatment 2006/2007. http://www.hfea.gov.uk

The UK Human Fertilisation and Embryology Authority (2011). Fertility Treatment in 2010-trends and figures. http://www.hfea.gov.uk

Wagnild, G., & Young, H. (1993).Development and psychometric evaluation of the Resilience Scale. *Journal of Nursing Measurement*, 1(2), 165-178.

Wagnild, G. (2009).A review of the resilience scale. *Journal of Nursing Measurement*, 17(2), 105-113.

Willig, C. (2008) Introducing qualitative research in psychology. Phenomenological methods, 52-73. Open University Press.

Yin, R.K. (1984).Case study research: Design and methods. Newbury Park, CA: Sage

Yin, R.K. (1994). Case Study Research: Design and Methods. Thousand Oaks, CA: Sage Publications.

Yin, R.K. (1999). Enhancing the quality of case studies in health services research. *Health Services Research*, 24, 1209-1224.

Yin, R.K. (2002).Case Study Research: Design and Methods. Thousand Oaks, CA: Sage Publications (2nd edit).

PUBLIC DOMAIN BRIEFING DOCUMENT

A study exploring the added value and feasibility of psychological interventions for couples on a waiting list for IVF within the NHS care pathway.

LIVING WITH THE WAIT: A study exploring the added value and feasibility of psychological interventions for couples on a waiting list for IVF within the NHS care pathway.

Background

Sub fertility currently occurs in one in seven couples in Great Britain. Most sub-fertile patients especially women consider the assessment, evaluation and treatment of infertility to be the most upsetting experience of their lives. In this context, finding methods to reduce psychological distress and potentially improve outcomes is important.

Psychological interventions have shown promise in improving coping mechanisms but the research has been predominantly focused on those who have already accessed fertility clinics rather than those waiting to receive an appointment. This point on the care pathway was the primary focus of the study as well as exploring the experience of couples in this NHS context.

Aims of the study

The aim of the study was to use psychological models to better understand the experience of couples waiting for the clinical procedure in vitro fertilisation (IVF). The aim was also to explore whether a group psycho-educational workshop could give added value at this time. By using a recognised research framework it was intended to explore the relationship between **who** would benefit from **what** intervention and **why** at this interim stage of their journey on the infertility care pathway**.**

Method

The study had two parts. Firstly 28 participants were interviewed. Questionnaires were used to identify characteristics such as resilience and emotional well-being. A compassion-focused Cognitive Behaviour Therapy (CBT) workshop was provided to half of those who had responded from the waiting list. Part two of the study used a conceptual framework and involved following

six cases over two years, monitoring their experience and using a multiple-case study approach to explore and evaluate this experience.

Main Findings

The main findings were that the UK context seems to provide some unique stressors which need be considered in future research. Responses suggested that those participants who accepted the invitation from the waiting list had similar or higher levels of distress to that reported in the literature.

A generic psychosocial intervention at this time on the waiting list for IVF seemed to have low feasibility suggesting the target population is split into specific sub-categories for the purpose of future research. It is proposed that participants be selected for research studies in terms of medical reason for reduced fertility and its psychological significance to their experience rather than the medical procedure for which they are waiting.

Summary and Conclusions

Exploring individual experiences against psychological models provided insight and the generation of new hypotheses. It suggested that future research be commissioned to look at the effects of cognitive models on couples specifically with "Unexplained Reduced Fertility"; that future research investigate the relationship between provision of "Information on Donor Sperm" during the waiting period and its relationship to anticipatory coping; and finally that research should look at the effectiveness of improved information systems on sustained coping over extended periods of unknown waiting time

Appendices

Appendix 1

Search Strategies

Appendix 1

Search strategies for Medline and PsychINFO

MEDLINE SEARCH

Database: Ovid MEDLINE(R) <1950 to September Week 1 2008>

Search for: limit="2000 - 2008"

---

1. CONDITION KEYWORDS- Infertility or IVF

2. INTERVENTION TYPES- Psycho-Social Intervention or Group Intervention or psycho-education

3. PSYCHOLOGICAL THERAPIES- Cognitive Therapy or CBT

4. OUTCOMES- Stress or Psychological Stress.

Step 1: Combine keywords for condition and intervention types

Step 2: Combine step 1 with keywords for psychological therapies and outcomes.

PsychINFO SEARCH

Database: PsycINFO <1987 to September Week 3 2008>

Search for: limit="2000 - 2008"

---

1 CONDITION KEYWORDS- Infertility or IVF.

2. INTERVENTION TYPES- Psycho-Social Intervention or psycho-education or Group Intervention

3. PSYCHOLOGICAL THERAPIES- Cognitive Therapy or CBT

4. OUTCOMES - Stress or Psychological Stress.

Step 1: Combine keywords for condition and intervention types

Step 2: Combine step 1 with keywords for psychological therapies and outcomes.

Appendix 2

Description of Measures

Appendix 2

Description of Measures

POMS (Profile of Mood Scale)

The POMS is a validated measure designed to assess transient, fluctuating mood states .It consists of a questionnaire with 65 items measuring 6 mood states: tension, depression, anger, vigour, fatigue, and confusion. Items are rated on a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely).The alpha coefficients for internal consistency are high, ranging from 0.84 to 0.95 and the test-retest reliability coefficients from 0.65 to 0.74.The validity of the POMS has been supported by analyses of factorial, face, predictive and construct validity(McNair 1971).

BDI (Beck Depression Inventory)

The Beck depression inventory is a validated measure used to screen for clinical depression. It is a questionnaire with 21 items each rated on a four point scale ranging from 1 to 3.The maximum total score is 63 The score categories depend on the context but are usually in the ranges from minimal (0-13); mild (14-18); moderate (19-28) to severe (29-63). The test retest reliability of the BDI yields a coefficient alpha of .92 for an outpatient population (n = 500).

STAI (Spielberger State Trait Anxiety Scale)

The Spielberger Anxiety Scale is a validated measure of both stable and individual differences in anxiety-proneness and situation induced anxiety. It is a questionnaire with two parts. The range of scores for both parts is 20 to 80 and state anxiety usually has the cut off score at 39 with the score categories (39 -45) above average and (46-63) moderately high. The test-retest reliability for the trait scale ranges from 0.65 to 0.86 whereas the state scale is lower ranging from 0.16 to 0.62. Both state and trait scales have high construct validity ranging from 0.73 to 0.85(Spielberger 1970).

HAD (Hospital Anxiety and Depression Scale)

The HAD is a reliable instrument for detecting the presence and severity of anxiety and depression in hospital outpatient departments. It consists of 14 items each scoring from 0-3.

For anxiety (HADS-A) this has a specificity of 0.78 and a sensitivity of 0.9. For depression (HADS-D) this has a reported specificity of 0.79 and a sensitivity of 0.83(Zigmond 1983).

GHQ (General Health Questionnaire)

The General health Questionnaire is used to identify individuals with psychiatric problems or reduced psychological well-being. It was originally a 60 item instrument but there are now 4 shorter versions. Each item is rated on a 4 point scale

It has a high degree of internal consistency with Cronbach's alpha value of 0.37-0.79.Correlation coefficient are high (0.35-0.79) showing a high degree of sensitivity and specificity to the effects of treatment (Goldberg 1988).

KINT (Kognitionen bei Infertilitat)

(German interpretation)Principal component analysis revealed four factors showing adequate internal consistencies. These were scales related to stress-thoughts, emotion-focussed thoughts, problem focussed thoughts and thoughts of helplessness. Results were supported by confirmatory factor analysis and reliability analysis on data of a second sample. In validation, all four scales were correlated with depressive. Furthermore; different scales were related to external criteria, including specific coping strategies and resources(German translation)

FAI (Feelings about Infertility Questionnaire)

Non-standardised questionnaires and not referenced.

RS 14(Resilience)

This questionnaire has 14 items and covers five characteristics which include self reliance; meaning; equanimity; perseverance and existential aloneness. Each item is rated in a seven point scale and overall scores range from 14 to 98.The categories are 65 to 73(low resilience),74 to 81(moderate) and 82 to 90 (strong resilience).The scale has demonstrated internal consistency reliability with alpha coefficients 0.84 to 0.94.

RCI (Reliable Change Index)

Reliable change is a concept introduced by Jacobson, Follette and Ravensdorf (1984) and modified by Christensen and Mendoza (1986). Reliable change measures whether clinical

significant change has occurred in an individual undergoing therapy, and that the change is not due only to measurement error. "Clinical significant change" is change that has taken a person's score that is typical of a dysfunctional group, to a score in the "normal" population. Jacobsen and Truax (1991) suggest ways of calculating whether that change towards the functional group is large enough and reliable enough to be considered beyond error measurement. This calculation is called the Reliable Change Index (RCI) and is calculated by dividing the difference between the pre-experience and post-experience scores of the patient by the standard error of the difference between the two scores. If the RCI is greater than 1.96 ($P>.05$) then the difference is considered reliable and not only due to standard measurement error.

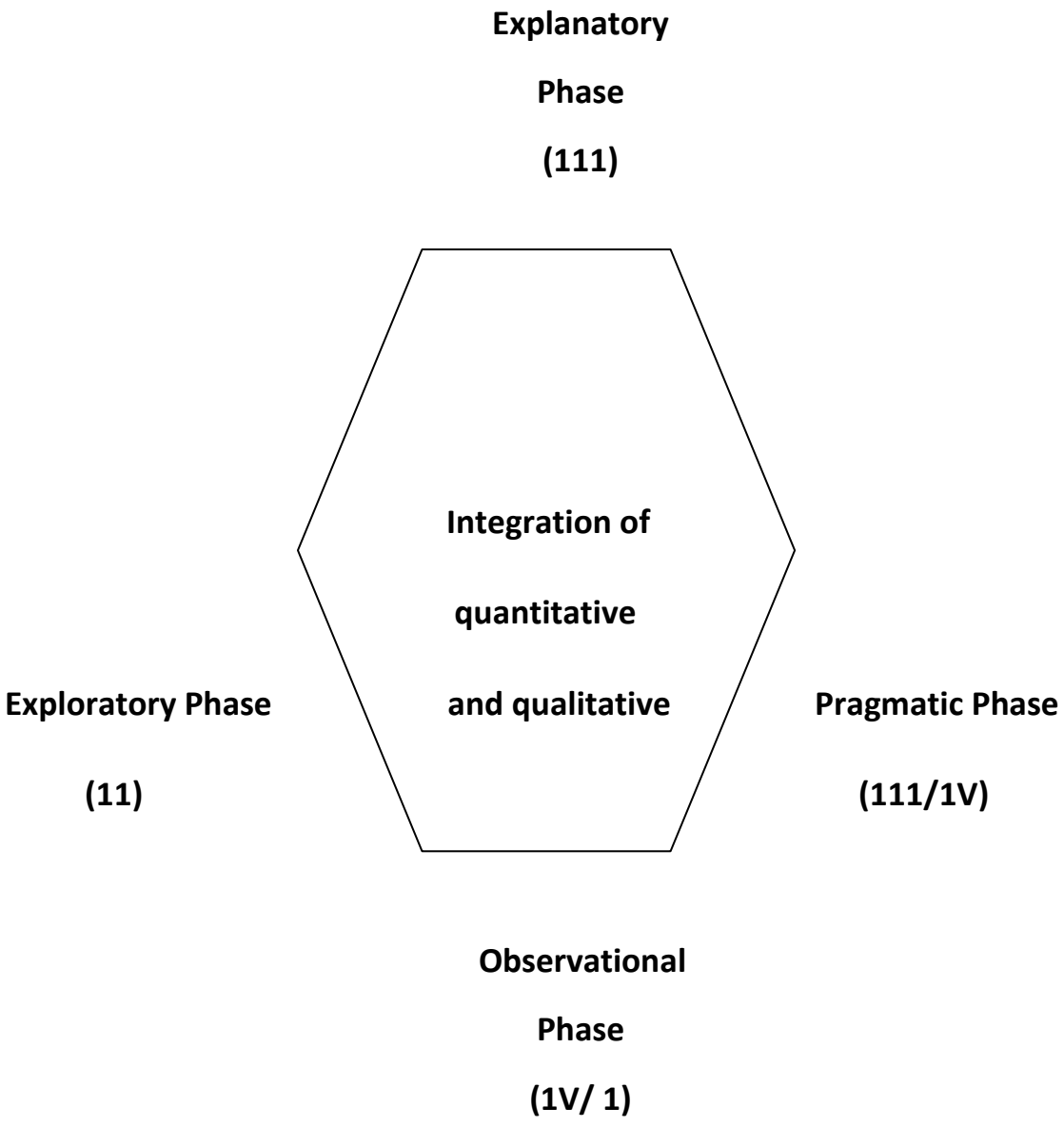
Appendix 3

Framework for Research Design: Figure 2

Appendix 3

Campbell, Fitzpatrick et al (2000)

Framework for Design and Evaluation of Complex Interventions to Improve health



The use of an iterative phased approach can harness qualitative and quantitative methods and lead to improved study design, execution and generalisability of results.

Appendix 4

Opinion Questionnaires

EVALUATION FORM 1

Instructions

For all the following questions, please circle a number that corresponds to the way you think and feel about the course/information you received. It is important that you are honest and that you answer all the questions.

1. **How helpful was the course you received?**

1 2 3 4 5 6
Not at all Somewhat Extremely

2. **In your opinion how suitable was the course to someone awaiting an IVF treatment appointment?**

1 2 3 4 5 6
Not at all Somewhat Extremely

3. **How confident are you that this intervention helped you cope DURING the IVF procedure?**

1 2 3 4 5 6
Not at all Somewhat Extremely

4. **How confident are you that this course helped you cope AFTER the IVF procedure?**

1 2 3 4 5 6
Not at all **Somewhat** **Extremely**

5. **Did the course help you look at the situation in a different light?**

1 2 3 4 5 6 7
Yes it made me see it more negatively **it made no difference** **yes it made me see it more positively**

6. **Would you change the course in any way?**

(1) No_____

(11)Yes_____

If yes please help us further and add your suggestions below

_____

_____

_____

AFTER IVF INTERVENTION CYCLE 1

A) How helpful was the information you received when you attended your appointment at the Fertility Services Clinic

1 2 3 4 5 6
Not at all **Somewhat** **Extremely**

B) In your opinion how supportive in general were the staff DURING the IVF intervention?

1 2 3 4 5 6
Not at all **Somewhat** **Extremely**

C) How confident are you that the information you received at the Fertility Services Clinic helped you cope AFTER the IVF procedure

1 2 3 4 5 6
Not at all **Somewhat** **Extremely**

D) In your opinion could the information you received when you attended your appointment at the Fertility Services Clinic be improved?

(1) No_____

(11)Yes_____

If yes please help us further and add your suggestions below

_____

_____

_____

E) What was the result for you of the IVF procedure cycle 1

1-Pregnancy_____

2-Unsuccessful this time_____

F) If the outcome was unsuccessful this time do you intend to;

1-definately return to the clinic and repeat the intervention _____

2-wait a while then return and repeat the intervention _____

3-not repeat the intervention _____

4-give myself sometime as I don't know what to do _____

EVALUATION FORM 2

Instructions

For all the following questions, please circle a number that corresponds to the way you think and feel about the experience /information you received. It is important that you are honest and that you answer all the questions.

AFTER IVF INTERVENTION CYCLE 1

G) How helpful was the information you received when you attended your appointment at the Fertility Services Clinic

1 2 3 4 5 6
Not at all **Somewhat** **Extremely**

H) In your opinion how supportive in general were the staff DURING the IVF intervention?

1 2 3 4 5 6
Not at all **Somewhat** **Extremely**

I) How confident are you that the information you received at the Fertility Services Clinic helped you cope AFTER the IVF procedure

1 2 3 4 5 6
Not at all **Somewhat** **Extremely**

J) In your opinion could the information you received when you attended your appointment at the Fertility Services Clinic be improved?

(1) No_____
(11)Yes_____

If yes please help us further and add your suggestions below

_____

_____

_____

K) What was the result for you of the IVF procedure cycle 1

1-Pregnancy_____

2-Unsuccessful this time_____

L) If the outcome was unsuccessful this time do you intend to;

1-definately return to the clinic and repeat the intervention _____

2-wait a while then return and repeat the intervention _____

3-not repeat the intervention _____

4-give myself sometime as I don't know what to do _____

Appendix 5

Proforma for Triangulating Evidence

Appendix 5

CASE No Triangulation of Evidence Implications

Resilience Model **(Wagnild)**	+				
	–				
Transactional Stress Model **(Folkman &Lazarus)**	+				
	–				
Model Stages of Grief **(Kubler-Ross)**	+				
	–				
Compassion-Focussed CBTModel **(Gilbert)**	+				
	–				

Appendix 6

Case Studies Raw Data

6a) One set as an example

6b) Summary word tables for all cases

Appendix 6b

Evidence for Cases/Word Tables (names are anonymised and used in results section)

Table 1.2 Responses of significance to the 4 theoretical models for Case 1 (Ann)

First contact	**End of Experience**
BDI	
I feel sad much of the time I am more discouraged about my future I am disappointed in myself I cry more than I used to I am so restless and agitated that it's hard to stay still I am more irritable than usual	I do not feel sad I am not discouraged about my future I have failed more than I should I have lost confidence in myself I don't cry anymore than I used to I am no more restless or wound up than usual I am no more irritable than usual
STAI	
I am worried- very much so	I am not at all worried over possible misfortunes Some unimportant thought runs through my mind and bothers me –very much so
RS 14	
I can get through difficult time because I have experienced difficulty before I can usually find something to laugh about	I usually manage one way or another
Interviews and Postal Report	
I have no idea how long we will have to wait I'm telling myself it will be fine but am anxious as the success rate is low I phoned unsuccessfully to find timescale and felt abandoned	I changed the way I looked at the situation and I had kinder thoughts. I tried swimming and relaxing with yoga

Table 2.2 Responses of significance to the 4 theoretical models for Case 2(Andrew)

First contact	**End of Experience**
BDI	
I feel sad much of the time I see a lot of failures I am more critical of myself than I used to be	I do not feel sad. I feel more discouraged about my future than I used to be. I have failed more than I should have. I have lost confidence in myself

I feel more restless and wound up than usual	I don't cry anymore than I used to. I am no more restless or wound up than usual I am much more irritable than usual
STAI	
I am presently worrying over possible misfortunes-very much so	I am somewhat worrying over possible misfortunes. I am moderately worried. I worry too much over something that really doesn't matter.
RS	
I usually take things in my stride. In an emergency I am not someone people can rely on.	In an emergency I am not someone people can rely on.
Interviews and Postal Report	
I have no idea how long we will have to wait I phoned unsuccessfully to find timescale so don't know where we stand and maybe two years/don't think they know themselves.	I changed the way I looked at the situation –I saw it more positively. I tried keeping fit. I found the course practical.

Table 3.2 Responses of significance to the 4 theoretical models for Case 3(Beverly)

First contact	**End of experience**
BDI	
I feel sad much of the time	I feel sad much of the time. I am more critical of myself than I used to be.

STAI	
I am not at all worried I am almost always satisfied with myself I do not feel difficulties are piling up. I almost never worry too much over things that don't matter I almost never have disturbing thoughts Unimportant thoughts don't bother me	I am very much worrying over possible misfortunes. I am very much satisfied with myself. I very much worry too much over things that don't matter. I very much feel inadequate. Unimportant thoughts very much bother me
RS	
I usually manage one way or another. I usually take things in my stride. I can get through difficult times because I've experienced difficulty before. I can usually find something to laugh about.	I usually manage one way or another I am friends with myself I can usually find something to laugh about.
Interviews and Postal Report	
I have no idea how long we will have to wait. No-one tells us anything. Others have been helped with IVF.	I found the course helpful overall I am in a dilemma as I want to keep trying. We could try clinics abroad but my husband doesn't trust them. It's not my fault.

Table 4.2 Responses of significance to the 4 theoretical models for Case 4(Brian)

Pre-	**Post-**
BDI	
I am not discouraged about my future. As I look back I see a lot of failures. I don't criticise or blame myself. I don't cry anymore than I used to. I am no more wound up or irritable than usual.	I do not feel sad. I feel more discouraged about my future than I used to be. As I look back I see a lot of failures. I am disappointed in myself. I am no more wound up or irritable than usual.
STAI	
I am not at all worried. I do not feel difficulties are piling up.	I am somewhat worried. I am very much satisfied with myself. I do not worry too much over things that

I almost never worry too much over things that don't matter. I almost never have disturbing thoughts. I don't feel inadequate. Unimportant thoughts don't bother me.	don't matter . I very much have disturbing thoughts. Unimportant thoughts don't bother me.
RS	
I am friends with myself. In an emergency I am someone people can rely on.	I am friends with myself. I can usually find something to laugh about. In an emergency I am someone people can rely on.
Interviews and Postal Report	
I have no idea how long we have to wait /we are in the dark. Friends are pregnant and the family want it too. No-one tells us anything. The workshop made no difference. I had stopped smoking	I found the workshop somewhat helpful I would not return to the IVF clinic. I found the clinic staff abrupt when they couldn't help. I do not want someone else's child. I am lucky to be alive. I have drunk less and eaten healthily. My wife is preoccupied with parenthood I couldn't cope without my parents support/they are pleased I am well. I was given insufficient information about donor sperm and on my options so it was a shock.

Table 5.2 Responses of significance to the 4 theoretical models for Case 5(Carol)

Pre-	**Post-**
BDI	
I do not feel sad I feel more discouraged about my future than I used to. I am more critical of myself than I used to be. I cry more than I used to.	I feel sad much of the time. I feel more discouraged about my future than I used to be. As I look back I see a lot of failures. I am disappointed in myself. I cry over every little thing

I am more irritable than usual.	I am more wound up and irritable than usual.
STAI	
I am very much worrying over possible misfortunes I am very much worried. I do not feel inadequate	I am very much worrying over possible misfortunes. I am very much worried I am not at all satisfied with myself. I very much feel like a failure. I worry too much over things that don't matter.
RS	
I usually manage one way or another. I am friends with myself. I can't get through difficult times because I have experienced difficulties before.	I don't usually take things in my stride. I can't get through difficult times because I have experienced difficulties before.
Interviews and Postal Report	
I have no idea how long we have to wait. I don't know what to expect.	I didn't receive any advice or help while on the waiting list I have carried on as normal but eaten healthily. I wish I had known it would take this long as the impression given is it would be quick once it starts. I can't prepare for my future while in limbo I wasn't clear about what we were eligible for from NHS funding and we had to ask about funding freezing embryos.

Table 6.2 Responses of significance to the 4 theoretical models for Case 6(Colin)

Pre-	**Post-**
BDI	
I feel sad much of the time. I feel more discouraged about my future than I used to. I am more critical of myself than I used to be.	I feel sad much of the time. I am not discouraged about my future I have failed more than I should have. I am more critical of myself than I used to be.
STAI	
I am somewhat worrying over possible misfortunes. I am somewhat worried. I feel somewhat like a failure. I feel somewhat inadequate. I almost never have disturbing or unimportant thoughts.	I am not worrying over possible misfortunes. I am not worried. I do not feel like a failure. I do not feel inadequate. I almost never have disturbing or unimportant thoughts.
RS	
I usually manage one way or another. I don't usually find something to laugh about.	I usually manage one way or another. I usually take things in my stride. I am friends with myself. I can get through difficult times as I've experienced difficulties before
Interviews and Postal Report	
I have no idea how long we have to wait.	I would have appreciated information on donor sperm.

Appendix 7

Research Ethics Approval

Appendix 8

Letter of Invite

Appendix 8 **logo deleted**

Invitation letter anonymised

11 August 2010

Dear

XXXXX NHS Services are committed to Providing High Quality Healthcare and we are currently looking at how to improve services to couples intending to undertaken In-Vitro Fertilization treatment (IVF). We are writing to you to invite you to participate in a small research project to investigate how to improve the effectiveness of this service and improve your experience.

The aim of the project is to evaluate whether additional preparation and advice before IVF treatment is helpful and to get user feedback on how to improve future services.

The research involves all participants completing questionnaires before and after the IVF treatment and some participants having access to additional advice and information

If you might like to take part then the researcher will meet with you briefly to explain the project more fully at which point you can decide whether to join the research or not.

Please reply in the stamped addressed envelope to indicate if you would be willing to speak with/meet the researcher and find out more without any obligation.

Yours sincerely

Mr -----

Consultant Obstetrician and Gynaecologist

Medical Director

PLEASE COMPLETE BELOW

Name: (capitals)_____

Address: (capitals)_____

_____

Postcode: _____

Telephone Number: _____

I am interested to learn more about the research project (Please tick a box)

Yes	
No	

Please return in the stamped addressed envelope to:

Appendix 9

Information Sheet

Consent Form

INFORMATION SHEET (Anonymised version)

A Study to Develop an Educational Self-help Programme to Support Coping with IVF Treatment

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study

If there is anything that is not clear or if you would like more information please ask.

Part 1:

Purpose of the study: The aim of the study is to investigate the helpfulness of the current information given to couples undertaking IVF and to identify if additional information would improve the experience

This will enable us to focus on the information which is important to couples and identify what helps them to cope with the procedure.

There has been some similar research done for other medical procedures. There is also an increasing amount of evidence from research in other countries that supporting couples to self-help might improve outcomes following IVF.

You have been invited to participate as you are on the waiting list for IVF procedure. We are aiming to recruit approximately 22 couples. Participation is entirely voluntary. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time without giving a reason. This would not affect your normal care in the Health Services.

If you agree to participate in the study, you will be asked to fill out 3 questionnaires. You will then be asked to fill out the same 3 questionnaires again plus additional questionnaires after you have completed IVF (total4). The questionnaires are straightforward and ask you about how you cope generally, how you are feeling and what is your opinion of the information you received as part of your care. They involve reading questions and ticking a box in response. The 4 questionnaires will take approximately 20 minutes in total to complete.

After filling out the initial questionnaires participants will be invited to attend an educational course on which there are places for 11 couples .This course would last approximately 2hours 30mins and invited participants will have a choice over whether to attend an evening or afternoon workshop.

We cannot promise the study will help you though research so far has shown benefits. Your opinion and feedback will help us improve services in the future

If the information in part 1 has interested you and you are considering participation, please read the additional information in part 2 before making any decision.

Part 2:

We will follow ethical and legal practice and all information about you will be handled in confidence. Information you provide on the questionnaires or at interview will be confidential and stored on a computer under an anonymous identification number. Therefore, the information provided by you will be stored anonymously.

If you add comments to the evaluation questionnaire direct quotations may be used in a resulting report. Quotations would be used anonymously and any that identified individuals by the information included in them would not be used.

The information provided by you will not be used for any other purpose apart from the study. When reporting and discussing the results, no individual will be identifiable by their names. Information will be retained for 1 year after which it will be disposed of securely.

The study involves filling out 4 questionnaires which are:

1. The Resilience Questionnaire. This scale describes coping methods

2. The Beck Depression Scale (BDI). This scale gives some indication of an individual's emotional state in terms of levels of depression.

3. The Spielberger Anxiety Scale (STAI).This scale gives some indication of an individual's emotional state in terms of levels of anxiety

4. An Evaluation form. This questionnaire asks for your opinion on the helpfulness of the information you received as part of the fertility service

If participation in the study raises any significant well-being issues that you would like to discuss with someone, the researcher will help you access additional services

A summary of the research findings will be sent to you in written form if you wish

If you have a concern about any aspect of this study, you should ask to speak to the Research supervisor. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the Hospital or Primary Care trust.

This research is being carried out as part of a continuing professional development course at the University of Birmingham and is sponsored by a Primary Care Trust.

Further information about this study can be obtained by contacting the Chief Investigator Phone:

You will be given a copy of the information sheet and consent form to keep if you decide to participate.

We will follow up this invitation with a phone call to you in a weeks' time to see if you would like to take part or not

PLEASE TURN OVER PAGE

KEY FACTS:

- Invitation to participate in a study looking at developing better information/advise to support coping with IVF

- This will involve attending an interview and then filling out 4 questionnaires twice. Questionnaires should take approximately 20 minutes.

- The questionnaires will ask you about the information you need and receive and how you are coping and feeling.

- Some participants will also be invited to attend a workshop

- Some participants will be given self-help leaflets

- You are free to withdraw from the study at any time without giving a reason. This would not in any way affect the care you receive from the Health Service.

- Any information you provide will be confidential and stored anonymously. You will not be identified in any results or reports.

- Participation or non participation in the study will in no way affect your normal care in any part of the Health Service.

Anonymised Consent Form
Title of Project

A Study to Develop an Educational Self-help Programme to Support Coping with IVF Treatment

Name of Researcher :
Patient Identification Number:

Please initial box

1 I confirm that I have read and understand the information sheet dated _____ (version_____) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2 **I** understand that my participation is voluntary and that I am free to withdraw at any time Without giving any reason, without my medical care or legal rights being affected. ☐

3 **I** understand the data collected during the study will be anonymised ☐

4 **I** agree to take part in the study ☐

Name (printed) _____

Signature _____ Date _____

Name (researcher) _____

Signature _____Date _____

Version 2-June 2010

Appendix 10

Guidelines for Authors from Journal