#### BRIEF CLINICAL REPORT



# Evaluating the efficacy of an internet-based cognitive behavioural therapy intervention for fertility stress in women: a feasibility study

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#### Abstract

**Background:** Women who are trying to conceive may be at risk of experiencing psychological distress. However, only a small proportion receive appropriate care, although interventions such as cognitive behavioural therapy (CBT) can effectively reduce levels of distress.

**Aims:** Our aim was to determine the efficacy and feasibility of an internet-based CBT intervention, called Overcome Fertility Stress (OFS).

**Method:** Fifty-five women who were struggling with conception were offered 3-month access to OFS, which is a fully automated yet individualized program via pre-programmed text, video and audio files. The program tailors its intervention around the symptoms the users report to the program.

**Results:** Significant improvements were demonstrated on infertility-related stress, with small-to-large effect sizes (d = 0.49 to 0.75). Furthermore, there was a significant decline in symptoms of depression and stress from pre- to post-treatment (d = 0.41 to 0.42, respectively). Finally, participants expressed overall satisfaction with the intervention.

**Conclusions:** These preliminary results suggest it is feasible and effective for women who experience fertility stress to receive an internet-based CBT intervention. Finally, these results add to the literature on the effectiveness of psychological treatments for those who struggle with fertility issues.

Keywords: cognitive behavioural therapy; fertility-related stress; internet-based intervention

# Introduction

Women who are trying to conceive may be at risk of experiencing psychological distress (Pasch *et al.*, 2016). The emotional effects of fertility problems are often neglected as psychological support is rarely an option, although interventions such as cognitive behavioural therapy (CBT) can reduce fertility-related distress (Faramarzi *et al.*, 2013). Internet-based treatments offer flexibility and accessibility for individuals experiencing geographical and financial challenges. However, internet programs typically face methodological limitations such as high drop-out rates, low completion frequency, and lack of individualized programs to address different variations of symptoms (Helgadottir *et al.*, 2009; McCall *et al.*, 2018). Overcome Fertility Stress (OFS) was designed to address some of the limitations of using computer systems in healthcare.

The purpose of this pilot study was to evaluate the feasibility and efficacy of OFS, an online computerized CBT program targeted to reduce psychological distress among women in Iceland experiencing fertility stress.

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# Method

# Participants

Participants were 55 Icelandic women, aged 33.62 years (SD = 4.93; range 24–43) who were experiencing fertility-related distress. Recruitment was through social media postings and media coverage in early 2021. Inclusion criteria were: (a) a diagnosis of fertility problems or a history of unsuccessful conception for 12 months or longer, (b) being at least 18 years old, (c) being able to read and understand English, and (d) access to a computer with internet and a valid email address.

#### Measures

#### Fertility Problem Inventory (FPI) (Newton et al., 1999)

The FPI is a 46-item self-report instrument measuring perceived infertility-related stress. The FPI scores are structured on five central domains: 'social concerns', 'sexual concerns', 'relationship concerns', 'need for parenthood' and 'rejection of childfree lifestyle', all contributing to a global infertility-related stress score (Newton *et al.*, 1999). The scale was translated into Icelandic and then back-translated to confirm the accuracy of the initial translation.

#### The Depression Anxiety Stress Scale (DASS-21) (Lovibond and Lovibond, 1995)

The DASS-21 consists of 21 items assessing psychological distress over the previous week. The response format is on a 4-point scale, where a higher score indicates more severe symptoms. DASS-21 aims to capture three subscales: depression, anxiety and stress. DASS-21 is the short form of the DASS-42 and was interpreted by multiplying each scale score by 2.

#### Feasibility

To determine treatment adherence, we assessed participants' number of completed modules, which were automatically recorded by the program. Participants who completed four or more modules were considered adhered to the program, equivalent to other studies (Clifton *et al.*, 2020). A qualitative questionnaire about feasibility and the acceptance of internet-based interventions was administered post-treatment.

#### The intervention, Overcome Fertility Stress

OFS is an internet-based CBT program designed to reduce distress among those who are trying to conceive. OFS is a stand-alone yet individualized online treatment that requires no input from a real-life therapist. A clinical psychologist presents individualized feedback using a large database of audio/video clips and text throughout the program. The program tailors the intervention around the symptoms the users report to the program. An idiosyncratic profile is created from a pre-assessment which is used to individualize the intervention for each user. Throughout the program, participants receive automatic emails to target adherence. The program consists of five different modules, each emphasizing different aspects of struggling to conceive. The structure of the program is as follows:

*Part A: Getting started.* Basic psychoeducation on the concepts of CBT is presented in the context for those who are struggling to conceive.

*Part B: Behaviour.* Users are taught to identify their own unhelpful behaviour and understand its maladaptive effects and a behavioural experiment is proposed.

*Part C: Thoughts and worries.* The user is taught to recognize unhelpful thoughts and how they may be re-evaluated. A worry session experiment is directed, and how one's own thoughts can be critically examined and challenged.

*Part D: Relationships.* This section focuses on relationships and pressure from society. Appropriate strategies for sharing information about the infertility with others are discussed.

*Part E: Redefine your life.* Guidelines are presented on how to design life plans which are not solely focused on having a child. Users are guided to write their goals and passion for the future, and finally, the aspects of living a childfree lifestyle are discussed.

# Procedure

All participants registered for the study through a website. First, subjects gave informed consent through an online questionnaire form. Second, they completed the baseline questionnaires. Thirdly, subjects who met the inclusion criteria were invited to participate in the study.

Eligible participants received an access code via email to activate their 3-month OFS account. Throughout the study, subjects were not contacted by the researchers. No face-to-face contact occurred at any point during the research period as contact was solely limited to email. After the 3-month period expired, participants were emailed a link to an online questionnaire for post-assessment measures. Only the first author had access to psychometric data from participants to conduct an independent evaluation.

# Results

# **Retention of participants**

Overall, 97 females showed interest in participation. Of those, 18 subjects were excluded from the study as they did not provide informed consent or did not complete baseline questionnaires. Therefore, 79 females were considered eligible to participate and received access to OFS. Out of the eligible participants, 15.2% never activated their account, and another 15.2% did not complete any module. Subsequently, they were excluded from the study and 55 participants entered the study. Three participants withdrew from the study due to reported pregnancy. A total of 35 (63%) provided data post-treatment. We observed no significant differences in baseline or demographic measures between non-users, participants lost to follow-up, and those who completed the study (all p values >.05).

#### Treatment efficacy

There were significant improvements on all FPI subscales from pre- to post-treatment (all p values < .05). As seen in Table 1, the improvements on the FPI subscales yielded small-tomedium effect sizes (d ranged from 0.49 to 0.72). The overall global score of FPI decreased significantly ( $t_{33} = 4.35$ , p < .05), with a large effect size (d = 0.75).

Table 1 presents the pre- and post-assessment means, *t*-values and effect sizes for all participants' symptom outcome variables. A comparison of the mean DASS-21 scores with paired *t*-test at pre- and post-treatment indicated a significant decrease in symptoms of depression ( $t_{33} = 2.46$ , p < .05) and stress ( $t_{33} = 2.43$ , p < .05) at post-treatment, with a small effect size (d = 0.42 and 0.41, respectively). However, the reduction on the DASS-21 anxiety subscale was not significant ( $t_{33} = 1.38$ , p > .05).

	Pre-intervention	Post-intervention		
Outcome	M (SD)	M (SD)	t	Cohen's <i>d</i> (95% CI)
FPI				
Global score	165.06 (27.36)	143.26 (34.32)	4.35*	0.75 (0.36-1.12)
Social	38.79 (8.87)	33.00 (10.50)	3.24*	0.56 (0.19-0.91)
Sexual	26.00 (7.81)	22.15 (8.01)	4.11*	0.71 (0.33-1.08)
Relationship	26.18 (8.78)	22.70 (10.19)	2.87*	0.49 (0.13-0.85)
Childfree	30.56 (7.00)	25.74 (6.47)	4.17*	0.72 (0.33-1.09)
Parenthood	43.53 (7.31)	39.68 (7.67)	3.39*	0.58 (0.21-0.94)
DASS-21				
Depression	16.88 (10.14)	11.82 (9.24)	2.46*	0.42 (0.07-0.77)
Anxiety	7.59 (7.97)	5.88 (6.71)	1.38	0.24 (-0.10-0.58)
Stress	18.82 (7.99)	14.82 (7.86)	2.43*	0.41 (0.06-0.76)

Table 1. Paired t-tests examining participants' symptom outcome variables at pre- and post-treatment

*M*, mean; *SD*, standard deviation; *t*, *t*-test; *d*, standardized mean change effect size; CI, 95% confidence limit for *d*; DASS, Depression Anxiety Stress Scale; FPI, Fertility Problem Inventory (Subscales: Social Concern, Sexual Concern, Relationship Concerns, Rejection of Childfree Lifestyle, Need for Parenthood). \*p<.05.

#### Intervention feasibility: treatment adherence, acceptance and overall satisfaction

On average, participants completed 3.69 (SD = 2.27) modules out of the five modules. Treatment adherence was moderate, with 43% (25/55) completing four or more modules (Clifton *et al.*, 2020). A total of 29% (16/55) completed the whole program.

Among the participants (35/55) that provided data post-treatment, our acceptance and satisfaction analyses revealed that 63% of participants reported being 'very satisfied' or 'rather satisfied' with the program. A high proportion of participants (69%) expressed that they were 'very likely' or 'rather likely' to recommend the intervention to a friend with infertility. Finally, the qualitative feedback from participants revealed an overall satisfaction with the program (examples of participants feedback can be seen in the Supplementary material).

# Discussion

The aims of the current study were to investigate preliminary efficacy and feasibility of the OFS internet-based intervention. Participants demonstrated a reduction in global infertility-related stress on all subscales from pre- to post-treatment. In other words, participants reported less distress in the following domain areas: social concerns, sexual concern, relationship concerns, rejection of a childfree lifestyle, and need for parenthood. Furthermore, participants showed a reduction from pre- to post-assessment for depression and stress symptoms, with small effect sizes. Despite the clinically significant reduction in depression and stress, symptoms remained somewhat high. These results are consistent with Faramarzi *et al.* (2013) who demonstrated that CBT was superior to fluoxetine for resolving fertility stress.

The secondary aim was to evaluate OFS feasibility. Our results suggested that 43% of participants were considered adhered to the program. The completion rate (16/55, 29%) of the program was moderately high, compared with other studies on automated unguided internet-based interventions. Qualitative results suggested users' satisfaction.

#### Limitations and future research

Firstly, there was no control or placebo condition, so it is impossible to state the overall efficacy of the intervention. Secondly, our results are based on relatively few participants due to drop-out. Furthermore, we failed to report the length of time the participants had been trying to conceive, so we could not examine if there was an association between the length of time trying to conceive and

distress symptoms. Finally, we have no information about whether participants were undergoing fertility treatment which may have had an impact on our results.

Future research should aim to understand the variables that influence fertility-related stress, to understand how interventions such as CBT can lead to improvements. The qualitative feedback from the current pilot study will be instrumental in this endeavour. Future research should also aim to focus on understanding how to improve adherence and acceptability for both men and women who are experiencing fertility stress. Additionally, future research should explore with focus groups of prospective participants how to improve adherence. Finally, it is important that future studies collect information about infertility duration and if participants are undergoing a fertility treatment, as these data can have an important impact on results. Although these preliminary results demonstrating reduction in distress are promising, the overall efficacy of OFS remains unclear, until a randomized controlled trial is conducted.

# Conclusion

Despite the limitations, this study offers valuable insights. This study acknowledges vital attention to the mental health of women who experience fertility-related stresses and highlights the great need for psychological support. Our results indicate that psychological distress may be treated with a relatively accessible and non-time-consuming intervention and adds to the literature of the advantages of receiving unguided internet-based intervention.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/ S1352465822000534

Data availability statement. Data are available on request.

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Author contributions. Rakel Bjornsdottir: Conceptualization (lead), Data curation (lead), Formal analysis (lead), Investigation (lead), Methodology (lead), Writing – original draft (lead); Fjola Helgadottir: Conceptualization (equal), Data curation (equal), Formal analysis (equal), Investigation (equal), Methodology (equal), Project administration (equal), Resources (equal), Software (equal), Supervision (equal), Validation (equal), Visualization (equal), Writing – original draft (equal), Writing – review & editing (equal); Magnús Sighvatsson: Supervision (supporting), Writing – review & editing (supporting).

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**Conflict of interest.** One of the authors of the study, F.D. Helgadóttir, is the owner and creator of Overcome Fertility Stress. Helgadóttir provided an important contribution to the design of this study. The two other authors declare that they have no conflicts of interest, financial or otherwise. The potential for conflict of interest was mitigated in that Helgadóttir or her company had no access to participant data, was not involved in data collection, analysis or interpretations, and provided no funding for this study. The authors confirm that they have not been encouraged or asked to repress, withhold, or modify any data, results or conclusions.

**Ethical standards.** The study's protocol was approved in full by the Icelandic National Bioethics Committee (clinical study registration number: VSN-20-111-1). The research was conformed to the Declaration of Helsinki.

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