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Smartphone-supported Positive Adjustment Coping Intervention (PACI) for couples undergoing fertility treatment: a randomised controlled trial protocol

Maren Schick,[1] Sabine Roesner,[2] Ariane Germeyer,[2] Markus Moessner,[3] Stephanie Bauer,[3] Beate Ditzen,[1] Tewes Wischmann[1]

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For numbered affiliations see end of article.

Correspondence to
Maren Schick;
maren.schick@med.uni-heidelberg.de

ABSTRACT

Introduction Infertility generally counts as a profound crisis in the lives of couples and as an emotionally stressful experience. For couples undergoing fertility treatment, this is especially true of the waiting period following embryo transfer, which couples say is the most stressful period during treatment. However, at this specific phase, psychosocial counselling is not always available on the spot. The aim of this randomised controlled trial (RCT) study was to test the Positive Adjustment Coping Intervention (PACI), a low-dose, smartphone-supported psychological intervention for women and men undergoing fertility treatment.

Methods and analysis The effectiveness of PACI is tested by means of a prospective two-arm RCT. During the 14-day waiting period between oocyte puncture/oocyte thawing and pregnancy test, participants are randomly assigned to one of the two groups, and both women and men receive daily text messages on their smartphones. One group receives text messages with statements reflecting positive-adjustment coping attitudes, the other group messages containing cognitive distractions. The primary outcome of this study is the reduction of psychosocial burden during the waiting period of reproductive treatment. Furthermore, we want to assess whether there are differences between the interventions in a pre-post assessment. The secondary outcomes are information on perceived effectiveness and practicability of the intervention one month after the waiting period.

Ethics and dissemination Ethical approval has been obtained from the Ethics Committee of Heidelberg University Faculty of Medicine (S-074/2017). Study findings are planned for dissemination via peer-reviewed journal articles and at national and international conferences.

Trial registration number NCT03118219; Pre-results.

Protocol version Version 2.0 dated 18/02/2019.

Strengths and limitations of this study

- The study tests a validated tool in a fully powered randomised controlled trial, adapted for a German sample.
- The study addresses the tool in a novel smartphone-supported approach and works with male participants, a study population not previously investigated with this tool.
- For methodological and practicability reasons, there is no routine care group for comparison; instead, two active interventions are assessed.

INTRODUCTION

Having children is seen as a momentous component of most people's expectations in life.[1] However, about 8% of couples at a reproductive age are unintentionally childless, and approximately 25 000 couples undergo assisted reproductive technology (ART) in Germany every year.[2]

Infertility, as representing the inability to fulfil one of the essential goals in life, is considered a fundamental life crisis for couples, a crisis associated with feelings of grief, anger, guilt, envy or depression and potentially entailing severe, long-term social and psychological consequences.[3–5]

Psychological impact of fertility treatment

Many couples undergoing ART perceive fertility treatment as very stressful.[6] This accounts also for men, as recent findings suggest that men and women are equally affected by involuntary childlessness[7] and that the often stated higher distress for women may be due to outdated gender stereotyping.[8 9] In vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI) are held to be particularly distressing due to the various hormonal treatments, the numerous appointments and the costs involved. Experience of infertility and the medical treatment for it can lead to emotional maladjustment, so

it is essential to address the psychosocial needs of couples during fertility treatment.[10] Verhaak *et al*[11] singled out anxiety, depression, helplessness, low acceptance and low social support as risk factors for infertile patients. They have developed the ScreenIVF questionnaire,[12] which is validated for women and men.[13 14]

Alongside successful pregnancy, another important aspect of fertility treatment is the patients' satisfaction with the entire treatment process.[10] Accordingly, it is essential to safeguard the mental health of couples in what can be an extended and chronically stressful phase. Targeted coping strategies using a low-threshold smartphone-supported intervention may thus constitute a new strategy improving patients' prospects of coming to terms with the course of treatment and possible treatment failures.

Waiting time and fertility treatment

Osuna[15] described the development of anxiety and stress in waiting situations. They derive from the uncertainty and feelings of futility typical of waiting periods in medical contexts. Previous studies on waiting time in medical contexts (eg, waiting for breast cancer diagnosis, gastrointestinal endoscopy investigations, fertility treatment) underline the specific emotional nature of this situation, in which the ultimate diagnoses may pose a threat to the patients' well-being or survival.[16–18]

In fertility treatment, having to wait is an integral part of the whole reproductive cycle, like waiting for appointments at the clinic or for the maturation of oocytes to embark on the next cycle. This compounds the fact that infertility and its treatment are low-control chronic stressors.[4] However, whereas during other stages in fertility treatment there is at least something the patients can do (eg, self-injections of hormones), this does not apply to the waiting phase between embryo transfer and pregnancy test (or return of monthly menorrhoea). Indeed, the waiting period after embryo transfer is experienced by many women as the most emotionally challenging and distressing part of reproductive treatment, often even more challenging than medical interventions such as laparoscopies.[19] During this phase, perceived sense of control is extremely low due to the fact that there is hardly anything one can do to facilitate the implantation of the fertilised oocyte in the uterus and enhance the prospects of a desired pregnancy.

The effectiveness of 'face-to-face' counselling in providing emotional relief for people with desire to have children has been previously demonstrated.[20] This is not yet the case for a variety of other forms of intervention (eg, telephone or online counselling),[19] although a first feasibility study regarding the effects of e-therapy on psychological distress in reproductive treatment yields promising aspects.[21] Psychosocial counselling is not always available on the spot or, if available, is often not taken advantage of for fear of stigmatisation.[22] Self-help coping interventions are feasible and may serve as low-threshold, easy-access interventions during the IVF waiting period. Internet-based interventions provide a range of features particularly beneficial for the provision of low-threshold supportive offers, such as no additional appointment at the clinic and lower financial costs.[23] As things stand, interventions or other possibilities for easing this specific kind of distress are limited.

The Positive Adjustment Coping Intervention during the waiting period

In support of women in the waiting phase of infertility treatment, Lancastle and Boivin[24] have developed the 'Positive Reappraisal Coping Intervention (PRCI)' as a low-threshold psychological intervention. In theoretical terms, this intervention is based on the technique of cognitive restructuring used in cognitive behavioural therapy. Coping is a conscious effort to reduce stress.[25] Accordingly, the capacity to adapt to infertility-related stress depends on psychological coping mechanisms or coping strategies.[26 27] As pointed out earlier, infertility is a low-control stressor, particularly during the waiting period. Terry and Hynes[28] have examined women's adjustment to a failed IVF attempt and found that there is a relation between problem-appraisal (eg, trying to make the best of the situation) and emotional approach coping (eg, let my feelings out somehow) in women's self-reported adjustment efforts. PRCI consists of an introductory text and a card with 10 core statements describing positive thoughts and/or behaviours. In an initial feasibility study, Lancastle and Boivin[24] were able to demonstrate the efficacy and acceptance of this intervention by administering it to 28 women in IVF treatment during the waiting period between embryo transfer and pregnancy test. Ockhuijsen *et al*[29] used the same PRCI in a randomised controlled trial (RCT) study and reported positive psychological effects as a result of the intervention.

Furthermore, besides the waiting time in IVF treatment, the PRCI was used recently during the waiting period of intrauterine insemination treatment[30] and as an intervention for pregnant women with a miscarriage history.[31 32]

For this study, we use the approved German version of the PRCI tool and modify it to 'Positive Adjustment Coping Intervention (PACI)' (see attachment *Instructions and interventions*). Instead of 'reappraisal' we use the German term 'Neuausrichtung', translated here as 'adjustment', which focuses more on the behavioural process of balancing personal needs. Psychological adjustment reflects whether an individual is able to effectively adjust to the demands of the environmental context and to the stress created by those demands.[33] Psychological adjustment to challenging life crises is multifactorially determined, comprising adequate coping strategies, sufficient social support and lack of negative cognitions. Quality of life depends on how successful one is in adjusting to challenges in life. Poor adjustment is connected to anxiety or depression.[34]

Besides PRCI, there is only one other self-administered coping intervention specifically designed for patients to use at home during medical waiting periods.[35] Qualitative

and quantitative data on a distraction-based coping intervention (eg, 'count to 50 while imaging the numbers in your head'; 'take some exercise—keeps you fit and takes your mind off your worries') for women and men referred for genetic cancer-risk assessment show that this distraction intervention is helpful in lowering distress, although only among participants with high baseline stress.[35–37] In our study, we use this kind of cognitive distraction in a much less specific form. We modified this distraction-based coping intervention into simple one-time brainteasers instead of repeatable interventions. Furthermore, since distractive focusing is assumed to be not maladaptive in regard to well-being,[38] we choose cognitive distraction as a comparison intervention in our study, designed to mildly distract the patients during the waiting period.

The implementation of a waiting-list control group was not possible for organisational staff reasons in the clinic and also for methodological reasons. These included the risk of patient talks in the waiting room and the attrition risk of patients feeling left out because of not getting an intervention at all or not at the time they are in need of this intervention.

Objective

The primary outcome of the study is the reduction of psychosocial burden during the waiting period of reproductive treatment. We aim to test in a pre-post assessment whether a Positive Adjustment Coping Intervention (PACI) for couples during the waiting period in fertility treatment will alter the ScreenIVF variables anxiety, depression, perception of social support and dysfunctional cognition compared with couples receiving cognitive distractions. The secondary outcomes of this study are information on perceived effectiveness and practicability of the intervention.

We expect the PACI to be more effective in reducing psychosocial burden than the cognitive distraction intervention. PACI is designed to encourage a more positive attitude during this waiting phase, which is typically characterised by brooding and worries.

Based on previous research regarding the PRCI,[24 29 31 32 39–41] this study extends the scope of existing data on two major scores: First, we employ modern media (smartphones) instead of a card with a list of statements. Second, we assess both women and men, since men have been shown to be equally affected by the treatment at a psychological level.[7 42] Furthermore, being in fertility treatment is challenging for any couple, so examining the couple as a dyadic system in this phase of treatment gives us valuable insights into reciprocal alliances.[43]

METHODS AND ANALYSIS

Study design

The effectiveness of a smartphone-supported psychosocial intervention for women and men undergoing reproductive treatment is examined in the framework of a two-arm RCT. During the waiting phase after IVF or ICSI, participants are randomised either to the PACI or to a comparative intervention group (cognitive distractions). To capture the general impact of PACI, both groups are asked to complete questionnaires at three time points: (1) just before the waiting period (Time 0: preintervention), (2) on day 13 of the 14-day waiting period (Time 2: postintervention) and (3) one month after the waiting period (Time 3: evaluation). See figure 1 for the timeplan of enrolment, interventions and assessments.

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Follow-Up
TIMEPOINT	t_0		t_1	t_2	t_3
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Mobile phone number	X				
Allocation		X			
INTERVENTIONS:					
Positive Adjustment Coping Intervention			←	→	
Cognitive Distraction			←	→	
ASSESSMENTS:					
Sociodemographics	X				
SCREEN-IVF	X			X	
Pregnancy				X	X
Evaluation					X

Figure 1 Positive Adjustment Coping Intervention: schedule of enrolment, interventions and assessments.

Participants and recruitment

The RCT is being conducted over a 2-year period from August 2017 to August 2019 at a fertility clinic of a university women's hospital in Germany. See figure 2 for the flow chart of the study. The study population consists of couples undergoing a fresh or cryopreserved fertility treatment cycle with IVF or ICSI. Since fertility treatment in this clinic must comply with statutory provisions and insurance company rules, all women treated with IVF or ICSI have to be in a relationship and between 18 and 45 years of age. Prior to the thawing of cryopreserved fertilised oocytes or after oocyte puncture, doctors inform all couples about the study. Inclusion criteria are willingness to participate in the study, written consent to participation, a smartphone of one's own (able to receive text messages and display internet links) and disclosure of the respective mobile phone number. Women and men are excluded from the study if they do not have sufficient knowledge of the German language, since all study materials (including PACI) are currently in German only. If one partner refuses to participate, the other partner can still be admitted as an individual participant. Participants can withdraw their consent for participation at any time without giving reasons and without any disadvantages for

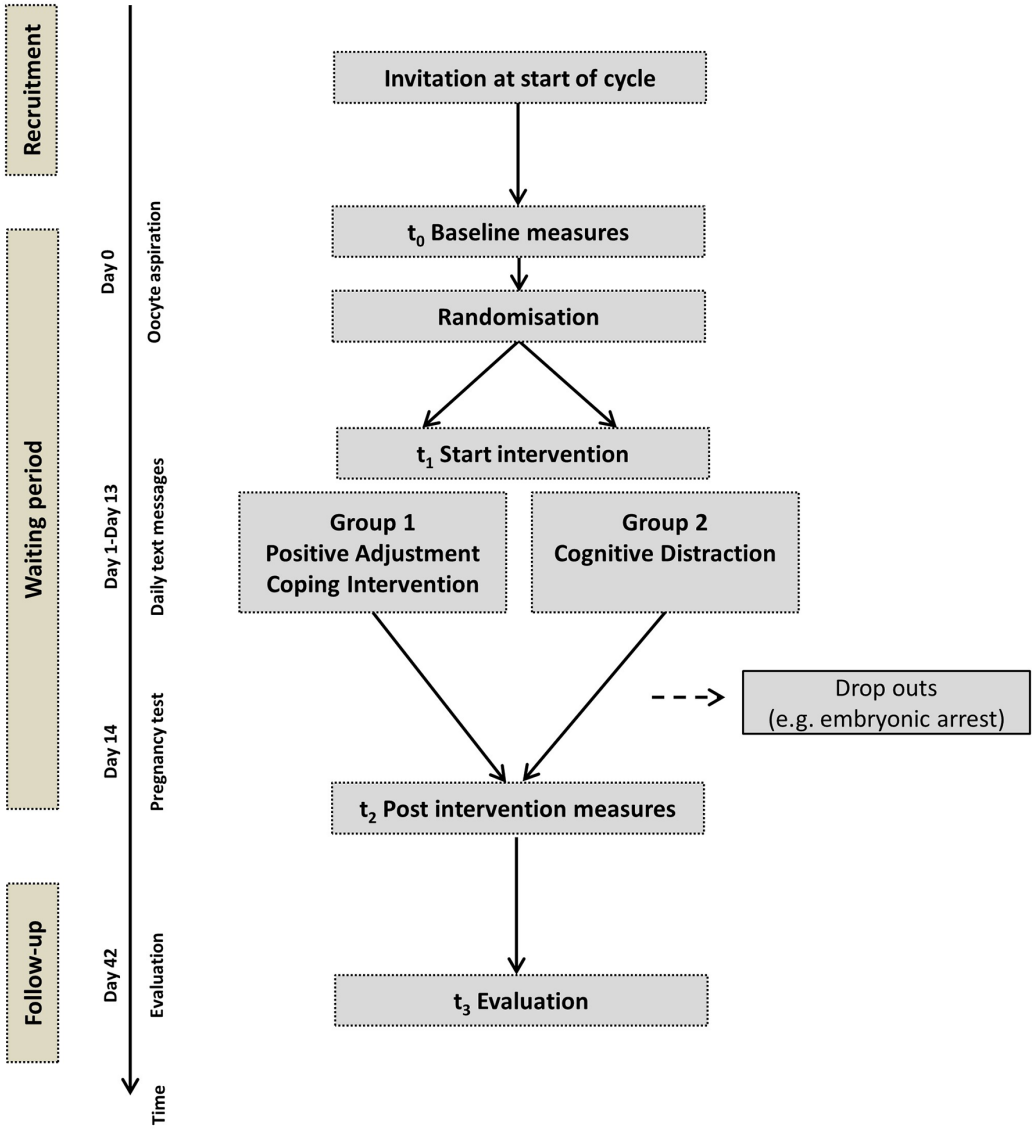

Figure 2 Positive Adjustment Coping Intervention: flow chart.

the continuation of their medical care or that of their partner. In the event of fertilisation failure, degeneration of all cryopreserved embryos after thawing or medical reasons for cancelling embryo transfer (eg, ovarian hyperstimulation syndrome, embryonic arrest) text messages will be stopped as soon as the study team has been informed. Since the text messages are designed to accompany the waiting period between oocyte puncture/thawing and embryo transfer, unfortunately participants with cancelled embryo transfers cannot proceed in the study.

All patients willing to participate receive an information document about the study (see attachment *Information document*) and a declaration of consent that they are asked to read and sign (see attachment *Declaration of consent*). In the information document, patients are informed about the two different interventions and their randomised assignment to one of the groups. Afterwards, the participants receive brief written instructions pertaining to positive adjustment and creative distraction (see attachment *Instructions and interventions*). At this time point, patients are given the first questionnaire (see attachment *Time 0: preintervention questionnaire*) and asked to return it immediately after completion. At all times, patients can ask any questions they may have. However, they are all given the same information in accordance with a written protocol.

Sample size

Differences between the groups in the ScreenIVF variables are tested for using a mixed factorial analysis of variance (ANOVA) with repeated measures. Assuming a medium effect size of d=0.25 and a correlation of r=0.5 between repeated measures, a total of 158 participants (individuals or as part of a couple) need to be recruited (79 participants per group) in order to test group differences with a power of 95% at an alpha level of α=0.05.[37 44] Calculation on effect size and power analysis were done using the statistical program G*Power.[45] Taking into account an estimated 30% attrition rate,[24 29] at least 113 participants thus need to be recruited for each group.

Randomisation

Couples are randomly assigned to the PACI group or the comparison intervention group. Randomisation into one of the two intervention groups is performed by a computerised randomisation system. Randomisation takes place on the day of oocyte puncture/thawing on waiting period day 0, after the first assessment (Time 0: preintervention questionnaire). Randomisation is carried out by the study statistician, who has no contact with participants at any time. Clinic staff is blinded and will not be told which intervention the couples have been assigned to. Assigning woman and man of a couple to the same intervention group is designed in order to be able to clearly distinguish the effects of the respective interventions from each other. Patients are told about their group assignment when they receive the first text message.

Intervention groups

At the beginning of the study, both intervention groups receive the same information sheet about the study and brief written instructions on positive adjustment technique and on cognitive distraction. Both groups receive the first of 13 daily text messages to their smartphones 1 day after oocyte puncture or on the day the cryopreserved embryos are thawed.

All patients allocated to the PACI group receive positive adjustment statements on a daily basis. They are designed to encourage participants to adjust more positively to the waiting period. Women and men are recommended to read the text message as soon as they get it and subsequently whenever they feel the need (see attachment *Instructions and interventions*). All patients are asked to relate the positive adjustment statement to their personal situation at least twice a day.

Patients allocated to the comparison intervention group receive daily brainteasers as a cognitive distraction (eg, 'The day before yesterday, Martin was still 35—next year he will be 38. When is his birthday?'; 'What's the next number in this series: 1–2 - 3–5 - 8–13 - 21–34 -?', with solutions written backwards). The idea is that the distraction thus created will help them to keep their worries under control.[35]

All text messages are sent via a safe modem platform system operated by the Center for Psychotherapy Research at Heidelberg University Hospital, which is specialised in developing and evaluating internet and mobile phone services for patients in the area of E-Mental Health (eg, Kindermann *et al*[46]). Mobile phone numbers are stored at the University Hospital's server, which is subject to the Hospital's data protection system.

Materials and study measures

Data are obtained via self-report questionnaires and medical records. By grounds of its comprehensive collection of psychosocial burden during fertility treatment, we choose the ScreenIVF as progression instrument to compare two different measurement time points. Main outcome measure is the pre-post difference in ScreenIVF variables anxiety, depression, perception of social support and dysfunctional cognition. Sociographic variables, medical data and possible pregnancies at the time of postintervention measurement are assessed as potential moderators.

Participants in both intervention groups are asked to complete questionnaires at three specific time points.

Time 0: preintervention questionnaire

This paper questionnaire (see attachment *Time 0: preintervention questionnaire)* collects sociodemographic information (age, education, occupation, family status, children, length of partnership) and gynaecological and reproductive facts (length of desire for child, length of fertility treatment, cause of fertility treatment) with a view to appraising the clinical characteristics of study participants and assessing possible moderators. As a primary outcome measure, all participants are asked to fill in the ScreenIVF. It consists of 34 items: anxiety (10 items), depression (7 items), social support (5 items) and, with regard to cognition about fertility problems, helplessness (6 items) and lack of acceptance (6 items). Each item is rated on a four-point Likert scale. The score for each scale is calculated by adding up the answers for each item and contemplated with clinically relevant cut-off scores (anxiety ≥24, depression ≥4, social support ≤15, helplessness ≥14, acceptance ≤11). The internal consistency of all ScreenIVF scales is satisfying with Cronbach's alpha for anxiety=0.88, depression=0.82, social support=0.89, helplessness=0.87 and acceptance=0.92.[12]

Time 2: postintervention questionnaire

One day before the pregnancy test at the clinic, participants receive a link via smartphone enabling them to fill in the postintervention questionnaire online on Unipark, a research online survey website. The questionnaire consists of the ScreenIVF (see above) and questions about whether the patients have already taken a pregnancy test at home and, if so, what the result was. These questions are asked to control for possible moderating factors in answering the ScreenIVF in the light of a positive or negative pregnancy test result. If participants fail to fill in the postintervention questionnaire, they receive a reminder text message after 7 and again after 14 days (if necessary).

Time 3: evaluation questionnaire

One month after the waiting period, participants receive a link on their smartphone. This evaluation questionnaire (see attachment *Time 3: evaluation questionnaire)* is presented on Unipark. The evaluation questionnaire consists of six items. Participants are questioned on a rating scale about their perceptions of the time involved, the efficacy and the practicability of the intervention techniques and whether they would recommend the intervention to others. Participants are also asked to comment on the study in an open question. Controlling for a possible moderating factor, participants are questioned about their pregnancy status again. If participants fail to fill in

the evaluation questionnaire, they receive a reminder text message after 7 and another after 14 days (if necessary).

Data analysis

IBM's SPSS Statistics V.24 is used for statistical analysis. Analysis will be carried out blind to couples' group assignment to avoid detection bias. Descriptive statistics and t-tests are used for baseline equivalence between the two intervention groups. Preanalysis and postanalysis on ScreenIVF scales are calculated using a mixed factorial ANOVA with repeated measures taking moderator factors into account. Intracouple associations and influences of one partner on the other are calculated using the Actor-Partner Interdependence Model.[47] All analyses will be conducted in accordance with an intention to treat approach.[48] Missing data will be accommodated by multiple imputation.

Patient and public involvement

There was no direct involvement of patients in designing and conducting the study. However, the basic idea for a low-threshold intervention during waiting time evolved by numerous consultations with clients being in reproductive treatment and asking for support. At Time 3 (evaluation questionnaire), patients are asked about the burden of the intervention and have the additionally option to comment in a free text field. Results will be disseminated through display in waiting room in clinic, on clinic and institutes website and if requested per email (mail address on information document and in text messages).

ETHICS AND DISSEMINATION

All questionnaires in paper form have code numbers and are free of personal data of the participants (eg, names or birthdays). All online data entries are stored pseudonymously and in encrypted form on the Unipark servers. The evaluation of the study is carried out at the Institute of Medical Psychology. The results are published in the name of all three institutions participating in the study.

Author affiliations
[1]Institute of Medical Psychology, University Hospital Heidelberg, Center for Psychosocial Medicine, Heidelberg, Germany
[2]Department of Gynecologic Endocrinology and Fertility Disorders, University Women's Hospital Heidelberg, Heidelberg, Germany
[3]Center for Psychotherapy Research, University Hospital Heidelberg, Center for Psychosocial Medicine, Heidelberg, Germany

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Contributors All authors have contributed to the design of the study. MS, SR, AG, BD and TW were involved in adapting and compiling the interventions. SR and AG were responsible for developing the recruitment process. MM and SB were responsible for operating the safe modem platform system over which all text messages were send. MS and TW were responsible for obtaining the ethical approval and drafting the manuscript. MS planned the statistical analysis. MS, SR, AG, MM, SB, BD and TW have read, revised and approved the final manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The Ethical Committee of Heidelberg University's Faculty of Medicine has evaluated and approved this study (protocol number S-074/2017).

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