Improving patient-centredness in partnership with female patients: a cluster RCT in fertility care

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SUMMARY QUESTION: What is the effect of a multifaceted intervention with participation of patients on improvement of patient-centredness in fertility care?

SUMMARY ANSWER: A multifaceted intervention with participation of patients did not improve total patient-centredness scores provided by women in fertility care.

WHAT IS KNOWN ALREADY: We should provide care that takes into account the preferences and needs of patients, i.e. patient-centred care. Especially infertile patients who suffer from a high emotional burden of treatment could benefit from a more patient-centred approach in healthcare. However, the improvement of patient-centred care is still needed, because effective strategies to come to improvement are lacking.

STUDY DESIGN, SIZE AND DURATION: A cluster RCT was performed within 32 Dutch fertility clinics, covering about one-third of all Dutch hospitals. After randomization, 16 clinics in the intervention group were exposed to a multifaceted improvement strategy for patient-centred fertility care for 1 year. This strategy comprised audit and feedback, educational outreach visits and patient-mediated interventions. The remaining 16 clinics in the control group performed care as usual.

PARTICIPANTS/MATERIALS, SETTING AND METHODS: The clinics’ levels of patient-centredness were measured, using the validated Patient-centredness Questionnaire-Infertility (PCQ-Infertility). At baseline measurement, a total of 1620 women in couples undergoing fertility care (this included both male, female, mixed infertility and infertility of unknown cause) in one of the participating clinics were randomly selected to participate in the study and complete the questionnaire. For the after measurement, we randomly selected a comparable sample of 1565 women in infertile couples. Both women who had already started their treatment before the start of the study (67%) and women who started their treatment after the start of this study (33%) were included. To avoid bias, we only included the responses of non-pregnant respondents.

MAIN RESULTS AND ROLE OF CHANCE: The final analysis involved 30 clinics. A total of 946 women (response 58.4%) completed their questionnaire at baseline measurement and also a total of 946 women (response 60.4%) at after measurement. After excluding the pregnant patients, respectively 696 and 730 questionnaires were eligible for analysis at baseline and after measurement. The total score of case-mix adjusted PCQ-Infertility at after measurement did not differ significantly between the intervention and control group (B = 0.06; 95% confidence interval (CI) = −0.04–0.15; P = 0.25). However, scores on the continuity of care subscale were significantly higher in the intervention group compared with the control group (B = 0.20; 95% CI = 0.00–0.40; P < 0.05). The addition of three interaction terms to the model had a significant impact: (i) being younger than 36 years, (ii) beginning treatment after the study had started and (iii) using complementary and alternative medicine. If women met all three conditions, the scores in the intervention group were on average 0.31 points higher compared with the control group (95% CI = 0.14–0.48; P = <0.001).

LIMITATIONS, REASONS FOR CAUTION: Our response rates are sufficient, but the responses of many women are still lacking which might have biased our results. Furthermore, the PCQ-Infertility scores at baseline measurement were already reasonably high, which could have limited the effect of the multifaceted improvement strategy. Because we only included women in infertile couples in our study, we cannot draw conclusions on the effect of an improvement strategy for patient-centred fertility care for partners.
WIDER IMPLICATION OF THE FINDINGS: A multifaceted intervention with participation of patients did not improve total patient-centredness scores, although some effect could be observed in specific groups of women and in specific dimensions of patient-centredness. These results can guide future research, in which we should focus more on personalized strategies and outcome measures.

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Key words: patient-centredness / improvement strategy / multifaceted approach / audit and feedback / RCTs

Introduction

‘Patient-centredness is not the route to the point, it is the point’. With this statement, Don Berwick emphasizes the importance of providing care that is adjusted to patients’ preferences, needs and values (Institute of Medicine, 2001; Berwick, 2009). Patient-centredness is a contemporary theme given the rising number of publications on this subject (West et al., 2005; Alexander and Bae, 2012; Dwamena et al., 2012; Hudon et al., 2012; DiGioia et al., 2013). There are several reasons why healthcare should become more patient-centred. First, because it is ‘just the right thing to do’, reflecting the ethical norms inherent in medicine (Duggan et al., 2006). Moreover, there are indications that patient-centred care is associated with improved clinical outcomes (Mead and Bower, 2002; Epstein et al., 2010), decreased healthcare costs (Stewart et al., 2000; Epstein et al., 2005) and more satisfaction among patients and healthcare workers (WHO, 2007; Glasper, 2010; Heje et al., 2011).

Listening to patients’ preferences and needs would especially be helpful for patients who suffer from a high emotional burden and intensive treatment periods (Boivin et al., 2007; Verhaak et al., 2007). Therefore, healthcare areas such as oncology and rheumatic care as well as fertility care could mainly benefit from a patient-centred approach (Boivin et al., 2007; Verhaak et al., 2007). Previous studies in the area of fertility care have shown that the level of patient-centredness is not optimal yet (Dancet et al., 2010; van Empel et al., 2010a). Consistent and well-performed improvement projects are obviously needed (Quill and Holloway, 2012). The design of an effective improvement strategy should include the wishes and preferences of patients and tackle the barriers that professionals experience (West et al., 2005; Dwamena et al., 2012; DiGioia et al., 2013). Known barriers are a lack of professional urge to change, difficulty in translating the feedback into a concrete improvement and a lack of time and monetary resources (Elwyn et al., 2000; Dunn, 2003; West et al., 2005; Grol et al., 2008; Aarts et al., 2011; Huppelschoten et al., 2013a).

The optimal improvement strategy to overcome these barriers has not been found yet. Many studies include audit and feedback as a key component of quality improvement (Groene, 2011), and suggest that feedback should be part of an intervention with multiple components (Grimsshaw et al., 2004; Jamtvedt et al., 2006; Hysong, 2009). The experiences with participation of patients in improvement programmes are limited (Boivin et al., 2014), despite the trend that their role in clinical practice is recognized more and more (Richards et al., 2013). Particularly in improving patient-centredness, it seems obvious to involve patients. Patients experience the impact of patient-centredness and may have good ideas for improvement. Moreover, they may motivate professionals to improve their level of patient-centredness, and thus, increase the sense of urgency.

The primary aim of our study is to determine the effect of a multifaceted approach with participation of patients, consisting of (i) audit and feedback, (ii) educational outreach visits and (iii) patient-mediated interventions, on the improvement of patient-centred fertility care.

The secondary aim of the study is to look at determinants of the effect of our intervention to identify which patient groups perceive a higher change in patient-centredness. Patient-centredness is associated with several characteristics of the patient, such as age and education (Dancet et al., 2010; Mourad et al., 2010; van Empel et al., 2010a), but their effect on an improvement strategy for patient-centred fertility care is still unknown.

Methods

Study design

We performed a cluster RCT in 32 Dutch fertility clinics to determine the effect of a multifaceted approach on the level of patient-centred fertility care. After randomization, 16 clinics were exposed to the intervention for 1 year and the other 16 clinics performed care as usual. The institutional ethics committee of our centre provided ethical approval (CMO nr 2011/034). Our trial was registered with ClinicalTrials.gov (NCT01481064) and we reported our results according to the CONSORT statement for cluster randomized trials. An extensive description of the design of our study is published elsewhere (Huppelschoten et al., 2012). Written informed consent was not required for this study.

Randomization

We used fertility clinics instead of patients as the unit of randomization to avoid contamination of the intervention. For randomization, clinics were stratified according to the clinic size (large, medium and small) and subsequently assigned to either the control group or multifaceted (intervention) strategy. Three research associates performed the blinded randomization procedure by drawing randomly numbered and sealed envelopes.

Setting and study population

In the Netherlands, fertility care is provided through three types of fertility clinics. Large clinics are licensed to perform all kinds of medically assisted reproduction (MAR). Intermediate clinics refer their patients to these larger clinics for the laboratory phase and embryo transfers of IVF. Small fertility clinics only perform fertility assessment, ovulation induction (OI) and intrauterine inseminations (IUI). For our study, we included patients who underwent at least one cycle of MAR. We asked clinics to extract the names and addresses of all patients who underwent MAR in their clinic in the past 3 months (i.e. summer 2011 and winter 2012) from their national coding system. For the after measurement, both patients who started their treatment before and after the start of this study were included. Subsequently, we randomly selected 25–75 patients per clinic, depending on the clinic...
size. We invited only the women of the couples to participate as previous research has shown that women and their partners have comparable results on the primary outcome measure, patient-centred care (Huppelschoten et al., 2013b). Therefore, conclusions on the effect of our improvement strategy can only be drawn for women in fertility care. To avoid bias, we only included the responses of non-pregnant respondents, since previous studies showed a strong association between outcome of fertility treatment and patient-centredness (Dancet et al., 2010; van Empel et al., 2010b).

Sample size

Our sample size calculation was based on a previous study using the same questionnaire (van Empel et al., 2010b). The mean overall patient-centredness score was 2.19 (SD 0.43), and ranged from 1.72 (SD 0.62) to 2.47 (SD 0.28) on a scale from 0 to 3. We expected the intervention clinics to improve their patient-centredness score from a national mean result towards the best results in the country. Therefore, we considered an improvement of 0.25 points in our study as relevant. To detect this difference ($\alpha = 0.05$, two-sided testing, $\beta = 0.8$) at least 93 couples were required. Taking into account clustering of couples (30 couples per clinic) and a mean intracluster-correlation coefficient of 0.13 (van Empel et al., 2010b), 1023 couples had to be involved. With an expected response rate of 70% (van Empel et al., 2010b), at least 1462 couples had to be invited at both baseline and after measurement.

Intervention

The content of the intervention was based on the literature about effective improvement strategies in healthcare (Wensing et al., 1998; Jamtvedt et al., 2006; Hysong, 2009; Aarts et al., 2011; Dwamena et al., 2012) and on previous interviews with Dutch fertility care professionals (Huppelschoten et al., 2013a). The Dutch Patient Association ‘Freya’ was involved in the design of the intervention. During 1 year, all 16 intervention clinics were exposed to the multifaceted approach, which consisted of three elements: (i) audit and feedback, (ii) educational outreach visits (EOV) and (iii) patient-mediated interventions. The audit was performed by means of patient-centredness questionnaires filled in by patients. The feedback consisted of a paper report with the clinic’s own results on patient-centredness according to their patients. These results were benchmarked in relation to all 32 participating clinics. We calculated quality improvement scores (QI scores) to identify aspects of care with priority for improvement. The QI scores were based on both patients’ importance of and experiences with patient-centred fertility care (van Empel et al., 2010b). The higher a QI score, the more need for improvement. Two weeks after the feedback report, we performed an EOV in the 16 clinics. We discussed the feedback report with the team, paying special attention to the highest QI scores. For each clinic, a former female patient and her partner and a quality officer participated in these EOVs as well. The Dutch Patient Association ‘Freya’ recruited the patients. Prior to the EOV, they received a manual and underwent a short training. The main goal of each EOV was to define improvement goals. We aimed for concrete actions, such as ‘Give all patients a small card with the name of their main doctor’. Furthermore, clinics were informed about different patient-mediated interventions to enhance the communication with their patients (e.g. organizing focus groups). The fertility teams were responsible for the execution of the plans, although the researcher monitored this process and called the team every 2 months to discuss progress. Moreover, we started an online community for the participating professionals and patients to exchange their ideas and actions regarding the improvement. Finally, clinics received a newsletter about progress every 2 months.

Outcome measures

Patient-centredness of fertility care

To measure the level of patient-centredness in fertility care, we used the Patient-Centredness Questionnaire-Infertility (PCQ-Infertility). This is a validated instrument asking patients about their experiences with fertility care (van Empel et al., 2010b). The PCQ-Infertility is composed of 46 questions and contains seven subscales, namely (i) Accessibility of care (e.g. ‘Was it a problem for you to contact staff if you had any questions?’ Answers: Yes, always/Yes, sometimes/No); (ii) Information provision (e.g. ‘Did you receive an overview of your treatment plan with a time schedule?’ Answers: Yes/No); (iii) Communication (e.g. ‘How often did your physician listen to you?’ Answers: Always/Most of the time/Sometimes/Never); (iv) Respect for patients’ values (e.g. ‘How often did your physician show an interest in your personal situation?’ Answers: Always/Most of the time/Sometimes/Never); (v) Continuity and transition of care (e.g. ‘How often did you have an appointment with the same physician?’ Answers: Always/Most of the time/Sometimes/Never); and (vi) Staff’s competence (e.g. ‘How often was your physician well-prepared for an appointment?’ Answers: Always/Most of the time/Sometimes/Never). A higher score on the total PCQ score or on one of the subscales (range 0–3) indicates a higher level of experienced patient-centredness (van Empel et al., 2010b).

Determinants of the effect of the multifaceted intervention

We also asked for patients’ background characteristics. Based on the literature (Mourad et al., 2010; Nefs et al., 2011a,b; Cho et al., 2013), we asked for age, ethnicity, level of education, duration and cause of infertility, use of professional emotional support and recent life events. Because of the association between patient-centredness and patients’ psychosocial status (Aarts et al., 2012), we also measured quality of life and risk factors for emotional maladjustment, using the FertiQoL and SCREENIVF questionnaires respectively (Verhaak et al., 2010; Boivin et al., 2011). Results from these questionnaires are presented elsewhere (Huppelschoten et al., 2013c).

Data collection

For data collection, we composed an online patient questionnaire consisting of background questions, PCQ-Infertility, FertiQoL and SCREENIVF. During baseline and after measurement, all patients received a mail in which they were asked to complete the online questionnaires. Two weeks later, a reminder was sent by mail. The non-responders received a paper version of the questionnaires 3 weeks later.

Statistical analysis

We compared all characteristics of the participating women between the control and intervention groups using t-tests for independent samples and chi-square tests when appropriate. We determined the effect of the multifaceted approach on the level of patient-centredness by comparing PCQ-Infertility total and subscale scores at the after measurement between the intervention and control group. Differences at baseline were corrected for by taking median baseline scores at the clinic level up as a covariate.

Our analyses were performed with adjustment for clustering of patients within clinics and by taking into account relevant case-mix adjusters. Therefore, we performed multilevel multivariate regression analysis in which the PCQ-Infertility total and subscale scores acted as the dependent variables. The group variable, baseline scores and case-mix adjusters acted as the independent variables. To select relevant case-mix adjusters, we performed a series of univariate analyses with all background characteristics, including the FertiQoL and SCREENIVF scores. Those associated with the PCQ-Infertility total score ($P < 0.20$) were selected as case-mix adjusters. In case of collinearity (correlation analyses; Spearman’s $r > 0.6$), we selected the most relevant characteristic. Finally, we excluded the statistically insignificant variables via manual backward elimination to come to our final model.
Subsequently, we included interaction terms from our previous model to study which female patient characteristics might have moderated the effect of the intervention on the total PCQ-Infertility score. We first dichotomized the continuous background characteristics into clinically relevant categories. Then we created interaction terms for the background characteristics (intervention versus control) and deleted the insignificant interaction terms through manual backward elimination.

Significance for the analyses was set at \( P < 0.05 \). Analyses were performed using the Statistical Package for the Social Sciences (version 20.0 for Windows®, SPSS, Inc., Chicago, IL, USA).

**Results**

At baseline measurement, a total of 1620 women in fertility care were invited to participate and 946 women (response 58.4%) completed the questionnaire set. After excluding 250 pregnant women, the results of 696 women were taken up in the analysis. Shortly after baseline measurement, two intermediate fertility clinics merged, one control clinic and one intervention clinic. We decided to exclude these clinics from our study to avoid extensive contamination of our intervention. Therefore measurement was performed in only 30 clinics. We invited a total of 1565 women in fertility care and 946 women (response 60.4%) completed the questionnaire set. After excluding 216 pregnant women, 730 women were eligible for our main analysis. Figure 1 shows the flowchart of this study.

Women’s background characteristics (Table I) at baseline measurement did not differ between the control and intervention group (\( P > 0.05 \)), except for the scores on the FertiQoL and SCREENIVF questionnaires. Fourteen background characteristics were selected as case-mix adjusters for our main analysis (Table I, last column). For example, we adjusted our results for treatment type by including assisted reproductive technology (ART) versus non ART in our analysis.

Table II shows the mean PCQ-Infertility total and subscale scores from baseline and after measurement, and the results of the multilevel multivariate regression analysis (i.e. case-mix adjusted differences). Baseline PCQ-Infertility scores did not differ between the intervention and control group. At after measurement, case-mix adjusted PCQ-Infertility total scores did not significantly differ either (\( B = 0.06; 95\% \) confidence interval (CI) = \(-0.04 – 0.15; P = 0.25\)). However, on the PCQ-Infertility subscale ‘Continuity of care’, the case-mix adjusted scores were significantly higher in the intervention group compared with the control group (\( B = 0.20; 95\% \) CI = \(0.00 – 0.40; P < 0.05\)).

No significant differences were found on the remaining PCQ-Infertility subscales.

The addition of three interaction terms to the model had a significant impact: the effect of the intervention turned out to be significantly higher when women (i) were younger than 36 years, (ii) started their fertility treatment after the start of the intervention or (iii) used complementary and alternative medicine (CAM). If women met all three conditions, the scores in the intervention group were on average 0.31 points higher compared with the control group (\( 95\% \) CI = \(0.14 – 0.48; P < 0.001 \)). Figure 2 provides an overview of the effect of the intervention for all different combinations of the three characteristics. In four of the eight possible scenarios (i.e. 35% of our entire patient group), the intervention group scored significantly better than the control group.
Discussion

A multifaceted intervention with participation of patients did not improve total patient-centredness scores, although positive effects were observed in specific female patient groups and in specific dimensions of patient-centredness. These results might suggest that initiatives for improvement of patient-centredness should focus on groups of patients or on dimensions that needed improvement.

This randomized study on the improvement of patient-centredness was done in full partnership with patients. They were involved in the design of the study, in the development of the questionnaires, in the audit and feedback procedure and in the outcome measurements.

Moreover, patients played an important role in the execution of the intervention, as former patients of the participating clinics (i.e. both male and female patients) took part in the EOVs as consultants of the team. Another strength was the size of the study with >3000 participating women in fertility care. Furthermore, we measured the level of patient-centred care with a validated questionnaire asking for objective women’s experiences with care. Finally, we corrected for clustering of patients within one clinic and adjusted for relevant background characteristics related to patient-centred care.

Some limitations of our study should also be taken into account. First, although our response rates seem acceptable (i.e. about 60%), it was lower than we expected. Therefore, our final sample size was smaller...
Table II Differences between intervention and control groups at baseline and after measurement. Differences are the result of the multilevel multivariate linear regression analyses with manual backward elimination of 14 relevant case-mix adjusters and baseline scores.

<table>
<thead>
<tr>
<th>PCQ-total</th>
<th>Accessibility</th>
<th>Communication</th>
<th>Respect of patients’ values</th>
<th>Continuity of care</th>
<th>Patient involvement</th>
<th>Staff competence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>2.15 (0.43)</td>
<td>2.17 (0.44)</td>
<td>1.85 (0.57)</td>
<td>1.74 (0.77)</td>
<td>2.28 (0.67)</td>
<td>2.41 (0.42)</td>
</tr>
<tr>
<td>Case-mix adjusted differences (95% CI)</td>
<td>0.06 (0.04 to 0.15)</td>
<td>0.02 (0.00 to 0.06)</td>
<td>0.05 (0.02 to 0.08)</td>
<td>0.04 (0.01 to 0.06)</td>
<td>0.00 (0.00 to 0.00)</td>
<td>0.02 (0.00 to 0.04)</td>
</tr>
</tbody>
</table>

CI, confidence interval.

*Results in the intervention group were significantly higher (i.e. 0.20 points; *P* = 0.047) on the Continuity of care subscale compared with the intervention group when adjusted for diagnosis, treatment type, CAM use, having a recent medical history, quality of life and PCQ-Infertility scores at baseline measurement.

The results of our study are of interest, as the evidence on how to improve patient-centredness in current healthcare is scarce. A review of Dwamena et al. showed that many interventions that promote patient-centred approaches were largely successful in teaching professionals new skills (Dwamena et al., 2012). However, when providers practised these skills, it was not clear whether patients were more satisfied with their care (Dwamena et al., 2012). These conflicting results might be due to poor methodological quality or the use of less relevant strategies for care improvement (Dwamena et al., 2012; Rathert et al., 2013). It might also be explained by the use of satisfaction surveys, which lack discriminative power as they often provide an overly optimistic picture of patients’ perception of health care (Jenkinson et al., 2002). We therefore asked patients for their more objective experiences with care instead of measuring patient satisfaction.

Despite this, our multifaceted approach did not show a significant effect in total PCQ-Infertility scores of the entire patient group. This could be due to an incomplete execution of the action points or to contamination by major clinic changes that were executed apart from the intervention (e.g. new buildings or changes in staff). Therefore, a next and important step would be to perform an extensive and systematic process evaluation of our improvement strategy to evaluate the actual exposure to the several elements of the multifaceted approach. These results will make us aware whether a clinic’s higher performance rate on the improvement strategy relates to a higher increase in patient-centredness scores (Hulscher et al., 2003).

However, we did find an increase in women’s experiences with fertility care within specific patient groups, of which the implications should be
considered in more detail. First, patient-centredness significantly improved due to the multifaceted approach when women started treatment during the intervention period. In other words, our intervention seemed to be less effective for women who were already under treatment before the study started. Patients may be biased by their expectations and previous experiences, reducing the effect of the intervention (McKinley et al., 2002; Bleich et al., 2009). Second, patient-centredness significantly improved in women younger than 36 years. Previous studies about the relation between patients’ perspectives on fertility care and age did not always find significant associations (Malin et al., 2001; Leite et al., 2005). An explanation for our study results might however be found in women’s infertility problem per se. Because older women have decreasing pregnancy rates, they might care less about patient-centredness as getting pregnant is the most important thing in their mind (van Empel et al., 2011b). Third, the multifaceted approach appeared to be more effective when women received CAM, such as homeopathy or acupuncture. About 20% of our patients used CAM, which is quite comparable with other western countries (Coulson and Jenkins, 2005; Smith et al., 2010). The relation between CAM and patient-centred care or its improvement has never been studied. Nachtigall et al. suggest that cultural factors affect patients’ decision to choose for CAM (Nachtigall et al., 2009). Presumably, CAM users are more sensitive to the improvement of patient-centred care. This is in concordance with results showing that CAM users believe in the value of treating the person as a whole and strive for more patient participation (Vincent and Furnham, 1996).

These results suggest that we should focus more on strategies and outcome measures at the sub group level, or even at the individual level. In the last decades, physician-defined outcomes were mainly evaluated in research to determine the success of new therapies or medication (Brubaker et al., 2011). Recently, important steps have been made towards the use of more patient-reported outcome measures as we did in our study through the PCQ-Infertility questionnaire. The introduction of more individual reported outcome measures has now been suggested in the literature as the next innovative step (Mannion et al., 2010; Brubaker et al., 2011; Ekman et al., 2012). By putting the patient in the centre of outcome assessment, we could improve the interaction between patients and professionals and patients’ experiences with care. This is especially true in cases of a wide inter-individual variation in patients’ needs and expectations, causing a limited responsiveness of a fixed-item instrument, such as the PCQ-Infertility (Ekman et al., 2012). Future research should concentrate on the value of these personalized outcome measures and its integration into standard care.

In conclusion, a multifaceted intervention with a major role for patients did not improve total patient-centredness scores in fertility care, although positive effects were observed in specific female patient groups and in specific dimensions of patient-centredness. Future studies should focus on specific dimensions of patient-centredness with high improvement potential and on more personalized strategies and outcome measures.

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Authors’ roles
A.G.H. designed the trial, developed and managed the main database, performed and interpreted the analysis, and drafted the paper. W.L.D.M.N. designed the trial, interpreted the data, and drafted the paper. G.P.W. revised the paper critically for important intellectual content. R.J.T.v.G. provided input for the design of the trial and drafted the paper. E.M.M.A. provided input for the design of the trial and drafted the paper. J.A.M.K. was principle investigator, and drafted the paper. All authors reviewed successive drafts of the paper.

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Conflict of interest
None declared.

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