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**ORIGINAL ARTICLE** ***Psychology and counselling***

# Tailored expectant management in couples with unexplained infertility does not influence their experiences with the quality of fertility care

**F.A.M. Kersten[1], R.P.G.M. Hermens[2], D.D.M. Braat[1], E. Tepe[3], A. Sluijmer[4], W.K. Kuchenbecker[5], N. Van den Boogaard[6], B.W.J. Mol[7], M. Goddijn[8], and W.L.D.M. Nelen[1,*] on behalf of the Improvement study Group[†]**

[1]Department of Obstetrics and Gynaecology, Radboud University Medical Center, PO Box 9101, 6500 HB, Nijmegen, The Netherlands [2]Scientific institute for Quality of Healthcare, Radboud University Medical Center, PO Box 9101, 6500 HB, Nijmegen, The Netherlands [3]Department of Obstetrics and Gynaecology, Slingeland Ziekenhuis, PO Box 169, 7000 AD, Doetinchem, The Netherlands [4]Department of Obstetrics and Gynaecology, Wilhelmina Ziekenhuis Assen, PO Box 30001, 9400 RA, Assen, The Netherlands [5]Department of Obstetrics and Gynaecology, Isala Clinics, PO Box 10400, 8000 GK, Zwolle, The Netherlands [6]Department of Obstetrics and Gynaecology, Academic Medical Centre, University of Amsterdam, PO Box 22660, Amsterdam DD 1100, The Netherlands [7]The Robinson Institute, School of Paediatrics and Reproductive Health, University of Adelaide, 5005 SA Adelaide, Australia [8]Centre for Reproductive Medicine, Academic Medical Centre, PO Box 22660, 1100 DD Amsterdam, The Netherlands

*Correspondence address. Tel: +31-243617351; E-mail: willianne.nelen@radboudumc.nl

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**STUDY QUESTION:** Do couples who were eligible for tailored expectant management (TEM) and did not start treatment within 6 months after the fertility work-up, have different experiences with the quality of care than couples that were also eligible for TEM but started treatment right after the fertility work-up?

**SUMMARY ANSWER:** Tailored expectant management of at least 6 months in couples with unexplained infertility is not associated with the experiences with quality of care or trust in their physician.

**WHAT IS KNOWN ALREADY:** In couples with unexplained infertility and a good prognosis of natural conception within 1 year, expectant management for 6–12 months does not compromise ongoing birth rates and is equally as effective as starting medically assisted reproduction immediately. Therefore, TEM is recommended by various international clinical guidelines. Implementation of TEM is still not optimal because of existing barriers on both patient and professional level. An important barrier is the hesitance of professionals to counsel their patients for TEM because they fear that patients will be dissatisfied with care. However, if and how adherence to TEM actually affects the couples' experience with care is unknown. Experiences with the quality care can be measured by evaluating the patient-centredness of care and the patients' trust in their physician.

**STUDY DESIGN, SIZE, DURATION:** This is a retrospective cross-sectional study. A survey with written questionnaires was performed among all couples who participated in the retrospective audit of guideline adherence on TEM in 25 Dutch clinics.

**PARTICIPANTS/MATERIALS, SETTING, METHODS:** Couples were eligible to participate if they were diagnosed with unexplained infertility and had a good prognosis (>30%) of natural conception within 1 year based on the Hunault prediction model. We used patient's questionnaires to collect data on the couples' experience with the quality of care and possible confounders for their experiences other than having undergone TEM or not. Multilevel regression analyses were performed to investigate case-mix adjusted association of TEM with the patient-centredness of care (PCQ-Infertility) and the patients' trust in their physician (Wake Forest Trust Scale).

**MAIN RESULTS AND THE ROLE OF CHANCE:** Couples who adhered to TEM experienced the quality of care on the same level as couples who were exposed to early treatment, i.e. started fertility treatment within 6 months after fertility work-up. There were no associations between adherence to TEM and the patient-centredness of care or the patients' trust in their physician.

[†] Members of the Improvement Study Group are listed in the Acknowledgements.

**LIMITATIONS, REASONS FOR CAUTION:** Because this study is retrospective, recall bias might occur. Furthermore, we were unable to measure the difference in experience with care over time. Therefore, our results have to be interpreted carefully.

**WIDER IMPLICATIONS OF THE FINDINGS:** Prospective research on couples undergoing TEM have to be performed to provide more detailed insight in the patients' experiences with the decision making process and subsequently the expectant period. Tackling the barriers surrounding TEM, i.e. better counselling and more patient information material, could further improve patient experiences with the quality of care for couples who are advised TEM.

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**Key words:** unexplained infertility / expectant management / patient-centredness / guideline adherence / experience with care / trust in physician / early treatment / prognostic model

# Introduction

Unexplained infertility is a common diagnosis in fertility care (Brandes *et al.*, 2010). For couples with unexplained infertility, the prognosis of spontaneous conception within 1 year can be calculated by the prognostic model of Hunault (Hunault *et al.*, 2004). For couples with a calculated prognosis over 30%, a tailored expectant management (TEM) of 6–12 months does not compromise ongoing birth rates compared to starting medically assisted reproduction (MAR) immediately (Steures *et al.*, 2008; Custers *et al.*, 2012). Furthermore, TEM is more cost-effective, has lower multiple pregnancy rates, and minimizes the significant physical and psychological burdens that accompany MAR (Verhaak *et al.*, 2002; Verberg *et al.*, 2008; Brandes *et al.*, 2009; Wu *et al.*, 2013). Therefore, national Dutch guidelines have formulated recommendations for TEM (NVOG, 2004; NHG, 2010).

Unfortunately, the implementation of TEM is still incomplete; over one third of couples eligible for TEM are exposed to early treatment, i.e. starting treatment within 6 months after basic fertility work-up (van den Boogaard *et al.*, 2011a; Kersten *et al.*, 2015). This is due to barriers on both the professional and patient level (van den Boogaard *et al.*, 2012). For patients, a lack of confidence in natural conception, perception that TEM is a waste of time, inappropriate expectations prior to the first consultation, and an overestimation of treatment success rates were mentioned as barriers. Management of a couple's expectations from the first visit is essential in order to create the opportunity to counsel couples for TEM after completing the basic fertility work-up. Among professionals, limited counselling skills on TEM have also been recognized as a barrier. Both patients and professionals regarded the absence of patient information material as the main barrier (van den Boogaard *et al.*, 2011a,b).

If these barriers on TEM are not addressed properly, it can lead to uncomfortable situations between couples and their physicians when TEM is advised and it can finally result in non-adherence. Furthermore, it can cause conflicts between patients and their physicians, patients dissatisfied with the care they receive, shopping for fertility treatment in other clinics, and even discontinuation of care (Brandes *et al.*, 2009). In order to avoid such situations, it is plausible that physicians can be reluctant to advise TEM, as they aim to maintain a good relationship with their patients and want them to experience good care. The question is, do couples who were eligible for TEM and did not start treatment within 6 months after the fertility work-up, have experienced their quality of care in a different way than couples that were also eligible for TEM but started treatment right after the fertility work-up?

To answer this question it is necessary to compare the experiences with quality of fertility care between the two groups. In the Netherlands, the standard for the measurement of patient experiences in healthcare is the Consumer Quality Index (CQI) (Delnoij *et al.*, 2010). This is a questionnaire, which asks clients about their concrete experiences and how much they value certain aspects of care. In fertility care the CQI is the validated Patient Centeredness Questionnaire-Infertility (PCQ-Infertility) (van Empel *et al.*, 2010). Because a main barrier in adherence to TEM is communication, we will also evaluate the patients' trust in their physician since this is an important determinant for experiences with communication (Haywood *et al.*, 2010). Furthermore, trust is associated with satisfaction with the physician, adherence to treatment, and continuity of care (Pearson and Raeke, 2000; Ommen *et al.*, 2008; Bachinger *et al.*, 2009).

Therefore, we will investigate the association between having undergone or not undergone TEM and patient-centredness of care and patients' trust in their physician to evaluate the effect of TEM on couples' experiences with the quality of fertility care.

# Materials and Methods

## Study design

This is a retrospective cross-sectional study. A survey with written questionnaires was performed among all couples who participated in the retrospective audit of guideline adherence on TEM in 25 Dutch clinics (Kersten et al., 2015). To ensure national representativeness of data, 6 fully IVF licensed centres, 11 intermediate centres and 8 centres without IVF facilities participated. Initial fertility work-up, ovulation induction (OI) and intrauterine insemination (IUI) can be carried out in all Dutch clinics. Intermediate clinics can start and monitor the *in vitro* fertilization (IVF) and intracytoplasmic sperm injection (ICSI) treatment. However, the laboratory phase of IVF and embryo transfer has to be carried out in a fully licensed fertility clinic.

## Ethical approval

The institutional ethics committee of Radboud university medical center provided ethical approval for this study (CMO no.2012/130).

## Setting

The basic insurance coverage for each Dutch citizen fully reimburses all treatment cycles of ovulation induction (OI) and intrauterine insemination (IUI), with or without controlled ovarian hyperstimulation, as well as a maximum of three IVF and/or ICSI cycles per ongoing pregnancy. Clinical guidelines are well known and used in Dutch fertility care, specifically the Dutch Network Guideline Infertility 2010 (NHG, 2010). This guideline, just as the NICE ('National Institute for Health and Care Excellence') clinical guideline makes recommendations on expectant management for couples with unexplained infertility (Fields *et al.*, 2013).

## Study population

We aimed to include a representative Dutch patient group of couples with unexplained infertility with a good prognosis of a natural conception within 1 year (>30%), based on Hunault's prediction model, i.e. couples who were eligible for TEM (Hunault *et al.*, 2004).

The female partner of the couple had to be between 18 and 38 years. The diagnosis of unexplained infertility included, apart from no cause found during the fertility work-up, one-sided tubal pathology (diagnosed by HSG or laparoscopy), cervical factor (i.e. Post coital test abnormal/negative with normal semen), mild male infertility (i.e. total motile sperm count [TMSC] 3–10 million), and/or mild endometrioses (American Society of Reproductive Medicine stage I/II). Couples with a previous fertility treatment (before March 2011) or with infertility based on bilateral tubal pathology, anovulation, severe endometrioses (American Society of Reproductive Medicine stage III/IV) or severe male factor (TMSC < 3 million) were excluded.

## Recruitment

In the Netherlands each clinic has a financial DBC (Diagnosis/Treatment Combination code) registration database. In this national database, all patients undergoing diagnostics or treatment for infertility are identified with a specific Fertility-code for new patients. In order to select as many participants as possible we recruited all couples who had an active Fertility-code for new patients between March 2011 and February 2012. Nine thousand eight hundred and nineteen couples were sent an information letter and an informed consent form. Three thousand four hundred and twenty-eight couples gave informed consent, we performed medical record searches to assess if they indeed fitted the in- and exclusion criteria. This resulted in 544 couples, eligible for this survey study. The details of the study population and recruitment have been described in detail previously (Kersten et al., 2015).

We sent all 544 couples a questionnaire by post between November 2012 and June 2013. Two weeks after the initial mailing we sent a reminder card to non-responders. Couples received a second copy of the questionnaire if they did not return the first questionnaire within 4 weeks. To ensure the highest response rate the questionnaire had a maximum completion time of 25 min.

## Data collection

Data collection was obtained from medical records and written patient questionnaires. These questionnaires consisted of five parts. Three parts were based on the confounding factors that could influence the experience with care (see confounders beneath). Two parts included validated questionnaires about patient-centredness of fertility care (PCQ-Infertility (van Empel *et al.*, 2010)), and patients' trust in the physician (Wake Forest Trust scale (WFTS) (Bachinger *et al.*, 2009)) (see outcome measures beneath). Data on the clinic characteristics were obtained by sending one gynaecologist, specialized in reproductive medicine, from each participating clinic a digital questionnaire.

### *TEM versus early treatment*

We obtained information about the fertility work-up, diagnosis, course of treatment, and treatment outcome from the medical record search, performed as part of the audit on guideline adherence on TEM. With this information, we divided the couples in two groups; couples who adhered to tailored expectant management (TEM), and couples who were exposed to early treatment. Couples were considered to adhere to TEM if they did not start treatment within 6 months after the basic fertility work-up. Early treatment meant that the couple started treatment immediately or within 6 months after the fertility work-up.

### *Confounders*

Previous studies showed that several demographic characteristics, type of treatment received, mental health status (quality of life), several clinic characteristics, and the amount of information provision can influence the experience with fertility care ( Haagen *et al.*, 2008; Hermens *et al.*, 2011; Mourad *et al.*, 2010; van Empel *et al*, 2011; Aarts *et al.*, 2012). We added two quality indicators for TEM to the possible confounders. We investigated the role of the following possible confounders.

### *Baseline characteristics*

The baseline characteristics of couples consisted of female and male age, socio-economic status measured by postal code, country of birth (female and male), highest educational level (female and male), duration of infertility (in months), type of treatment last received (none/IUI with or without mild ovarian hyperstimulation/IVF), mean number of treatment cycles received (no. IUI and IVF/ICSI cycles), and live birth achieved since 1st visit to the clinic or currently pregnant (yes/no).

### *Quality indicators on TEM*

To assess the process that leads to adherence to TEM we extracted two quality indicators from medical record research.

- The first indicator is the percentage of couples for which the prognosis of a natural conception within 1 year was calculated by the physician after the fertility work-up.
- The second indicator is the percentage of couples that were advised an expectant management of at least 6 months by their physician after the fertility work-up.

### *Quality of life*

We used the core module of the standardized FertiQol questionnaire to assess quality of life specific to infertility (see also www.fertiqol.org, Boivin *et al.*, 2011). The FertiQoL was only measured in couples with an unfulfilled childwish. A higher score on the FertiQol means a better quality of life. The reliability of this questionnaire was good with Cronbach's alpha >0.8 in our sample.

### *Clinic characteristics*

Clinic characteristics included the type of clinic (none/intermediate/fully licensed clinics), academic clinic (yes/no), fertility doctor present (yes/no), specialized fertility nurse present (yes/no), local protocol on expectant management available (yes/no), and did couples have digital access to their personal medical record (yes/no).

### *Information provision*

Information provision included items on education and counselling, based on what patients have mentioned as either barriers or facilitators on TEM in a previous study (van den Boogaard *et al.*, 2011a,b). 'Has the physician talked about the possibility of TEM during the first visit?', 'Did the physician explain the factors of the prognostic model?', 'Did the physician provide

information about the risks and complications of fertility treatments?', 'Did the physician compare the chances of conception with TEM and with other fertility treatments?', 'Did you look at the prognostic model yourself, with or without the physician?'. All questions were multiple-choice questions (yes/no/I don't remember).

## Outcome measures on patient experiences with quality of care

*PCQ-Infertility*

The patient-centredness of fertility care was measured with a modified version of the PCQ-Infertility questionnaire (PCQ-I) (van Empel *et al.*, 2010). This validated instrument measures patient-centredness of fertility care by asking patients about their experiences with care. It consists of 46 questions and 7 subscales: Accessibility (2 items, e.g. 'Was it a problem for you to contact staff if you had any questions?'); Information (11 items, e.g. Have you been informed about the various treatment options?'); Communication (7 items, e.g. 'Did the physician listen to you attentively?'); Patient involvement (3 items, e.g. 'Was it possible to make a shared-decision with the physician about your treatment?'); Respect for patients' values (7 items, e.g. 'Was your physician sympathetic to your emotions and current situation?'); Continuity and transition (7 items, e.g. 'How often did you receive contradictory information or advice?'); and Competence (6 items, e.g. 'How often was your physician well prepared for an appointment?'). A higher score on the total PCQ-I scale or one of the subscales (range 0–3) indicates a higher level of experienced patient-centredness (van Empel *et al.*, 2010). We excluded some questions from the categories Information (5 out of 11), Communication (1 out of 7) and Respect for patients' values (3 out of 7) because the questions overlapped with specific questions about information and communication on TEM. To assure the internal consistency of the subscales and the total PCQ-I scale, we computed Cronbach's alpha coefficients, all were alphas higher than 0.6 and considered acceptable.

*Wake Forest Trust Scale*

The WFTS is a validated instrument measuring patients trust in their physician with 10 items on a 5-point-Likert scale ('totally agree' = 1, to 'totally disagree' = 5), e.g. 'Your doctor will do whatever it takes to get you all the care your need', and 'You completely trust your doctor's decision about which medical treatments are best for you'. A higher score indicates more trust. An overall trust score is obtained by averaging the responses (sum of scores/10) (Bachinger *et al.*, 2009). The reliability of this questionnaire was good with Cronbach's alpha $> 0.7$ in our sample.

## Statistical analyses

The background characteristics, the mean total FertiQol score, and the scores on the information provision items between couples who adhered to TEM and couples who were exposed to early treatment were compared. We used the *t*-test for the continuous variables and the chi-square test for categorical variables. We performed multilevel analyses to take into account the clustering of couples by clinic with compound symmetry as covariance structure. First of all, linear mixed models were used to estimate the relationship between TEM and the outcome of the total PCQ-I, the seven subscales of the PCQ-I, and the WFTS, respectively (dependent variables). Series of multilevel univariate analysis were performed with the PCQ-I and the WFTS as the dependent variable. All possible confounders acted separately as independent variables. Variables with $P < 0.20$ in the univariate analysis were selected to perform correlation analysis with spearman's rho to evaluate collinearity between the selected characteristics. In case of two strongly correlating variables (rho $> 0.6$), only the clinically most relevant characteristic was included in the multivariate analyses. Four highly correlated ($R > 0.5$) items on education and counselling were aggregated (not informed = 0 and informed = 1, SUM/4) into one continuous variable 'the couple was educated on the medical and psychological consequences of MAR' for the multivariate analyses. In addition to adherence to TEM, we put the possible confounders in the multivariable analyses. Manual backward elimination was used to select confounders with a *P*-value $<0.05$, separately for the total PCQ-I and the WFTS. The FertiQoL can only be measured in couples with an unfulfilled childwish. Therefore, we did a second analysis, which only included the couples with an unfulfilled childwish. Analyses were performed with SPSS (version 20.0 for Windows, SPSS Inc., Chicago, IL, USA).

# Results

## Couple and clinic characteristics

In total, 384 of 544 invited couples completed the questionnaire (response rate 71%). Table I presents the background characteristics comparing couples with TEM and couples with early treatment. The mean duration between completing the fertility work-up and filling in the questionnaire (follow-up period) was similar between both groups (15.5 months versus 15.0 months). The percentage of couples that went to another clinic because they were not satisfied with the care they received or wanted a second opinion is comparable between both groups, 4.1% in the group with early treatment versus 4.7% in the group with TEM, $P = 0.5$. Overall, the percentage of couples that were exposed to MAR during the follow-up period was significantly lower in couples who adhered to TEM of at least 6 months compared with couples exposed to early treatment (IUI (+mild ovarian hyperstimulation): 25.8 versus 69.6%, $P < 0.01$, IVF/ICSI: 6.4 versus 30.4%, $P < 0.05$). The mean prognosis of natural conception is significant higher in couples with TEM compared with couples with early treatment, 43.1 versus 39.8%, $P < 0.05$. Couples who adhered to TEM more often had a live birth since the first visit to the clinic or were pregnant at time of completing questionnaire, compared with couples with early treatment (64.4 versus 54.1%, $P < 0.05$). The clinic characteristics were all comparable between both groups.

## Information provision

Table II presents couples' scores on the information provision items. Couples with TEM less often received information on the difference in chances of pregnancy with TEM and MAR (42.7 versus 57.5%, $P < 0.01$), the medical risks of MAR (44.6 versus 73.6%, $P < 0.01$), the higher chance of multiple pregnancy with MAR (54.4 versus 97.3%, $P < 0.01$), the complications in multiple pregnancy (38.5 versus 74.8%. $P < 0.01$), and the psychological consequences of MAR (45.0 versus 60.5%, $P < 0.01$), compared with couples with early treatment.

## PCQ-Infertility

*TEM*

Results in Table III show that there is no univariate association between TEM and the outcome of the total scale PCQ-I, couples who adhered to TEM scored 2.28 and couples with early treatment 2.29 (OR 1.02; 95% CI 0.96–1.08). We also analysed the seven subscales of the PCQ-Infertility, which shows that TEM is positively associated in univariate analyses with the subscale 'Accessibility' (OR 1.25; 95% CI 1.05–1.49) and 'Continuity and transition' (OR 1.14; 95% CI 1.02–1.27). The other five subscales were comparable between both groups.

**Table I Couple and clinic characteristics, comparing couples who adhered to tailored expectant management (TEM) and couples who were exposed to early treatment.**

| Characteristics | | Couples with overtreatment N = 148 (39.5%) | Couples with TEM N = 236 (61.5%) |
|---|---|---|---|
| At first visit to clinic: | | | |
| Mean female age, years (SD) | | 30.5 (3.4) | 30.4 (3.2) |
| Mean male age, years (SD) | | 33.1 (4.7) | 33.1 (4.6) |
| Non-Dutch ethnic background[a] | | 22 (14.9%) | 23 (9.7%) |
| Education level per couple:[b] | High | 105 (71.0%) | 173 (73.3%) |
| | Medium/Low | 43 (29.0%) | 63 (26.7%) |
| Socio-economic status: | High | 23 (15.8%) | 29 (12.5%) |
| | Medium | 105 (71.9%) | 177 (76.3%) |
| | Low | 18 (12.3%) | 26 (11.2%) |
| After finalizing fertility work-up: | | | |
| Type of infertility: | Primary | 102 (68.9%) | 148 (62.7%) |
| | Secondary | 46 (31.1%) | 88 (37.3%) |
| Mean duration of infertility in years (SD) | | 1.45 (0.6) | 1.34 (0.5) |
| Mean prognosis of natural conception (SD) | | 39.8% (8.2) | 43.1% (9.0)* |
| Prognosis calculated by physician | | 98 (66.2%) | 157 (66.5%) |
| Expectant period of 6–12 months advised (TEM advised) | | 37 (25.0%) | 186 (78.8%)* |
| At moment of completing questionnaire: | | | |
| Mean duration follow-up (month [range])[c] | | 15.0 [5–25] | 15.5 [5–25] |
| Type of treatment last received: | | | |
| None | | 0 | 157 (66.5%)* |
| IUI with or without mild ovarian hyperstimulation | | 103 (69.6%) | 61 (25.8%) |
| IVF/ICSI | | 45 (30.4%) | 15 (6.4%) |
| Mean no. of treatment cycles received during follow-up: | | | |
| IUI with or without mild ovarian stimulation (SD) | | 3.8 (2.4) | 0.86 (1.7)* |
| IVF/ICSI (SD) | | 0.30 (0.7) | 0.03 (0.3)* |
| Live birth achieved or currently pregnant[d] | | 80 (54.1%) | 152 (64.4%)* |
| Mean FertiQol score[range] *(only if childwish not yet fulfilled)* | | 68.8 [35–91] | 65.6 [32–97] |
| Clinic characteristics | | | |
| Academic clinic | | 54 (36.5%) | 81 (34.4%) |
| Type of clinic (IVF facilities): | None | 40 (27.0%) | 61 (25.8%) |
| | Intermediate | 70 (47.3%) | 124 (52.5%) |
| | Fully licensed | 38 (25.7%) | 51 (21.6%) |
| Fertility doctor present | | 106 (71.6%) | 180 (76.3%) |
| Specialized fertility nurse present: | | 119 (80.4%) | 176 (74.6%) |
| Local protocol on expectant management available | | 137 (92.6%) | 226 (95.8%) |
| Digital access to personal medical record | | 5 (3.4%) | 14 (5.9%) |

Data are *n* (%) unless otherwise stated.
[a]Ethnic background of the couples was determined by the origin of both partners: Dutch = one or both partners are of Dutch origin; non-Dutch = both partners are not of Dutch origin.
[b]Education level of the couples was determined by the highest education level of both partners: Primary or lower vocational education; intermediate = secondary or intermediate vocational education; High = higher professional education or university.
[c]Follow-up: (date finalizing fertility work-up until date entering data questionnaire in SPSS) − 1 month.
[d]Fulfilled child wish: The woman is currently pregnant (at time of completing the questionnaire) or had a live birth since the first visit to the clinic.
*$P < 0.05$.

### *Multivariable analyses*

Table IV shows the results of the multivariable analyses. TEM has no significant association with the PCQ-I score after adjustment for case-mix. Confounders for a significantly higher outcome of the PCQ-I are fulfilment of childwish, higher female age, TEM was discussed during the first visit to the clinic, and the education on medical and psychological consequences of MAR. A lead physician for each couple in a clinic was negatively associated with the PCQ-I score.

The multivariate analysis that only includes couples with an unfulfilled childwish, shows that a higher score on the FertiQol, and education of the couple on the psychological consequences of MAR were significantly associated with a higher outcome of the PCQ-I. A lead physician for

each couple in a clinic and the presence of a local protocol were negatively associated with the PCQ-I score.

### Wake Forest Trust Scale

*TEM*

Table III shows that there is no univariate association between TEM and the outcome of the WFTS. Couples who adhered to TEM and couples with early treatment had similar trust in their physician (WFTS score 4.1 (OR 0.97; 95% CI 0.89–1.06)).

*Multivariate analyses*

Table V shows the results of the multivariate analyses. It shows that TEM has no significant association with the WFTS score after adjustment for case-mix. Confounders for a significantly higher outcome of the WFTS are education on medical and psychological consequences of MAR, a clinic with none or intermediate IVF facilities (compared with fully licensed clinics), and the presence of a local protocol on expectant management.

The second multivariable analyses (only couples with unfulfilled childwish) show that a higher score on the FertiQol, educating the couple on the psychological consequences of MAR, and a higher male age are significantly associated with a higher outcome of the WFTS.

**Table II Education and counselling on tailored expectant management (TEM) compared between couples exposed to early treatment and couples who were not (TEM).**

| Items on education and counselling | Couples with early treatment *N* = 148 | Couples with TEM *N* = 236 |
|---|---|---|
| TEM was discussed during 1st visit | 101 (68.2%) | 173 (73.6%) |
| Received explanation on the items included in the prognostic model | 99 (66.9%) | 150 (63.8%) |
| Couple used the prognostic model themselves | 19 (12.9%) | 38 (16.2%) |
| Chances of pregnancy compared for TEM and MAR | 88 (57.5%) | 100 (42.7%)* |
| The couple was educated on: | | |
| Risks of MAR | 109 (73.6%) | 103 (44.6%)* |
| Multiple pregnancy chance | 144 (97.3%) | 126 (54.5%)* |
| Complications in multiple pregnancy | 110 (74.8%) | 89 (38.5%)* |
| Psychological consequences of MAR | 89 (60.5%) | 104 (45.0%)* |

Data are *n* (%).
MAR, medically assisted reproduction.
*$P < 0.05$.

## Discussion

This retrospective study shows that couples with unexplained infertility, who adhered to TEM evaluated their experiences with the quality of care in a similar way as couples who had treatment within 6 months after the basic fertility work-up. Furthermore, we did not find any associations between adherence to TEM and the patients' trust in their physicians.

The impact of expectant management on experience with care has to our knowledge not been investigated before in fertility care or in any other fields of medicine. Therefore, it is hard to compare our main outcome to other research. However, when comparing the outcome of the PCQ-I of our study population with previous research it is striking that our study population scores higher on the total score and almost all subscales of the PCQ-I (van Empel *et al.*, 2010). The only subscale that scored lower is 'Information'. This result underlines the previously mentioned barrier for TEM, i.e. the lack of patient information material for couples eligible for TEM (van den Boogaard *et al.*, 2012).

Previous research on the patient-centredness of fertility care has been focused on clinical and patient characteristics that influence the

**Table III Couples scores in the patient-centredness of fertility care [PCQ-Infertility] and patients' trust in the physician [Wake Forest Trust Scale] questionnaires according to whether they had tailored expectant management (TEM) or received early treatment and the association of the scores with TEM expressed as the odds ratio (OR) from multilevel univariate analyses.**

| Experience with care: | Couples with early treatment *N* = 148 | Couples with TEM *N* = 236 | OR [95% CI][a] |
|---|---|---|---|
| **Patient-centredness of care** | **Mean (SD)** | **Mean (SD)** | |
| PCQ-Infertility total score [0–3] | 2.28 (0.38) | 2.29 (0.39) | 1.02 [0.96–1.08] |
| Accessibility | 2.35 (0.79) | 2.58 (0.61) | 1.25 [1.05–1.49] |
| Information | 1.95 (0.71) | 1.83 (0.78) | 0.90 [0.78–1.03] |
| Communication | 2.67 (0.50) | 2.68 (0.48) | 1.01 [0.92–1.11] |
| Patient Involvement | 2.48 (0.61) | 2.49 (0.56) | 1.02 [0.91–1.14] |
| Respect for patient's values | 2.22 (0.82) | 2.28 (0.77) | 1.06 [0.94–1.20] |
| Continuity and transition | 2.06 (0.57) | 2.16 (0.57) | 1.14 [1.02–1.27] |
| Competence | 2.46 (0.39) | 2.45 (0.41) | 1.00 [0.92–1.08] |
| Trust in gynaecologist/fertility doctor | | | |
| Wake Forest Trust Scale [0–5] | 4.10 (0.66) | 4.10 (0.86) | 0.97 [0.89–1.06] |

[a]OR > 1 means a positive association with a higher PCQ-I or WFTS score.

**Table IV Case-mix adjusted association of tailored expectant management (TEM) on the patient-centredness of fertility care (PCQ-Infertility) in multilevel multivariate analyses.**

| Determinants | All couples ($n = 384$) | | Couples with an unfulfilled childwish ($n = 150$)[a] | |
|---|---|---|---|---|
| | OR [95% CI][b] | *P* | OR [95% CI][b] | *P* |
| TEM | **1.04 [0.98–1.10]** | **0.20** | **1.02 [0.92–1.12]** | **0.57** |
| Higher female age (per year)[c] | 1.02 [1.01–1.03] | <0.01 | – | N.S. |
| Low/medium educational level couple[d] | 1.13 [1.05–1.21] | <0.01 | – | N.S. |
| Fulfilment of childwish | 1.10 [1.03–1.17] | <0.01 | Not included | |
| Higher FertiQol score (per point) | Not included | | 1.01 [1.01–1.02] | <0.01 |
| TEM was discussed during first visit | 0.11 [0.01–0.21] | 0.03 | – | N.S. |
| Educated on the consequences of MAR | 1.29 [1.20–1.40] | <0.01 | 1.30 [1.17–1.44] | <0.01 |
| None/intermediate IVF clinic[e] | – | N.S | 1.23 [1.06–1.42] | <0.01 |

MAR, medically assisted reproduction.
[a]The FertiQol can only be measured in women with an unfulfilled child wish. Therefore, it is not possible to put the variables 'fulfilment of childwish' and 'FertiQol score' in the same model.
[b]OR > 1 means a positive association with a higher PCQ-I score.
[c]Per year increase in the female age the chance of one point higher on the PCQ-I score [range 0–3] increases with an OR of 1.03.
[d]Compared with couples with a high educational level.
[e]Compared with fully licensed IVF clinics.

**Table V Case-mix adjusted association of tailored expectant management (TEM) on the patients' trust in their physician (Wake Forest Trust Scale) in multilevel multivariate analyses.**

| Determinants | All couples ($n = 384$) | | Couples with an unfulfilled childwish ($n = 150$)[a] | |
|---|---|---|---|---|
| | OR [95% CI][b] | *P* | OR [95% CI][b] | *P* |
| TEM | **1.01 [0.91–1.12]** | **0.85** | **0.85 [0.70–1.04]** | **0.11** |
| Higher male age (per year)[c] | – | N.S. | 1.03 [1.01–1.05] | <0.01 |
| Low/medium educational level couple[d] | 1.14 [1.01–1.32] | 0.047 | – | N.S |
| Higher FertiQol score | Not included | | 1.02 [1.01–1.03] | <0.01 |
| Education on the consequences of MAR | 1.29 [1.09–1.53] | <0.01 | 1.31 [1.00–1.72] | 0.047 |
| None/intermediate IVF clinics[e] | 1.18 [1.01–1.38] | 0.02 | – | N.S. |

MAR, medically assisted reproduction.
[a]The FertiQol can only be measured in women with an unfulfilled child wish. Therefore, it is not possible to put the variables 'fulfilment of childwish' and 'FertiQol score' in the same model.
[b]OR > 1 means a positive association with a higher WFTS score.
[c]Per year increase in the male age the chance of one point higher on the WFTS scale [range 1–5] increases with an OR of 1.03.
[d]Compared with couples with a high educational level.
[e]Compared with fully licensed IVF clinics.

experience with care (Mourad *et al.*, 2010; Hermens *et al.*, 2011; van Empel *et al.*, 2011; Aarts *et al.*, 2012). Our findings in the multivariate analyses are partly congruent with the characteristics they found to be associated with experiences with care. We found four characteristics to be positively associated with both the patient-centredness of care and the patients' trust in their physician: low/medium educational level, higher FertiQol score, type of clinic with no/intermediate IVF facilities, and education on the medical and psychological consequences or MAR. Last mentioned has the strongest association with experiences with care. This underlines the importance of education and information for these couples. However, if this also positively influenced adherence to TEM cannot be derived from our results, as couples with early treatment more often received information on the medical and psychological consequences of MAR. Since we do not know at what time this information was provided, before or after the choice of expectant management or fertility treatment or at the commencement of a fertility treatment, we cannot conclude from our results whether more or less information has an association with adherence to TEM. On the other hand, we already identified the lack of information material and counselling as a main barrier for adherence to TEM (van den Boogaard *et al.*, 2011a,b).

This study has some limitations, mainly due to the retrospective design of the study. First, there is the possibility of recall bias when completing the questionnaire. For some couples, the time between the fertility work-up and filling in the questionnaire (follow-up period) was as long as 2 years. Despite the fact that our results show that the mean follow-up period is equal between couples that adhered to TEM and couples exposed to early treatment we do not know how their experiences with care might have changed over time. It is possible that during the

expectant period couples had different experiences with their care than they recalled at the time of completing the questionnaire. The second limitation is that the PCQ-I is specifically developed to measure experiences with the patient-centredness during fertility treatment. This questionnaire has not been validated for our specific study population, i.e. couples eligible for TEM. Many couples that completed the questionnaire for our study were not undergoing a fertility treatment at that time. We assured the internal consistency by computing Cronbach's alpha coefficients, all were higher than 0.6. However, how the different study populations affected the results of the PCQ-I is not known. The third limitation is that we specifically looked at TEM and experiences with care in the Netherlands. How our results will translate to other countries that have recommendations on TEM is difficult to say (Farquhar *et al.*, 2011; Fields *et al.*, 2013). The use of clinical guidelines is common practice in Dutch fertility care and most fertility treatments are reimbursed (NHG, 2010). In countries where providing fertility care according to guidelines is uncommon and the monetary or cultural incentive to start treatment is different, it might be harder to advise TEM without negatively affecting experiences with care.

Otherwise, this study has several strengths. We conducted a large national multicentre study in almost one third of all Dutch fertility clinics. This ensures representativeness of Dutch fertility care. Furthermore, we used validated questionnaires to evaluate experiences with care. This minimizes measurement errors and makes our outcomes comparable to other studies investigating experiences with care. Finally, the extent to which guideline adherence, specifically TEM, influences experiences with care has not been researched in fertility or other health care before. The effect guideline adherence has on experiences with care is a very important aspect to improve guideline implementation. Physicians are given feedback on what affect TEM actually has on the patients' experiences with care.

Our results underline that Dutch physicians should not be hesitant to advise TEM if they properly manage the couples expectations on TEM and fertility treatments. How you communicate and inform couples is very important, if this goes well, patients will experience better quality of care. This is congruent with the barriers mentioned earlier. Managing the expectations of couples on TEM and fertility treatments from the first visit, counselling and informing them on TEM, and providing more information material (paper or digital) could not only increase adherence to TEM but also provide better experiences with the quality of care. This knowledge is also important for other countries that make guideline recommendations on TEM. Results of this study may help to overcome barriers that professionals might have to advise an expectant management. However, as mentioned before, our study design was retrospective and therefore our results have to be interpreted carefully. Prospective research on couples undergoing TEM have to be performed to provide more detailed insight in the patients' experiences with the decision making process and subsequently the expectant period.

In conclusion, a tailored expectant management of at least 6 months in couples with unexplained infertility is not associated with the overall experiences with the quality of care or their trust in their physician. However, prospective research could provide more information on the cause-effect relationship between patient experiences and TEM. Furthermore, tackling the barriers surrounding TEM, i.e. better counselling and more patient information material, could further improve patient experiences with quality of care for couples who are advised TEM.


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## Authors' roles

W.L.D.M.N., M.G., B.W.J.M., E.T., A.S., N.v.d.B., W.K.K., D.D.M.B., R.P.G.M.H. and F.A.M.K. were involved in conception and design of the study. F.A.M.K. led data collection, performed data analysis and interpretation, and wrote this manuscript. R.P.G.M.H. and W.L.D.M.N. contributed substantially to data interpretation and manuscript revisions. M.G., E.T., A.S., N.v.d.B., W.K.K., B.W.J.M. and D.D.M.B. contributed to data interpretation and provided critical revision. All authors read and approved the final manuscript.


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## Conflict of interest

None declared.

## References


Aarts JW, Huppelschoten A, van Empel IWH, Boivin J, Verhaak CM, Kremer JAM, Nelen WL. How patient-centred care relates to patients' quality of life and distress: a study in 427 women experiencing infertility. *Hum Reprod* 2012;**27**:488–495.

Bachinger SM, Kolk AM, Smets EM. Patients' trust in their physician—psychometric properties of the Dutch version of the 'Wake Forest Physician Trust Scale'. *Patient Educ Couns* 2009;**76**:126–131.

Boivin J, Takefman J, Braverman A. The Fertility Quality of Life (FertiQoL) tool: development and general psychometric properties. *Hum Reprod* 2011;**26**:2084–2091.

Brandes M, van der Steen JO, Bokdam SB, Hamilton CJCM, de Bruin JP, Nelen WLDM, Kremer JA. When and why do subfertile couples discontinue their fertility care? A longitudinal cohort study in a secondary care subfertility population. *Hum Reprod* 2009;**24**:3127–3135.

Brandes M, Hamilton CJ, de Bruin JP, Nelen WLDM, Kremer JA. The relative contribution of IVF to the total ongoing pregnancy rate in a subfertile cohort. *Hum Reprod* 2010;**25**:118–126.

Custers IM, van Rumste MM, van der Steeg JW, van Wely M, Hompes PG, Bossuyt P, Broekmans FJ, Renckens CN, Eijkemans MJ, van Dessel TJ *et al*. Long-term outcome in couples with unexplained subfertility and an intermediate prognosis initially randomized between expectant management and immediate treatment. *Hum Reprod* 2012;**27**:444–450.

Delnoij DM, Rademakers JJ, Groenewegen PP. The Dutch consumer quality index: an example of stakeholder involvement in indicator development. *BMC Health Serv Res* 2010;**10**:88.

Farquhar CM, van den Boogaard NM, Riddell C, Macdonald A, Chan E, Mol BW. Accessing fertility treatment in New Zealand: a comparison of the clinical priority access criteria with a prediction model for couples with unexplained subfertility. *Hum Reprod* 2011;**26**:3037–3044.

Fields E, Chard J, James D, Treasure T and Guideline Development Group. Fertility (update): summary of NICE guidance. *BMJ* 2013;346:f650.

Haagen EC, Hermens RP, Nelen WL, Braat DD, Kremer JA, Grol RP. Subfertile couples' negative experiences with intrauterine insemination care. *Fertil Steril* 2008;**89**:809–816.

Haywood C, Lanzkron S, Ratanawongsa N, Bediako SM, Lattimer L, Powe NR, Beach MC. The association of provider communication with trust among adults with sickle cell disease. *J Gen Intern Med* 2010; **25**:543–548.

Hermens RP, Haagen EC, Nelen WL, Tepe EM, Akkermans R, Kremer JA, Grol RP. Patient and hospital characteristics associated with variation in guideline adherence in intrauterine insemination care. *Int J Qual Health Care* 2011;**23**:574–582.

Hunault CC, Habbema JD, Eijkemans MJ, Collins JA, Evers JL, te Velde ER. Two new prediction rules for spontaneous pregnancy leading to live birth among subfertile couples, based on the synthesis of three previous models. *Hum Reprod* 2004;**19**:2019–2026.

Kersten FA, Hermens RP, Braat DD, Hoek A, Mol BW, Goddijn M, Nelen WL. Overtreatment in couples with unexplained infertility. *Hum Reprod* 2015;**30**:71–80.

Mourad SM, Nelen WL, Akkermans RP, Vollebergh JH, Grol RP, Hermens RP, Kremer JA. Determinants of patients' experiences and satisfaction with fertility care. *Fertil Steril* 2010;**94**:1254–1260.

NHG N. National network guideline on infertility. 2010.

NVOG. Guideline NVOG, OFO. 2004.

Ommen O, Janssen C, Neugebauer E, Bouillon B, Rehm K, Rangger C, Erli HJ, Pfaff H. Trust, social support and patient type—associations between patients perceived trust, supportive communication and patients preferences in regard to paternalism, clarification and participation of severely injured patients. *Patient Educ Couns* 2008;**73**:196–204.

Pearson SD, Raeke LH. Patients' trust in physicians: many theories, few measures, and little data. *J Gen Intern Med* 2000;**15**:509–513.

Steures P, van der Steeg JW, Hompes PG, Bossuyt PM, van der Veen F, Habbema JD, Eijkemans MJ, Broekmans FJ, Verhoeve HR, Mol BW. Intra-uterine insemination with controlled ovarian hyperstimulation compared to an expectant management in couples with unexplained subfertility and an intermediate prognosis: a randomised study. *Ned Tijdschr Geneeskd* 2008;**152**:1525–1531.

van den Boogaard NM, Oude Rengerink K, Steures P, Bossuyt PM, Hompes PG, van der Veen F, Mol BW, van der Steeg JW. Tailored expectant management: risk factors for non-adherence. *Hum Reprod* 2011a;**26**:1784–1789.

van den Boogaard NM, van den Boogaard E, Bokslag A, van Zwieten MC, Hompes PG, Bhattacharya S, Nelen W, van der Veen F, Mol BW. Patients' and professionals' barriers and facilitators of tailored expectant management in subfertile couples with a good prognosis of a natural conception. *Hum Reprod* 2011b;**26**:2122–2128.

van den Boogaard NM, Musters AM, Bruhl SW, Tankens T, Kremer JA, Mol BW, Hompes PG, Nelen WL, van der Veen F. Tailored expectant management: a nationwide survey to quantify patients' and professionals' barriers and facilitators. *Hum Reprod* 2012;**27**:1050–1057.

van Empel IW, Aarts JW, Cohlen BJ, Huppelschoten DA, Laven JS, Nelen WL, Kremer JA. Measuring patient-centeredness, the neglected outcome in fertility care: a random multicentre validation study. *Hum Reprod* 2010;**25**:2516–2526.

van Empel IW, Hermens RP, Akkermans RP, Hollander KW, Nelen WL, Kremer JA. Organizational determinants of patient-centered fertility care: a multilevel analysis. *Fertil Steril* 2011;**95**:513–519.

Verberg MF, Eijkemans MJ, Heijnen EM, Broekmans FJ, de Klerk C, Fauser BC, Macklon NS. Why do couples drop-out from IVF treatment? A prospective cohort study. *Hum Reprod* 2008;**23**:2050–2055.

Verhaak CM, Smeenk JM, Kremer JA, Braat DD, Kraaimaat FW. The emotional burden of artificial insemination: increased anxiety and depression following an unsuccessful treatment. *Ned Tijdschr Geneeskd* 2002;**146**:2363–2366.

Wu AK, Elliott P, Katz PP, Smith JF. Time costs of fertility care: the hidden hardship of building a family. *Fertil Steril* 2013;**99**:2025–2030.