

# Effects of fertility education on knowledge, desires and anxiety among the reproductive-aged population: findings from a randomized controlled trial

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**STUDY QUESTION:** What are the effects of fertility education on knowledge, childbearing desires and anxiety?

**SUMMARY ANSWER:** Providing fertility information contributed to greater knowledge, but increased anxiety.

**WHAT IS KNOWN ALREADY:** Past studies have found that exposure to educational material improved fertility awareness and changed desires toward childbearing and its timing. Existing educational websites with evidence-based medical information provided in a non-judgmental manner have received favorable responses from reproductive-aged men and women.

**STUDY DESIGN, SIZE, DURATION:** This three-armed (one intervention and two control groups), randomized controlled trial was conducted using online social research panels (SRPs) in Japan in January 2015.

**PARTICIPANTS/MATERIALS, SETTING, METHODS:** A total of 1455 participants (726 men and 729 women) between 20 and 39 years of age who hoped to have (more) children in the future were block-randomized and exposed to one of three information brochures: fertility education (intervention group), intake of folic acid during pregnancy (control group 1) or governmental financial support for pregnancy and child-birth (control group 2). Fertility knowledge was measured with the Japanese version of the Cardiff Fertility Knowledge Scale (CFKS-J). Knowledge, child-number and child-timing desires, subjective anxiety (i.e. whether participants felt anxiety [primary outcome]), and scores on the State-Trait Anxiety Inventory were assessed immediately after exposure. Non-inferiority comparisons were performed on subjective anxiety with non-inferiority declared if the upper limit of the two-sided 95% confidence interval (CI) for risk difference did not exceed a margin of 0.15. This test for non-inferiority was only performed for subjective anxiety; all the other variables were tests of superiority.

**MAIN RESULTS AND THE ROLE OF CHANCE:** Posttest scores on the CFKS-J (mean, SD) were higher in the intervention group than that of the control groups: intervention versus Control 1 and versus Control 2: 52.8 (28.8) versus 40.9 (26.2) ( $P < 0.001$ ) versus 45.1 (27.1) ( $P = 0.003$ ) among men and 64.6 (26.0) versus 50.8 (26.9) ( $P < 0.001$ ) versus 53.0 (26.4) ( $P < 0.001$ ) among women.

The percentage of participants who felt subjective anxiety after exposure to the intervention brochure was significantly higher than that of the control groups: intervention versus Control 1 and versus Control 2: 32.6 versus 17.8% (risk difference [RD] = 0.149, 95% CI: 0.073–0.225) versus 14.5% (RD = 0.182, 95% CI: 0.108–0.256) among men, and 50.2 versus 26.3% (RD = 0.239, 95% CI: 0.155–0.322) versus 14.0% (RD = 0.362, 95% CI: 0.286–0.439) among women. Non-inferiority of the intervention was inconclusive (i.e. the CI included 0.15) among men whereas inferiority was declared among women. The incidence of anxiety was higher in the intervention group than that of the control groups especially among men aged 30 and older and among women aged 25 and older. No difference existed in childbearing desires between groups after exposure.

**LIMITATIONS, REASONS FOR CAUTION:** The possibility of selection bias associated with the use of SRPs (higher socioeconomic status and education) and volunteer bias toward those more interested in fertility may limit the generalizability of these findings.

**WIDER IMPLICATIONS OF THE FINDINGS:** In addition to education targeting a younger generation, psychological approaches are needed to alleviate possible anxiety caused by fertility information.

**STUDY FUNDING/COMPETING INTEREST(S):** This study was funded by National Center for Child Health and Development, Seiiku Medical Study Grant (24-6), the Daiwa Foundation Small Grants and Grant-in-Aid for JSPS Fellows (26-1591). No competing interest declared.

**TRIAL REGISTRATION NUMBER:** UMIN Clinical Trials Registry. Trial registration number, 000016168.

**TRIAL REGISTRATION DATE:** 13 January 2015.

**DATE OF FIRST PATIENT'S ENROLMENT:** 15 January 2015.

**Key words:** fertility / awareness / risk communication / anxiety / education

## Introduction

The total fertility rate is decreasing and age at first birth is increasing worldwide (World Bank, 2015). Especially in developed countries, substantial decline in fertility and the growing trend to delay childbearing are serious concerns (ESHRE Capri Workshop Group, 2005; Organisation for Economic Co-operation and Development, 2014). In Japan, where this study was conducted, the total fertility rate is among the lowest (1.43 in 2013), and the parental age at first birth has now reached more than 30 years of age (30.4 and 32.5 years for women and men, respectively, in 2013) (Ministry of Health Labour and Welfare, 2013). Although delayed childbearing is a consequence of a multifactorial decision-making process related to career, education, relationships, partner's desire, financial security, health etc. (Cooke et al., 2010, 2012; Mills et al., 2011; Roberts et al., 2011), research suggests that a lack of accurate fertility information might explain sub-optimal fertility behavior (Bunting and Boivin, 2010). Many people overestimate the duration of the reproductive lifespan and the likelihood of conceiving (Lampic et al., 2006; Bretherick et al., 2010; Ali et al., 2011; Daniluk et al., 2012; Peterson et al., 2012; Bunting et al., 2013; Lundsberg et al., 2014; Maeda et al., 2015), which sometimes results in unintended childlessness (Benzies et al., 2006; Friese et al., 2006; Cooke et al., 2010). In this context, educational initiatives have been undertaken in many countries (De Cock, 2011; Daniluk and Koert, 2013; Hammarberg et al., 2013).

However, the timing of childbearing can be perceived as dependent on factors outside one's control (e.g. timing of promotion, partner's willingness) (Cooke et al., 2012). According to the risk perception model, risk behavior perceived to be under the control of others is also perceived to be less modifiable (Covello et al., 2001). In such contexts, a fertility education campaigns could cause people to experience concern if they perceive that the behavior (childbearing efforts) is not entirely within their control to change. Indeed, recent fertility campaigns have met with public disapproval in the USA (Soules, 2003; Reynolds, 2009) and the UK (Gray, 2013) because they appeared to force a specific childbearing deadline on women who were not yet ready to conceive. A similar campaign suggested by the Japanese Government in 2013 sparked much public debate about the need to educate people (Hongo, 2013; Maeda et al., 2015). On the other hand, several initiatives (De Cock, 2011; Daniluk and Koert, 2013; Hammarberg et al., 2013) that presented participants with evidence-based medical information and emphasized

informed decision-making in non-judgmental attitudes received favorable responses (Daniluk and Koert, 2012). Specifically, previous studies showed that exposure to online educational material regarding fertility, improved fertility awareness and changed knowledge about the timing of childbearing (Wojcieszek and Thompson, 2013; Daniluk and Koert, 2015). Despite a growing interest and recognition in the need for fertility education among health professionals, the effect of such information on knowledge and especially psychological reactions is still poorly understood among reproductive-aged men and women. In addition, there is a lack of information about factors that covary with such anxiety and that could provide important background to tailor and promote effective and acceptable education.

The aim of the present study was to evaluate the effects of fertility information on knowledge, desires and anxiety. Participants were randomized to receive the intervention, which comprised evidence-based medical information about male and female fertility (intervention), or to one of two information control groups that received the typical health and government support information issued regarding pregnancy and childbirth. It was hypothesized that the intervention group would show increased fertility knowledge and sooner timing of next birth compared with the control groups but given positive public reaction to existing educational websites (De Cock, 2011; Daniluk and Koert, 2013; Hammarberg et al., 2013) the fertility information was not expected to increase anxiety compared with the control information.

## Materials and Methods

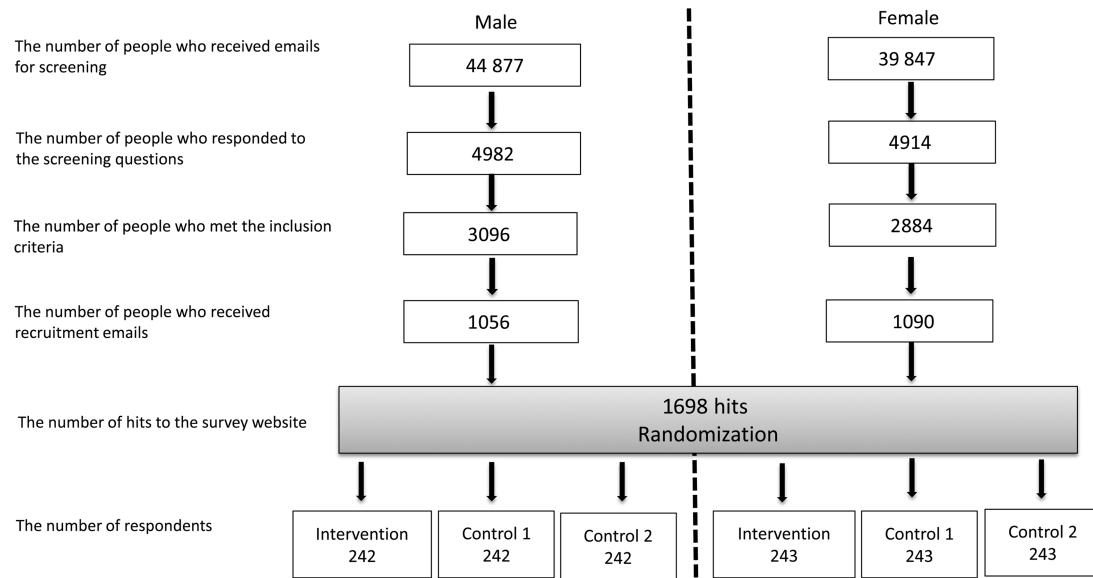
We conducted a three-armed (one intervention and two control groups), randomized controlled non-inferiority trial in January 2015. Participants were randomly assigned to one of the information brochures.

### Ethical approval

The ethics committee at Akita University Graduate School of Medicine approved the study protocol.

### Participants

Participants were recruited via online social research panels (SRPs). Inclusion criteria included men and women aged between 20 and 39 years of age, hoping to have children (or more children) in the future, and currently not pregnant ( $n = 1455$ ). Medical and advertising professionals were excluded from the recruitment.



**Figure 1** Flowchart showing the procedure.

## Procedures

An online market research company (Macromil, Tokyo, Japan), which has a nationwide SRP of more than 1 million registrants, sent prescreening emails for the inclusion criteria to 84 724 people aged 20–39 years who were randomly selected from its registrants (Fig. 1). Of the 5980 eligible people, 2146 people were sent recruitment emails and 1455 people completed the survey (67.8% participation rate of eligible). We performed quota sampling by gender and age-group block, setting the sample composition roughly the same as the Japanese adult population.

Participants were block-randomized to one of the three groups using a central computerized random allocation system (ScreeningMacro, Macromil, Japan). All study materials were presented online using Airs software (Macromil, Japan). After completion of the pretest survey, one of the brochures was presented. Participants were asked to read the entire brochure. Participants were not informed how many brochures existed. After the brochure presentation participants were provided with the posttest survey. Participants were allowed to take as much time as needed to read the brochure. It was not possible to reread the brochure during the posttest survey. Those who completed the survey were provided coupons worth several hundred yen (a few USD). Participant responses were anonymous.

## Intervention

An educational brochure on infertility facts and infertility risks factors (lifestyle, reproductive) was created. The information in the Fertility Education intervention group (2968 characters, in Japanese) consisted mainly of excerpts from an educational booklet for general readers published by the [Japan Society of Obstetrics and Gynecology \(2014\)](#) and from the website for patients produced by the [Japan Society for Reproductive Medicine \(2013\)](#), including the definition, prevalence and causes of infertility (paragraphs titled 'What is infertility?' and 'What can cause infertility?'), the ages at which female fertility declines (paragraphs titled 'Both men and women are affected by reproductive ageing', 'What is the ideal age for women to conceive and give birth?', and 'What is 'ageing of the ovum'?'), timing, and the risks of sexually transmitted infections and psychological stress on fertility (a paragraph titled 'To have a child'). We consulted several other educational

websites for the general population to add facts about male fertility and age (a paragraph titled 'What is the relationship with male age?') ([Saito, 2015](#)) and the risks to fertility associated with unhealthy weight, smoking, and alcohol drinking (a paragraph titled 'To have a child') ([NHS choices, 2014](#)) to the brochure. Two experts on reproductive medicine confirmed the scientific validity and the neutral stance of the intervention brochure.

There were two control brochures to control for existing education relevant to reproduction. Information in the Folic Acid control group 1 (2202 characters) was selected from the website of the [National Institute of Health and Nutrition \(2015\)](#) as a control brochure that provided information about intake of folic acid during pregnancy, including efficacy (i.e. reduction of the risk of neural tube defects in the fetus), appropriate amount, and the period of intake. The information in the Government Finance control group 2 (2729 characters) was excerpted from the [Japan Institute of Life Insurance \(2015\)](#) website that presented information about government financial and social support during pregnancy and childbirth. We set two control groups to test the robustness of our study because people may react differently to the information related to diseases (e.g. infertility, folate deficiency) than to general reproductive information.

We conducted a pilot survey on 24 university students and a small group of our colleagues to ensure that the information brochures and the questionnaire were understandable.

## Measures

The pre- and postsurvey consisted of 119 items that covered six domains developed to investigate factors associated with low fertility in Japan. Only questions relevant to the analyses presented in this paper are described here.

### Fertility knowledge

We used the Japanese version of the Cardiff Fertility Knowledge Scale (CFKS-J) ([Bunting et al., 2013; Maeda et al., 2015](#)) to assess fertility knowledge in the pre and posttest survey. The CFKS-J consisted of 13 items that measured knowledge about facts, risks and myths of fertility. Participants responded to all items as true, false or do not know. A correct answer was assigned one point and an incorrect or 'do not know' answer was assigned

zero points. Scores are reported as the percent correct score (0–100%). Internal consistency coefficient  $\alpha$  of the CFKS-J was 0.74, and a factor analysis showed the scale had a one-factor structure (Maeda et al., 2015).

#### Childbearing desires

In the pre- and posttest survey, participants stated their desired number of (additional) children (child-number desire) and the age at which they hoped to have their first and last child (child-timing desire) with the option of 'I don't know'. Those who had children stated the desired age at which they hoped to have their additional child and their last child.

#### State-anxiety psychological assessment

Psychological measurement was taken once immediately after exposure to the information brochure.

We used two indicators to examine anxiety. The primary indicator was a single item rated on a 5-point Likert scale: 'How do you feel about the brochure just presented?' 'I—Strongly disagree; 2—Disagree; 3—Neither agree nor disagree; 4—Agree or 5—Strongly agree.' We categorized participants who answered 4 or 5 as those who felt anxiety.

The secondary indicator was the Japanese version of the State-Trait Anxiety Inventory (STAI) (Spielberger et al., 1970; Nakazato and Mizuguchi, 1982), which has a 4-point Likert scale used with 20 state-anxiety items (STAI-S; range 20–80) and 20 trait-anxiety items (STAI-T; range 20–80). State-anxiety items measure the current anxiety level, whereas trait-anxiety refers to the characteristic (trait) anxiety level. Higher scores indicate greater anxiety. High internal consistency of STAI-S (coefficient  $\alpha$  = 0.92) and test-retest reliability of STAI-T (0.76 for 1 h later and 0.71 for 3 months later) was reported in the Japanese version (Nakazato and Mizuguchi, 1982).

#### Sociodemographic variables

The online market research company provided participant gender and age. Participants indicated their annual household incomes, educational backgrounds and relationship status. Annual household income was categorized into four groups: low < 4 million Japanese Yen (JPY); moderate 4–7 million

JPY; high ≥ 8 million JPY and 'unknown.' At the time of the study, 1 US Dollar = 117 JPY. Educational background was categorized into two groups (university education, yes/no). Relationship status was categorized into three groups: single; having a partner but not married; and married. The rate of cohabitation is extremely low in Japan, ~1%, (Cabinet Office, Government of Japan, 2011) and was not measured.

#### Fertility status

Participants reported whether they had given birth to/fathered a child (yes/no), whether they currently wanted to conceive immediately (yes/no), and whether they had sought a medical consultation or treatment regarding fertility (yes/no).

### Statistical analyses

We used a non-inferiority margin of 15% and estimated the sample size of one group ( $n = 244$ ), based on the assumption that the proportion of those who would feel anxiety was 55% in the pilot survey with 90% power at a significance level of 5%. The non-inferiority margin was based on clinically important differences as well as cost and feasibility.

We compared the baseline characteristics, pretest knowledge and pretest desires between the intervention and each control group stratified by sex. Posttest knowledge, desires and psychological assessments were also compared between the intervention and control groups. Statistical comparisons were carried out using Student's *t* tests, two-group variance-comparison tests, Fisher's exact tests and  $\chi^2$  tests according to the type and distribution of the variables. We performed all analyses on an intention-to-treat basis.

For the primary outcome regarding anxiety (subjective anxiety), non-inferiority of fertility information could be claimed if the upper limit of the two-sided 95% confidence interval (CI) for the difference in the proportion of those who felt subjective anxiety did not exceed 0.15. This test for non-inferiority was only performed for the primary outcome for anxiety; all other variables were tests of superiority. A two-sided *P*-value of <0.05 was used to define statistical significance. All the analyses were performed using STATA12-SE (StataCorp LP, College Station, TX, USA).

**Table 1** Pretest characteristics of the intervention and control groups.

	Male		Female			
	Intervention ( <i>n</i> = 242)	Control 1 ( <i>n</i> = 242)	Control 2 ( <i>n</i> = 242)	Intervention ( <i>n</i> = 243)	Control 1 ( <i>n</i> = 243)	Control 2 ( <i>n</i> = 243)
Age in years, mean (SD)	30.9 (5.8)	30.8 (5.7)	30.9 (5.7)	30.5 (5.6)	30.4 (5.6)	30.2 (5.5)
Annual household income ( <i>n</i> , %)						
<4 million JPY	73 (30.2)	77 (31.8)	72 (29.8)	90 (37.0)	84 (34.6)	75 (30.9)
4–7 million JPY	99 (40.9)	80 (33.1)	85 (35.1)	75 (30.9)	90 (37.0)	87 (35.8)
≥8 million JPY	38 (15.7)	36 (14.9)	38 (15.7)	26 (10.7)	21 (8.6)	25 (10.3)
Unknown	32 (13.2)	49 (20.2)	47 (19.4)	52 (21.4)	48 (19.8)	56 (23.0)
University education ( <i>n</i> , % yes)	133 (55.0)	140 (57.9)	127 (52.5)	100 (41.2)	79 (32.5)	111 (45.7)
Relationship status ( <i>n</i> , %)						
Single	123 (50.8)	117 (48.4)	105 (43.4)	71 (29.2)	73 (30.0)	73 (30.0)
Having partners, not married	58 (24.0)	55 (22.7)	64 (26.4)	55 (22.6)	58 (23.9)	64 (26.3)
Married	61 (25.2)	70 (28.9)	73 (30.2)	117 (48.2)	112 (46.1)	106 (43.6)
Whether or not given birth to/fathered a child ( <i>n</i> , % yes)	34 (14.0)	52 (21.5)	49 (20.2)	73 (30.0)	75 (30.9)	75 (30.9)
Whether or not wanted to conceive now ( <i>n</i> , % yes)	49 (20.2)	55 (22.7)	44 (18.2)	86 (35.4)	74 (30.5)	71 (29.2)
Prior medical consultation for fertility ( <i>n</i> , % yes)	10 (4.1)	13 (5.4)	14 (5.8)	24 (9.9)	24 (9.9)	21 (8.6)

## Results

### Background characteristics and group equivalence

There were 1455 participants in total, 242 male and 243 female in each group. In total, 31 participants stated they did not want to have children in the future, contrary to their responses in the screening survey. These participants were included in the following analyses, which remained the same whether or not these participants were included.

Table I shows demographic characteristics of the sample. Participants were about 30 years of age, were of low or middle income, with about one half having a university education. The majority was single or partnered without marriage, and without children. Few wanted to conceive immediately, and <10% had consulted for fertility problems.

Some baseline characteristics were not well-balanced between groups. The percentage of female participants who were university educated in control group 1 was lower than the intervention group ( $P = 0.048$ ), and the percentage of male participants who had fathered a child in the intervention group was lower than control group 1 ( $P = 0.03$ ).

### Effect of the intervention on outcomes

#### Fertility knowledge and child desires

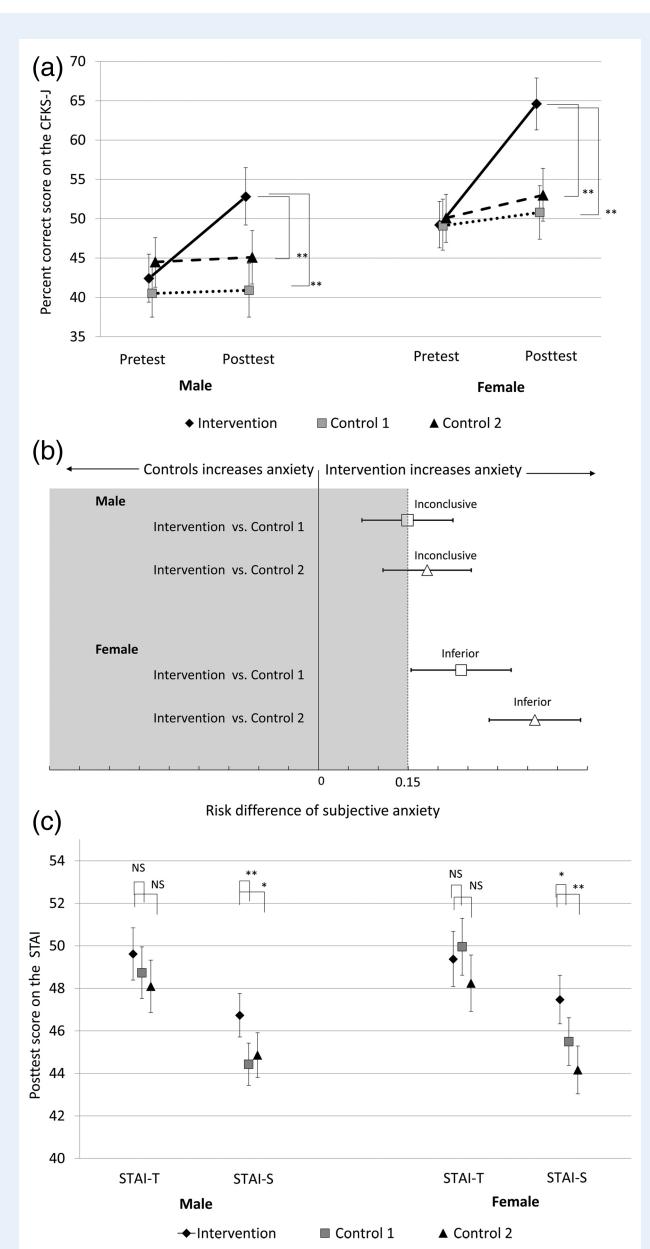
The pretest average scores on the CFKS-J did not differ according to group or gender (Fig. 2a). Percent correct scores were 42.5 ( $SD = 24.0$ ) among men and 49.5 ( $SD = 23.9$ ) among women. The pretest child-number and child-timing desire was also not different according to group and gender (Table II). At pretest the majority of participants wanted one to two children, and most wanted to have completed their family before age 37 years. About one-third of participants did not know at what age they would want to have their first or last child.

Posttest scores on the CFKS-J (mean,  $SD$ ) were significantly higher (increased knowledge) in the intervention group than that of the control groups: intervention versus Control 1 and versus Control 2: 52.8 (28.8) versus 40.9 (26.2) ( $P < 0.001$ ) versus 45.1 (27.1) ( $P = 0.003$ ) among men and 64.6 (26.0) versus 50.8 (26.9) ( $P < 0.001$ ) versus 53.0 (26.4) ( $P < 0.001$ ) among women (Fig. 2a). There were no differences between groups in the posttest child-number and child-timing desire (Table II).

#### State anxiety

The percentage of those who felt subjective anxiety after exposure to the intervention brochure (posttest scores) was significantly higher than that of the control groups: intervention versus Control 1 and versus Control 2: 32.6 versus 17.8% ( $P < 0.001$ ) versus 14.5% ( $P < 0.001$ ) among men and 50.2 versus 26.3% ( $P < 0.001$ ) versus 14.0% ( $P < 0.001$ ) among women (Table III). Among men, the risk differences of the intervention increasing the incidence of higher subjective anxiety versus Control 1 and versus Control 2 were 0.149 (95% CI: 0.073–0.225) and 0.182 (95% CI: 0.108–0.256), respectively (Fig. 2b). Therefore, the differences were statistically significant, but the hypothesis of non-inferiority was inconclusive as the CIs included 0.15 (i.e. the non-inferiority margin). Among women, the risk differences versus Control 1 and versus Control 2 were 0.239 (95% CI: 0.155–0.322) and 0.362 (95% CI: 0.286–0.439), respectively. The hypothesis of non-inferiority was refuted and inferiority of the fertility information group was declared among women. Analyses by age group showed that the percentage of

those who felt subjective anxiety was higher in the intervention group than that of the control groups especially among men aged 30 and older and among women aged 25 and older (Table III).



**Figure 2** Pre- and posttest fertility knowledge and posttest psychometric measurements by group. Posttest indicators were measured after exposure to the assigned brochures; fertility information (intervention), folic acid information (Control 1) or government finance information (Control 2). The CFKS-J, the Japanese version of the Cardiff Fertility Knowledge Scale; the STAI-T, the Trait score of the State-Trait Anxiety Inventory; the STAI-S, the State score of the State-Trait Anxiety Inventory: NS, not significant. (a) Pre- and posttest mean scores (95% confidence interval) on the CFKS-J. (b) Risk differences (95% confidence interval) of subjective anxiety between groups. Dashed line at 0.15 indicates non-inferiority margin. (c) Posttest mean scores (95% confidence interval) on the STAI-T and the STAI-S. Significance of t-test comparisons was indicated by \* $P < 0.05$  and \*\* $P < 0.01$ .

**Table II** Pre and posttest child-number and child-timing desires by group.

	Male					Female				
	Intervention (n = 242)	Control I (n = 242)	P values	Control 2 (n = 242)	P values	Intervention (n = 243)	Control I (n = 243)	P values	Control 2 (n = 243)	P values
Pretest desires										
Desired number of (additional) children										
None <sup>a</sup>	8 (3.3)	6 (2.5)	0.30 <sup>b</sup>	7 (2.9)	0.49 <sup>b</sup>	2 (0.8)	5 (2.1)	0.65 <sup>b</sup>	3 (1.2)	0.92 <sup>b</sup>
One	70 (28.9)	90 (37.2)		82 (33.9)		89 (36.6)	90 (37.0)		89 (36.6)	
Two	127 (52.5)	115 (47.5)		128 (52.9)		120 (49.4)	120 (49.4)		120 (49.4)	
Three	33 (13.6)	25 (10.3)		23 (9.5)		30 (12.3)	24 (9.9)		27 (11.1)	
Four or more	4 (1.7)	6 (2.5)		2 (0.8)		2 (0.8)	4 (1.6)		4 (1.6)	
Desired age at first (additional) child <sup>c</sup>										
Mean (SD)	33.9 (4.2)	34.0 (4.7)	0.94 <sup>d</sup>	33.9 (4.7)	0.98 <sup>d</sup>	32.2 (4.7)	32.4 (4.5)	0.66 <sup>d</sup>	32.3 (4.6)	0.81 <sup>d</sup>
Unknown (n, %)	128 (54.7)	123 (52.1)	0.58 <sup>e</sup>	125 (53.2)	0.74 <sup>e</sup>	66 (27.4)	70 (29.4)	0.62 <sup>e</sup>	63 (26.2)	0.78 <sup>e</sup>
Desired age at last child <sup>c</sup>										
Mean (SD)	36.3 (4.2)	35.6 (4.5)	0.20 <sup>d</sup>	35.6 (4.3)	0.22 <sup>d</sup>	34.1 (4.2)	34.1 (4.0)	0.996 <sup>d</sup>	33.8 (4.2)	0.53 <sup>d</sup>
Unknown (n, %)	88 (37.6)	78 (33.1)	0.30 <sup>e</sup>	89 (37.9)	0.95 <sup>e</sup>	55 (22.8)	52 (21.8)	0.80 <sup>e</sup>	53 (22.1)	0.85 <sup>e</sup>
Posttest desires										
Desired number of (additional) children (n, %)										
None	2 (0.8)	3 (1.2)	0.42 <sup>b</sup>	0	0.39 <sup>b</sup>	1 (0.4)	1 (0.4)	0.96 <sup>b</sup>	0	1.00 <sup>b</sup>
One	77 (31.8)	96 (39.7)		86 (35.5)		96 (39.5)	94 (38.7)		97 (39.9)	
Two	125 (51.7)	111 (45.9)		129 (52.2)		117 (48.1)	121 (49.8)		118 (48.6)	
Three	32 (13.2)	26 (10.7)		23 (9.5)		27 (11.1)	24 (9.9)		27 (11.1)	
Four or more	6 (2.5)	6 (2.5)		4 (1.7)		2 (0.8)	3 (1.2)		1 (0.4)	
Desired age at first (additional) child <sup>c</sup>										
Mean (SD)	33.9 (4.3)	34.1 (4.7)	0.68 <sup>d</sup>	33.8 (4.9)	0.86 <sup>d</sup>	32.1 (4.6)	32.5 (4.4)	0.35 <sup>d</sup>	32.3 (4.5)	0.57 <sup>d</sup>
Unknown (n, %)	128 (53.3)	130 (54.4)	0.82 <sup>e</sup>	140 (57.9)	0.32 <sup>e</sup>	75 (31.0)	78 (32.2)	0.77 <sup>e</sup>	70 (28.8)	0.60 <sup>e</sup>
Desired age at last child <sup>c</sup>										
Mean (SD)	36.1 (4.3)	35.8 (4.2)	0.61 <sup>d</sup>	35.5 (4.5)	0.35 <sup>d</sup>	33.9 (4.0)	34.1 (4.0)	0.74 <sup>d</sup>	33.7 (4.0)	0.56 <sup>d</sup>
Unknown (n, %)	85 (35.4)	81 (33.9)	0.73 <sup>e</sup>	91 (37.6)	0.62 <sup>e</sup>	51 (21.1)	57 (23.5)	0.58 <sup>e</sup>	57 (23.5)	0.53 <sup>e</sup>

<sup>a</sup>There were 31 participants who did not want to have children in the future, contrary to their responses in the screening survey.

<sup>b</sup>Fisher's exact tests.

<sup>c</sup>Only those who answered one or more to 'desired number of (additional) children' were included.

<sup>d</sup>Two-tailed t test.

<sup>e</sup> $\chi^2$  test.

P-Values compare the preceding control group with the Intervention group.

**Table III** The proportion of participants who felt subjective anxiety after the exposure to the assigned brochures by age group.

	Male		Female		<b>P values</b>	<b>P values</b>	<b>P values</b>
	<b>Intervention</b>	<b>No. of events/total no. (%)</b>	<b>Intervention</b>	<b>No. of events/total no. (%)</b>			
Overall	79/242 (32.6)	43/242 (17.8)	<0.001	35/242 (14.5)	<0.001	122/243 (50.2)	<0.001
Age group							
20–24	9/42 (21.4)	9/40 (22.5)	0.91	5/39 (12.8)	0.31	13/43 (30.2)	0.70
25–29	18/58 (31.0)	12/62 (19.4)	0.14	9/58 (15.5)	0.048	35/68 (51.5)	<0.001
30–34	26/62 (41.9)	11/60 (18.3)	0.005	13/65 (20.0)	0.007	31/52 (59.6)	10/50 (20.0)
35–39	26/80 (32.5)	11/80 (13.8)	0.005	8/80 (10.0)	0.001	43/80 (53.8)	26/80 (32.5)
						0.007	0.007
						8/80 (10.0)	8/80 (10.0)

P-values compare the preceding control group with the intervention group using  $\chi^2$  tests.

Posttest scores on the STAI-S (mean, SD) were significantly higher (greater anxiety) in the intervention groups than that of the control groups: intervention versus Control 1 and versus Control 2: 46.7 (8.1) versus 44.4 (7.9) ( $P = 0.002$ ) versus 44.9 (8.3) ( $P = 0.01$ ) among men and 47.5 (9.0) versus 45.5 (8.9) ( $P = 0.02$ ) versus 44.2 (8.9) ( $P < 0.001$ ) among women, whereas no difference in the posttest scores on the STAI-T existed between groups (Fig. 2c), indicating that differences in state anxiety was not due to underlying differences in personality traits between groups.

## Discussion

We showed that exposure to fertility information via an inexpensive brochure can improve knowledge by about 10 points on the CFKS-J but doing so doubled the proportion of people who felt anxiety compared with the provision of other healthcare and general information. These findings negate our prediction especially among women, and revealed that fertility information, even when neutral and evidence-based, induced anxiety among the reproductive-aged population. This is the first quantitative study to evaluate the psychological change of people exposed to fertility information.

A strength of our study was the randomized controlled study design with a large sample size. Although there was a disproportion of some baseline characteristics between groups, these were negligible in light of the randomized study design and multiple comparisons. Even when we adjusted for whether participants had fathered a child among male participants and whether participants were university educated among female participants using logistic regression model or analysis of covariance, the results were not markedly different. In addition, the large sample size allowed analyses by age group to identify for whom fertility education could be more anxiety provoking. It was found that women in their mid-20s and men in their early 30s felt anxiety after exposure to fertility information despite still being younger than the average parental age at first birth in Japan. Furthermore, the chance of reacting with anxiety seemed to increase linearly with older age.

Another strength was the use of validated scales, the CFKS and the STAI. The use of a pre and posttesting phase also enabled assessment of baseline equivalence on knowledge before the information was provided. The pretest knowledge score was similar to that in our previous survey (~50% correct score, Maeda *et al.*, 2015). The significantly higher score on the STAI-S (acute state) in the intervention groups and the similar scores on the STAI-T (a personality trait) between the study groups demonstrate the robustness of our main results.

The present study was intended to assess the non-inferiority of subjective anxiety after exposure to fertility information compared with that of the control groups. The risk difference of subjective anxiety was found to exceed the non-inferiority margin among women, showing the inferiority of the fertility information group relative to controls. Although the result regarding non-inferiority was inconclusive among men, possibly because the predetermined non-inferiority margin was wide, it was shown that the incidence of subjective anxiety after exposure to fertility information was significantly higher than that of the control groups among both men and women, which was consistent with the results on the STAI. These results indicate that provision of fertility education has benefits but also costs, and these should be considered in education interventions.

Regarding the effects of information brochures on knowledge, our findings are consistent with those of previous studies. It is possible to improve fertility knowledge with low cost information brochures. Wojcieszek and Thompson (2013) reported that male and female university students had better fertility knowledge after reading an educational brochure presented online. Daniluk and Koert (2015) also showed currently childless men and women were more aware of fertility immediately after the intervention, although the improvement was not maintained 6 months later. In the present study, we replicated those findings: participants in the intervention group had significantly better knowledge immediately after exposure.

The results on childbearing desires (child-number, child-timing) were inconsistent with past research showing that fertility information produced a decrease in desired or ideal age for childbearing (Wojcieszek and Thompson, 2013; Daniluk and Koert, 2015). In the present study, no apparent difference was found in the posttest on child-timing desires between the study groups. One possible reason was the higher age of participants (the mean age in years in present study: 30.6) compared with those in the previous studies (19.05 years old in Wojcieszek and Thompson, 2013; 28 years old in Daniluk and Koert, 2015). In general, people tend to postpone parenthood as they age (Virtala et al., 2011) or as they have difficulty finding a partner or balancing their educations, careers and other factors (Cooke et al., 2012; Peterson et al., 2012). Our participants might have experienced such struggles and accommodated their priorities more so than the above studies (Wojcieszek and Thompson, 2013; Daniluk and Koert, 2015). Another reason was the high proportion of participants that answered 'I don't know.' Longitudinal assessments would show the real effects of knowledge and potential changes in attitude of those who prevaricated over their family planning. An alternative explanation is that the fertility education provided in the present study did not sufficiently target child-number and child-timing desires to make an impact on these outcomes. For example, information in Daniluk and Koert (2015) has 10 sections over multiple pages and thousands of words concerned with when is the right time to have children whereas the present fertility education focused brochure had a simple message about declining fertility according to age and risk factors for reduced fertility. In addition, it is hard to know whether the participants read the brochure or did so in sufficient depth to absorb the contents even though they were asked to read the entire brochure carefully. The results indicate that educators must ensure that the fertility education provided aligns with the outcomes they would want to change.

Fertility educational initiatives have increased across developed countries over the past few years (De Cock, 2011; Daniluk and Koert, 2013; Hammarberg et al., 2013) and are increasingly widespread (Centers for Disease Control and Prevention, 2014; Cabinet Office, Government of Japan, 2015). However, the main targets are the reproductive-aged generation and the introduction of fertility issues to school education is just beginning (Boivin et al., 2013; Department of Education and Early Childhood Development, 2013). In view of our findings, educational interventions should target a younger generation than currently intended. Our results showed that young women in their mid-20s were much more likely to report anxiety when confronted with fertility-related information, suggesting that fertility could be an area of worry for them. If fertility information were provided as part of educational initiatives, and provided in a more safe and helpful way, then people would be better able to manage such information when exposed in the community or health services.

Development of communication strategies that relieves the anxiety of reproductive-aged people is also important because there was an overall effect of fertility education on anxiety. In light of the close relations between fertility knowledge and personal relevance of childbearing (Bunting et al., 2013; Daniluk and Koert, 2015; Maeda et al., 2015), making accurate information accessible to an older generation nearing or at the stage of wanting children, and who may experience fertility issues is necessary. However, given the fact that people generally fail to process information effectively and efficiently when they are in a state of high concern (Covello et al., 2001), addition of psychological approaches, such as introducing decision-making strategies or providing information about counseling, would be required more than in other health education (Webb et al., 2010) in which most factors could be perceived to depend more on one's decisions (e.g. smoking cessation or dietary behavior).

This study has some limitations. First, the use of SRPs could have caused selection bias associated with higher education (Haagen et al., 2003; Takahashi et al., 2011) and more interest in childbearing. Second, the outcomes were measured only once, immediately after reading the brochures. Anxiety we measured might be a short-term effect that may reduce with the passage of time. As a future direction, measurements of changes over time should be explored. Finally, responses to fertility information might differ in Western countries. This study was conducted in Japan where referring to fertility has been a taboo for a long time and the level of knowledge is quite low (Maeda et al., 2015) as reported in other Asian countries (Asia Pacific Initiative on Reproduction, 2013; Chan et al., 2015) compared with non-Asian countries (Bunting et al., 2013). Assessment of cultural relevance to perceptions of fertility information would be an area of future research.

In conclusion, it is possible to increase fertility knowledge using an inexpensive fertility education brochure. However, such initiatives could increase anxiety, especially among women of reproductive-age. Early education and fertility awareness campaigns that took account of psychological impacts of fertility education could result in a positive reception and enhanced the educational effects.

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## Authors' roles

E.M. and F.N. contributed to the conception and design of the study, the acquisition of data and the analysis and interpretation of data. They drafted all versions of the article and approved the final version for publication. Y.K. and H. Saito contributed to the conception and design of the study, the revisions of each version, and the approval of the final version for publication. J.B. contributed to the analysis and interpretation of data, the revisions of each version, and the approval of the final version for publication. All the other co-authors contributed towards critical revision of the paper and final approval of the manuscript.

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## Conflict of interest

None declared.

## References

Ali S, Sophie R, Imam AM, Khan FI, Ali SF, Shaikh A, Farid-ul-Hasnain S. Knowledge, perceptions and myths regarding infertility among selected adult population in Pakistan: a cross-sectional study. *BMC Public Health* 2011; **11**:760.

Asia Pacific Initiative on Reproduction. Starting Families Asia Study: Helping Families, 2013. [http://www.tuvanhiemuon.com/vi.country.fertility/vi/images/SFA%20Study%20Report\\_Merck%20Serono\\_tcm863\\_14502.pdf](http://www.tuvanhiemuon.com/vi.country.fertility/vi/images/SFA%20Study%20Report_Merck%20Serono_tcm863_14502.pdf) (30 May 2016, date last accessed).

Benzies K, Tough S, Tofflemire K, Frick C, Faber A, Newburn-Cook C. Factors influencing women's decisions about timing of motherhood. *J Obstet Gynaecol Neonatal Nurs* 2006; **35**:625–633.

Boivin J, Bunting L, Gameiro S. "Cassandra's prophecy: a psychological perspective. Why we need to do more than just tell women". *Reprod Biomed Online* 2013; **27**:11–14.

Bretherick KL, Fairbrother N, Avila L, Harbord SH, Robinson WP. Fertility and aging: do reproductive-aged Canadian women know what they need to know? *Fertil Steril* 2010; **93**:2162–2168.

Bunting L, Boivin J. Development and preliminary validation of the fertility status awareness tool: FertiSTAT. *Hum Reprod* 2010; **25**:1722–1733.

Bunting L, Tsibulsky I, Boivin J. Fertility knowledge and beliefs about fertility treatment: findings from the International Fertility Decision-making Study. *Hum Reprod (Oxford, England)* 2013; **28**:385–397.

Cabinet Office, Government of Japan. Heisei 22 nendo shoshikashakai ni kansuru kokusai ishiki chosa houkokusho (International survey on low fertility, in Japanese), 2011. [http://www8.cao.go.jp/shoushi/shoushika/research/cyousa22/kokusai/mokuj\\_i\\_pdf.html](http://www8.cao.go.jp/shoushi/shoushika/research/cyousa22/kokusai/mokuj_i_pdf.html) (30 May 2016, date last accessed).

Cabinet Office, Government of Japan. Shoshika shakai taisaku taiko (Policy outline on the Declining Birthrate, in Japanese), 2015. <http://www8.cao.go.jp/shoushi/shoushika/law/taikou2.html> (30 May 2016, date last accessed).

Centers for Disease Control and Prevention. National Public Health Action Plan for the Detection, prevention, and Management of Infertility, 2014. [http://www.cdc.gov/reproductivehealth/Infertility/PDF/DRH\\_NAP\\_Final\\_508.pdf](http://www.cdc.gov/reproductivehealth/Infertility/PDF/DRH_NAP_Final_508.pdf) (29 May 2016, date last accessed).

Chan CHY, Chan THY, Peterson BD, Lampic C, Tam MYJ. Intentions and attitudes towards parenthood and fertility awareness among Chinese university students in Hong Kong: a comparison with Western samples. *Hum Reprod* 2015; **30**:364–372.

Cooke A, Mills TA, Lavender T. 'Informed and uninformed decision making'—women's reasoning, experiences and perceptions with regard to advanced maternal age and delayed childbearing: a meta-synthesis. *Int J Nurs Stud* 2010; **47**:1317–1329.

Cooke A, Mills TA, Lavender T. Advanced maternal age: delayed childbearing is rarely a conscious choice a qualitative study of women's views and experiences. *Int J Nurs Stud* 2012; **49**:30–39.

Covello VT, Peters RG, Wojtecki JG, Hyde RC. Risk communication, the West Nile virus epidemic, and bioterrorism: responding to the communication challenges posed by the intentional or unintentional release of a pathogen in an urban setting. *J Urban Health* 2001; **78**:382–391.

Daniluk JC, Koert E. "I wish I had known!" – supporting informed reproductive and childbearing decisions for women and men. *Hum Reprod* 2012; **27**(Suppl 2):i82–i83.

Daniluk JC, Koert E. The other side of the fertility coin: a comparison of childless men's and women's knowledge of fertility and assisted reproductive technology. *Fertil Steril* 2013; **99**:839–846.

Daniluk JC, Koert E. Fertility awareness online: the efficacy of a fertility education website in increasing knowledge and changing fertility beliefs. *Hum Reprod* 2015; **30**:353–363.

Daniluk JC, Koert E, Cheung A. Childless women's knowledge of fertility and assisted human reproduction: identifying the gaps. *Fertil Steril* 2012; **97**:420–426.

De Cock G. Infertility prevention campaign: a multi-stakeholder example from Flanders, Belgium. *Hum Reprod* 2011; **26**(Suppl 1):i58–i60.

Department of Education and Early Childhood Development, Melbourne. Catching on later: Sexuality Education Resource for Secondary Schools, 2013. <https://fuse.education.vic.gov.au/pages/View.aspx?id=407ed837-2c8b-4842-9a22-fe7f8bb07b99&Source=%252fpages%252fResults.aspx%253fs%253dCatching%252bon%252blater%25253a%252bSexuality%252bEducation%252bResource%252bför%252bSecondary%252bSchools%25252c> (30 May 2016, date last accessed).

ESHRE Capri Workshop Group. Fertility and ageing. *Hum Reprod Update* 2005; **11**:261–276.

Friese C, Becker G, Nachtigall RD. Rethinking the biological clock: eleventh-hour moms, miracle moms and meanings of age-related infertility. *Soc Sci Med* 2006; **63**:1550–1560.

Gray E. 'Get Britain Fertile': Does This Fertility ad campaign 'shame' women? 2013. [http://www.huffingtonpost.com/2013/05/29/get-britain-fertile-fertility-ad-campaign-british-shame-women\\_n\\_3353160.html](http://www.huffingtonpost.com/2013/05/29/get-britain-fertile-fertility-ad-campaign-british-shame-women_n_3353160.html) (30 May 2016, date last accessed).

Haagen EC, Tuil W, Hendriks J, de Bruijn RP, Braat DD, Kremer JA. Current Internet use and preferences of IVF and ICSI patients. *Hum Reprod* 2003; **18**:2073–2078.

Hammarberg K, Setter T, Norman RJ, Holden CA, Michelmore J, Johnson L. Knowledge about factors that influence fertility among Australians of reproductive age: a population-based survey. *Fertil Steril* 2013; **99**:502–507.

Hongo J. Flak dooms handbook pushing motherhood. *Japan Times (Newspaper)* 30 May 2013. <http://www.japantimes.co.jp/news/2013/05/30/national/flak-dooms-handbook-pushing-motherhood/#.Uzg0009Kig> (30 May 2016, date last accessed).

Japan Institute of Life Insurance, 2015. Public financial supports for bearing and raising of children (in Japanese). <http://www.jili.or.jp/lifeplan/lifeevent/birth/8.html> (28 May 2016, date last accessed).

Japan Society of Obstetrics and Gynecology, 2014. Dictionary for women and men (in Japanese) [http://www.jsog.or.jp/public/human\\_plus\\_dictionary/index.html#page=1](http://www.jsog.or.jp/public/human_plus_dictionary/index.html#page=1) (30 May 2016, date last accessed).

Japan Society for Reproductive Medicine, 2013. Questions & answers for infertility. (in Japanese). <http://www.jsrm.or.jp/public/> (30 May 2016, date last accessed).

Lampic C, Svanberg AS, Karlstrom P, Tyden T. Fertility awareness, intentions concerning childbearing, and attitudes towards parenthood among female and male academics. *Hum Reprod* 2006; **21**:558–564.

Lundsberg LS, Pal L, Gariepy AM, Xu X, Chu MC, Illuzzi JL. Knowledge, attitudes, and practices regarding conception and fertility: a population-based survey among reproductive-age United States women. *Fertil Steril* 2014; **101**:767–774.

Maeda E, Sugimori H, Nakamura F, Kobayashi Y, Green J, Suka M, Okamoto M, Boivin J, Saito H. A cross sectional study on fertility knowledge in Japan, measured with the Japanese version of Cardiff Fertility Knowledge Scale (CFKS-J). *Reprod Health* 2015; **12**.

Mills M, Rindfuss RR, McDonald P, te Velde E. Why do people postpone parenthood? Reasons and social policy incentives. *Hum Reprod* 2011; **17**:848–860.

Ministry of Health Labour and Welfare. Vital Statistics, 2013. <http://www.e-stat.go.jp/SG1/estat>List.do?id=00001127058> (30 May 2016, date last accessed).

Nakazato K, Mizuguchi K. Development and validation of Japanese version of State-Trait Anxiety Inventory (STA). *Jpn J Psychosom Med* 1982; **22**:107–112.

National Institute of Health and Nutrition. Intake of folic acid during pregnancy (in Japanese), 2015. <http://hfnet.nih.go.jp/contents/detail1550.html#2> (30 May 2016, date last accessed).

NHS choices, 2014. Protect your fertility. <http://www.nhs.uk/Livewell/Fertility/Pages/Protectyourfertility.aspx> (28 May 2016, date last accessed).

Organisation for Economic Co-operation and Development (OECD). OECD Family Database, Indicator SF2.1, "Fertility Rates", 2014. <http://www.oecd.org/els/family/database.htm> (18 January 2016, date last accessed).

Peterson BD, Pirritano M, Tucker L, Lampic C. Fertility awareness and parenting attitudes among American male and female undergraduate university students. *Hum Reprod* 2012; **27**:1375–1382.

Reynolds J. An industry-funded 'awareness' campaign, 2009. <http://www.biopoliticaltimes.org/article.php?id=4496> (10 March 2015, date last accessed).

Roberts E, Metcalfe A, Jack M, Tough SC. Factors that influence the childbearing intentions of Canadian men. *Hum Reprod* 2011; **26**:1202–1208.

Saito H. Fertility knowledge for men and women (in Japanese), 2015. <http://www.asahi.com/apital/healthguide/ninkatsu/> (30 May 2016, date last accessed).

Soules MR. The story behind the American Society for Reproductive Medicine's prevention of infertility campaign. *Fertil Steril* 2003; **80**:295–299.

Spielberger CD, Gorsuch RL, Lushene RE. Manual for State-Trait Anxiety Inventory (Self-Evaluatin Questionnaire). Palo Alto, 1970.

Takahashi Y, Ohura T, Ishizaki T, Okamoto S, Miki K, Naito M, Akamatsu R, Sugimori H, Yoshiike N, Miyaki K et al. Internet use for health-related information via personal computers and cell phones in Japan: a cross-sectional population-based survey. *J Med Internet Res* 2011; **13**:e110.

Virtala A, Vilska S, Huttunen T, Kunttu K. Childbearing, the desire to have children, and awareness about the impact of age on female fertility among Finnish university students. *Eur J Contracept Reprod Health Care* 2011; **16**:108–115.

Webb T, Joseph J, Yardley L, Michie S. Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. *J Med Internet Res* 2010; **12**:e4.

Wojcieszek AM, Thompson R. Conceiving of change: a brief intervention increases young adults' knowledge of fertility and the effectiveness of *in vitro* fertilization. *Fertil Steril* 2013; **100**:523–529.

World Bank. Fertility rate, total (births per woman), 2015. <http://data.worldbank.org/indicator/SP.DYN.TFRT.IN> (28 May 2016, date last accessed).