Author/s:
Sandhu, S;Hickey, M;Koye, DN;Braat, S;Lew, R;Hart, R;Norman, RJ;Hammarberg, K;Anderson, RA;Peate, M

Title:
Eggsurance? A randomized controlled trial of a decision aid for elective egg freezing

Date:
2024-08-01

Citation:
Sandhu, S., Hickey, M., Koye, D. N., Braat, S., Lew, R., Hart, R., Norman, R. J., Hammarberg, K., Anderson, R. A. & Peate, M. (2024). Eggsurance? A randomized controlled trial of a decision aid for elective egg freezing. Human Reproduction, 39 (8), pp.1724-1734. https://doi.org/10.1093/humrep/deae121.

Persistent Link:
https://hdl.handle.net/11343/351712

OXFORD

human reproduction

Human Reproduction, 2024, **39(8),** 1724–1734

https://doi.org/10.1093/humrep/deae121

Advance Access Publication Date: June 15, 2024

Original Article

Psychology and counselling

Eggsurance? A randomized controlled trial of a decision aid for elective egg freezing

Sherine Sandhu [1,*], Martha Hickey [1], Digsu N. Koye [2,3], Sabine Braat [2,3], Raelia Lew [1,4], Roger Hart [5,6], Robert J. Norman [7], Karin Hammarberg [8,9], Richard A. Anderson [10], Michelle Peate [1] and on behalf of the Eggsurance Collaborative Group[†]

[1]Department of Obstetrics, Gynaecology & Newborn Health, University of Melbourne, Royal Women's Hospital, Melbourne, VIC, Australia
[2]Centre for Epidemiology and Biostatistics, Melbourne School of Population and Global Health, University of Melbourne, Melbourne, VIC, Australia
[3]MISCH (Methods and Implementation Support for Clinical and Health) research Hub, Faculty of Medicine, Dentistry and Health Sciences, University of Melbourne, Melbourne, VIC, Australia
[4]Reproductive Services Unit, Royal Women's Hospital, Melbourne, VIC, Australia
[5]Division of Obstetrics and Gynaecology, The University of Western Australia, King Edward Memorial Hospital, Perth, WA, Australia
[6]Fertility Specialists of Western Australia and City Fertility, Bethesda Hospital, Claremont, WA, Australia
[7]Robinson Research Institute, Adelaide Medical School, The University of Adelaide, Adelaide, SA, Australia
[8]School of Public Health and Preventive Medicine, Monash University, Melbourne, VIC, Australia
[9]Victorian Assisted Reproductive Treatment Authority, Melbourne, VIC, Australia
[10]Centre for Reproductive Health, Institute for Repair and Regeneration, University of Edinburgh, Edinburgh, UK

*Correspondence address. Department of Obstetrics, Gynaecology & Newborn Health, University of Melbourne, Level 7, Royal Women's Hospital, Corner of Grattan Street & Flemington Road, Parkville, VIC 3052, Australia. E-mail: sherine.sandhu@unimelb.edu.au https://orcid.org/0000-0002-3294-3340

[†]The investigators in the Eggsurance Collaborative Group are available in the Acknowledgements section.

ABSTRACT

STUDY QUESTION: Does a purpose-designed Decision Aid for women considering elective egg freezing (EEF) impact decisional conflict and other decision-related outcomes?

SUMMARY ANSWER: The Decision Aid reduces decisional conflict, prepares women for decision-making, and does not cause distress.

WHAT IS ALREADY KNOWN: Elective egg-freezing decisions are complex, with 78% of women reporting high decisional conflict. Decision Aids are used to support complex health decisions. We developed an online Decision Aid for women considering EEF and demonstrated that it was acceptable and useful in Phase 1 testing.

STUDY DESIGN, SIZE, DURATION: A single-blind, two-arm parallel group randomized controlled trial was carried out. Target sample size was 286 participants. Randomization was 1:1 to the control (existing website information) or intervention (Decision Aid plus existing website information) group and stratified by Australian state/territory and prior IVF specialist consultation. Participants were recruited between September 2020 and March 2021 with outcomes recorded over 12 months. Data were collected using online surveys and data collection was completed in March 2022.

PARTICIPANTS/MATERIALS, SETTING, METHODS: Females aged ≥18 years, living in Australia, considering EEF, proficient in English, and with internet access were recruited using multiple methods including social media posts, Google advertising, newsletter/noticeboard posts, and fertility clinic promotion. After completing the baseline survey, participants were emailed their allocated website link(s). Follow-up surveys were sent at 6 and 12 months. Primary outcome was decisional conflict (Decisional Conflict Scale). Other outcomes included distress (Depression Anxiety and Stress Scale), knowledge about egg freezing and female age-related infertility (study-specific measure), whether a decision was made, preparedness to decide about egg freezing (Preparation for Decision-Making Scale), informed choice (Multi-Dimensional Measure of Informed Choice), and decision regret (Decision Regret Scale).

MAIN RESULTS AND THE ROLE OF CHANCE: Overall, 306 participants (mean age 30 years; SD: 5.2) were randomized (intervention n = 150, control n = 156). Decisional Conflict Scale scores were significantly lower at 12 months (mean score difference: −6.99 [95% CI: −12.96, −1.02], $P = 0.022$) for the intervention versus control group after adjusting for baseline decisional conflict. At 6 months, the intervention group felt significantly more prepared to decide about EEF than the control (mean score difference: 9.22 [95% CI: 2.35, 16.08], $P = 0.009$). At 12 months, no group differences were observed in distress (mean score difference: 0.61 [95% CI: −3.72, 4.93], $P = 0.783$), knowledge (mean score difference: 0.23 [95% CI: −0.21, 0.66], $P = 0.309$), or whether a decision was made (relative risk: 1.21 [95% CI: 0.90, 1.64], $P = 0.212$). No group differences were found in informed choice (relative risk: 1.00 [95% CI: 0.81, 1.25], $P = 0.983$) or decision regret (median score difference: −5.00 [95% CI: −15.30, 5.30], $P = 0.337$) amongst participants who had decided about EEF by 12 months (intervention n = 48, control n = 45).

LIMITATIONS, REASONS FOR CAUTION: Unknown participant uptake and potential sampling bias due to the recruitment methods used and restrictions caused by the coronavirus disease 2019 pandemic. Some outcomes had small sample sizes limiting the

Received: November 18, 2023. **Revised:** May 10, 2024. **Editorial decision:** May 20, 2024.

inferences made. The use of study-specific or adapted validated measures may impact the reliability of some results.

WIDER IMPLICATIONS OF THE FINDINGS: This is the first randomized controlled trial to evaluate a Decision Aid for EEF. The Decision Aid reduced decisional conflict and improved women's preparation for decision making. The tool will be made publicly available and can be tailored for international use.

STUDY FUNDING/COMPETING INTEREST(S): The Decision Aid was developed with funding from the Royal Women's Hospital Foundation and McBain Family Trust. The study was funded by a National Health and Medical Research Council (NHMRC) Project Grant APP1163202, awarded to M. Hickey, M. Peate, R.J. Norman, and R. Hart (2019–2021). S.S., M.P., D.K., and S.B. were supported by the NHMRC Project Grant APP1163202 to perform this work. R.H. is Medical Director of Fertility Specialists of Western Australia and National Medical Director of City Fertility. He has received grants from MSD, Merck-Serono, and Ferring Pharmaceuticals unrelated to this study and is a shareholder of CHA-SMG. R.L. is Director of Women's Health Melbourne (Medical Practice), ANZSREI Executive Secretary (Honorary), RANZCOG CREI Subspecialty Committee Member (Honorary), and a Fertility Specialist at Life Fertility Clinic Melbourne and Royal Women's Hospital Public Fertility Service. R.A.A. has received grants from Ferring Pharmaceuticals unrelated to this study. M.H., K.H., and R.J.N. have no conflicts to declare.

TRIAL REGISTRATION NUMBER: ACTRN12620001032943

TRIAL REGISTRATION DATE: 11 August 2020

DATE OF FIRST PATIENT'S ENROLMENT: 29 September 2020

Keywords: egg freezing / oocyte cryopreservation / decision aid / randomized, RCT / decision making / decisional conflict / decision support / information / fertility preservation

Introduction

Elective egg freezing (EEF) has become a widely accepted fertility preservation method for women concerned about age-related infertility (Dondorp *et al.*, 2012; Ethics Committee of the American Society of Reproductive Medicine, 2018; Anderson *et al.*, 2020b, Nuffield Council on Bioethics, 2020). Uptake of egg freezing has risen substantially since the removal of its experimental label over a decade ago (Practice Committees of the American Society of Reproductive Medicine and the Society for Assisted Reproductive Technology, 2013). Between 2014 and 2021, the number of egg freezing cycles performed increased exponentially in the UK (454%), USA (303%), and Australia and New Zealand (527%) (Johnston *et al.*, 2020; Human Fertilisation and Embryology Authority, 2023; Newman *et al.*, 2023; Society for Assisted Reproductive Technology, 2023). Similarly, there was a 120% rise in egg freezing across other European countries between 2016–2019 (Wyns *et al.*, 2020; Smeenk *et al.*, 2023). Increased utilization of EEF coincides with greater availability and public awareness coupled with considerable media attention (Ethics Committee of the American Society of Reproductive Medicine, 2018; Platts *et al.*, 2021; Giannopapa *et al.*, 2022). In addition, regulatory changes to gamete storage time limits in the UK, and the introduction of EEF in France and Singapore (De Proost and Johnston, 2022; UK Government, 2022; Chin *et al.*, 2023), means that more women are considering the option.

The timing of parenthood can be complicated with socioeconomic and personal factors often influencing this decision (Mills *et al.*, 2011). The most common reason for pursuing EEF is the lack of a suitable partner to co-parent with (Platts *et al.*, 2021). Other common motives include alleviating time pressure, avoiding future regret, and having a backup plan against future infertility (Platts *et al.*, 2021).

The decision to freeze eggs is complex as there are a range of benefits and trade-offs to consider. EEF is costly, invasive, and poses very small but significant health risks (D'Angelo *et al.*, 2019; Gurtin and Tiemann, 2021). In addition, outcomes are uncertain with no guarantee that eggs will be collected, used, or will result in a live birth (Blakemore *et al.*, 2021; Kawwass *et al.*, 2021). EEF can provide women greater reproductive autonomy (Argyle *et al.*, 2016) and whilst some users feel empowered by taking control of their situation and having more options for childbearing in the future, others find EEF emotionally challenging (Baldwin and Culley, 2020; Jaswa *et al.*, 2023).

Data on EEF decisions demonstrate a need for more decisional support. Most (78%) women who consider EEF have high decisional conflict (Sandhu *et al.*, 2023a). Whilst IVF specialist counselling can lower decisional conflict, many women continue to feel uncertain and have difficulty deciding on their course of action (Kim *et al.*, 2018; Yee *et al.*, 2021; Sandhu *et al.*, 2023a). In studies from the USA and Turkey, decision regret was generally low amongst EEF users. However, 9–16% experienced moderate-high regret with greater remorse inversely associated with the adequacy of information and support received (Greenwood *et al.*, 2018; Gurbuz *et al.*, 2021; Jaswa *et al.*, 2023). In addition, 51% (n = 20) of those who decided against EEF had moderate-high regret about their decision (Jaswa *et al.*, 2023). Current information sources
(e.g. print and electronic media, primary care physicians, and fertility clinics) are unable to adequately and independently inform decision-making about EEF (Sandhu *et al.*, 2023a).

To address this, we developed an online Decision Aid for women considering EEF. Decision Aids are recommended for complex health decisions by the UK National Institute of Clinical Excellence, Australian Commission on Safety and Quality in Healthcare, and the US Affordable Care Act (Australian Commission on Safety and Quality in Healthcare, National Institute for Health and Care Excellence (NICE), US Congress). They are also recommended in fertility preservation contexts (Anderson *et al.*, 2020a). Decision Aids are used in scenarios where the correct choice is based on how an individual values the risks and benefits of their options (International Patient Decision Aid Standards (IPDAS) Collaboration, 2005). These tools are designed to provide users with information about their options, help clarify values, and support shared decision-making (International Patient Decision Aid Standards (IPDAS) Collaboration, 2005). They are also shown to effectively reduce decisional conflict and improve knowledge (Stacey *et al.*, 2017), ultimately supporting informed decision-making.

Phase 1 evaluation of our Decision Aid showed that it improved knowledge, reduced decisional conflict, and did not cause serious concern. Clarity, presentation, amount, and utility of content were also deemed acceptable (Sandhu *et al.*, 2023b). We now aimed to evaluate the effectiveness of the Decision Aid on decisional conflict and other decision-related outcomes in a prospective randomized controlled trial (RCT). We hypothesized that the Decision Aid plus existing information (intervention) would

result in lower decisional conflict at 12 months compared to information alone (control). Secondary hypotheses were that the intervention would lead to greater knowledge about EEF and age-related infertility, less distress, faster decision-making, less decision regret, greater informed choice, and greater involvement in decision-making compared to the control at 12 months.

Materials and methods

The protocol for this study is published elsewhere (Peate *et al.*, 2022) and was approved by the University of Melbourne Human Research Ethics Committee (2056457). All methods performed followed applicable regulations and guidelines. Written consent was provided by all participants. No protocol changes were made after participant recruitment commenced.

Trial design

This study was a single-blind two-arm parallel group RCT. Participants were individually randomized 1:1 to the control or intervention group. Online surveys were completed at baseline (time of recruitment) and at 6 and 12 months post-randomization.

Participants

Females aged ≥18 years, considering EEF for themselves, residing in Australia, proficient in English, and with internet access were eligible to participate. Those considering egg freezing for medical reasons, had already frozen their eggs, were postmenopausal, or were involved in the Decision Aid's Phase 1 evaluation (Sandhu *et al.*, 2023b) were excluded.

Recruitment

Study promotion included newsletter, noticeboard, social media, and website posts by our recruitment partners, and paid Facebook and Google advertising. It was also promoted at affiliated fertility clinics with study postcards or by informing eligible patients about the trial. All promotion methods directed prospective participants to our webpage (eggfreezing.org.au) for more information. Those interested in participating were then directed to our online eligibility screening questions and participant information and consent form.

Procedure

After consenting and completing the baseline survey, participants were enrolled, randomized, and emailed their allocated website link(s) by the Project Coordinator. The intervention group also received an activation email to access their personalized Decision Aid account. Follow-up surveys were emailed to all participants at 6 and 12 months post-randomization (Fig. 1). Those with incomplete surveys were followed up three times at most.

Control

All participants were directed to the Victorian Assisted Reproductive Treatment Authority (VARTA) website (https://www.varta.org.au/) which provides independent information about fertility and ART, including EEF.

Intervention

In addition to the VARTA website, the intervention group received our Decision Aid. The development and content of the Decision Aid are described in detail elsewhere (Sandhu *et al.*, 2023b). In brief, it contains information about female age-related infertility, and EEF including the procedure, costs, success rates, health risks, implications, and alternatives. It also contains a values clarification exercise to help users weigh up the risks and benefits of their options (i.e. to freeze/not freeze eggs). A feature of this exercise is that it provides automated feedback to users about whether they are leaning towards/away from EEF based on their responses to a question set.

Outcomes

Study measures are detailed in our protocol (Peate *et al.*, 2022) and pre-specified statistical analysis plan (Supplementary Data File S1).

Demographic, decision-making, and reproductive characteristics

Data collected at baseline were: demographics; reproductive history; motivations for considering EEF; prior sources of EEF information; desired level of decision-making control (adapted Control Preferences Scale (Degner *et al.*, 1997)) and preferences for EEF information (adapted Information Preference Style Scale (Cassileth *et al.*, 1980; Butow *et al.*, 1998)). Questions about the use of anti-Mullerian hormone (AMH) testing and its impact on decision-making were asked at baseline and 12-months. Data on pregnancy attempts and birth outcomes were collected at 12 months. Questions about relationship status and the impact of the coronavirus disease 2019 (COVID-19) pandemic on EEF decision-making, ability to seek EEF information, and reproductive aspirations were asked at all timepoints. Participants who were affected by the pandemic were also asked to elaborate on their response(s) (free text).

Primary outcome

The validated 10-item low literacy Decisional Conflict Scale (DCS) (O'Connor, 2010) measured decisional conflict about whether to pursue EEF at 12 months. Decisional conflict refers to feelings of uncertainty when making a health decision (O'Connor, 2010). The DCS scale has four subscales; uncertainty, and three modifiable factors associated with uncertainty (feeling uninformed, unsupported in decision-making, and unclear about personal values). Total scores were calculated (range: 0–100) according to the DCS user manual (O'Connor, 2010). Higher DCS scores indicate greater decisional conflict. The DCS scale has good reliability ($\alpha > 0.80$) and validity (O'Connor, 2010; Linder *et al.*, 2011). A positioning question that typically precedes the DCS asked participants their preferred course of action (e.g. EEF or an alternative) at each timepoint.

Secondary outcomes

These measures were related to the decision-making process or decision quality at 12 months. Their psychometric properties (where applicable) are included in the study protocol (Peate *et al.*, 2022). Process-related items were: level of distress (Depression, Anxiety and Stress Scale, DASS-21 (Lovibond and Lovibond, 1995)), and whether a decision was made about EEF. Perceived involvement in decision-making (adapted Perceived Involvement in Care Scale (Lerman *et al.*, 1990)) was also measured at 12 months among the subgroup of participants who had consulted a clinician (any type) about EEF. Decision quality outcomes included knowledge about egg freezing and female age-related infertility (a 13-item purposively designed scale) at all timepoints, and informed choice (adapted Multidimensional Measure of Informed Choice (Marteau *et al.*, 2001; Michie *et al.*, 2002)) and decision regret (Decision Regret Scale (O'Connor, 2003)) in participants who had decided about EEF at 6 and 12 months.

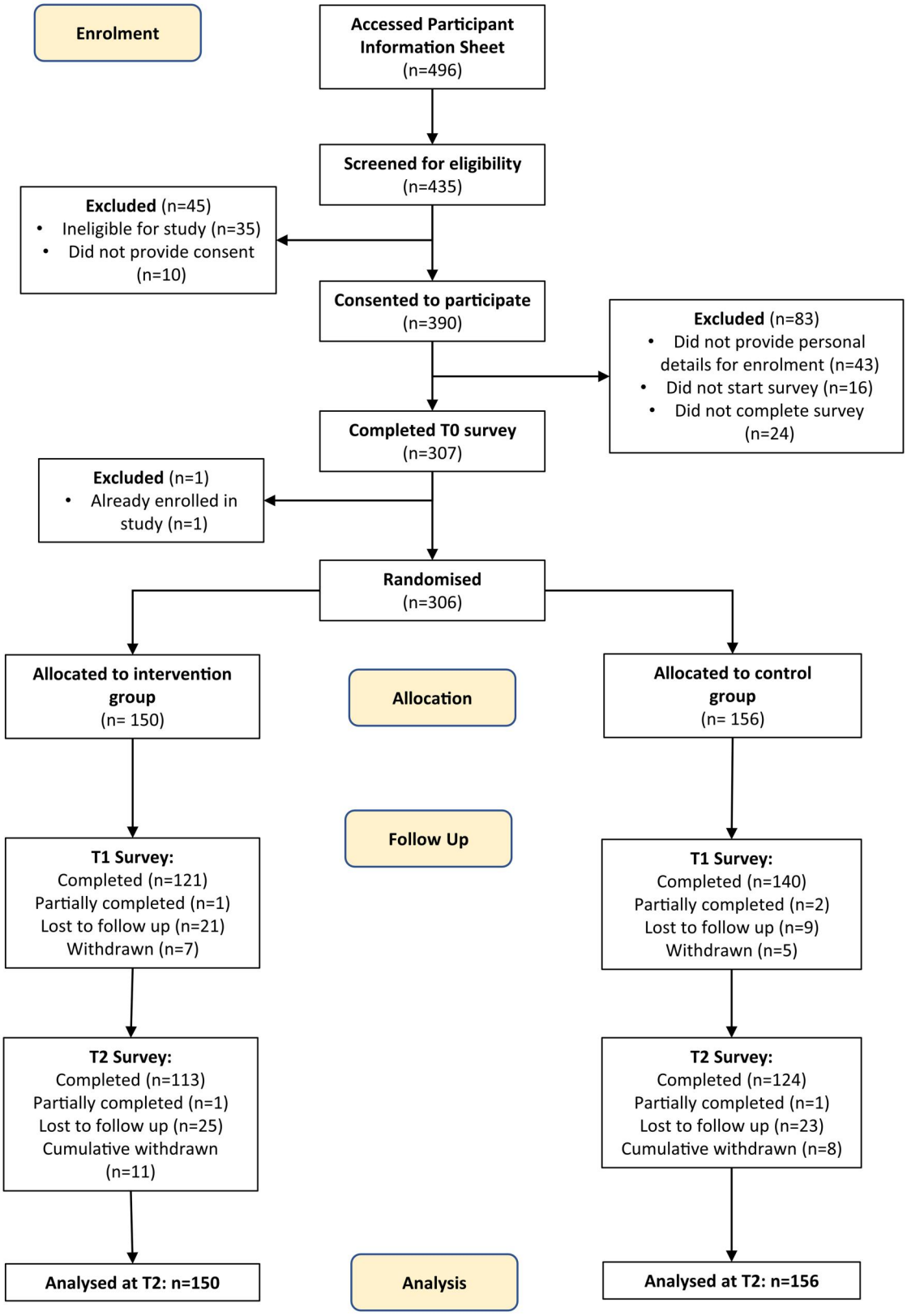

Figure 1. CONSORT flow diagram for a randomized controlled trial of a Decision Aid for elective egg freezing. Completion of the primary outcome (Decisional Conflict Scale) at baseline (T0), 6 months (T1), and 12 months (T2). Surveys completed >2 months after the original send date (n = 1 at T1) were excluded from the analysis. Control group: received existing information on elective egg freezing only. Intervention group: received existing information on elective egg freezing plus the Decision Aid. Partially completed means the primary outcome was partially complete and therefore a total score was not derived.

Other decision quality outcomes

Preparedness to decide about EEF (adapted Preparation for Decision-Making Scale (Graham and O'Connor, 2010)) was measured at 6 months. The importance placed on the risks and benefits of EEF (adapted Values measure (O'Connor, 2004)) were measured at 6 and 12 months. Perceived chances of having a baby naturally, and with frozen eggs (adapted Realistic Expectations measure (O'Connor, 1995b)) were measured at all timepoints. Decision concordance with personal values, and decision satisfaction (adapted Satisfaction with Decision Scale (Wills and Holmes-Rovner, 2003)) were measured at 6 and 12 months in participants who had made their decision about EEF.

Other decision process outcomes

Participants' confidence in their decision-making ability (Decision Self-Efficacy Scale (O'Connor, 1995a)), and readiness to engage in decision-making (adapted Stage of Decision-Making Scale (O'Connor, 2000)) were measured at all timepoints. Participants' use of their allocated resource(s) was measured at 6 and 12 months.

Utility of the Decision Aid's values clarification exercise

Two items at the end of the Decision Aid's values clarification exercise measured whether participants agreed with their output provided, and where they believed they were positioned on a scale from 0 (leaning away from egg freezing) to 100 (leaning towards egg freezing).

All surveys were piloted with nine individuals. The estimated completion time was 10–25 min per survey.

Sample size calculation

We calculated that a sample size of 200 participants (100 per group) would be needed to detect an effect size (Cohen's *d*) of 0.4 standard deviation (SD) in DCS scores at 12 months, at 80% power with a two-sided 0.05 significance level. Expected mean DCS score for the control group was 48.3 (SD: 31.9) (Peate *et al.*, 2011). Assuming the same SD for both groups, a 0.4 SD reduction would result in a mean DCS score of 35.5 for the intervention group. This effect size was considered clinically meaningful and worth implementing (Ringash *et al.*, 2007; O'Connor, 2010). With 30% attrition expected at 12 months, target sample size was therefore 286 participants (143 per group).

Randomization

Randomization was 1:1 to the control or intervention group using a computer-generated list of randomly permuted blocks of size two and four. This was generated by an independent statistician and stratified by Australian state/territory and prior consultation with an IVF specialist about EEF. Randomization was performed using the Research Electronic Data Capture (REDCap) tool.

Blinding

Participants were blinded to their allocation by being told that the study was about comparing different information resources (rather than specifically comparing a Decision Aid against other information). Study statisticians were blinded to allocations until the database was locked for analysis. The Project Coordinator was not blinded as they needed to enroll participants, send their respective information resources, and address any queries.

Data management

All screening, consent, and survey data were collected using REDCap (Harris *et al.*, 2009, 2019) data collection tools hosted at the University of Melbourne. Data from the values clarification exercise were extracted from the Decision Aid website.

Statistical analysis

Data were analyzed using an intention-to-treat approach, and prespecified statistical analysis plan (Supplementary Data File S1). Primary outcome (total DCS score) was analyzed using a likelihood-based constrained longitudinal data analysis (cLDA) model, with the outcome consisting of all timepoints. The model assumed a common baseline mean across treatment groups and unstructured variance-covariance among repeated measurements. Treatment groups, timepoints, treatment group by timepoint interaction, and whether participants had consulted an IVF specialist about EEF were included in the cLDA model as fixed effects.

Continuous outcomes (total DASS-21, knowledge, and decision self-efficacy scale scores) used a similar cLDA model for analysis. Decision made/not made used a repeated measures logistic regression model. Some outcomes were collected for a subset of participants based on conditional questions. For participants who had consulted a clinician about EEF, Perceived Involvement in Care Scale scores were summarized by treatment arm but not statistically tested due to small sample size. Informed choice, decision regret, and decision satisfaction were analyzed for decided participants using logistic regression, quantile regression, and linear regression, respectively.

Preparedness for decision-making and personal values scores (risks and benefits separately) were assessed using linear regression and longitudinal data analysis (LDA) models, respectively. Median realistic expectations data were summarized by timepoint, treatment arm, and age group.

Further analyses of primary and secondary outcomes (total DASS-21, decisions made about egg freezing, and knowledge scores) included adjusted analyses for prespecified covariates (relationship status, education status, income, age, and stage of decision-making). The primary outcome model was fitted under the missing-at-random assumption. Additional analysis based on a pattern-mixture model was conducted to assess sensitivity to outcome data missing not at random.

Results for primary, secondary, and other outcomes are presented as point estimates, two-sided 95% CIs and *P*-values. Use of the Holm procedure to control family-wise error rate at 0.05 was planned for secondary outcomes (distress, decision made/not made, and knowledge), however, it was not applied as they were not statistically significant at 0.05. Prespecified sub-group analyses based on age-group and relationship status were performed on the primary outcome.

The DCS subscale scores were summarized by timepoint and treatment arm using median and interquartile range (25th–75th percentile) and compared using Mann–Whitney *U*-test.

Accuracy of the calculation used for the values clarification exercise output was assessed by comparing where the exercise positioned participants on a scale leaning towards/away from EEF versus where participants positioned themselves on the same scale.

Free-text comments contextualizing the impact of the COVID-19 pandemic on EEF information seeking and decision-making were thematically grouped and summarized.

All data were analyzed in Stata SE, version 16 (STATACorp., LLC, 2021).

Results

The online participant information sheet was accessed 496 times. Of the 390 individuals who consented to participate, 306 (78.5%)

completed the baseline survey and were randomized (intervention n = 150; control n = 156). We exceeded the sample size target because of rapid uptake in participation at the end of the recruitment period. At 12 months, 237 (77.5%) participants completed and two (0.7%) partially completed the primary outcome measure. Forty-eight (15.7%) were lost to follow-up, and 19 (6.2%) withdrew from the study (Fig. 1). Participants were recruited between September 2020 and March 2021, 40.2% from newsletter or noticeboard posts, 23.5% from social media, and 22.2% from Google advertising (Supplementary Table S1). Data collection was completed in March 2022.

Baseline characteristics

At baseline, there were no apparent differences in participant characteristics between treatment groups (Table 1). Mean age was 30 years (SD: 5.2) across both groups and most (77%) were from Victoria, Australia. Approximately half were single, separated or divorced (intervention: 54.0%; control: 50.0%). Few had consulted an IVF specialist about EEF (intervention: 8.7%; control: 10.3%). Most participants wanted to make their decision about EEF after seriously considering the opinion of an IVF specialist (intervention: 83.3%; control: 82.1%). Mean Information Preference Style scores were <10 (intervention: 9.3 (SD: 1.8); control: 9.3 (SD: 1.8)) suggesting both cohorts were low information seekers. Median time spent considering EEF was 12 months for both cohorts (IQR: 6–24). See Supplementary Tables S1 and S2 for additional data.

Table 1. Baseline characteristics of participants by treatment group (intention-to-treat population).

	Intervention group N = 150	Control group N = 156
Age (years), mean (SD)	29.6 (5.3)	30.3 (5.1)
Age groups		
<25 years	28 (18.7%)	23 (15.0%)
25–29 years	49 (32.7%)	37 (24.2%)
30–34 years	46 (30.7%)	58 (37.9%)
≥35 years	27 (18.0%)	35 (22.9%)
Relationship status		
Single/separated/divorced	81 (54.0%)	78 (50.0%)
In a relationship	69 (46.0%)	78 (50.0%)
Relationship length		
Not in a relationship	81 (54.4%)	77 (49.7%)
<1 year	9 (6.0%)	12 (7.7%)
1 to <5 years	33 (22.1%)	41 (26.5%)
≥5 years	26 (17.4%)	25 (16.1%)
Australian state/territory		
Victoria	118 (78.7%)	119 (76.3%)
New South Wales	16 (10.7%)	16 (10.3%)
Others	16 (10.7%)	21 (13.5%)
Remoteness		
Major city	140 (93.3%)	141 (90.4%)
Regional or remote area	10 (6.7%)	15 (9.6%)
Highest level of education completed		
Certificate/diploma/ undergraduate degree	58 (38.7%)	59 (37.8%)
Postgraduate studies	92 (61.3%)	97 (62.2%)
Profession		
Professional	90 (60.0%)	110 (70.5%)
Student	43 (28.7%)	34 (21.8%)
Others	17 (11.3%)	12 (7.7%)
Annual household income*		
$0–$37 000	29 (19.3%)	29 (18.6%)
$37 001–$90 000	35 (23.3%)	41 (26.3%)
$90 001 and over	69 (46.0%)	71 (45.5%)
Prefer not to say	17 (11.3%)	15 (9.6%)
Existing children		
No children	144 (96.0%)	150 (96.2%)
At least one child (biological or non-biological)	6 (4.0%)	6 (3.8%)
Time spent considering egg freezing (months), median (IQR)	12.0 (6.0–24.0)	12.0 (6.0–24.0)
Consulted an IVF specialist	13 (8.7%)	16 (10.3%)

Results are presented as n (%) unless otherwise stated. Control group: received existing information on EEF only. Intervention group: received existing information on EEF plus the Decision Aid. Missing data: age (years) = 3; relationship length = 2; time spent considering egg freezing = 5. Percentages may not total 100 because of rounding.
* Australian $. EEF, elective egg freezing; SD, standard deviation; IQR, 25th–75th percentile.

Primary outcome (Decisional Conflict Scale)

Mean DCS scores decreased from baseline (intervention: 62.5 (SD: 23.6); control 62.9 (SD: 23.4)) to 12 months (intervention: 26.5 (SD: 23.8); control: 31.3 (SD: 27.1)) for both groups. The two groups were very similar at baseline but the intervention group had significantly lower DCS scores compared to the control at 12 months after adjusting for baseline decisional conflict (mean score difference: −6.99; 95% CI [−12.96, −1.02]; $P = 0.02$; Table 2). This finding did not change after also adjusting for age-group, relationship status, education level, income, and stage of decision-making at baseline (Supplementary Table S3), and was robust to missing data assumptions (Supplementary Table S4). In prespecified subgroup analyses, there were no significant differences in effect sizes between age-groups or relationship status (Supplementary Tables S5 and S6). Median DCS subscale scores also decreased between baseline and 12 months for both groups. The reduction was greater for the intervention than the control group on the informed subscale ($P = 0.02$; Supplementary Tables S7 and S8).

Secondary outcomes

At 12 months, there was no evidence of an intervention effect for distress (mean score difference: 0.61 [95% CI: −3.72, 4.93], $P = 0.783$), whether a decision had been made about EEF (relative risk: 1.21 [95% CI: 0.90, 1.64], $P = 0.212$) or knowledge (mean score difference: 0.23 [95% CI: −0.21, 0.66], $P = 0.309$) (Table 2). Thirty-four (30.4%) intervention and 47 (38.8%) control group participants had consulted a clinician about EEF by 12 months. Mean Perceived Involvement in Care Scale scores were 7.2 (SD: 2.8) for the intervention and 6.5 (SD: 3.1) for the control group at this timepoint. By the end of the study, 48 intervention and 45 control group participants had made their decision about EEF (Table 2). No group differences were observed for informed choice (relative risk: 1.00 [95% CI: 0.81, 1.25], $P = 0.983$) or decision regret (median score difference: −5.00 [95% CI: −15.30, 5.30], $P = 0.337$) at 12 months for these participants (Table 3). See Supplementary Tables S9, S10, and S11 for additional data.

Other decision quality outcomes

The intervention group was significantly more prepared to decide about EEF at 6 months than the control (9.22; 95% CI 2.35, 16.08; $P = 0.01$). At 12 months, there were no group differences in personal values or decision satisfaction (Table 2). See Supplementary Table S12 for additional data on personal values. Participants' perceived chances of conceiving naturally or with frozen eggs did not appear affected by the intervention (Supplementary Figs S1 and S2).

Other decision process outcomes

No group differences were observed in decision self-efficacy at 12 months (Table 2). At 6 months, 67.0% of the intervention group and 68.4% of the control group had accessed their allocated resource(s). This increased to 73.5% for the intervention group and 75.8% for the control group by 12 months. The proportion of participants who had started to consider their options increased

Table 2. Primary, secondary, and other outcomes by treatment group (intention-to-treat population).

	Baseline		Month 6		Month 12		Unadjusted Estimate (95% CI) at 12 months	P-value
	Intervention group N = 150	Control group N = 156	Intervention group N = 121	Control group N = 140	Intervention group N = 113	Control group N = 124		
Primary outcome								
Decisional Conflict Scale	62.5 (23.6)	62.9 (23.4)	36.9 (27.1)	41.3 (27.5)	26.5 (23.8)	31.3 (27.1)	−6.99 (−12.96, −1.02)	0.022
Secondary outcomes								
Depression Anxiety Stress Scale	25.2 (17.7)	28.8 (19.5)	30.5 (22.3)	32.0 (20.5)	27.6 (22.1)	28.9 (21.8)	0.61 (−3.72, 4.93)	0.783
Decision made about egg freezing*	12/150 (8.0%)	15/156 (9.6%)	29/114 (25.4%)	28/131 (21.4%)	48/112 (42.9%)	45/119 (37.8%)	1.21 (0.90, 1.64)†	0.212
Knowledge about egg freezing	7.6 (2.7)	7.1 (2.7)	8.8 (2.7)	8.5 (2.4)	9.5 (2.2)	9.1 (2.1)	0.23 (−0.21, 0.66)	0.309
Other outcomes								
Decision self-efficacy scale	77.9 (16.2)	75.5 (20.0)	76.9 (19.5)	72.7 (20.7)	81.8 (17.1)	79.0 (16.9)	2.18 (−1.40, 5.75)	0.233
Preparation for decision-making	—	—	60.5 (25.3)	51.4 (23.7)	—	—	9.22 (2.35, 16.08)	0.009
Values—benefits	—	—	27.6 (9.5)	27.0 (9.0)	27.2 (9.3)	27.7 (9.1)	−0.60 (−2.92, 1.73)	0.615
Values—risks	—	—	25.9 (8.2)	26.5 (7.7)	24.7 (8.3)	25.8 (8.2)	−1.18 (−3.24, 0.87)	0.259

* Binary outcome. Responses from the Stage of Decision-Making measure 'have already made a decision but are likely to change my mind', 'have already made a decision but still willing to reconsider', and 'have already made a definite decision' are categorized as 'decision made'. All other responses are categorized as 'undecided'.
† Relative risk. The Decisional Conflict Scale is scored from 0 to 100, with lower scores indicating lower decisional conflict about EEF. Preparation for decision-making was collected at 6 months only. Personal values (values—benefits and values—risks) were collected at 6 and 12 months only. Control group: received existing information on EEF only. Intervention group: received existing information on EEF plus the Decision Aid. EEF, elective egg freezing.

Table 3. Secondary and other outcomes by treatment group (among participants who made a decision about freezing their eggs).

	Month 6		Month 12			
	Intervention group N = 29	Control group N = 28	Intervention group N = 48	Control group N = 45	Adjusted estimate (95% CI) at 12 months	P-value
Secondary outcomes						
Made an informed choice (MMIC)*	24 (83%)	20 (71%)	38 (79%)	35 (78%)	1.00 (0.81, 1.25)	0.983
Decisional Regret Scale	20.0 (10.0–35.0)	17.5 (0.0–32.5)	15.0 (5.0–25.0)	25.0 (10.0–35.0)	−5.00 (−15.30, 5.30)	0.337
Other outcomes						
Satisfaction with decision scale	25.1 (4.0)	25.7 (3.4)	25.5 (4.5)	25.6 (3.7)	−0.41 (−2.22, 1.40)	0.655

* Binary outcome. Participants who had: (1) good knowledge + positive attitudes + decided to use EEF, or (2) good knowledge + negative attitudes + decided not to use EEF, were considered as having made an informed choice. All other combinations were considered uninformed. Estimates are presented as relative risk for making an informed choice, the between-group difference in medians for the decisional regret scale, and the between-group mean difference for the satisfaction with decision scale, for the intervention compared with the control group. Models were adjusted for whether a participant had seen a fertility specialist about EEF or not, age, relationship status, and income. Control group: received existing information on EEF only. Intervention group: received existing information on EEF plus the Decision Aid. Sample size at 6 and 12 months are not cumulative. MMIC, Multidimensional Measure of Informed Choice; EEF, elective egg freezing.

from baseline (intervention: 41.4%; control: 37.2%) to 12 months (intervention: 73.2%; control: 64.7%) for both groups. Additional data are presented in Supplementary Table S13.

Other reproductive and decision-making characteristics

Most participants believed the COVID-19 pandemic did not impact their ability to seek EEF information at 12 months (intervention: 73.2%; control: 71.4%). Those who were impacted often reported reluctance or dissatisfaction with the use of telehealth appointments, greater difficulty organizing doctor consultations, and wanting to avoid healthcare settings. Most participants also felt the pandemic did not affect their decision about EEF by the end of the study (intervention: 79.5%; control: 70.6%). Participants who were affected commonly indicated that the pandemic changed or prevented partnership formation, prompted the re-evaluation of life priorities and reproductive plans, and sparked concerns about raising children in an uncertain environment.

Few participants (intervention: n = 25; control: n = 34) had their AMH levels tested by 12 months. Of these participants, most believed the test influenced their decision about EEF (intervention: 64.0%; control: 61.8%). Additional data are presented in Supplementary Tables S14, S15, and S16.

Utility of the Decision Aid

Fifteen (10%) intervention group participants completed the values clarification exercise by 12 months. Eight agreed with the output provided by the exercise positioning them on a scale leaning towards/away from EEF. Six disagreed and one was unsure. When assessing the accuracy of the output calculation, nine participants' responses sat within ±1 SD of the output result and therefore were deemed accurate.

No harm or unintended effects were identified during this study for participants in either group.

Discussion

This is the first study to assess the impact of a Decision Aid for women considering EEF in a prospective randomized controlled trial. The Decision Aid significantly reduced decisional conflict

(primary outcome), improved women's preparation to decide about EEF and did not increase distress.

Participants with access to the Decision Aid had significantly lower decisional conflict than the control group at 12 months. The seven-point mean difference is consistent with other health-related Decision Aid research (Stacey *et al.*, 2017), demonstrating similar levels of effectiveness. Meta-analysis across different health conditions found that for every one-point lower DCS score, people are 23 times less likely to experience decision delay, five times less likely to experience decision regret, and three times less likely to demonstrate poor knowledge of their options (O'Connor, 2010). Our Decision Aid will likely have a similar impact with respect to these outcomes in the longer-term.

The Decision Aid was most effective at decreasing scores on the DCS informed sub-scale indicating that it improved women's perceived understanding of their options, including the risks and benefits of each. In addition, women who received the Decision Aid felt more prepared to decide about EEF compared to those who received information alone. Both of these benefits are similar to other Decision Aids (Stacey *et al.*, 2017) and highly correlated (Bennett *et al.*, 2010). These findings demonstrate that the Decision Aid's design and content are effective in facilitating EEF decision-making.

No group differences were observed in DASS-21 scores across timepoints indicating the Decision Aid had no effect on levels of distress. This is consistent with other studies demonstrating that Decision Aids have no detrimental effect on users' emotional wellbeing (Stacey *et al.*, 2017). Overall, our finding confirms that use of the Decision Aid is unlikely to be psychologically harmful if implemented in a real-world setting.

No group differences were observed in mean knowledge score at 12 months. This contrasts with high-quality evidence showing that Decision Aids improve patient knowledge in other health decision contexts (Stacey *et al.*, 2017). Prior research suggests that decision support tools are more effective in increasing comprehension in low literacy and low knowledge populations (Gentles *et al.*, 2013; Durand *et al.*, 2014). Most of our participants were highly educated, and some had received health-related training. Whilst these characteristics are consistent with women who consider EEF (Inhorn *et al.*, 2018; Giannopapa *et al.*, 2022; Sandhu *et al.*, 2023a), they may influence the capacity for knowledge gain from the Decision Aid. In fact, at baseline, both cohorts showed a moderate understanding of EEF and age-related infertility, which could explain why no group differences were observed. Also, the knowledge measure used was purpose-designed and may not have adequate sensitivity to assess differences between the groups.

No group differences were observed in final decision-making about EEF at 12 months. Decision Aids typically reduce indecision (Stacey *et al.*, 2017) and lower DCS scores are associated with faster decision-making (O'Connor, 2010). Our data suggest that a 12-month follow-up may be insufficient to capture an intervention effect since median time to decision about EEF is around 2 years (Sandhu *et al.*, 2023a). Final decision-making may be motivated by multiple factors including changing relationships (De Proost and Paton, 2022) and increasing age (Sousa-Leite *et al.*, 2019). Our participants were on average 30 years old and may not have felt the urgency to decide. The Decision Aid's impact on time to decision should be evaluated in a cohort of older reproductive aged women where the adverse impact of age on fertility and the efficacy of EEF is likely to be of greater importance (Steiner and Jukic, 2016; Kawwass *et al.*, 2021).

No group differences were observed for informed choice or decision regret at 12 months. This is likely because only a small sample of women had decided about EEF by the end of the study. Assessment of the Decision Aid with a longer follow-up period is warranted to assess these outcomes with a larger cohort.

It is uncertain why only 15 (10%) women in the intervention group completed the Decision Aid's values clarification exercise. Much higher (81%) activity completion rates were reported in female cancer patients using a fertility preservation Decision Aid (Ehrbar *et al.*, 2019). A common reason for not completing a values clarification exercise is that people may feel they are able to weigh up risks and benefits and make a decision without needing to complete a physical activity (Peate *et al.*, 2013; Garvelink *et al.*, 2014). Our finding suggests that a values clarification exercise may have limited utility in the EEF context possibly because the information in the Decision Aid may be sufficient to support decision-making.

Although some participants felt affected, most believed the COVID-19 pandemic did not impact their information-seeking or decision about EEF. This finding is similar to Huttler *et al.* (2022) who reported that consideration of EEF was mostly unaffected by the pandemic. Given the influence of COVID-19 on our participants appears similar between groups, it is unlikely to have confounded the Decision Aid's effect on study outcomes.

Study strengths include a randomized controlled trial design, the gold standard for evaluating clinical interventions. Our broad recruitment approach allowed us to reach women from across Australia who were considering EEF (not only those who attend a fertility clinic). EEF is generally a self-initiated decision and few women consult IVF specialists when deciding (Sandhu *et al.*, 2023a), making this an optimal recruitment approach. Limitations include unknown participant uptake and potential sampling bias with a high proportion of participants recruited from the state of Victoria, Australia. Fewer women than expected were recruited via fertility clinics, which may reflect the COVID-19 lockdowns and restrictions to in-clinic attendance imposed at the time. Future research evaluating the Decision Aid in a clinic setting is encouraged as these tools are often used with clinicians to facilitate shared decision-making (Beach and Sugarman, 2019). Some validated measures were adapted to improve relevance for an EEF context. The changes made to these instruments may have impacted their validity. Finally, our study was Australian-based and the generalizability of these findings internationally are unknown. The tool was tailored for Australian women, although it can be adapted for an international audience. Further evaluation of the Decision Aid in international settings is endorsed. The Decision Aid will be made publicly available and should be accessed by women early in the consideration process (Sandhu *et al.*, 2023b).

Conclusion

Using a randomized controlled trial, we demonstrated that a purpose-designed Decision Aid for EEF is effective in reducing decisional conflict and better preparing women to decide about EEF compared to information alone. In addition, the Decision Aid did not increase distress.

Supplementary data

Supplementary data are available at *Human Reproduction* online.

Data availability

The datasets generated and/or analyzed during the current study cannot be shared as participants were assured that their data would not be used for purposes outside of this research project.

Acknowledgements

Throughout the article, we refer to those who access and use elective egg freezing as women. However, we acknowledge that egg freezing may also be relevant for people who do not identify as women. We would like to thank our study participants, affiliated recruitment partners and the Eggsurance Collaborative Group (A. Parle, W. Ledger, J. Fisher, F. Agresta, L. Johnson, J. Michelmore, F. Summers, D. Lieberman, C. Allingham) for their involvement in this trial.

Authors' roles

All authors (S.S., M.H., D.N.K., S.B., R.L., R.H., R.J.N., K.H., R.AA., and M.P.) contributed to the study's conception and design. M.P. and S.S. contributed to the acquisition of data. All authors (S.S., M.H., D.N.K., S.B., R.L., R.H., R.J.N., K.H., R.A.A., and M.P.) contributed to the analysis and interpretation of data. S.S. drafted this research paper and M.H., D.N.K., S.B., R.L., R.H., R.J.N., K.H., R.A.A., and M.P. reviewed it for important intellectual content.

Funding

The Decision Aid was developed with funding from the Royal Women's Hospital Foundation and McBain Family Trust. The study was funded by a National Health and Medical Research Council (NHMRC) Project Grant (APP1163202) awarded to M. Hickey, M. Peate, R.J. Norman, and R. Hart (2019–2021).

Conflict of interest

S.S., M.P., D.K., and S.B. were supported by the NHMRC Project Grant APP1163202 to perform this work. R.H. is Medical Director of Fertility Specialists of Western Australia and National Medical Director of City Fertility. He has received grants from MSD, Merck-Serono, and Ferring Pharmaceuticals unrelated to this study and is a shareholder of CHA-SMG. R.L. is Director of Women's Health Melbourne (Medical Practice), ANZSREI Executive Secretary (Honorary), RANZCOG CREI Subspecialty Committee Member (Honorary), and a Fertility Specialist at Life Fertility Clinic Melbourne and Royal Women's Hospital Public Fertility Service. R.A.A. has received grants from Ferring Pharmaceuticals unrelated to this study. M.H., K.H., and R.J.N. have no conflicts to declare.

References

Anderson RA, Amant F, Braat D, D'Angelo A, Chuva de Sousa Lopes SM, Demeestere I, Dwek S, Frith L, Lambertini M, Maslin C *et al.* ESHRE guideline: female fertility preservation. *Hum Reprod Open* 2020a;**2020**:hoaa052.

Anderson RA, Davies MC, Lavery SA; Royal College of Obstetricians Gynaecologists. Elective egg freezing for non-medical reasons: scientific impact paper no. 63. *BJOG* 2020b;**127**:e113–e121.

Argyle CE, Harper JC, Davies MC. Oocyte cryopreservation: where are we now? *Hum Reprod Update* 2016;**22**:440–449.

Australian Commission on Safety and Quality in Healthcare. *Decision Support Tools for Consumers*. https://www.safetyandquality.gov.au/our-work/partnering-consumers/shared-decision-making/decision-support-tools-patients (1 August 2022, date last accessed).

Baldwin K, Culley L. Women's experience of social egg freezing: perceptions of success, risks, and 'going it alone'. *Hum Fertil (Camb)* 2020;**23**:186–192.

Beach MC, Sugarman J. Realizing shared decision-making in practice. *JAMA* 2019;**322**:811–812.

Bennett C, Graham ID, Kristjansson E, Kearing SA, Clay KF, O'Connor AM. Validation of a preparation for decision making scale. *Patient Educ Couns* 2010;**78**:130–133.

Blakemore JK, Grifo JA, DeVore SM, Hodes-Wertz B, Berkeley AS. Planned oocyte cryopreservation—10–15-year follow-up: return rates and cycle outcomes. *Fertil Steril* 2021;**115**:1511–1520.

Butow P, Brindle E, McConnell D, Boakes R, Tattersall M. Information booklets about cancer: factors influencing patient satisfaction and utilisation. *Patient Educ Couns* 1998;**33**:129–141.

Cassileth BR, Zupkis RV, Sutton-Smith K, March V. Information and participation preferences among cancer patients. *Ann Intern Med* 1980;**92**:832–836.

Chin AHB, Sandhu S, Caughey L, Ahmad MF, Peate M. Systematic protocol and methodology needed for pre-procedure counselling of elective egg freezing patients in Singapore. *Hum Fertil (Camb)* 2023;**26**:385–397.

D'Angelo A, Panayotidis C, Amso N, Marci R, Matorras R, Onofriescu M, Turp AB, Vandekerckhovem F, Veleva Z, Vermeulen N *et al.*; The ESHRE Working Group on Ultrasound in ART. Recommendations for good practice in ultrasound: oocyte pick up. *Hum Reprod Open* 2019;**2019**:hoz025.

De Proost M, Johnston M. The revision of the French bioethics law and the questions it raises for the future of funding for egg freezing. *Reprod Biomed Online* 2022;**44**:591–593.

De Proost M, Paton A. Medical versus social egg freezing: the importance of future choice for women's decision-making. *Monash Bioeth Rev* 2022;**40**:145–156.

Degner LF, Sloan JA, Venkatesh P. The control preferences scale. *Can J Nurs Res Arch* 1997;**29**:21–43.

Durand MA, Carpenter L, Dolan H, Bravo P, Mann M, Bunn F, Elwyn G. Do interventions designed to support shared decision-making reduce health inequalities? A systematic review and meta-analysis. *PLoS One* 2014;**9**:e94670.

Ehrbar V, Urech C, Rochlitz C, Zanetti Dällenbach R, Moffat R, Stiller R, Germeyer A, Nawroth F, Dangel A, Findeklee S *et al.* Randomized controlled trial on the effect of an online decision aid for young female cancer patients regarding fertility preservation. *Hum Reprod* 2019;**34**:1726–1734.

Dondorp W, de Wert G, Pennings G, Shenfield F, Devroey P, Tarlatzis B, Barri P, Diedrich K; ESHRE Task Force on Ethics and Law. Oocyte cryopreservation for age-related fertility loss. *Hum Reprod* 2012;**27**:1231–1237.

Ethics Committee of the American Society of Reproductive Medicine. Planned oocyte cryopreservation for women seeking to preserve future reproductive potential: an Ethics Committee opinion. *Fertil Steril* 2018;**110**:1022–1028.

Garvelink MM, ter Kuile MM, Stiggelbout AM, de Vries M. Values clarification in a decision aid about fertility preservation: does it add to information provision? *BMC Med Inform Decis Mak* 2014;**14**:68.

Gentles SJ, Stacey D, Bennett C, Alshurafa M, Walter SD. Factors explaining the heterogeneity of effects of patient decision aids on knowledge of outcome probabilities: a systematic review subanalysis. *Syst Rev* 2013;**2**:95.

Giannopapa M, Sakellaridi A, Pana A, Velonaki VS. Women electing oocyte cryopreservation: characteristics, information sources, and oocyte disposition: a systematic review. *J Midwifery Womens Health* 2022;**67**:178–201.

Graham ID, O'Connor AM. *User Manual—Preparation for Decision Making Scale [Document on the Internet]*. Ottawa: Ottawa Hospital Research Institute, 2010, 3.

Greenwood EA, Pasch LA, Hastie J, Cedars MI, Huddleston HG. To freeze or not to freeze: decision regret and satisfaction following elective oocyte cryopreservation. *Fertil Steril* 2018; **109**:1097–1104.

Gurbuz A, Cil AP, Karakis LS, Abali R, Ceyhan M, Aksakal E, Kilic A, Bahceci M, Urman B. Decision regret and associated factors following oocyte cryopreservation in patients with diminished ovarian reserve and/or age-related fertility decline. *J Assist Reprod Genet* 2021;**38**:1469–1479.

Gurtin ZB, Tiemann E. The marketing of elective egg freezing: a content, cost and quality analysis of UK fertility clinic websites. *Reprod Biomed Soc Online* 2021;**12**:56–68.

Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, McLeod L, Delacqua G, Delacqua F, Kirby J *et al.*; REDCap Consortium. The REDCap consortium: building an international community of software platform partners. *J Biomed Inform* 2019; **95**:103208.

Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;**42**:377–381.

Human Fertilisation and Embryology Authority. (2023). *Fertility Treatment 2021: Preliminary Trends and Figures*. https://www.hfea.gov.uk/about-us/publications/research-and-data/fertility-treatment-2021-preliminary-trends-and-figures/ (28 September 2023, date last accessed).

Huttler A, Koelper N, Mainigi M, Gracia C, Senapati S. Impact of the COVID-19 pandemic on the perception of planned oocyte cryopreservation in the United States. *F S Rep* 2022;**3**:145–152.

Inhorn MC, Birenbaum-Carmeli D, Birger J, Westphal LM, Doyle J, Gleicher N, Meirow D, Dirnfeld M, Seidman D, Kahane A *et al.* Elective egg freezing and its underlying socio-demography: a binational analysis with global implications. *Reprod Biol Endocrinol* 2018;**16**:70.

International Patient Decision Aid Standards (IPDAS) Collaboration. (2005). *IPDAS 2005: Criteria for Judging the Quality of Patient Decision Aids*. http://ipdas.ohri.ca/IPDAS_checklist.pdf (8 June 2020, date last accessed).

Jaswa EG, Pasch LA, McGough A, Wong R, Corley J, Cedars MI, Huddleston HG. Decision regret among women considering planned oocyte cryopreservation: a prospective cohort study. *J Assist Reprod Genet* 2023;**40**:1281–1290.

Johnston M, Richings NM, Leung A, Sakkas D, Catt S. A major increase in oocyte cryopreservation cycles in the USA, Australia and New Zealand since 2010 is highlighted by younger women but a need for standardized data collection. *Hum Reprod* 2020; **24**:24.

Kawwass JF, Crawford S, Hipp HS. Frozen eggs: national autologous oocyte thaw outcomes. *Fertil. Steril* 2021;**116**:1077–1084.

Kim R, Yoon TK, Kang IS, Koong MK, Kim YS, Kim MJ, Lee Y, Kim J. Decision making processes of women who seek elective oocyte cryopreservation. *J Assist Reprod Genet* 2018;**35**:1623–1630.

Lerman CE, Brody DS, Caputo GC, Smith DG, Lazaro CG, Wolfson HG. Patients' perceived involvement in care scale: Relationship to attitudes about illness and medical care. *J Gen Intern Med* 1990; **5**:29–33.

Linder SK, Swank PR, Vernon SW, Mullen PD, Morgan RO, Volk RJ. Validity of a low literacy version of the Decisional Conflict Scale. *Patient Educ Couns* 2011;**85**:521–524.

Lovibond SH, Lovibond PF. *Manual for the Depression Anxiety Stress Scales*. Sydney: Psychology Foundation, 1995.

Marteau TM, Dormandy E, Michie S. A measure of informed choice. *Health Expect* 2001;**4**:99–108.

Michie S, Dormandy E, Marteau TM. The multi-dimensional measure of informed choice: a validation study. *Patient Educ Couns* 2002;**48**:87–91.

Mills M, Rindfuss RR, McDonald P, Te Velde E; ESHRE Reproduction and Society Task Force. Why do people postpone parenthood? Reasons and social policy incentives. *Hum Reprod Update* 2011; **17**:848–860.

National Institute for Health and Care Excellence (NICE). *Shared Decision Making*. https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making (15 August 2022, date last accessed).

Newman JE, Rc P, Chambers GM. (2023). *Assisted Reproductive Technology in Australia and New Zealand 2021*. https://npesu.unsw.edu.au/data-collection/australian-new-zealand-assisted-reproduction-database-anzard (29 September 2023, date last accessed).

Nuffield Council on Bioethics. (2020). *Egg Freezing in the UK*. https://www.nuffieldbioethics.org/publications/egg-freezing-in-the-uk/introduction/egg-freezing-in-the-uk-law (8 November 2023, date last accessed).

O'Connor AM. *User Manual—Decision Self-Efficacy Scale [Document on the Internet]*. Ottawa: Ottawa Hospital Research Institute, 1995a/2002, 4.

O'Connor AM. *User Manual—Realistic Expectations [Document on the Internet]*. Ottawa: Ottawa Hospital Research Institute, 1995b, 6.

O'Connor AM. *User Manual—Stage of Decision Making [Document on the Internet]*. Ottawa: Ottawa Hospital Research Institute, 2000/2003, 3.

O'Connor AM. *User Manual—Decision Regret Scale [Document on the Internet]*. Ottawa: Ottawa Hospital Research Institute, 2003/1996.

O'Connor AM. *User Manual—Values [Document on the Internet]*. Ottawa: Ottawa Hospital Research Institute, 2004, 4.

O'Connor AM. (2010). *User Manual—Decisional Conflict Scale (10 Item Question Format)*. http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decisional_Conflict.pdf (28 April 2022, date last accessed).

Peate M, Meiser B, Friedlander M, Zorbas H, Rovelli S, Sansom-Daly U, Sangster J, Hadzi-Pavlovic D, Hickey M. It's now or never: fertility-related knowledge, decision-making preferences, and treatment intentions in young women with breast cancer-an Australian fertility decision aid collaborative group study. *J Clin Oncol* 2011;**29**:1670–1677.

Peate M, Sandhu S, Braat S, Hart R, Norman R, Parle A, Lew R, Hickey M. Randomized control trial of a decision aid for women considering elective egg freezing: the Eggsurance study protocol. *Womens Health (Lond)* 2022;**18**:17455057221139673.

Peate M, Watts K, Wakefield CE. The 'value' of values clarification in cancer-related decision aids. *Patient Educ Counsel* 2013; **90**:281–283.

Platts S, Trigg B, Bracewell-Milnes T, Jones BP, Saso S, Parikh J, Nicopoullos J, Almeida P, Norman-Taylor J, Nikolaou D *et al.* Exploring women's attitudes, knowledge, and intentions to use oocyte freezing for non-medical reasons: a systematic review. *Acta Obstet Gynecol Scand* 2021;**100**:383–393.

Practice Committees of the American Society of Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. *Fertil Steril* 2013; **99**:37–43.

Ringash J, O'Sullivan B, Bezjak A, Redelmeier DA. Interpreting clinically significant changes in patient-reported outcomes. *Cancer* 2007;**110**:196–202.

Sandhu S, Hickey M, Braat S, Hammarberg K, Lew R, Fisher J, Ledger W, Peate M; Eggsurance Collaborative Group. Information and decision support needs: a survey of women interested in receiving planned oocyte cryopreservation information. *J Assist Reprod Genet* 2023a;**40**:1265–1280.

Sandhu S, Hickey M, Lew R, Hammarberg K, Braat S, Agresta F, Parle A, Allingham C, Peate M; Eggsurance Collaborative Group. The development and phase 1 evaluation of a Decision Aid for elective egg freezing. *BMC Med Inform Decis Mak* 2023b;**23**:83.

Smeenk J, Wyns C, De Geyter C, Kupka M, Bergh C, Cuevas Saiz I, De Neubourg D, Rezabek K, Tandler-Schneider A, Rugescu I *et al.* ART in Europe, 2019: results generated from European registries by ESHRE†. *Hum Reprod* 2023;**38**:2321–2338.

Society for Assisted Reproductive Technology. *National Summary Report*. https://sartcorsonline.com/Csr/Public?ClinicPKID=0&reportingYear=2021&newReport=True (29 September 2023, date last accessed).

Sousa-Leite M, Figueiredo B, Ter Keurst A, Boivin J, Gameiro S. Women's attitudes and beliefs about using fertility preservation to prevent age-related fertility decline: a two-year follow-up. *Patient Educ Couns* 2019;**102**:1695–1702.

Stacey D, Lewis KB, Smith M, Carley M, Volk R, Douglas EE, Pacheco-Brousseau L, Finderup J, Gunderson J, Barry MJ *et al.* Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017;**1**:CD001431.

STATACorp., LLC. *Stata Statistical Software: Release 17*. College Station, TX: StataCorp LLC, 2021.

Steiner AZ, Jukic AM. Impact of female age and nulligravidity on fecundity in an older reproductive age cohort. *Fertil Steril* 2016;**105**:1584–1588.e1581.

UK Government. *Health and Care Act 2022 Schedule 17*, 2022. https://www.legislation.gov.uk/ukpga/2022/31/schedule/17/enacted (29 September 2023, date last accessed).

US Congress. *H.R.3590: Patient Protection and Affordable Care Act*. https://www.congress.gov/bill/111th-congress/house-bill/3590/text (8 June 2020, date last accessed).

Wills CE, Holmes-Rovner M. Preliminary validation of the satisfaction with decision scale with depressed primary care patients. *Health Expect* 2003;**6**:149–159.

Wyns C, Bergh C, Calhaz-Jorge C, De Geyter C, Kupka MS, Motrenko T, Rugescu I, Smeenk J, Tandler-Schneider A, Vidakovic S *et al.*; European IVF-Monitoring Consortium (EIM)‡ for the European Society of Human Reproduction and Embryology (ESHRE). ART in Europe, 2016: results generated from European registries by ESHRE. *Human Reprod Open* 2020;**2020**:hoaa032.

Yee S, Goodman CV, Fu V, Lipton NJ, Dviri M, Mashiach J, Librach CL. Assessing the quality of decision-making for planned oocyte cryopreservation. *J Assist Reprod Genet* 2021;**38**:907–916.

Human Reproduction, 2024, 39, 1724–1734
https://doi.org/10.1093/humrep/deae121
Original Article