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BMJ Open Effect of fertility health awareness strategies on fertility knowledge and childbearing in young married couples (FertStart): study protocol for an effectiveness-implementation hybrid type I multicentre three-arm parallel group open-label randomised clinical trial

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ABSTRACT

Introduction Birth rates have been declining in many advanced societies including Singapore. We designed two interventions with vastly different resource requirements, which include fertility education, personalised fertility information and a behavioural change component targeting modifiable psychological constructs to modify fertility awareness and childbearing intentions. We aim to evaluate the effect of these two interventions on knowledge, attitudes and practice around childbearing compared with a control group among young married couples in Singapore and understand the implementation factors in the setting of an effectiveness-implementation hybrid type 1 three-arm randomised trial.

Methods and analysis We will randomise 1200 young married couples to no intervention (control), Fertility Health Screening group (FHS) or Fertility Awareness Tools (FAT) in a 7:5:5 ratio. Couples in FHS will undergo an anti-Mullerian hormone test and semen analysis, a doctor's consultation to explain the results and standardised reproductive counselling by a trained nurse. Couples in FAT will watch a standardised video, complete an adapted fertility status awareness (FertiSTAT) tool and receive an educational brochure. The attitudes, fertility knowledge and efforts to achieve pregnancy of all couples will be assessed at baseline and 6 months post-randomisation. Birth statistics will be tracked using administrative records at 2 and 3 years. The primary outcome is the change in the woman's self-reported intended age at first birth between baseline and 6 months post-randomisation. In addition, implementation outcomes and cost-effectiveness of the two interventions will be assessed.

Ethics and dissemination This study has been reviewed and approved by the Centralized Institutional Review Board of SingHealth (2019/2095). Study results will be reported

Strengths and limitations of this study

- This is the first randomised controlled trial studying two novel theory-based interventions designed to encourage earlier childbearing.
- Both intermediate and final outcomes will be measured in this study.
- Implementation outcomes will be concurrently.
- The limitation of this study is that the recruitment strategy may not yield couples representative of the target population.

to the study funder and there are plans to disseminate them in scientific conferences and publications, where authorship will be determined by the International Committee of Medical Journal Editors guidelines. Trial registration number NCT04647136; ClinicalTrails. gov Identifier.

BACKGROUND

Birth rates have been declining over the past decades in many advanced societies including Singapore, where the resident total fertility rate was 1.14 births per woman in 2019. Concurrently, there is also a trend of increasing median age at first marriage and childbirth² and use of assisted reproductive technology (ART).³ As couples marry and attempt pregnancy at a later age, chances are more and will face infertility issues. 4 5 However, ART is invasive, expensive, stressful



and cannot guarantee a live birth or completely compensate for age-related fertility decline. 46

Childbearing is a decision affected by a complex interplay of personal, financial, employment, social and psychological factors. Commonly cited factors affecting the decision to have children include financial considerations, pursuit of career, personal interests or education, emotional readiness, access to childcare and work demands. Similar sentiments are echoed by Singaporeans as well. 89

While there are ongoing efforts by the Singapore government and the wider community to support marriage and parenthood, there is low public awareness of age-related fertility decline and the limitations of fertility treatments. Fertility awareness surveys across different countries have consistently showed an overestimation of age-related female fecundity and ART success rates. 10-17 In Singapore, the 2016 Marriage & Parenthood Survey revealed that 52% of married respondents agreed with the statement that 'Medical advances have extended the natural biological clock such that couples can plan to start families at a much later age' and 72% of married respondents agreed with the statement that 'With medical advances, ART treatments have very high success rates. In addition, interviews with women who conceived through in vitro fertilisation (IVF) after the age of 40 revealed inaccurate perceptions regarding the relationship between age and fertility prior to IVF.¹⁸

Randomised controlled trials (RCTs) show that both individualised interventions involving counselling 19 20 and generic educational materials (brochure, website or video) can increase fertility knowledge in the short term. 21-24 A recent follow-up report of an RCT on the effect of generic fertility information (brochure) demonstrated some knowledge retention after 2 years, and although there was no difference in incidence of new births between the intervention and control groups, the timing was accelerated among those who had a partner. 25

There is evidence that tailored interventions are better at generating desirable results than generic interventions. A three-arm RCT of 201 women undergoing oocyte donation showed that only the tailored education arm achieved significant improvement in knowledge scores compared with untailored education and no education (control). Another study at a Swedish student's health centre had a midwife conduct counselling on reproductive life plans in addition to 'standard care' (contraceptive counselling, chlamydia awareness, cervical screening), which increased fertility awareness and mildly reduced the preferred age of having last child at 2 months postintervention, as compared with standard care alone. On the contract of the con

Although personalised risk messages are more effective than generic messages, more is needed for sustained behavioural change. Studies in other health behaviours such as smoking, physical activity, diet and alcohol consumption suggest that even personalised risk information does not produce strong or sustained effects. We, therefore, designed two theory-guided, evidence-based

personalised fertility interventions to deliver fertility education coupled with behavioural change nudges. We propose to compare them in a three-arm open-label RCT with a control group to assess their effects on knowledge, attitudes and practice around childbearing among young Singaporean married couples. We also plan to compare the cost-effectiveness of both interventions and to conduct this study as an effectiveness-implementation hybrid type 1 trial to understand intervention effectiveness and potential implementation barriers.²⁹

METHODS/DESIGN

Aims

Primary aim

To determine whether Fertility Health Screening (FHS) and/or Fertility Awareness Tools (FAT) enhance parent-hood intentions (as defined by the wife's intended age at first birth) compared with no intervention among young Singaporean/Permanent Resident (PR) married couples at 6 months post-randomisation.

Secondary aims

- 1. To determine whether FHS and/or FAT
 - increase fertility awareness
 - accelerate efforts to achieve pregnancy
 - improve live birth statistics among young Singaporean/PR married couples at 6 months postrandomisation compared with no intervention.
- 2. To compare the cost-effectiveness of FHS and FAT.
- 3. To understand the potential barriers and facilitators from different perspectives to implementing and scaling up these intervention strategies.

Study design

This is an effectiveness-implementation hybrid type 1 trial²⁹ with a multicentre three-arm parallel group openlabel RCT at its core and supplemented by qualitative studies with selected participants and key stakeholders and collection of relevant data and process indicators. The study is expected to take place from January 2021 to December 2025. The protocol and description of the interventions conform to the SPIRIT 2013 (online supplemental additional file 1) and template for intervention description and replication (TIDierR) (online supplemental additional file 2) checklists, respectively. In addition, we assessed our study using the revised Cochrane risk-of-bias tool (RoB 2) for randomised trials (online supplemental additional file 3).

Setting and eligibility criteria

Heterosexual couples will be recruited as a unit and included into the study if they are agreeable and able to complete study procedures, provided that they are married, Singapore Citizens or PRs, and the wife is 25–34 years old at time of recruitment. This age range was chosen as women getting married at this age made up 70% of all married couples in 2019³⁰ and is the ideal



age range to encourage childbearing before age-fertility decline sets in. There was no restriction on the husband's age to maximise generalisability of our results, given the evidence that female fertility drops more significantly with age, compared with men. They are excluded if they already have children, are pregnant, are currently undergoing or had previously undergone any fertility evaluation and/or treatments, have self-reported history of previous ectopic pregnancy in the wife or at least one partner is unable to complete a self-administered questionnaire in English. We excluded couples with at least one child, even from previous marriages, because motivations to have a second child are likely to differ from those who plan to have a first child and couples who already have a child are more likely to have received fertility advice than couples with no children.

Recruitment

This study will adopt open recruitment approaches. The primary strategy involves approaching potential participants at selected primary healthcare centres serving a younger demographic in our healthcare cluster. This will be supplemented by other publicity measures such as a media interview on fertility issues (with mention of this study), email communications to staff, postings on institutional internal webpage and posters and brochures at healthcare institutions. If necessary, further publicity may be conducted through social media, institutions' online portals, applications and/or publications, outreach talks and/or working with external organisations.

All recruitment strategies will be supported by a study website that contains details of the study. Posters and recruitment flyers will direct potential participants to this website for detailed information.

Eligible couples willing to participate will call the study hotline. Verbal consent will be recorded during the first phone contact. Couples involved in FHS will eventually have their written informed consent taken, as biological testing is involved (online supplemental additional file 4). In addition, written informed consent will also be taken from participants for the qualitative component.

Randomisation

Stratified block randomisation by the wife's age group (25–29 years and 30–34 years) to the control and two treatment arms in a 7:5:5 ratio (figure 1) will be performed by an independent statistician outside the study team and uploaded to the Research Electronic Data Capture (REDCap) randomisation module, thereby effecting allocation concealment. 31 32

Blinding

Due to the nature of the intervention, the research coordinator, participants and doctors are not blinded to the treatment assignment. However, the study statistician will be blinded to treatment assignment and shall not be unblinded under any circumstance.

Design of the interventions

Fertility education component

Gynaecologists on the study team curated key facts on age-related fertility decline and limitations of ART. These were phrased in appropriate lay language, reviewed and refined by other study team members and communications professionals, before finally rendered into a brochure for participants. The key points that fertility decreases significantly after age 35, and that the success of ART is also dependent on age, will also be highlighted during a reproductive counselling or in a video as well as in email reminders for couples receiving interventions.

Behavioural change component

Briefly, we drew on the literature, behavioural change theories (theory of planned behaviour (TPB) and health belief model (HBM)) and used Intervention Mapping, a six-step protocol for systematic theory and evidence-based behavioural change planning to design the behavioural change component. ^{33–36} Details are given in online supplemental additional file 5.

Interventions

We bundled the fertility education and behavioural change components into two interventions of different approaches. One is a one-time fertility screening and support through private interaction with trained health-care professionals, which is personalised but potentially costly. The other offers general and tailored information along with behavioural nudges through a video and a self-administered questionnaire, which is less expensive and scalable.

Fertility health screening

This is a basic fertility screening comprising an anti-Mullerian hormone test and semen analysis, a doctor's consultation to explain the results, and standardised reproductive counselling by a trained nurse. For young couples without prior known fertility issues, this basic screening can provide an estimate of their reproductive capacity and encourage early intervention if any abnormalities are found. Couples with abnormal screening results will be managed at the discretion of the attending gynaecologist.

During the reproductive counselling, the nurse will elicit reproductive plans with the couple (guided in part by the reproductive life plan tool from the Centers for Disease Control and Prevention³⁷), educate the couple on age-related fertility decline and the limitations of ART and give appropriate advice on optimal reproductive age to meet their reproductive goals according to a standardised counselling guide.³⁸ A fertility educational brochure curated and designed for this study will also be given to the couples. This intervention, thus, offers personalised fertility information and counselling, employing behaviour change methods such as tailoring, motivational interviewing, consciousness raising and possibly anticipated regret. All seven doctors and three

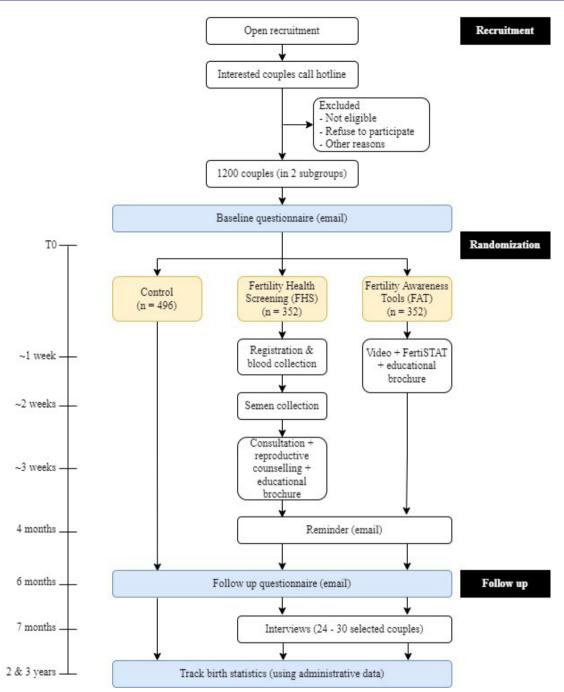


Figure 1 Study flowchart. FertiSTAT, fertility status awareness.

nurses involved in the consultation and reproductive counselling will be trained using the standardised counselling guides and educational content, as appropriate (available on request). Fidelity will be checked periodically by reviewing information recorded in the electronic medical records during consultations and reproductive counselling to determine if key activities have been carried out for a random 20% of couples in FHS, and refresher trainings given as necessary. During the consultations and counselling, main discussion points will be recorded on hard copy counselling guides and/or in the electronic medical records. Any unlikely adverse events related to

the intervention will be recorded and addressed by the doctor and/or nurse seeing the couple.

Fertility awareness tools

This intervention consists of three components: (1) a video that provides pertinent fertility knowledge and promotes positive attitude towards having children and the timing of childbearing, (2) adapted fertility status awareness (FertiSTAT), a tailored communication tool in the form of a validated, self-administered multifactorial questionnaire to help women make informed decisions about their lifestyle and/or seek the necessary medical



advice³⁹ and (3) a fertility educational brochure (same as the one in FHS). The video features three couples of different ages and childbearing journeys to highlight the significance of age on their fertility, and common personal, social and financial hurdles in starting a family. The intent is to effect behavioural change through modelling, persuasive communication and anticipated regret.

All components will be self-administered online. Couples will login to a dedicated website to watch the video and then download the FertiSTAT and fertility brochure to complete and read offline, respectively. We adapted the FertiSTAT to suit the local context by removing items pertaining to use of prohibited drugs and revising the alcohol and weight thresholds to match local recommendations, which would likely increase its relevance and acceptability. For the husbands, only the lifestyle factors and two specific risk factors (undescended testis and mumps after puberty) were given. Both husband and wife will receive their own FertiSTAT scores.

Control group

The control has no intervention but is exposed to usual information from the media, or other channels, on fertility and family benefits (same as the general population).

Patient and public involvement

Three couples from the public were featured in the video, which is part of the FAT intervention. Study materials that will be seen by participants also received inputs from laypeople not in the study team (eg, colleagues from other departments/disciplines).

Study protocol

Both husband and wife will complete a separate self-administered baseline questionnaire via email before being randomised to one of the three study arms, so that the follow-up period would not be affected by delays in returning the baseline questionnaires and to allow monitoring of attrition due to randomisation (figure 1).

Couples assigned to FHS will visit Singapore General Hospital (SGH) or KK Women's and Children's Hospital (KKH), and a blood sample will be taken from the wife. The husband will return on a second scheduled visit to provide a semen sample, and both will return for a third visit within 1–2 weeks for the consultation and reproductive counselling. If arrangements permit, the first two visits may be combined.

Couples randomised to FAT will access a web-based series of fertility awareness tools using credentials provided by the research coordinator. Couples will be asked to return the completed FertiSTAT to the research coordinator by email within 2 weeks as a means to track completion of FAT.

At 4 months, a follow-up email containing three key fertility messages will be sent to FHS and FAT couples. At 6 months, all couples will complete a self-administered questionnaire via email. After this, selected couples from

both intervention arms (FHS and FAT) will be invited for in-depth interviews (IDIs) (table 1).

There are no further specific recommendations or prohibitions on fertility checks, treatments or interventions during the study, but any such events will be collected in the 6-month questionnaire. In the event that at least one partner in the couple withdraws his/her consent, any uncompleted interventions will be discontinued. However, any data collected till that point will be stored and used as appropriate. The entire study is expected to span from January 2021 to around December 2025.

Outcomes

The primary outcome is the change in the wife's self-reported intended age at first birth between pre and 6 months post-randomisation. Secondary outcomes include change in fertility awareness between pre- and 6 months post-randomisation, proportions of couples who attempted to conceive are pregnant, pursued more comprehensive fertility screening and/or pursued fertility treatment at 6 months post-randomisation. Where available, the time to first birth since random group assignment and number of births (at 2 and 3 years post-randomisation) will also be tracked and analysed.

Data collection

Most data will be collected via self-administered questionnaires at baseline and at 6 months post-randomisation via an email attachment sent by study research coordinators, who will also follow-up with couples to encourage completion. All couples will also be reimbursed for their time and effort after completing the study procedures, with amounts varying according to the number of tasks or visits completed. Fertility screening results will be collected for couples in FHS by research coordinators. Finally, data relating to birth outcomes will be obtained through administrative records, at 2 and 3 years postrandomisation.

Questionnaire design

The primary outcome is elicited in the last of three items adapted from the Swedish Fertility Awareness Questionnaire. The first item is 'Do you plan to have children at some point in your life?' (yes/no). Those who answer 'yes' will go on to answer item 2 ('How many children would you like to have?') and item 3 ('At what age do you plan to have your first child born?'). Based on the Marriage & Parenthood survey 2016, the proportion of married respondents intending to have no children was 3%. Majority of the couples are expected to answer 'yes' to the first item and provide sufficient responses for the third item such that the power of the study is unlikely to be adversely affected by those not wanting children.

The instrument for measuring fertility knowledge is the Cardiff Fertility Knowledge Scale, a 13-item instrument



Table 1 Timeline of visits and assessments

	Study period						
	Enrolment	Allocation			Post-allocation		
Timepoint	Week -1 to day -1	0	Weeks 1-3	Month 4	Month 6	Month 7-8	Years 2 and 3
Enrolment							
Eligibility screen	Χ						
Informed consent	X						
Allocation		X					
Interventions							
Fertility health screening (FHS)			Χ	Χ			
Fertility awareness tools (FAT)			X	Χ			
Assessments							
Baseline socio-demographic characteristics, lifestyle and medical history	X						
Attitudes towards having children	Χ				Χ		
Fertility knowledge	Χ				Χ		
Efforts to achieve pregnancy	Χ				Χ		
Diagnostic procedures and treatments sought					X		
Productivity loss			X*		X†		
Views on interventions						X‡	
Births							Χ

^{*}For FHS couples only.

that assesses knowledge in indicators of reduced fertility, basic facts and misconceptions about fertility according to internationally recognised components of fertility awareness. Items measuring constructs in behavioural change theories (mainly TPB and HBM) that influence childbearing intentions (positive and negative attitudes, subjective norms, perceived control, perceived susceptibility and anticipated regret) were adapted from previous studies of intentions to have a child in the near future and intentions to delay childbearing (the contrary to having a child in the near future).

The baseline questionnaire will also collect sociodemographic details, relevant lifestyle and medical history, baseline fertility knowledge, attitudes and beliefs regarding childbearing, parenthood intentions and efforts to achieve pregnancy. The lifestyle and medical factors were selected from FertiSTAT and discussion with gynaecologists on the team.³⁹ The questionnaires for the wife and husband are similar except for certain lifestyle and reproductive factors. Questions that apply to the couple as a whole (living arrangement and marriage date) will be divided between the husband and wife, such that they answer different questions.

The follow-up questionnaire will assess the postintervention fertility knowledge, attitudes and beliefs, parenthood intentions, pregnancy status and efforts to achieve pregnancy in the same way. In addition, it will ask about any further fertility screening and/or treatments, the couple has undergone in the 6 months prior, the costs involved and feedback on the interventions (for couples in FHS and FAT).

Data management

The baseline and follow-up questionnaires will be administered via email. Responses will be transcribed and deposited in REDCap electronic data capture tools hosted at SGH and KKH. 31 32 Other data collected will also be stored in REDCap. The audio recordings and transcripts of the IDIs will be stored in a password-protected computer in host institutions. Only the principal investigators (PIs) and designated study team members will have access to the data. Data and safety monitoring will be performed by the PIs and coinvestigators. All trial data and documents will be subjected to independent periodic external audits.

Implementation factors

We plan to perform a process evaluation and qualitative study (see below) to understand factors affecting implementation outcomes (except sustainability) proposed by Procter *et al*¹⁵ to anticipate the potential barriers and facilitators to national implementation of the strategy with demonstrated effectiveness and to explain the observed effectiveness results.

[†]If couple underwent further fertility screening or treatments.

[‡]Selected FHS and FAT couples



Potential reach of the fertility awareness strategies will be assessed using process indicators such as response rate, number rejected due to quota limits being reached and dropout rate. Demographic characteristics of couples who dropped out and completed participation will be compared with assess the extent of selection bias. In addition, reasons for dropouts will be collected through phone interviews. Minutes of research meetings will also document any problems and significant events encountered during the trial. These will be coded and considered together with other sources of information to inform the relevant implementation outcomes. To inform feasibility and cost, we will collect information on time taken to complete the FHS (randomisation to consult), consultation time and counselling time.

Qualitative study

To further understand other implementation factors, after completion of the follow-up questionnaire at 6 months, some couples in FHS and FAT will be purposefully sampled by wife's age group, arm and response (change in fertility intention) for IDIs, until saturation is reached. An estimated 24-30 couples will be invited (table 1). Husband and wife will be interviewed separately to ensure that responses are independent and complete. The IDIs are aimed at eliciting couples' attitudes, perception and experience of the intervention they underwent, and ideas on how it can be improved, to inform acceptability and appropriateness of the interventions. Couples in the FHS group will also be asked about their willingness to pay for such a screening to inform its financial sustainability. The couple IDIs will be performed after collection of the primary outcomes and, therefore, will not affect the primary outcome. However, they still put couples through a reflective process, which may affect their attitudes and actions in unpredictable but generally small ways. Sensitivity analyses will be performed to determine if IDIs affect birth statistics at 2 and 3 years.

Separately, IDIs will be held with providers of the FHS (doctors, nurses, laboratory and administrative staff) and stakeholders in the possible implementation of the interventions to elicit views on relevant aspects pertaining to implementation.

All IDIs will be conducted by a trained interviewer in a private and conducive environment or via video conferencing depending on the COVID-19 situation. The interview guides for all target groups will be guided by the Consolidated Framework for Implementation Research (CFIR). The constructs to include will be decided by consensus within the study team. The IDIs will be audiorecorded and transcribed verbatim. For video conferencing, the session will be recorded. Coding of the transcripts will then be guided by the CFIR constructs using Nvivo, and findings will be summarised narratively. Reporting of the qualitative results will follow the Consolidated Criteria for Reporting Qualitative Studies (COREQ) checklist.

Cost-effectiveness

A within-trial cost-effectiveness analysis will be performed to compare costs and outcomes of each strategy with control and also with each other if appropriate, from the societal perspective. Direct cost will include human resources, laboratory investigations and publicity/educational materials. Manpower costs will be estimated using time-driven activity-based costing. Indirect costs will include the couple's productivity loss associated with FHS. Direct cost for further fertility screening or treatment is not included as these are not part of the interventions being evaluated. Sunk costs for development of the interventions will not be included. Outcomes include both increase in parenthood intentions and births over a 6-month and two-year and 3-year time horizon, respectively. For births, the indirect costs after 6 months will be assumed to be negligible. As cost-effectiveness analysis does not address affordability, we will also perform a 5-year budget impact analysis to estimate the cost of nationwide implementation of FHS compared with FAT.

Sample size

Comparative trials of fertility knowledge interventions demonstrated no or modest (-0.8 years) decreases in womens' intended age at first birth. 19-23 Based on a three-arm trial with several comparisons with the control, to detect a hypothesised difference of 0.5 years in the wife's intended age at first birth between the treatment arms at 6-month follow-up, with a hypothesised SD of 2 years, at a significance level of 5% (two-sided) and a power of 80%, we need to randomise 216 couples in each of the two intervention arms and 305 couples in the control arm. To account for a 30% dropout rate, 310 couples in each intervention arms and 440 in the control arm (total 1060) are needed. We target to recruit 1200 couples, 352 in each intervention arm and 496 in the control arm, stratified by the wife's age group (25-29 and 30-34 years old). This represents about 2.6% and 1.7% of eligible females in the two age groups. 49 The first 140 couples will be part of the pilot phase and may not be included in the final analysis if significant changes to the protocol are made thereafter.

Statistical analysis

Linear and logistic regression methods will be used according to types of outcome variables to estimate the difference in 6-month endpoints between the treatment and control groups. Time to first birth will be analysed using Cox proportional hazards regression. All analyses will be performed both on an intention-to-treat and perprotocol basis. There are no plans for interim analysis. Characteristics of couples who drop out will be compared with those who completed the trial.

DISCUSSION

Very few countries have managed to reverse the trend of decreasing fertility rate. Despite efforts at multiple levels to increase fertility rates, the decision is ultimately



a personal one. From the medical perspective, there is a research gap to address in lack of fertility awareness. Given the complex interplay of non-medical factors affecting childbearing, we foresee that providing fertility awareness information alone would be insufficient to modify childbearing decisions. We, therefore, conduct a national-level study of two theory and evidence-based interventions to provide the necessary information to help couples make informed decisions about childbearing.

FHS provides personalised information on couples' fertility status through biological testing and direct interaction with healthcare professionals. We expect this intervention to have the highest chance of impacting childbearing choices. However, it is resource intensive and would be challenging to scale up. Online self-administered FAT were, thus, designed and compared, an intervention which is relatively cheaper and easier to scale up. While fertility education has been tested in various forms in other studies, such personalised fertility interventions coupled with behavioural change influences have not been formally evaluated in Singapore or elsewhere.

Parenthood intentions are multifaceted and can include whether one desires children at some point, one's desired number of children and one's desired age to have each child. While all contribute to the final number of children a couple has, we focused on the wife's desired age at first birth as the primary outcome as we assessed this to be more relevant for interventions. With inaccurate knowledge of fertility, a couple may not achieve their desired family size if they start a family too late in life. Having the first child earlier not only provides couples with greater opportunities to achieve their desired family size but also to have more children than initially planned, should they wish to. We hope that at least one of the interventions can enhance parenthood intentions, manifesting as intending to have the first child at an earlier age.

Another novel aspect of this study is the analysis of implementation factors, which can expedite clinical best practice after research discovery.²⁹ Quantitative and qualitative process indicators (eg, cost-effectiveness, adoption challenges) will be analysed, complementing the research on interventions' effectiveness.

We anticipate certain limitations, notably the risk of bias as raised by RoB 2, mainly due to the inevitable inability to blind participants and intervention administrators, and the potential effects of this on the outcomes (online supplemental additional file 3). In summary, we anticipate this RCT of two novel theory-based interventions will provide insights on parenthood intentions in Singapore and beyond.

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REFERENCES

- 1 Department of Statistics. Understanding age-specific fertility rate & total fertility rate, 2020. Available: https://www.singstat.gov.sg/modules/infographics/total-fertility-rate
- 2 National Population and Talent Division, Strategy Group. Population in brief 2020. Singapore:, 2020. Available: https://www.strategygroup.gov.sg/files/media-centre/publications/population-in-brief-2020.pdf
- 3 Teo J. More Singapore couples getting help to conceive. The Straits times, 2016. Available: http://www.straitstimes.com/singapore/ health/more-singapore-couples-getting-help-to-conceive?login=true
- 4 Johnson J-A, Tough S, SOGC GENETICS COMMITTEE. Delayed child-bearing. J Obstet Gynaecol Can 2012;34:80–93.
- 5 Datta J, Palmer MJ, Tanton C, et al. Prevalence of infertility and help seeking among 15 000 women and men. Hum Reprod 2016;31:2108–18.
- 6 Harata T, Goto M, Iwase A, et al. Psychological stress during in vitro fertilization and embryo transfer is influenced by the patients' background and gender. Reprod Med Biol 2012;11:143–8.
- 7 Kearney AL, White KM. Examining the psychosocial determinants of women's decisions to delay childbearing. *Hum Reprod* 2016;31:1776–87.



- 8 Tan TC, Tan SQ, Wei X. Cross-Sectional pregnancy survey on fertility trends and pregnancy knowledge in Singapore. J Obstet Gynaecol Res 2011;37:992–6.
- 9 Key findings from marriage and parenthood survey 2016. Singapore, 2017. Available: https://www.strategygroup.gov.sg/media-centre/ press-releases/article/details/key-findings-from-marriage-andparenthood-survey-2016
- Peterson BD, Pirritano M, Tucker L, et al. Fertility awareness and parenting attitudes among American male and female undergraduate university students. Hum Reprod 2012;27:1375–82.
- 11 Chan CHY, Chan THY, Peterson BD, et al. Intentions and attitudes towards parenthood and fertility awareness among Chinese university students in Hong Kong: a comparison with Western samples. Hum Reprod 2015;30:364–72.
- 12 Virtala A, Vilska S, Huttunen T, et al. 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;16:108–15.
- 13 Lampic C, Svanberg AS, Karlström P, et al. Fertility awareness, intentions concerning childbearing, and attitudes towards parenthood among female and male academics. Hum Reprod 2006;21:558–64.
- 14 Mortensen LL, Hegaard HK, Andersen AN, et al. Attitudes towards motherhood and fertility awareness among 20-40-year-old female healthcare professionals. Eur J Contracept Reprod Health Care 2012;17:468–81.
- 15 Sørensen NO, Marcussen S, Backhausen MG, et al. Fertility awareness and attitudes towards parenthood among Danish university college students. Reprod Health 2016;13:146.
- 16 Kudesia R, Chernyak E, McAvey B. Low fertility awareness in United States reproductive-aged women and medical trainees: creation and validation of the Fertility & Infertility Treatment Knowledge Score (FIT-KS). Fertil Steril 2017;108;711–7.
- 17 Pedro J, Brandão T, Schmidt L, et al. What do people know about fertility? A systematic review on fertility awareness and its associated factors. Ups J Med Sci 2018;123:71–81.
- 18 Mac Dougall K, Beyene Y, Nachtigall RD. Age shock: misperceptions of the impact of age on fertility before and after IVF in women who conceived after age 40. *Hum Reprod* 2013;28:350–6.
- 19 García D, Vassena R, Prat A, et al. Increasing fertility knowledge and awareness by tailored education: a randomized controlled trial. Reprod Biomed Online 2016;32:113–20.
- 20 Stern J, Larsson M, Kristiansson P, et al. Introducing reproductive life plan-based information in contraceptive counselling: an RCT. Hum Reprod 2013;28:2450–61.
- 21 Daniluk JC, Koert E. Fertility awareness online: the efficacy of a fertility education website in increasing knowledge and changing fertility beliefs. *Hum Reprod* 2015;30:353–63.
- 22 Maeda E, Nakamura F, Kobayashi Y, et al. Effects of fertility education on knowledge, desires and anxiety among the reproductive-aged population: findings from a randomized controlled trial. Hum Reprod 2016;31:2051–60.
- 23 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;100:523–9.
- 24 Conceição C, Pedro J, Martins MV. Effectiveness of a video intervention on fertility knowledge among university students: a randomised pre-test/post-test study. Eur J Contracept Reprod Health Care 2017;22:107-113.
- 25 Maeda E, Boivin J, Toyokawa S, et al. Two-Year follow-up of a randomized controlled trial: knowledge and reproductive outcome after online fertility education. Hum Reprod 2018;33:2035-2042.
- 26 Kreuter MW, Wray RJ. Tailored and targeted health communication: strategies for enhancing information relevance. Am J Health Behav 2003;27 Suppl 3:S227–32.
- 27 Koert E, Sylvest R, Vittrup I, et al. Women's perceptions of fertility assessment and counselling 6 years after attending a Fertility Assessment and Counselling clinic in Denmark. Hum Reprod Open 2020;2020.
- 28 French DP, Cameron E, Benton JS, et al. Can communicating personalised disease risk promote healthy behaviour change?

- A systematic review of systematic reviews. *Ann Behav Med* 2017:51:718–29
- 29 Curran GM, Bauer M, Mittman B, et al. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care 2012;50:217–26.
- 30 Department of Statistics Singapore. Statistics on marriages and Divorces reference year 2019, 2020. Available: https://www.singstat. gov.sg/-/media/files/publications/population/smd2019.pdf
- 31 Harris PA, Taylor R, Minor BL, et al. The REDCap Consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208.
- 32 Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009:42:377–81.
- 33 Peters G. A practical guide to effective behaviour change: how to identify what to change in the first place. Eur Heal Psychol 2014;16:142–55.
- 34 Kok G. A practical guide to effective change: how to apply theoryand evidence-based behaviour change methods in an interventions. *Eur Heal Psychol* 2014;16:156–70.
- 35 Ter Keurst A, Boivin J, Gameiro S. Women's intentions to use fertility preservation to prevent age-related fertility decline. *Reprod Biomed Online* 2016;32:121–31.
- 36 Ajzen I, Klobas J. Fertility intentions: an approach based on the theory of planned behavior. *Demogr Res* 2013;29:203–32.
- 37 CDC, US Department of Health and Human Services. My reproductive life plan: preconception health and health care, 2010.
- 38 Habbema JDF, Eijkemans MJC, Leridon H, et al. Realizing a desired family size: when should couples start? Hum Reprod 2015;30:2215–21.
- 39 Bunting L, Boivin J. Development and preliminary validation of the fertility status awareness tool: FertiSTAT. *Hum Reprod* 2010;25:1722–33.
- 40 Bayoumi RR, van der Poel S, El Samani EZ, et al. An evaluation of comprehensiveness, feasibility and acceptability of a fertility awareness educational tool. Reprod Biomed Soc Online 2018;6:10–21.
- 41 Bunting L, Tsibulsky I, Boivin J. Fertility knowledge and beliefs about fertility treatment: findings from the International fertility decisionmaking study. *Hum Reprod* 2013;28:385–97.
- 42 Zegers-Hochschild F, Adamson GD, de Mouzon J, et al. The International Committee for monitoring assisted reproductive technology (ICMART) and the world Health organization (who) revised glossary on art terminology, 2009. Hum Reprod 2009:24:2683–7.
- 43 Mencarini L, Vignoli D, Gottard A. Fertility intentions and outcomes: implementing the theory of planned behavior with graphical models. Adv Life Course Res 2015;23:14–28.
- 44 Williamson LEA, Lawson KL. Young women's intentions to delay childbearing: A test of the theory of planned behaviour. J Reprod Infant Psychol 2015;33:205–13.
- 45 Proctor É, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health 2011;38:65–76.
- 46 Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci 200:4:50
- 47 CFIR Research Team. Consolidated Framework for Implementation Research - Evaluation Design - Qualitative Data. Available: https:// cfirguide.org/evaluation-design/qualitative-data/
- 48 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007;19:349–57.
- 49 Department of Statistics Singapore. Singapore census of population 2020, 2021. Available: https://www.singstat.gov.sg/publications/ reference/cop2020/cop2020-sr1/census20_stat_release1 [Accessed 13 Sep 2021].