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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

Sze Ling Chan ,[1] Julian Thumboo,[2] Jacky Boivin,[3] Seyed Ehsan Saffari,[4] Shanqing Yin,[5] Samantha Rachel Yeo,[6] Jerry Kok Yen Chan,[7] Kee Chong Ng,[5] Ka-Hee Chua,[7] Su Ling Yu[8]

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For numbered affiliations see end of article.

Correspondence to
Dr Su Ling Yu;
yu.su.ling@singhealth.com.sg and
Dr Su Ling Yu;
yu.su.ling@singhealth.com.sg

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 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.

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 assessed concurrently.
- The limitation of this study is that the recruitment strategy may not yield couples representative of the target population.

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.[1] Concurrently, there is also a trend of increasing median age at first marriage and childbirth[2] 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.[4 6]

Childbearing is a decision affected by a complex interplay of personal, financial, employment, social and psychological factors.[7] 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.[8 9]

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*'.[9] 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.[26 27] 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).[19] 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.[20]

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.[28] 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 parenthood 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 trial[29] with a multicentre three-arm parallel group open-label 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 2019[30] 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 healthcare 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 Prevention[37]), 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

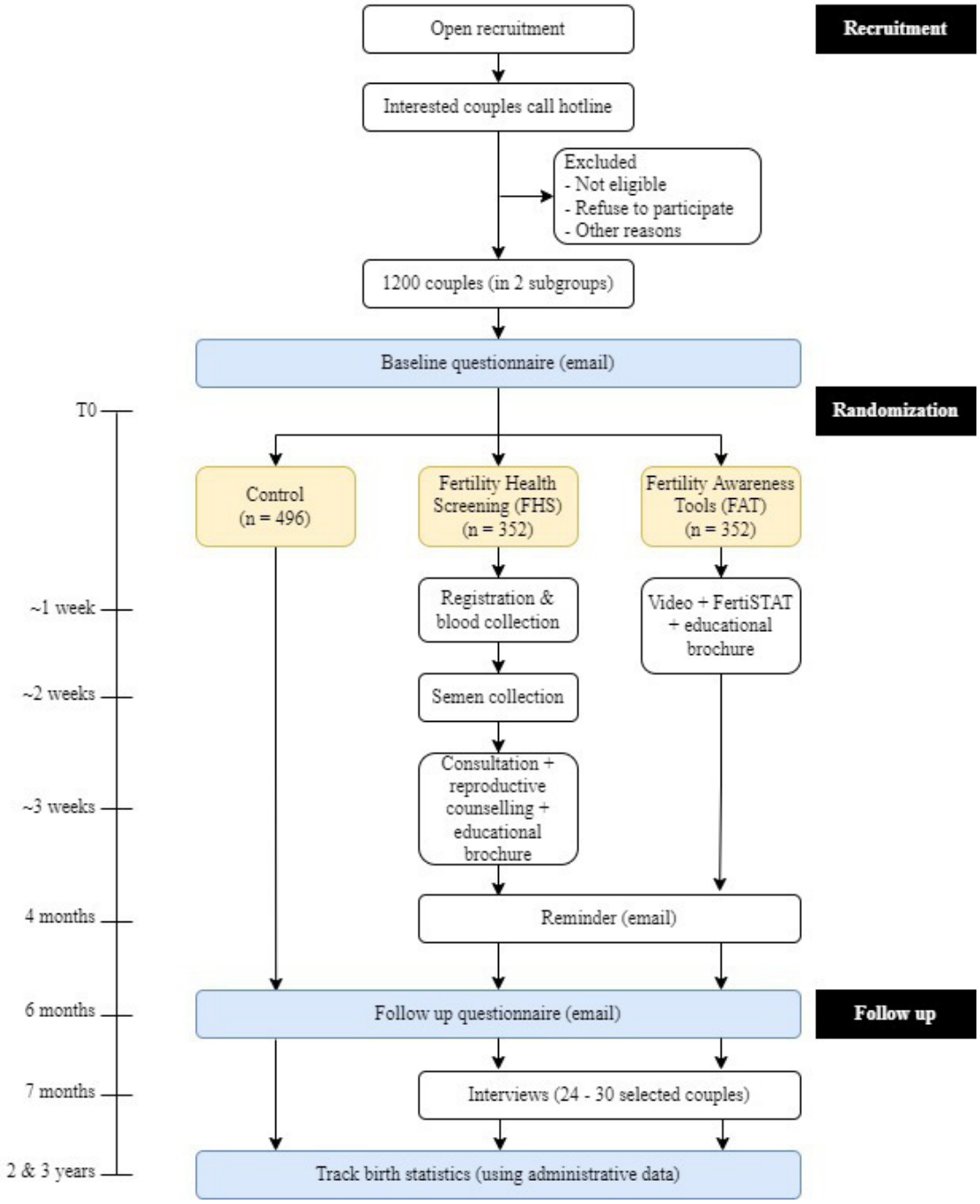

Figure 1 Study flowchart. FertiSTAT, fertility status awareness.

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

advice[39] 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.[40] For the husbands, only the lifestyle factors and two specific risk factors (undescended testis and mumps after puberty) were given.[39] 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.[13] 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%.[9] 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	X						
Informed consent	X						
Allocation		X					
Interventions							
Fertility health screening (FHS)			X	X			
Fertility awareness tools (FAT)			X	X			
Assessments							
Baseline socio-demographic characteristics, lifestyle and medical history	X						
Attitudes towards having children	X				X		
Fertility knowledge	X				X		
Efforts to achieve pregnancy	X				X		
Diagnostic procedures and treatments sought					X		
Productivity loss			X*		X†		
Views on interventions						X‡	
Births							X

*For FHS couples only.
†If couple underwent further fertility screening or treatments.
‡Selected FHS and FAT couples

that assesses knowledge in indicators of reduced fertility, basic facts and misconceptions about fertility[41] according to internationally recognised components of fertility awareness.[42] 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).[7 43 44]

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 post-intervention 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*[45] to anticipate the potential barriers and facilitators to national implementation of the strategy with demonstrated effectiveness and to explain the observed effectiveness results.

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).[46] The constructs to include will be decided by consensus within the study team. The IDIs will be audio-recorded 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.[47] Reporting of the qualitative results will follow the Consolidated Criteria for Reporting Qualitative Studies (COREQ) checklist.[48]

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 per-protocol 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.[13] 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.

Author affiliations
[1]Health Services Research Centre, Singhealth, Singapore
[2]Department of Rheumatology & Immunology, Singapore General Hospital, Singapore
[3]School of Psychology, Cardiff University, Cardiff, UK
[4]Centre for Quantitative Medicine, Duke-NUS Medical School, Singapore
[5]Chairman Medical Board Office, KK Women's and Children's Hospital, Singapore
[6]Division of Obstetrics & Gynaecology, KK Women's and Children's Hospital, Singapore
[7]Department of Reproductive Medicine, KK Women's and Children's Hospital, Singapore
[8]Department of Obstetrics & Gynaecology, Singapore General Hospital, Singapore

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Contributors SLC, JB, JT, SES, SY, SRY, JKYC, KCN, K-HC and SLY designed the study and interventions. SES advised on the statistical methods and will perform the statistical analysis. SLC, K-HC and SLY will oversee the overall conduct of the study. SLC wrote the manuscript and all co-authors critically reviewed and approved the final manuscript.

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ORCID iD
Sze Ling Chan http://orcid.org/0000-0003-4272-4595

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Additional File 1: SPIRIT checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	Refer to 2a
Protocol version	3	Date and version identifier	22
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	23
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22-23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	16

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-7
	6b	Explanation for choice of comparators	6, 10-11
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	14
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14-15
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	14
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14-16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 1, Fig 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	10
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15-18
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	19-20
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	19-20
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	19-20
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	19-20
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	16
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2,3, 22
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	22

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	22
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	22
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16, 22
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	2-3, 22
	31b	Authorship eligibility guidelines and any intended use of professional writers	2-3
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	22
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Additional File 2: TIDieR checklist

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	2, 11-12	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	10-13, Additional file 4	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	11-12	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	11-12	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	11-12	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	11-12	

	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	13	
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	11-13	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	11-12	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	11-12	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	13, 15	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	NA	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the

TIDieR checklist

TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist

Additional File 3: Revised Cochrane Risk-of-bias Tool for Randomized Trials (RoB 2)

Domain	Signalling question	Outcomes				Comments
		Wife's intended age at first birth	**Fertility awareness**	**Efforts to achieve pregnancy**	**Birth statistics**	
Bias arising from the randomization process	1.1 Was the allocation sequence random?	Y	Y	Y	Y	Allocation sequence generated by person outside study team. Randomization effected using REDCap
	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y	Y	Y	Y	
	1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	NI	NI	NI	NI	Study not started yet
	Risk of bias judgement	**Low**	**Low**	**Low**	**Low**	
Bias due to deviations from intended interventions	2.1.Were participants aware of their assigned intervention during the trial?	Y	Y	Y	Y	Only analysis is blinded due to nature of interventions
	2.2.Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Y	Y	Y	Y	
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	NI	NI	NI	NI	Study not started yet
	2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA	NA	NA	
	2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA	NA	NA	
	2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y	Y	Y	Y	ITT analysis will be done

	2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	NA	NA	NA	
	Risk of bias judgement	**Some concerns**	**Some concerns**	**Some concerns**	**Some concerns**	
Bias due to missing outcome data	3.1 Were data for this outcome available for all, or nearly all, participants randomized?	NI	NI	NI	NI	Study not started yet
	3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?	PY	PY	PY	PY	Baseline characteristics will be compared between responders and non-responders but no data yet
	3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA	NA	NA	
	3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA	NA	NA	
	Risk of bias judgement	**Low**	**Low**	**Low**	**Low**	
Bias in measurement of the outcome	4.1 Was the method of measuring the outcome inappropriate?	N	N	N	N	self-reported
	4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	N	N	N	N	all couples are assessed the same way
	4.3 Were outcome assessors aware of the intervention received by study participants?	Y	Y	Y	N	Participants themselves are outcome assessors. Birth data will be retrieved from administrative sources
	4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	PY	PY	PY	NA	Not blinded to intervention assignment but the outcome assessment is 6 months after the baseline and about 5 months after the interventions so responses are likely to reflect their true attitudes at that time.
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	PN	PN	PN	NA	

	Risk of bias judgement	**Some concerns**	**Some concerns**	**Some concerns**	**Low**	
Bias in selection of the reported result	5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Y	Y	Y	Y	
	5.2 ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	N	N	N	N	
	5.3 ... multiple eligible analyses of the data?	N	N	N	N	
	Risk of bias judgement	**Low**	**Low**	**Low**	**Low**	
Overall bias	**Risk of bias judgement**	**Some concerns**	**Some concerns**	**Some concerns**	**Some concerns**	

Y: yes, PY: possibly yes, PN: possibly no, N: no, NI: no information

Additional File 4: Informed Consent Form for FHS

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

STUDY INFORMATION

Protocol Title:

The Effect of **Fert**ility Health Awareness **Stra**tegies on Fe**rt**ility Knowledge and Childbearing in Young Married Couples (FertStart)

Principal Investigator:

A/Prof Yu Su Ling
Department of Obstetrics & Gynecology
Singapore General Hospital (SGH)
Outram Road
Singapore 169608
Tel: 6576 7743

Site Principal Investigator:

Dr Chua Ka Hee
Department of Reproductive Medicine
KK Women's and Children's Hospital (KKH)
100 Bukit Timah Road
Singapore 229899
Tel: 9822 7616

Sponsor:

Strategy Group, Prime Minister's Office (PMO)

PURPOSE OF THE RESEARCH STUDY

Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

The purpose of this study is to study the effect of fertility health screening and fertility awareness tools on parenthood intentions, as well as fertility awareness, conception efforts and births among young married couples. We hope to learn which method of providing fertility education and modifying childbearing beliefs is more effective. This study will recruit 1200 couples from the community.

You had earlier given your verbal consent to participate in the study and you were assigned to the fertility screening group. **As part of the study, we are seeking your written consent for the fertility health screening.**

STUDY PROCEDURES AND VISIT SCHEDULE

Participants are randomly assigned to receive fertility health screening, fertility awareness tools or no intervention. Randomisation means assigning you to one of 3 groups by chance, like tossing a coin or rolling dice.

As you have been assigned to the fertility health screening group, you will need to make 3 visits to SGH or KKH, based on where you prefer to be seen. At the first visit, you will register at the clinic so that the Anti-Mullerian Hormone (AMH) test and semen analysis can be ordered. In the same visit, 3ml (about ½ teaspoon) of blood will be taken from the female partner for the AMH test. AMH is a hormone secreted by cells in developing egg sacs, so the levels of AMH can give an indication of your ovarian reserve.

For the male partner, an appointment will be made for the semen sample to be collected another day. This is difficult to do at the same visit as the sample has to be produced after sexual abstinence for 3-5 days and analysed fresh.

When the AMH and semen analysis results are out, the research coordinator will arrange an appointment with you and your spouse for another consultation with the gynaecologist and a reproductive counselling session with a nurse. It is important that both of you attend this consultation together.

The fertility health screening (AMH test and semen analysis) performed in this study aims to raise participants' awareness and understanding of their fertility health. It is not a complete fertility health screening and would not fully reflect the fertility status of you and your spouse.

Schedule of visits and procedures:
Visit 1 (Week 1): Registration and blood taking (wife)
Visit 2 (Week 2): Semen collection (husband)
Final Visit (Week 3): Consultation and reproductive counselling (both)

Your records will be checked after two and three years for any pregnancy related updates (i.e. birth).

Any human biological material obtained during the course of this study will be stored in Singapore and analyzed only for the purposes of this study for a period not exceeding 6 months, and will be destroyed after completion of the study.

The human biological material collected will not be used in restricted human biomedical research involving human-animal combinations in accordance to the Human Biomedical Research Act 2015 of Singapore (HBRA).

Any individually-identifiable data obtained during the course of this study will be stored and used only for the purposes of this study. These data will not be used for future research.

YOUR RESPONSIBILITIES IN THIS STUDY

As part of your participation in this study, you should:

- Undergo the study procedures as instructed and follow the advice given to you by the study team.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Be prepared to visit the hospital up to 3 times and undergo all the procedures that are outlined above.

Chan SL, *et al. BMJ Open* 2022; 12:e051710. doi: 10.1136/bmjopen-2021-051710

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

The study is being conducted because fertility health screening and reproductive counselling is not yet proven to be a standard intervention in couples without known fertility issues. We hope that your participation will help us to determine whether fertility health screening has any effect on childbearing decisions compared to no intervention or fertility awareness tools.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

There may be mild pain and bruising for the female partner from blood sampling, and inconvenience for the male partner from having to produce a semen sample in the clinic. As with any screening test, there could be a small chance of inaccurate results, which could lead to you experiencing unnecessary anxiety and treatments (if falsely positive) or having a false sense of security (if falsely negative). Therefore, the limitations of the tests will be emphasised and you will be advised accordingly by the attending gynaecologist.

POTENTIAL BENEFITS

If you participate in this study you will get information on your fertility status to make more informed childbearing decisions. However, the fertility health screening provided is not meant to be a full fertility evaluation and cannot check for all conditions that may affect fertility.

ALTERNATIVES

The study is being conducted because fertility health screening and reproductive counselling is not yet proven to be a standard intervention in couples without known fertility issues. We hope that your participation will help us to determine whether fertility health screening has any effect on childbearing decisions compared to no intervention or fertility awareness tools.
If you choose not to take part in this study, the alternative is to have what is considered standard care.

COSTS OF PARTICIPATION

If you take part in this study, the fertility health screening (AMH, semen analysis, consultation and counselling) will be performed at no charge to you.

You will be reimbursed $50 for your time, effort and transportation costs per couple per visit. In total, you and your spouse will be reimbursed $150 for all 3 visits.

In the event that you and your spouse wish to seek further medical follow-ups which are beyond the scope of this study (e.g. further consultations, endometriosis screening, diagnosis or treatments), you may wish to consult your preferred healthcare provider. These additional expenses are not covered under this study.

INCIDENTAL FINDINGS

In the case of an “incidental finding” (i.e. any abnormality that we did not expect to see in this study or unrelated to the purpose of this study), we will not re-identify and give you any results from the research.

PARTICIPANT’S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

The human biological material collected for the study will be deemed to be given to SGH and KKH. You give up your rights to the human biological material and any intellectual property rights that may be derived from the use of the human biological material.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

The human biological material collected for the study will be deemed to be given to SGH and KKH and will not be returned to you. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if they have not been anonymised/ the human biological sample(s) is individually-identifiable and has not been used for the research or it has been used for research but it is practicable to discontinue further use of the human biological sample(s) for the research.

Your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment will not be provided by the SGH or KKH.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. Personal Data collected for this study will be kept confidential and used only for the purpose of the study in line with applicable laws and regulations. Only your Investigator(s) will have access to the confidential information being collected.

However, Regulatory Agencies, SingHealth Centralised Institutional Review Board and

Ministry of Health may be granted direct access to your original medical records to check study procedures and data, if necessary. None of your information will be made public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by SGH and KKH, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties.

"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this "Personal Data", will be subject to review by the relevant institutional review board.

Data collected and entered into the Data Collection Form(s) are the property of SGH and KKH. In the event of any publication regarding this study, your identity will remain confidential.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact the Principal Investigator A/Prof Yu Su Ling (6576 7743) or the Site Principal Investigator Dr Chua Ka Hee (9822 7616).

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 6323 7515 during office hours (8:30 am to 5:30pm).

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM

Details of Research Study

Protocol Title:

The Effect of **Fert**ility Health Awareness **Str**ategies on Fe**rt**ility Knowledge and Childbearing in Young Married Couples (FertStart)

Principal Investigator:
A/Prof Yu Su Ling
Department of Obstetrics & Gynecology
Singapore General Hospital (SGH)
Outram Road
Singapore 169608
Tel: 6576 7743

Site Principal Investigator:
Dr Chua Ka Hee
Department of Reproductive Medicine
KK Women's and Children's Hospital (KKH)
100 Bukit Timah Road
Singapore 229899
Tel: 9822 7616

I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for the above participant to participate in the proposed research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature/ Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant or legal representative thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of his/ her/ his ward's/ her ward's participation in the study.

_____	_____	_____
Name of Investigator/ Person obtaining consent	Signature	Date

Additional File 5: Design of Behavioural Change Component

The addition of a behavioural change component is necessary to maximise the chance of the intervention having a strong and sustained effect on childbearing decisions. We designed the behavioural change component using Intervention Mapping, a protocol for systematic theory and evidence-based behavioural change planning, described in Figure S1 [1,2].

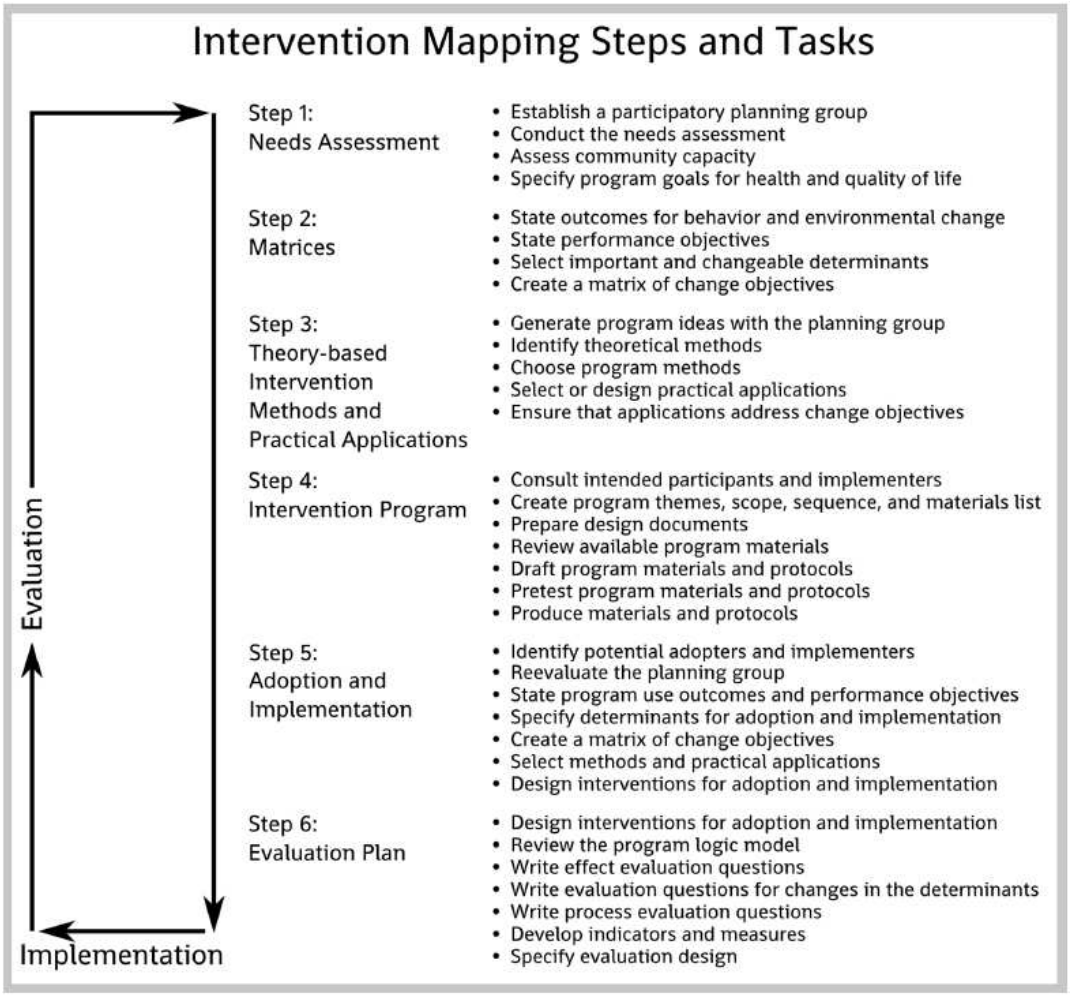

Figure S1 Intervention mapping steps and tasks [2]

For step 1, the overall goal and its rationale has been laid out in the introduction in the main article. In step 2, the overall goal is broken down into target behaviours, with specific change

objectives of the relevant determinants defined in a matrix. For a behaviour change method to be effective, it must i) target a determinant that predicts behaviour, ii) it must be able to change that determinant and iii) it must be translated into a practical application in a way that preserves the parameters (conditions) of effectiveness and fits the target population, culture and context [3].

To target intentions to have a child at an earlier age (primary outcome), we consolidated factors associated with childbearing intentions from the literature, determinants from the TPB and HBM (Figures S2 & S3) and constructs shown to affect fertility intentions in experimental studies (relationship with partner, cost of children, cultural norms, religiosity and mortality risk) (Table S1) [4–10].

Table S1 Factors affecting fertility desires and intention

Factors	Evidence type			Interventions		Ref
	surveys/ qualitative studies	Association (correlative studies)	Causative (experimental studies)	Studied	Proven	
Demographic						
Age	✓	✓				[5,11–21]
Gender		✓				[15–17,22–24]
Race/ethnicity		✓				[25–27]
Religiosity		✓				[5,10,13,28]
Educational status		✓				[13,20,25–27,29,30]
Relationship status (not married/ not finding right partner, not being in stable relationship)	✓	✓				[7,13–16,19–21,23,31–35]
Marriage duration		✓				[5,18]
Parity		✓				[13]
Financial/housing						
Financial security / cost of children / income	✓	✓	✓	Baby bonus (Australia)	Baby bonus (Australia)	[5,10,13–16,18–21,26,31–34,36,37]
Housing condition (owning a home / sufficiently large home)	✓					[5,13–16,27,34]
No access to childcare	✓					[13–16]
Not prepared to change lifestyle	✓					[35]
Fertility awareness		✓	✓	▪ Tailored edu (oral) ▪ Life-plan based contraceptive counselling ▪ Online fertility info	Tailored edu (oral) Brochure (written)	[8,24,38–45]

				▪ Brochures (written or online) ▪ Slide presentation ▪ Video		
Employment / workplace						
Pursuit of career, personal interests or education	✓	✓				[14–17,31–34]
Not having career stability (permanent position)	✓	✓				[5,13–16,20,33,34]
Not having work that can be combined with having children / workplace support	✓	✓	✓	Federal law of parental allowance and parental leave (Germany)	Federal law of parental allowance and parental leave	[14–16,29,46]
Psychological						
Heritability of need to nurture		✓				[10]
Childhood stress		✓	✓			[10,47]
Father absence		✓				[10]
Personality		✓				
Attachment style (in childhood)		✓	✓			
Reproductive autonomy		✓				
Mortality risk and salience		✓	✓			
Risk tolerance		✓				[48]
Not feeling emotionally ready or mature enough	✓					[14–16,31–34]
Attitudes towards having children (positive and negative)		✓				[4,5,7,18,36,49–51]
Anticipated regret		✓				[4]
Attitudes towards government incentives		✓				[52]

	Gender role attitude		✓				[13]
	Child desire		✓				[13]
	Individualism attitudes		✓				[13]
Health							
	Infertility	✓					[31,32]
	Anticipated fertility/infertility		✓				[7,8,53]
	Physical health		✓				[5,7,13,26]
	Quality of life		✓				[21]
	Depression/psychological health		✓				[13,24]
Social / environment							
	Cooperative breeding and kin support (family support)	✓	✓	✓			[5,10,13,21,35]
	Stressful environment		✓				[10]
	Societal/cultural norms	✓	✓	✓			[4,5,7,10,13,14,24,26,36,51]
	Colleagues giving birth		✓				[54]
	Resource stress & limitation (including materialism)		✓	✓			[10,55]
	Maternal education		✓				[30]
	Maternal expectations and education communication		✓				[56]
	Parental socioeconomic status		✓				[57]
	Spouse's desires		✓				[49,58]
	Partnership satisfaction		✓				[13]
	Family policies (e.g. availability of childcare services)		✓				[13]
	Child value		✓				[13]

Edu: education, info: information
Table updated on 30 August 2021
*Shown to have an effect on fertility desires and intentions in experimental studies

Table S1 lists the factors affecting fertility desires and intention. In Singapore, there are ongoing efforts by the government to address financial cost, housing issues, flexible work arrangements and childcare arrangements, which influence decisions on parenthood. These include shorter waiting time for new Housing Development Board (HDB) flats (public housing in Singapore), housing grants, use of MediSave for antenatal care and ART, Baby Bonus Scheme, expansion of childcare facilities, subsidies for infant care and childcare, parental and childcare leave, and encouraging employers to adopt flexible work arrangements [59]. The current efforts to increase fertility awareness are largely driven by voluntary welfare organisations such as I Love Children (https://ilovechildren.sg).

Miller *et al* proposed a framework to model couples' fertility motivation based on the Traits-Desires-Intentions-Behaviour framework [60]. In line with this framework, there is evidence that fertility events can be predicted from fertility motivations [61,62]. This supports the use of antecedents, such as intentions, as intermediate outcomes as well as the importance of collecting desire and motivation data from both partners. We then identified targetable constructs from the Theory of Planned Behavior (TPB) (Figure S2) and Health Belief Model (HBM) (Figure S3), models most commonly applied to childbearing decisions and with empirical support [4–9,51,62,63].

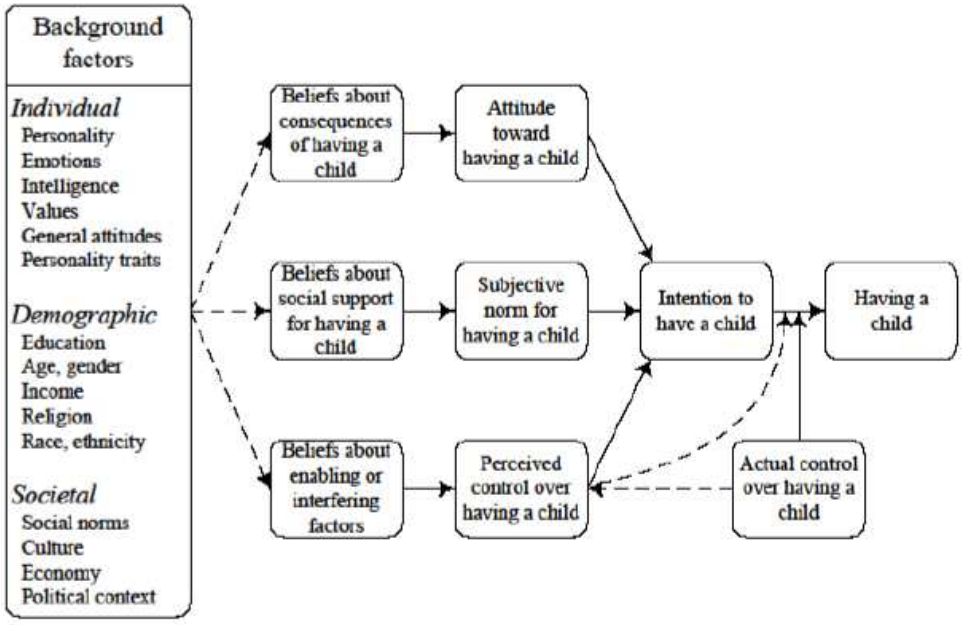

Figure S2 Theory of planned behaviour applied to fertility decisions [9]

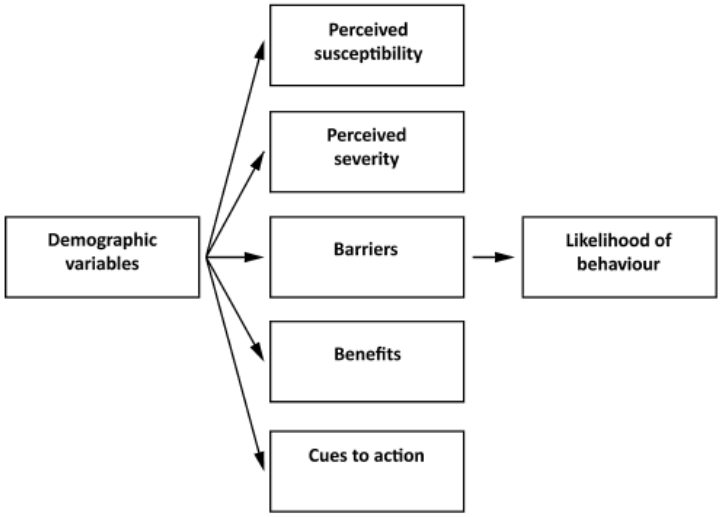

Figure S3 The Health Belief Model [6]

In addition, recent research in areas such as school achievement and marital relationships have found that brief, theory-based social-psychological interventions can cause large, enduring outcomes, and the proposed explanation is a 'field-theory model' that categorises interventions into 'nudges' (designed to change a specific decision or behaviour in a specific setting in a 'snapshot' in time) and 'movie' interventions (designed to change core beliefs or other aspects of the self, which interact with social contexts to produce sustained or amplified effects over time) [64]. To change fertility behaviours, the latter type of intervention is clearly more appropriate. Our interventions will therefore aim to change core beliefs from within, rather than provide external cues.

To target our primary outcome of intention to have a child at an earlier age, we consolidated factors associated with childbearing intentions from the literature, determinants from the TPB and HBM (Figures S2 & S3) and constructs shown to affect fertility intentions in experimental studies (relationship with partner, cost of children, cultural norms, religiosity and mortality risk) and targeted mainly fertility awareness and determinants of childbearing intentions (i.e. attitudes towards having children, anticipated regret, social norms and perceived control of the practical barriers) (Table S1) [4–10].

Mortality risk is one of these psychological factors but there is evidence that the effect of mortality risk cues on fertility intentions is modified by childhood socioeconomic status and gender differences [10]. We will therefore not target mortality risk to avoid producing a counterproductive effect. We will therefore target fertility awareness and determinants of childbearing intentions, which incorporates some of the psychological and social factors in Table S1 (i.e. attitudes towards having children, anticipated regret, social norms and perceived control of the practical barriers) in this study.

Since there are overlaps between constructs from different theories and studies, we used the Theoretical Domains Framework (TDF) to guide the grouping of relevant and modifiable determinants of into domains [65]. The primary target behaviour is to reduce the wife's self-

reported intended age at first birth and the matrix of change objectives for this objective is shown in Table S2.

Table S2 Matrix of change objectives

Determinant 1: Beliefs about consequences (attitudes, anticipated regret)	Determinant 2: Social influence (subjective norm)	Determinant 3: Beliefs about capabilities (perceived control)
Express agreement that… 1.1: children bring more joy and satisfaction 1.2: they would have more energy to care for children if they had them earlier 1.3: children would help them grow emotionally 1.4: children would help them grow closer as a couple 1.5: children will not hinder career progression 1.6: they can still find time to enjoy things/ activities that they like 1.7: finances will be manageable after having children 1.8: they can still find time to travel 1.9: they would regret it if they end up childless because they started trying too late 1.10: they would regret it if they cannot achieve their desired number of children because they started trying too late 1.11: they are more likely to have a healthy pregnancy and babies if they had them earlier	2.1: express agreement that their parents and peers would support them giving their parents grandchildren	Perceive a lower deterrence of … in decision to have a child earlier 3.1: current financial situation 3.2: not having a large enough house 3.3: Difficulty in securing childcare 3.4: Not having parental help 3.5: Not having a stable job 3.6: Difficulty in having flexible work arrangements

In step 3 of intervention mapping, these change objectives are then mapped to interventions methods and then translated in to practical applications (Table S3) [2].

Table S3 Mapping of change objectives to methods

Determinants	Change objective	Method	Parameters (conditions for effectiveness)	Practical application
Beliefs about consequences	1.1: agree that children bring more joy and satisfaction	Persuasive communication	Messages need to be relevant and not too discrepant from the beliefs of the individual; can be stimulated by surprise and repetition. Will include arguments.	Showcase couples who were hesitant due to these concerns but found them true after having children
	1.3: agree that children would help them grow emotionally			
	1.4: agree that children would help them grow closer as a couple			
	1.2: agree that they would have more energy to care for children if they had them earlier			Showcase couples who had children late and find themselves having less energy than they wished and also the opposite
	1.5: agree that children will not hinder career progression	Modeling	Attention, remembrance, self-efficacy and skills, reinforcement of model; identification with model, coping model instead of mastery model	Showcase couples who still have fulfilling careers with children
	1.6: agree that they can still find time to enjoy things/ activities that they like			Showcase couples who engage in these activities with children
	1.8: agree that they can still find time to travel even with children			
	1.7: agree that finances will be manageable even after having children			Showcase how couples with financial considerations still cope well with children + mention of different support available (e.g. Baby Bonus Scheme, MediSave Grant for Newborns, pre-school subsidies) and how it helped
	1.9: agree that they would regret it if they end up childless because they started trying too late	Anticipated regret	Stimulation of imagery; assumes positive intention to avoid the risky behaviour	Showcase couples who had/ tried having children late and ended up in this situation (highlight the regret)
	1.10: agree that they would regret it if they cannot achieve their desired number			

	of children because they started trying too late			
Societal influences	2.1: express agreement that their parents and peers would support this action	Information about others' approval	Positive expectations are available in the environment	Showcase couples (who had children young) recounting their parents and friends' reactions when pregnancy news broke
Beliefs about capabilities	3.1: lower perceived barrier because of current financial situation	Persuasive communication & modeling	As above	Showcase how couples with financial considerations still cope well with children + mention of different support available (e.g. Baby Bonus Scheme, MediSave Grant for Newborns, pre-school subsidies) and how it helped
	3.2: lower perceived barrier because of not having a large enough house			
	3.3: lower perceived barrier because of not having a stable job			
	3.4: lower perceived barrier because of difficulty in securing childcare			Showcase couples who manage themselves using other resources (childcare, FDWs, etc) + mention of increase in childcare accessibility, affordability & quality
	3.5: lower perceived barrier because of not having parental help			
	3.6: lower perceived barrier because of difficulty in having flexible work arrangements			Showcase couples with different ways of managing work and family commitments (including colleagues who are supportive of them when using flexible work arrangements, how having a non-permanent job can be an advantage)

Step 4 in the Intervention Mapping protocol was the creation of an intervention program from the practical applications laid out in step 3. In FHS, some of these practical applications may be applied during the reproductive counselling as appropriate but the focus is on matching the couples' plan to their stated reproductive goals and the emphasis on the reality of age-related fertility decline. For FAT, this intervention program would consist of i) a video containing information on age-related fertility decline and limitations of ART, curated by an expert panel of obstetricians and vignettes corresponding to the practical applications listed in Table S3 and ii) FertiSTAT [66]. In the making of the video, not all practical applications could be included as there was a need to maintain a good balance of flow, duration and positive feeling such that it is not perceived as pushy.

Steps 5 and 6 are more relevant after effectiveness has been demonstrated. Nevertheless, we are also exploring some implementation factors.

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