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# Protocol for a multicentre pragmatic randomised controlled feasibility trial of fertiShare: a brief eLearning course to increase fertility staff performance when sharing bad news with their patients

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**Abstract**

**Introduction**

Sharing bad news (SBN) is a recurring and stressful challenge for fertility staff and patients. Sub-optimal SBN is associated with staff burnout, patient dissatisfaction with care and lack of trust in staff, potentially leading to patient discontinuation. Patients value staff having SBN skills but staff feel unprepared to do this task. fertiShare is a 2-hour bespoke eLearning course to support fertility staff in SBN with their patients, organized into three modules, with each module offering video content-based lessons, simulated case studies showing optimal and suboptimal approaches to SBN, and brief quizzes for self-reflection and assessment. This protocol aims to evaluate if it is feasible to implement fertiShare at UK-based fertility clinics and if it is acceptable to staff and patients.

**Methods and analysis**

Multi-centre, two-arm, parallel-group, blinded, feasibility randomised controlled trial with 1:1 randomised staff allocation to fertiShare (intervention group) or general communication skills eLearning (control group). Six UK-based clinics, sixty staff spending a minimum of 10% week-time SBN, and 360 patients having received bad news from participating staff within the last month will be recruited. Two cohorts of patients will be recruited, one after staff consent to the study and before fertiShare or control eLearning course (pre-training patient cohort) and another 1-month post staff training (post-training patient cohort). Outcome measures relate to demand, acceptability, implementation, practicality, and limited efficacy testing, with the primary outcome being staff performance when SBN, reported by patients using an adapted version of the SBN Behavioural Assessment Scale[1]. Recruitment and data collection will span from September 2025 to February 2026.

**Ethics and dissemination**

The study was approved by the NHS Research Ethics Committee (23/LO/0864) and the Cardiff University – School of Psychology Research Ethics Committee (EC.23.08.08.6827). Results will be disseminated via publications in peer-reviewed journals, conference presentations, and public engagement, and will inform if fertiShare should proceed to efficacy evaluation. Insights from this study can inform the implementation of other SBN training in fertility or other healthcare domains and improve understanding of the impact SBN training has on patient experience and outcomes.

**Trial registration number:** Clinical Trials.gov (NCT06587360, https://www.clinicaltrials.gov/)

**Strengths and limitations of this study**

- The study is a pragmatic, multi-centre, two-arm, parallel-group, blinded, feasibility RCT with 1:1 computer-generated randomised staff allocation to fertiShare (intervention group) or general communication skills eLearning (control group)
- The trial methods balance real-world implementation evaluation (external validity) with sufficient design control to reach ecologically valid conclusions (internal validity).
- The study includes staff and patient outcomes, and this will advance knowledge about the impact of SBN training on patients' care experiences
- Multi-centre randomised trial was the preferred method because SBN training in fertility care is an individual endeavour rather than an organizational requirement, but this introduces risk of contamination, minor local variations in trial design, and logistic complexity.

## Introduction

Sharing bad news (SBN) is a daily challenge for fertility staff and patients. In fertility care many staff are involved in this task, from clinicians (e.g., infertility diagnosis) to embryologists (e.g., failed fertilisation or embryo development), nurses (negative pregnancy test or scan) and administrative staff (e.g., non-eligibility for treatment). Staff spend 19% of their week SBN and for each 10 women starting an In Vitro Fertilization (IVF) treatment cycle 7 receive news this fails[2]. SBN triggers stress and difficult emotions in staff[3]. About 15% of fertility staff see SBN as one of the biggest challenges of their job[4]. Staff reporting low confidence in SBN are more likely to report stress and burnout[5 6]. Insensitive staff communication can impact the therapeutic relationship, create distrust, and decrease satisfaction with care[7], aspects cited by fertility patients as reasons for stopping treatment and changing clinics[8]. However, if well shared, bad news can trigger relief, for instance by explaining symptoms and/or validating health concerns [9], and empower shared decision-making about future care[10]. Survey research indicates fertility staff and patients agree when SBN encounters go well but staff tend to overrate their performance and are not always able to recognise when SBN encounters are not positively evaluated by patients[11].

Fertility patients value staff skilled in SBN[12] and staff report being open to undergo communication training[4]. Meta-analytic evidence of evaluations of SBN training for physicians, medical students, or interns working in primary, secondary or intensive healthcare settings showed training is effective in improving SBN skills and confidence (assessed via behavioural observation)[13]. SPIKES[10 14] is an evidence-based protocol that offers step-by-step guidance to optimize SBN by staff, organized in six steps: Setting-up the interview, assessing patients' Perceptions of the situation, obtaining patients' Invitation to share news, giving Knowledge/information, addressing patients' Emotions empathically, and Summarizing and discussing treatment (or other) options. Meta-analysis also showed SPIKES-based training creates bigger improvements in staff confidence and performance than training using other or no protocol[13]. Patient preference review within oncology indicated that SPIKES-based training meets most patient SBN preferences[9].

**Figure 1. fertiShare logic model around here**

To support fertility staff in SBN we developed fertiShare, a 2-hour self-led, Continuous Professional Development (CPD) certified, eLearning SBN course that is based on the SPIKES framework and bespoke to fertility care. Its programme theory is presented in Figure 1, in the form of a logic model, and was informed by systematic review of SBN training in healthcare[13], narrative review of SPIKES-based training (16 experimental studies)[15], mixed-methods research conducted by the team focusing on the specificities of SBN in fertility care[11 16 17], healthcare communication literature more generally, and feedback from relevant stakeholders (patients and patient representatives, staff, clinic managers, eLearning specialist). fertiShare aims to improve staff SBN confidence and performance. It is expected this improvement will lead to higher patient trust in staff, satisfaction with care, perceived support for shared decision-making about continuing or stopping fertility treatment, and uptake of more treatment cycles.

There is a scarcity of communication training, and specifically SBN training, in fertility care. This raises uncertainty about the feasibility of implementing fertiShare. First, the feasibility of implementing SPIKES-based training in real-world complex settings is not yet known, as most evaluated SPIKES-training has focused on students[15]. Qualitative research suggests SPIKES would be a feasible SBN framework for fertility care as long as the specificities of SBN in (in)fertility news were accounted for[16]. Some of these specificities, for example the fact that much news is shared remotely, are addressed in fertiShare, but other specificities like high workloads and burnout levels for staff[18] and reception of successive and cumulative bad news for patients[17] need to be investigated. Second, fertility staff are used to eLearning and this digital literacy could suggest that a SPIKES-based eLearning course[19] would be appropriate to investigate diverse acceptability and learning dimensions[20] but this is yet unknown. Third, there is uncertainty around the appeal of learning soft skills such as SBN. One prospective evaluation showed a web-based training to promote communication about risk of infertility in oncology patients was completed by most staff (96%) and increased knowledge, confidence, and implementation of recommended behaviours over 12-months[21]. However, staff acceptability of training focusing exclusively on communication skills in SBN (versus risk communication) may be lower. Finally, even if staff engage with fertiShare, there is no definitive evidence that undergoing training will translate into benefits for patients[15]. In the only (exploratory) randomised controlled trial (RCT) investigating the impact of a SPIKES-adapted protocol to share bad fertility news, patients in the SPIKES group reported more distress than those receiving usual care[22]. However, the authors acknowledged they implemented SPIKES via a pre-written compulsory script staff needed to use, making it prescriptive instead of adaptive. Furthermore, this training did not include critical active components (e.g., exposure to modelling of optimal sharing bad news behaviours) known to trigger improvements in SBN.

**Objectives**

The aim of the present study is to evaluate if it is feasible to implement fertiShare at UK-based fertility clinics and if it is acceptable to staff and patients. The Control intervention consists of a general communication skills eLearning that emulates what many fertility staff could be expected to receive as part of general academic training[23], therefore equalising staff competence in what can be considered the care as usual standard in patient communication within fertility care.

To achieve this aim data about specific uncertainties regarding fertiShare's implementation and its evaluation will be collected including: what is the profile of fertility staff who do fertiShare and do they independently access and engage with it (demand); do fertility staff positively evaluate fertiShare and do patients positively evaluate their SBN encounters with staff who completed fertiShare (acceptability); do fertility staff engage with fertiShare as intended (i.e., complete all modules with associated quizzes and the course evaluation); are there barriers and facilitators of staff engagement with fertiShare and implementation of its SBN recommendations in daily practice (practicality); compared with general communication skills training, does fertiShare demonstrate efficacy in improving staff performance (primary outcome from limited efficacy testing) and confidence in SBN; does fertiShare demonstrate efficacy in improving patient trust in staff, satisfaction with care, shared decision-making support regarding doing or stopping fertility treatment, and uptake of another stimulated cycle(s); and are the evaluation methods and materials acceptable to staff and patients, and is it feasible to implement these methods in clinics.

## Methods and Analysis

### Study Design

Multi-centre, two-arm, parallel-group, blinded, feasibility RCT with 1:1 computer-generated randomised staff allocation to fertiShare (intervention group) or general communication skills eLearning (control group) designed to emulate typical content covered as part of general medical communication training[23]. The trial adopts a pragmatic attitude[24] to maximise the applicability of findings to fertility care practice (beyond the immediate trial setting). Specifically, eligibility criteria for clinics, staff and patients are not strict, fertiShare is implemented as it is expected to be used in routine care, no special strategies are used to maximise adherence to and compliance with fertiShare (beyond standard reminders), assessment intensity is minimised (short online surveys), and outcomes were co-designed with stakeholders. However, some explanatory trial design elements are kept, namely, randomisation, blinding, use of control intervention (instead of care as usual), analysis that accounts for non-adherence to fertiShare, and a qualitative process evaluation to develop in-depth understanding of staff and patients' views of fertiShare and its impact, and of the evaluation methods used[25]. Traffic-light progression criteria mapped to feasibility objectives[26] are defined and presented in Supplementary Table 1. Criteria are not strict because of the low cost of fertiShare (for healthcare systems and staff), low risk for unintended outcomes, and the contrast between wide use of SPIKES in clinical settings and lack of evidence about its impact on patient outcomes[15 27]. For fertiShare to progress to efficacy testing via multicentre pragmatic RCT, no feasibility outcome should fall in the red criteria defined.

### *Outcomes*

The study feasibility outcomes were informed by fertiShare's causal theory and guidance from Bowen's feasibility framework [28] and outcomes are described in Table 1 and Supplementary Table 3. In brief, outcome measures relate to demand, acceptability, implementation, practicality, and limited efficacy testing. The primary outcome is staff performance when SBN. Secondary outcomes are staff confidence in SBN and patient trust in staff, satisfaction with care, satisfaction with shared decision-making support regarding continuing or stopping fertility treatment, and uptake of and time to another stimulated IVF cycle.

**Table 1.** fertiShare feasibility outcomes organised according to Bowen's Feasibility Framework (Bowen et al., 2009)

| | Bowen's dimension | Outcomes |
|---|---|---|
| **fertiShare** | Demand | • Number of staff who registered with fertiShare and completed each lesson, module, and quiz: data stored by FertiShare<br>• Demographic and professional profile of staff who registered and completed fertiShare |
| | Acceptability | • Staff ratings regarding the experience of doing fertiShare (5 items, e.g., I benefited, I learned), with a Likert-type response scale ranging from 1 (not at all) to 5 (an extreme |

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| | amount) (Yilmaz *et al*. 2021), presented in the fertiShare Evaluation Form, which is embedded in the fertiShare course<br>• Staff ratings regarding the appropriateness and usefulness of fertiShare (5 items, e.g., The length of the modules was appropriate, I can use what I learned in my work/practice), with a Likert-type response scale ranging from 1 (strongly disagree) to 5 (strongly agree) (Yilmaz *et al*. 2021), presented in the fertiShare Evaluation form<br>• Proportion of staff reporting they recommend fertiShare to other colleagues in their situation, fertiShare improved their preparation to have difficult conversations with their patients, and fertiShare reduced their anxiety when having difficult conversations with their patients in the post-training staff assessment<br>• Patient self-reported satisfaction with how staff shared the bad news with them. Assessed with a single question "Overall, how satisfied are you with the way [name of participating staff member] shared or discussed with you the news that the IVF cycle was unsuccessful?", with a Likert-type response scale ranging from 1 (very dissatisfied) to 5 (very satisfied), presented in the patient pre- and post-cohorts' assessments<br>• Open ended questions included in semi-structured process evaluation interviews with staff (e.g., Which aspects of FertiShare were particularly useful, if any?) and patients (e.g., What are your views about how staff shared with you the news that the IVF cycle was unsuccessful?) |
| Implementation | • Number of staff who completed all Modules (i.e., used fertiShare as intended) and completed Module 1 and 2 only (i.e., completed sufficient dose) during the 4-week training period: data stored by FertiShare<br>• Open ended questions included in semi-structured process evaluation interviews with staff (e.g., Can you describe any changes you made in the way you SBN with your patients (if any) because of doing the fertiShare eLearning and why?) and patients (e.g., Can you describe how staff shared with you the news that the IVF cycle was unsuccessful?) |
| Practicality | • Staff answers to multiple choice question (yes, no) about experiencing technical issues during the course, presented in the fertiShare Evaluation form<br>• Open ended questions included in semi-structured process evaluation interviews with staff (e.g., Where there any factors that made it easier or harder for you to do fertiShare?) and patients (e.g., Can you think of any factors that made it harder or easier for staff to share the news with you in a sensitive way?) |
| Limited efficacy testing | Primary outcome:<br>• Modified intention-to-treat (mITT, all staff randomised) and per protocol (PP, only staff who completed a sufficient dose) analyses of mean differences in patient reported staff SBN performance (primary outcome) between patients in the pre- and post-training cohorts, assessed via online survey with an adapted version of the widely used SBN Behavioural Assessment Scale [1]<br>Secondary outcomes:<br>• mITT and PP analyses of mean differences in staff reported confidence in SBN, measured in the pre and post-training assessment, assessed via online survey with an adapted version of the SBN Behavioural Assessment Scale [1]<br>• mITT and PP analyses of mean differences in patient reported trust in staff (Forest Physician Trust Scale, [29]), satisfaction with care (four questions used by the UK Government Regulatory body for fertility care - HFEA - for patients to assess the quality of care provided by clinics, [30]), and satisfaction with shared decision-making support regarding continuing or stopping fertility treatment (Decisional Conflict Scale, [31]) between patients in the baseline and follow-up cohort, assessed via online survey<br>• mITT and PP analyses of mean differences in patient uptake of (yes, no, not recommended) and time to another stimulated IVF cycle (in days, not applicable) between patients in the baseline and follow-up cohort: data obtained via patient record review |

| | | |
|---|---|---|
| Study protocol | Demand / recruitment and retention | • Staff and patients' study participation and retention rates and reasons for non-participation/withdrawal from the study |
| | Acceptability | • Proportion of staff who complete background and professional form, and pre- and post-training assessments<br>• Proportion of patients in the pre- and post-training cohorts who complete their respective online assessments |
| | Implementation | • Issues reported by staff and patients to research team relating to study procedures or materials and reasons for non-participation/withdrawal from the study |
| | Practicality | • Time taken by staff and patients to complete online surveys and process evaluation interviews |
| | All dimensions | • Open-ended questions included in semi-structured process evaluation interviews with staff and patients about the study methods (e.g., 'How demanding was participation in this study?' and, for staff only, 'How did you find the randomization process?') |

**Note.** Validated questionnaires listed are described in detail in Supplementary Table 3. mITT = modified intention to treat; PP = Per protocol; HFEA = Human Fertilisation and Embryology Authority; SBN = Sharing Bad News

***Setting***

Eligible clinics are private and public fertility clinics in the UK. Three private (CREATE Fertility, Complete Fertility Centre, Herts and Essex Fertility Centre) and three public UK-based fertility clinics (Department of Reproductive Medicine at Saint Mary's Hospital Manchester, Newcastle Fertility Centre, King's Fertility at King's College Hospital NHS Foundation Trust) agreed to participate. There are 107 licensed fertility clinics in the UK[32]. Given heterogeneity in number of cycles done, patient ratings and research profile, we considered important to include multiple clinics in this feasibility testing.

***Participants and recruitment***

We will include any staff (e.g., administrators, nurses, embryologists) working at participating clinics whose role involves a minimum of half a day a week SBN. Exclusion criteria for staff are being unable to undergo the fertiShare training (e.g., due to visual impairments). Patient inclusion criteria are having received bad news from a participating staff within the last month. Other exclusion criteria for all participants are not being able to read, speak or understand English and not being able to provide consent.

For this study bad news is defined as any news resulting in a clinical pregnancy not being achieved in a first or second IVF cycle, regardless of when this happens in the cycle (i.e., due to no ovarian response, no eggs, no fertilisation, no transfer, no biochemical or clinical pregnancy). This operational definition is adopted because a negative cycle outcome is common, is challenging bad news shared by staff with different roles, and it ensures that patient outcome data are comparable.

**Sample size**

We followed guidance for feasibility studies to estimate participation rates. Based on review of evidence from RCTs focusing on patient-centred care and communication in fertility care, and

research on SBN training[13 20 22 33], we expect around 75% of staff and 60% of patients to be eligible and participate, but we opted for more conservative estimates of 50%. Recruiting 60 staff (10 per clinic) and 180 patients per cohort (30 per clinic, 3 per staff) will allow to calculate a 50% staff participation rate to 95%CI of ±11% and a 52% patient participation rate to 95%CI of ±8%. Estimated final sample size is 45 staff and 108 patients per cohort.

***Interventions***

fertiShare was developed by a team composed of reproductive health psychologists (SG, JB), communication researcher-practitioners working in fertility care (DL, EV), and reproductive clinicians experienced in scientific coordination of quality care and patient safety training (AD, ZV), with the involvement of other fertility care stakeholders (1 nurse, 1 embryologist, 2 patients, 1 patient representative) and in partnership with the Safety and Quality in ART (SQART) Special Interest Group of the European Society for Human Reproduction and Embryology (ESHRE), the British Fertility Society, and the Southwest and South Wales Infertility Group (SWIGS, Network of England and Wales South West with public and private fertility clinics membership). The fertiShare programme theory (see Figure 1) was developed by the team, based on evidence and the result of the fertiShare co-development process. The programme theory was reviewed to integrate views of the stakeholder group, specifically regarding outcomes that matter. These are, for staff, confidence and actual performance in SBN, and for patients, trust in staff, satisfaction with care, satisfaction with shared decision-making support about continuing or stopping treatment, and uptake of and time to another stimulated IVF cycle. A detailed description of fertiShare, according to the Template for Intervention Description and Replication (TIDieR) Checklist (Hoffman et al. 2014), is presented in Supplementary Table 2. In short, fertiShare is organised in three modules. Module 1 explores definitions of bad news, why it is challenging to fertility staff and patients, and the benefits of training. Module 2 offers SPIKES-based step-by-step guidance to ease SBN and Module 3 offers guidance to cope with common challenges fertility staff face (SBN remotely, managing anger and uncertainty, and using good news to lessen the impact of bad news). Each module offers video content-based lessons, simulated case studies that illustrate guidance, and brief quizzes for self-reflection and assessment. A fourth and final module presents learners with a brief conclusion, two summary guides they can use as memory aids during their routine practice, and an opportunity to evaluate the training.

The Control intervention consists of a general communication skills eLearning. In its form, the control eLearning is presented as if it was fertiShare (same visual layout, interface, module number and names), but it differs in that the active components of fertiShare are absent: SPIKES recommendations are replaced by information about the communication process in clinical encounters[34]; guidance to cope with common changes in fertility care is replaced with general information about communication skills (i.e., empathic and non-verbal communication, active listening, and communicating likelihood of outcome); case-studies modelling best practices are omitted; quizzes are modified to suit the new content and eliminate reflexive prompts.

***Procedures***

**Figure 2. Participant flowchart around here**

The participant flowchart is presented in Figure 2. For staff at each clinic, the research team will present the study aims and what participation entails at a whole-staff meeting. Staff interested in participating will be sent hyperlinks to the online participant information sheet and consent form (see Supplementary material 2). Those who provide written consent are presented with the demographic and professional forms to complete. Staff will be randomised to fertiShare or control conditions and then complete the online pre-training assessment (Time 1, T1), at the end of which they will be presented with a link to access the fertiShare or control eLearning course. Two weeks after course completion staff will be sent an email with a link to complete the post-training assessment (Time 2, T2).

For patients, two cohorts will be recruited, one completing an online assessment before the participating staff receive training (patient pre-training cohort) and another completing the same assessment 1-month after staff receive training with the fertiShare or control eLearning course (patient post-training cohort). At each clinic, support staff or research nurses will identify eligible patients and present these with the participant information sheet, in person or over the phone, via email, or the clinic's patient communication system. These patients will then be emailed a link to the consent form (see Supplementary material 3). Those who provide written consent will be asked to complete the online assessment (pre- or post- staff training, depending on cohort).

Participants will be compensated for the time spent on research activities according to national funder guidelines[35]. The project does not include incentives for staff to do the intervention, but clinics can choose to protect staff working time for its completion. Staff that complete fertiShare will receive a certificate that can be used to demonstrate CPD.

After the patient post-training cohort data collection is completed, one patient and one staff per clinic will be invited via email to participate in a semi-structured process evaluation interview. A patient-record review for pre- and post-training cohorts will be performed 6 months after patient consent. Note that for any email sent, two reminder emails will be sent, one and two weeks after. If participants do not complete assessments after all reminders, they will be sent an email with a link to fill a 1-question exit survey to determine reasons for withdrawal.

Recruitment started at the first centre on October 8, 2024. Predicted dates for the pre- and post-training patient cohorts' data collection were September 2024 to February 2025 and February to July 2025, respectively, with staff data being collected between January and March 2025. The patient record review was predicted to span from May 2025 to February 2026.

***Randomisation***

Randomisation will occur after staff consent and complete the demographic and professional form. Staff will be randomised on a 1:1 ratio via a computer-generated sequence of random numbers generated by SG, who will assign staff to groups. The randomisation sequence will be stratified by clinic with block sizes of 10 to ensure equal allocation to control and intervention groups. The trial management team (SG, JB) will know the randomisation result, but participants (staff, patients), clinic gatekeepers, research nurses, and the data analyst will not.

***Materials***

All validated questionnaires used are described in Supplementary Table 3.

Pre-training assessments

Staff: The staff demographic and professional data form will be used to collect data on age, gender, education, if English is the first language, professional title, time working in fertility care (years and months), experience of time pressure at work (from 1-not at all to 5- extremely), burnout (single item questionnaire[36]), proportion of weekly work time spent SBN (0-100%), previous training in communication and SBN (no, not sure, not applicable, yes [and how long ago, in years]), the extent to which staff is interested in improving skills in SBN and the extent to which their clinic value and invest in communication care, and encourage them to do continue professional development in patient care (1-not at all to 5- an extreme amount). The pre-training staff assessment will include two validated questionnaires assessing general communication skills (Sefl-Efficacy Questionnaire: SE-12[37]) and SBN confidence (Adapted version of the Behavioural Assessment Scale[1]).

Patients: The patient pre-training cohort assessment will be organised in three sections: sociodemographic, fertility history, and communication experiences with staff. The sociodemographic section will ask about gender, age, ethnicity, relationship status, duration of partnership (if there is one), education, and if English is first language. The fertility history section will ask if patients have children (no/yes – biological/ yes – adopted/yes – fostered/yes – stepchildren), time trying to have children and doing fertility care (years and months), if they are trying with a partner (with partner/independently/prefer not to say), how costs of fertility care are covered (all costs publicly funded/some publicly funded/will personally cover costs/unsure), extent to which they can afford fertility treatment (1-not at all to 5-completely), type of treatment done in the past (ovulation induction/intrauterine or artificial insemination/IVF or intracytoplasmic sperm injections/other [describe]/does not apply), and total of cycles done. Finally, the Communication Experiences with Staff (CES) section was designed for this study and will be used to elicit perceptions of sharing bad news at the clinic. Recall that an inclusion criterion is that patients will have received bad news from a participating staff within the last month. This experience is the index experience asked about in the CES. The CES starts with a description of what bad news is and asks patients to respond to subsequent questions in relation to the index experience when answering questions. The definition of bad news is as per Buckman[14] and presented as:

> "Any information that has a negative or serious effect on your view of your future, noting that what is bad news is always the opinion of the person receiving the bad news. We consider the sharing of the news as well as any following conversation during which the implications of the news are discussed".

Patients are asked to describe the index news in as much detail as possible (open text), and then state how long ago they received the news (weeks and days), if staff shared the news with them or vice-versa (yes/no-they found the news and told staff), where they were when the news was shared (the clinic/ home/work/other [describe]), how it was shared (in person/remote video call/phone or remote audio call/other [describe]), and if they were alone when shared (yes/no [describe who was present]). The survey ends with four validated questionnaires assessing patients' perception of staff performance when SBN with them (Adapted version of Behavioural Assessment Scale[1], trust in staff Forest Physician Trust Scale[29], satisfaction with care five questions used by the UK

Government Regulatory body for fertility care - HFEA - for patients to assess the quality of care provided by clinics[30], and satisfaction with shared decision-making support regarding continuing or stopping fertility treatment Decisional Conflict Scale[31].

Post-training assessments

Staff: Staff will complete the same validated measures as in the pre-training assessment. Additional feasibility questions will include three acceptability questions (see Table 1) and five questions to assess possible contamination (talked about fertiShare with colleagues at clinic [yes/no], of yes: describe what was said [open text], received other SBN training since consenting [yes/no], if yes, describe training [open text], which eLearning they think were allocated to [fertiShare/control]. Provide detail to justify answer [open text]). The topic guide for process evaluation interviews will provide a loose structure and a guide of sample questions based on the Bowen feasibility framework[28] (see Table 1 for examples) that may be asked to steer the discussion and promote the exploration of staff's experiences of doing fertiShare and sharing bad news, gather reflections on the perceived impact(s) of fertiShare (including harms), and explore how acceptable and feasible the study procedures and materials are. Questions can be modified or expanded in response to participants comments during the interview, encouraging them to explore what is significant to them.
Patients: The patient post-training cohort assessment is the same as the pre-training assessment. The patient topic guide for the process evaluation is like the one described for staff, however questions will focus on exploring patient's experiences of receiving news from participating staff, the impact this has had on them, and explore how acceptable and feasible the study procedures and materials are.

Six-month patient record-review

Information extracted from medical records will consist of any stimulated treatment cycle recommended (yes, no), recommended cycle attempted (yes, no), and time to cycle (in days, not applicable).

***Analytical plan***

The main quantitative data analyses will be performed by RM (blinded to randomisation result) and using SPSS and R software. Quantitative data regarding acceptability, feasibility, and efficacy will be reported with descriptive statistics (e.g., means, standard deviations or standard error of the means, frequencies, proportions).

Differences in demographic, professional (staff) and fertility history (patient) characteristics between groups (staff allocated to fertiShare vs control eLearning, patients receiving news from staff allocated to fertiShare vs control eLearning, pre- vs post-training patient cohorts) will be examined via t-tests and $\chi^2$ tests.

Two-level (staff, patients) multilevel modelling will be used for limited efficacy testing, which will be reported for modified Intention to Treat analysis (mITT, includes all staff randomised and provides a realist estimation of fertiShare's efficacy) and per protocol analysis (PP, incudes only staff who completed a sufficient dose, i.e, did Module 1 and 2, see Table 1, and provides an ideal efficacy estimate of fertiShare, when it is used as recommended). Models will be presented as unadjusted and adjusted for covariates significantly associated with outcomes or known from previous

research to be associated with outcomes (e.g., patient education is known to be associated with satisfaction with care). Effect sizes will be reported. No sub-group analyses are predicted.

Process evaluation interviews will be audio-recorded, transcribed verbatim and analysed with thematic analysis [38]. This will involve familiarisation with the data by repeatedly reading through the transcripts, followed by inductive generation of codes (that will describe a piece of information present in the data), which will be deductively organised in themes according to Bowen's[28] feasibility criteria, but other themes not fitting the framework may be considered. Risk for bias will be minimised by repeated peer debriefing, discussion and agreement of codes within the research team, and provision of opportunity for participants to comment on results. Similar approach will be used for open-ended text responses in pre and post-training assessments (staff, patients).

**D*ata management and monitoring***

Data will be processed in accordance with the Data Protection Act 2018 and the General Data Protection Regulation 2016 (GDPR). All information collected will be kept confidential. Data will only be viewed by the research team. All data will be stored on a password protected cloud location on a Cardiff University Server. Consent information will be kept separately from responses to minimise risk in the event of a data breach and linked via the use of a Unique Participant Identifier, also used to link prospective data and for randomization purposes. Qualitative data collected will be de-identified during the transcription process. Data will be shared with co-investigators and sponsors only when strictly necessary and via access to the cloud folder at the Cardiff University Server. No monitoring is planned given feasibility and low risk nature of study, but the trial has the oversight of the sponsor and periodic reporting to the stakeholder group (see section below).

***Patient and Public Involvement (PPI)***

The research programme involves PPI from inception comprising patient representatives in the multi-disciplinary stakeholder group that informs on all aspects of the study. The group also includes a fertility junior clinician, a health psychologist, a communication and an intervention evaluation expert, and together with patient representatives this group will meet in four pre-scheduled online meetings.

## Ethics and dissemination

The study has ethical approval from the NHS Research Ethics Committee (NHSREC, 23/LO/0864) and the Cardiff University – School of Psychology Research Ethics Committee (EC.23.08.08.6827). All protocol amendments will be submitted to NHSREC via standard procedure and communicated to Research Offices, site study Principal Investigator, and research nurses (as appropriate).Results will be disseminated via publications in peer-reviewed journals, conference presentations, and public engagement, and will inform if fertiShare should proceed to efficacy evaluation. Insights from this study can inform the implementation of other SBN training in fertility or other healthcare domains and improve understanding of the impact SBN training has on patient experience and outcomes.

## Discussion

The long-term aim of this study is to implement SBN training that is bespoke to fertility care and accepted and valued by fertility staff and patients because it improves the experiences of sharing and receiving difficult news and strengthens the partnership between patients and their clinics. To achieve this aim we will be assessing the feasibility and acceptability of fertiShare and its evaluation methods, and implementing limited efficacy testing on staff performance in SBN (from staff and patient perspectives), staff confidence in SBN (staff perspective), and trust in staff, satisfaction with care, shared decision-making support regarding the continuation or cessation of fertility treatment, and uptake of additional stimulated cycles (patient perspective).

We considered both cluster and multi-centre trial designs. Cluster trial designs are recommended when interventions are to be delivered at cluster level due to high risk of contamination, where scaling up is a goal and where randomisation at individual level would be perceived to be unfair or unethical. Although this design has many benefits, it did not present a good fit with implementation plans for fertiShare. Even though an ambition would be for all staff to be trained in fertiShare, the scaling up of its use would much depend on local considerations for implementation, including staff preferences, unlike for example use of a new screening test in clinics[39]. Indeed, the norm within the field is to offer communication training as continuous professional development (CPD) opportunities. This eLearning will be housed in the Women's Health Research Wales centre website (under construction), which will function as a hub for women's health professionals and include a training and professional development section, as per other eLearning courses co-produced by the centre team. Therefore, it will be available for clinics and individual fertility staff to use as they think adequate. To reflect this reality, the use of an individual level RCT is recommended[40]. Systematic reviews of communication skills training and SBN for healthcare professionals indicates this is the most used design[13,41]. Randomisation at staff level instead of clinic level generates risk of contamination (staff talking to each other) and makes it harder to sustain allocation concealment throughout the duration of the trial. We considered the risk of contamination to be minimal but controlled this risk by making experimental and control arms comparable (e.g., format, duration, case studies) and asking staff not to discuss course experiences. Further, staff deliver bad news in individual consultations, and evidence suggests staff do not talk much about this aspect of their work. In fact, lack of communication about bad news could itself be problematic in its delivery[42], although the trial context may alter such behaviours. Finally, free access to fertiShare will be provided to all trial participants at the end of the study, minimising perceptions of individual randomisation as unfair or unethical.

The strengths of the multi-centre trial are that it will involve multiple fertility clinics across the UK, it is a randomised controlled design with blinding (staff, patients, data analyst) and includes a strong comparator in a parallel-group design. We considered a three-arm parallel-group design with a no training arm but decided against it because communication training is increasingly embedded in medical and health sciences training and the probability that staff had been exposed to it was high. The chosen general communication skills eLearning can be perceived as the current Care as Usual standard in fertility care, with the advantage that it allows for blinding (while a third no training condition would not).

The pragmatic features of the trial balance real-world implementation evaluation (external validity) with sufficient design control to reach ecologically valid conclusions (internal validity), via the limited efficacy testing and process evaluation[43]. The mixed methods approach uses sound quantitative surveys, and the thematic analysis can inform on specific dimensions of feasibility and acceptability using deductive coding, while inductive coding allows for the possibility of emerging themes for adaptation of fertiShare and future trials[28]. Another strength of the trial is the inclusion of patient outcomes that will advance knowledge about the impact of SBN training on patients' care experiences and specifically of SPIKES-based training, which is an important contribution given SPIKES evaluation studies have rarely examined these outcomes[13] with only one SPIKES trial in fertility care[22].

Although multi-centre randomised trial was selected as the preferred method, it could also have risks. By design multi-centre trials require multiple clinics to participate, and too few clinics could be a risk. Variability between clinics in, for example, recruitment of staff and patients, how the study is introduced to staff, allocation of time for engaging with fertiShare and so on could also create additional analytic heterogeneity. The study design allows local variation for recruitment, provided inclusion and exclusion criteria are met. This flexibility reflects real world variation in how fertiShare would be shared with staff but can also introduce variation in the trial design (e.g., time for recruitment, interval between staff recruitment and course engagement etc). Another limitation is the potential complexity of the trial procedures because patients will need to be matched to participating staff, as patients will rate the performance of staff who SBN with them (i.e., matched dyads). This matching adds logistics complexity, and frequent contact between research team and research nurses to implement which could attract significant costs (time, human resources) or reduce the number of eligible patients, depending on how this process unfolds at each clinic. We addressed these challenges by ensuring named research nurses and dedicated staff in each clinic provide liaison to research team. However, matched dyads allow to address dependency of data between patients receiving news from same staff members. We use appropriate analytic approaches for analysis of between and within group variability at multiple levels. Finally, there is a risk that some patients could be recruited into the pre- and post-training cohorts. While this risk was deemed negligible given the low proportion of eligible patients from the clinics' total patient population, patient discontinuation rates between cycles, and average waiting time between cycles, it is of yet unknown. The trial provides an opportunity to estimate it and consider impact on future analytical plans.

We assume that the study will provide sufficient information to inform if fertiShare needs review and a future trial with high internal and external validity, as is expected of feasibility and acceptability studies[43]. More generally, knowledge gathered can be applied directly to fertility care but also other areas of assisted reproductive care, such as onco-fertility, early pregnancy units and recurrent miscarriage, or preimplantation genetic testing and counselling. As stated, we predict that, after all evaluations are concluded, fertiShare will be made available free of charge for fertility staff and clinics to use. Multiple international partners have contacted the team with a view to adapt fertiShare and this will be a further implementation route pursued.

**Author contributions**

SG conceptualised and designed all aspects of the study protocol with input from DL, AD'A, ZV, RM and JB. SG, JB and DL drafted and revised the manuscript with input from AD'A, ZV, and RM. All authors revised and approved the manuscript. SG is the guarantor.

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**Competing interests statement**

SG and JB report consultancy work for Ferring Pharmaceuticals UK. ZV reports a research grant from the Juhani Aaltonen Foundation, support from ESHRE to attend meetings and travel, and being SIG coordinator, past coordinator, and guideline coordinator for ESHRE. All other authors have no competing interest to declare.

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**Data statement**

Study data and materials will be made FAIR at OSF | Development and feasibility evaluation of a brief self-guided e-Learning training package to support fertility staff in sharing bad news with their patients.[44]

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**Figures legends**

Figure 1. Logic model of the fertiShare eLearning. Inputs represent the resources used to implement fertiShare. Outputs display the planned activities designed to target the active components through which fertiShare triggers change). Outcomes present the changes that are expected to be seen in real life after the planned activities are implemented. Note: *Not assessed in this trial to minimise assessment burden for staff.

Figure 2. Participant flowchart. Note participants in this trial are fertility staff and patients.