# Wellbeing of Women – Research Project Grant Application

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In 2013 686,271 cycles of Assisted Reproductive Technology (ART) were done in Europe and 536,805 (78%) were unsuccessful (no live birth). For each 10 women starting ART treatment in the UK 7 will receive news that their cycle failed. Delivering bad news (DBN) is a daily occurrence for Reproductive Health Practitioners (RHPs), including news of an infertility diagnosis, poor ovarian response to hormonal stimulation, failure of oocyte retrieval, fertilization or conception, poor prognosis, or recurrent miscarriage.

When informed that their cycle is unsuccessful, 4 in each 10 patients experience unexpected emotional or physical reactions (e.g., chock) and many develop depressive symptoms that can last for 6 months, with 30% of women and 10% of men presenting a psychiatric disorder. Patients often express that staff could better communicate the news and support them. RHPs perceive DBN as one of the biggest challenges of their job, fearing negative evaluations and stressful interactions with patients. Indeed, our research shows that dissatisfaction with perceived insensitive care and mismanagement of psychological aspects is one of the main reasons why ART patients discontinue recommended treatment and change clinics.

European guidelines for psychosocial care in ART recommend that interventions target specific needs patients experience at different moments in treatment and the HFEA recent code of practice requires clinics to show evidence of using evidence-based interventions to support patients before, during and after treatment. Receiving bad news in a sensitive way is an important aspect of Patient-Centred Care for which there are yet no ART tailored evidence-based interventions.

We will develop a 1-hour SPIKES-based E-learning course to improve DBN skills in ART, to be made available online free of costs: the TellMeART. It will include step-by-step recommendations to DBN, simulated video clips illustrating best practice and common challenges, quiz questions for self-assessment, and printable materials that RHPs can take into the DBN context.

Following MRC guidance for developing complex interventions, the research plan includes a development phase (rapid review, patients and RHPs online survey and focus groups) to identify patients' preferences and RHPs' current practices and perceived challenges in DBN and their views about the usefulness and usability of TellMeART, followed by an external feasibility pilot two-arm RCT to assess the acceptability of the TellMeArt E-learning to RHPs and the feasibility of conducting a definitive RCT to test its effectiveness.

Twenty RHPs will be randomised to undergo the E-learning course on DBN (TellMeART intervention) or a general communication skills E-learning course (GCS control), after which they will fill a perceived confidence to DBNs questionnaire and a training evaluation form.

Before and after receiving the training each RHP will be assessed while DBN to 3 different ART patients (N= 60). The sessions will be video- (in person) or audio- (over the phone) recorded and rated by two independent raters blind to RHPs' and patients' background, assessment moment (pre, post training) and exposure (intervention, control), using the Breaking Bad News Skills Rating Form Checklist (primary outcome). After the session patients will self-report on perceived stress during the session, patient-centred care experiences, and satisfaction with care. Compliance data will be extracted from patient records following recommended procedures.

Finally, we will conduct a qualitative process evaluation with a random subset of 6 RHPs and 6 patients (3 per arm), who will be interviewed via telephone one month after the DBN session. We will follow MRC guidance for process evaluations to collect data on TellMeART implementation (fidelity, dose, reach) and acceptability of methods (recruitment, randomisation, assessments).

Addressing patients need to receive bad news in a sensitive way will result in better patient treatment experiences (i.e., less stress while receiving news, better Patient-Centred Care) and more satisfaction with care. These are known to be conducive to compliance and we showed that patients who comply with 3 ART cycles increase their chance of conception by as much as 15%. RHPs will also experience benefits, namely improvement in skills and confidence to DBN.

Findings from this research project will provide proof of concept data to apply for funding to conduct a large effectiveness RCT.