Feminae: an international multisite innovative project for female athletes

Kirsty J Elliott-Sale [iD],[1] Kathryn E Ackerman,[2,3] Constance M Lebrun [iD],[4] Clare Minahan,[5] Craig Sale,[1] Trent Stellingwerff,[6] Paul A Swinton [iD],[7] Anthony C Hackney[8]

[1]Department of Sport and Exercise Sciences, Manchester Metropolitan University Institute of Sport, Manchester, UK
[2]Wu Tsai Female Athlete Program, Division of Sports Medicine, Boston Children's Hospital, Boston, MA, USA
[3]Neuroendocrine Unit, Massachusetts General Hospital and Harvard Medical School, Boston, MA, USA
[4]Department of Family Medicine, University of Alberta Faculty of Medicine & Dentistry, Edmonton, Alberta, Canada
[5]Griffith Sports Science, Griffith Health, Griffith University, Gold Coast, Queensland, Australia
[6]Canadian Sport Institute Pacific, Victoria, British Columbia, Canada
[7]School of Health Sciences, Robert Gordon University, Aberdeen, UK
[8]Department of Exercise & Sport Science – Department of Nutrition, The University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Correspondence to
Kirsty J Elliott-Sale;
k.elliott-sale@mmu.ac.uk

ABSTRACT

Sufficient high-quality studies in sport science using women as participants are lacking, meaning that our knowledge and understanding of female athletes in relation to their ovarian hormone profiles is limited. Consortia can be used to pool talent, expertise and data, thus accelerating our learning on a given topic and reducing research waste through collaboration. To this end, we have assembled an international multisite team, described here, to investigate the effects of the menstrual cycle and contraceptive pill phase on aspects of exercise physiology and sports performance in female athletes. We intend to produce an adequately powered, high-quality dataset, which can be used to inform the practices of female athletes. Our approach will also employ research transparency—through the inclusion of a process evaluation—and reproducibility—through a standardised study protocol.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There is no consensus on the effects of ovarian hormone profiles on female exercise physiology due to a shortage of first-class research.

WHAT THIS STUDY ADDS

⇒ We intend to adopt a consortium approach and gold-standard methodologies to produce an adequately powered high-quality dataset.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study will add to knowledge and understanding on the effects of menstrual cycle phase and oral contraceptive use on exercise physiology and sports performance in female athletes and will shape future ovarian hormone related guidance for female athletes.

BACKGROUND

While consortia are often used in public health research, they are seldom used in sport science research. Historically, studies in sports science—especially those using women as participants—have had small and often underpowered sample sizes, meaning that the study's findings may have limited generalisability and potential to identify small effects where they exist correctly. Indeed, Faber and Fonseca[1] advise that very small sample sizes generally undermine a study's internal and external validity, making this issue an important methodological consideration. Using a consortium involving multiple research sites is a means to overcome this problem and allow cost sharing. Additionally, greater heterogeneity introduced by studying subpopulations from different geographical areas may provide additional insights and potentially increase the generalisability of findings.

Sport science is—or at least was until circa 2020—predominantly male-centric regarding the focus and relevance of the available knowledge base and the target population for investigations and outcomes. Female physiology research has been mainly limited to reproduction and has rarely incorporated the non-reproductive functions of the ovarian steroid hormones; in fact, women have been rarely used as participants in sports science research,[2] and when females are used, gold-standard female methodologies are rarely used.[3 4] The restriction and exclusion of women from sports science research likely reflects: (1) the slower development of sports involving female athletes compared with sports involving male athletes, including at times the discouragement of women to participate in sports; (2) a lack of qualified researchers with expertise in female endocrinology and exercise physiology; (3) the higher monetary and time costs often associated with high-quality female-specific research compared with male-specific research (eg, ovarian hormonal profiling); (4) reduced funding going towards female-specific research projects compared with research in men and (5) the antiquated societal taboo associated with discussing and researching female-specific matters. The result is sports science is biased towards men and has largely adopted a 'one-size-fits-all' philosophy (ie, data derived from

men are frequently applied to women). While some principles of sports science may eventually hold for both sexes, ignoring female-specific considerations has undoubtedly weakened the development and application of sports science for women. These issues can be exacerbated because data supporting most sports consensus statements and policies frequently originate from male-derived information. These historical issues have contributed to the frequently cited statement that there is insufficient high-quality research evidence to provide fit-for-purpose guidance to female athletes; for a review of the current state of the art on the effects of menstrual cycle phase and oral contraceptive use on athletic performance, which underpins this statement see Elliott-Sale *et al*[5] and McNulty *et al*.[6] To address this issue, it seems prudent to model the public health approach to undertaking large-scale collaborative studies in female exercise physiology, thus strengthening and improving female athlete performance potential (training and competitive) and health.

OVERVIEW OF PROJECT

Disclosure: This project will be conducted with cisgender women (ie, adults assigned female at birth and whose gender identity is woman). For this project, 'female' will be used as an adjective and 'woman/women' as a noun (singular/plural, meaning an adult female human being). We aim to focus this project on adult (≥18and ≤ 40years) female athletes of reproductive age who tend to be either eumenorrheic or use hormonal contraceptives. Female athlete research participants will be categorised based on the criteria described by McKay *et al*[7] and Decroix *et al*.[8]

Our intent is to investigate the effects of menstrual cycle phases and contraceptive pill use on aspects of exercise physiology and sports performance in female athletes. We will investigate the effects of fluctuations in oestradiol and progesterone, experienced during the menstrual cycle and as a result of contraceptive pill use, on aspects of exercise physiology and sports performance in female athletes (ie, this research aims to determine if a particular hormonal profile is associated with optimal physiological functioning or sports performance in female athletes). We will measure aspects of exercise physiology and sports performance across three menstrual cycle phases and between contraceptive pill phases (ie, monophasic pill consumption vs pill withdrawal/placebo). This work programme will be completed using a standardised research design, which incorporates the best recommended methodological practices currently available in this field of research.[3] Implementing the same standardised methods, each site is responsible for independent data collection from two groups (ie, eumenorrheic women and existing contraceptive pill users), with a minimum of 10 participants in each group.

The a priori aims of the project are to:

1. Determine the effects of menstrual cycle phases (and their resultant hormonal profiles) on aspects of exercise physiology and sports performance in female athletes.

2. Determine the effects of monophasic, combined, second-generation oral contraceptive pills on aspects of exercise physiology and sports performance in female athletes.

3. Produce a high-quality, independently replicated, adequately powered dataset using current best practice processes.

4. Establish a research design blueprint that can be used to assess other outcomes (ie, outside of the exact measures we intend to make in our project) of exercise physiology and sports performance in female athletes.

5. Provide evidence-informed guidelines for use in an applied sports setting for women.

By realising these aims, we intend to: (1) advance knowledge and understanding in female athletes by adding to the international state of the art, which is lacking (eg, Cowley *et al*[9] showed that only ~6% of sport and exercise science has been conducted in female-only cohorts); (2) improve the quality of research in female athletes, by overcoming the methodological flaws previously reported in this area (for an overview of the methodological considerations, see Elliott-Sale *et al*[3]) and (3) leave a research and applied legacy for researchers, practitioners and athletes, by adopting an open-science approach (ie, publishing the full research protocol, an evaluation of the project and a translation of the data from paper to podium).

APPROACH

We have formed a collaborative network of researchers (ie, a consortium) to work on a project (titled Feminae—Latin for female and women) that addresses the quality-related and quantity-related issues currently associated with studies on female sport/exercise physiology. To this end, we have adopted a multisite approach to produce adequately powered datasets and demonstrate how to achieve stronger scientific outcomes in female-based sports science research. We have assembled a group of researchers to inform and undertake the project, who are outstanding in several areas of sports science but notably with demonstrable knowledge, interest and advocacy in and for female-based physiology and gold-standard methodologies. This collective approach is critical to the success of this project, as prior solo endeavours have failed to consistently produce robust, valid datasets capable of meaningful, practical application. The sites in our consortia are positioned worldwide and represent institutions that support advanced scientific research and strengthen the overall generalisability of our findings.

STRUCTURE
Steering group

An academic and clinical steering group supports Feminae

1. Professor Kirsty Elliott-Sale, PhD (Manchester Metropolitan University, UK)—Chair.

2. Associate Professor Kathryn Ackerman, MD, MPH (Harvard Medical School, USA).
3. Professor Anthony Hackney, PhD, DSc (University of North Carolina Chapel Hill, USA).
4. Professor Constance Lebrun, MD (University of Alberta, Canada).
5. Associate Professor Clare Minahan, PhD (Griffith University, Australia).
6. Professor Craig Sale, PhD (Manchester Metropolitan University, UK).
7. Trent Stellingwerff, PhD (Canadian Sport Institute Pacific, Canada).
8. Associate Professor Paul Swinton, PhD (Robert Gordon University, UK).

All steering group members have a proven track record in female-centric research or clinical practice. The steering group was responsible for setting the research agenda (ie, research priorities, questions, design and protocols) and the ethos for Feminae. The steering group will have oversight of the project throughout its lifespan and will perform a retrospective process evaluation on the project once data collection and analyses have been completed; noting that the site principal investigators will perform a real-time process evaluation; that is, they will note the challenges and strengths of the research design in real-time but will not make real-time changes to the protocol. In addition, the steering group will strive to translate Feminae's laboratory-based findings into applied practice.

Athlete advisory group
Feminae has an athlete advisory group who were consulted on all aspects of the project design before implementation:
1. Lauren Delaney: Current international rugby union player for Ireland; sports nutritionist; PhD student.
2. Catherine Pendrel: Two-time World Champion and three-time Canadian Olympian and Olympic Medallist in cross-country mountain biking; last Olympics Tokyo 2020, now a national team mountain coach.
3. Hilary Stellingwerff: Two-time Canadian Olympian and 10-time Canadian National Team member in track and field; last Olympics Rio 2016, now a university/collegiate athletics coach.

Like the steering group, the athlete advisory team will contribute to generating and disseminating the findings of Feminae to the athletic community. Specifically, this group will be actively involved in translating the findings from this project from paper to podium (ie, coauthors on relevant publications). They will also participate in disseminating the findings in academic (eg, conferences) and applied (eg, practitioner, entourage and athlete facing workshops and peer to peer social media) settings by providing an athletes voice/perspective to the dataset.

Research sites
Feminae has seven research sites spread throughout the world. Each site has a principal investigator(s)

1. Professor Shawn Arent, PhD: University of South Carolina, USA.
2. Dr Eimear Dolan, PhD and Dr Bryan Saunders, PhD: University of Sao Paulo, Brazil.
3. Professor Kirsty Elliott-Sale, PhD: Manchester Metropolitan University, UK.
4. Dr Mette Hansen, PhD: Aarhus University, Denmark.
5. Dr Ritva Mikkonen, PhD and Dr Johanna Ihalainen, PhD: University of Jyvaskyla, Finland.
6. Associate Prof Clare Minahan, PhD: Griffith University, Australia.
7. Dr Jane Thornton, MD, PhD: Western University, Canada.

Data collection will be overseen by the site principal investigator(s) and supported by postdoctoral or postgraduate students.

INNOVATION
The full Feminae research design and protocol will be published elsewhere (see the Dissemination plan section). In brief, Feminae has an innovative biopsychosocial research agenda. The following measures, reflecting physical, psychological ovarian and sociological elements, will be assessed: laboratory and field-based sports performance tests, biochemical markers, symptoms and side effects, lived experiences (eg, emotional well-being), and details on the athletic training environment (eg, menstrual cycle tracking practices). Ultimately, the project aims to raise standards (ie, high-quality datasets), increase participation (ie, women as participants in sport and exercise science-based studies), remove perceived and actual barriers to participation (ie, in research and practice), and develop processes, designs, systems and mindsets that account for female-specific issues. By restructuring our approach to female athlete research, through adopting a consortium model, we hope to revolutionise this research area and leave a novel high-quality blueprint for other researchers to use and learn from.

DISSEMINATION PLAN
The study protocol will be published first, followed by the resultant pooled data, and then the process evaluation. All scientific publications are to appear in open-access peer-reviewed journals with a strong reputation in the field. Ultimately, the project's findings will be translated into applied outcomes/practical considerations for use in the athletic environment. We are committed to transparent methodological reporting, including providing details of our live and post hoc process evaluations, with the quality assurance provided by the steering group. In addition, this work will be presented at conferences and other scientific and applied sports meetings.

EPILOGUE
Women make up half the world's population, and nearly all of them will menstruate at some point. Yet in sport science, women have been and remain understudied, as has the role of female ovarian hormones beyond their effects

in reproductive physiology. The tide is turning on these points, but many unanswered scientific questions remain to be addressed. We view Feminae as an approach to moving the needle on female physiology, particularly in relation to athletes.

ORCID iDs
Kirsty J Elliott-Sale http://orcid.org/0000-0003-1122-5099
Constance M Lebrun http://orcid.org/0000-0002-7408-4521
Paul A Swinton http://orcid.org/0000-0001-9663-0696

REFERENCES

1. Faber J, Fonseca LM. How sample size influences research outcomes. *Dental Press J Orthod* 2014;19:27–9.
2. Costello JT, Bieuzen F, Bleakley CM. Where are all the female participants in sports and exercise medicine research *Eur J Sport Sci* 2014;14:847–51.
3. Elliott-Sale KJ, Minahan CL, de Jonge XAKJ, *et al*. Methodological considerations for studies in sport and exercise science with women as participants: A working guide for standards of practice for research on women. *Sports Med* 2021;51:843–61.
4. Smith ES, McKay AKA, Kuikman M, *et al*. Auditing the representation of female versus male athletes in sports science and sports medicine research: evidence-based performance supplements. *Nutrients* 2022;14:953.
5. Elliott-Sale KJ, McNulty KL, Ansdell P, *et al*. The effects of oral contraceptives on exercise performance in women: A systematic review and meta-analysis. *Sports Med* 2020;50:1785–812.
6. McNulty KL, Elliott-Sale KJ, Dolan E, *et al*. The effects of Menstrual cycle phase on exercise performance in Eumenorrheic women: A systematic review and meta-analysis. *Sports Med* 2020;50:1813–27.
7. McKay AKA, Stellingwerff T, Smith ES, *et al*. Defining training and performance caliber: A participant classification framework. *Int J Sports Physiol Perform* 2022;17:317–31.
8. Decroix L, De Pauw K, Foster C, *et al*. Guidelines to classify female subject groups in sport-science research. *Int J Sports Physiol Perform* 2016;11:204–13.
9. Cowley ES, Olenick AA, McNulty KL, *et al*. Invisible Sportswomen: the sex data gap in sport and exercise science research. *Women in Sport and Physical Activity Journal* 2021;29:146–51.