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ELLIOTT-SALE, K.J., ACKERMAN, K.E., LEBRUN, C.M., MINAHAN, C., SALE, C., STELLINGWERFF, T., SWINTON, P.A. and HACKNEY, A.C.

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Title

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Authors

Kirsty J. Elliott-Sale[1], Kathryn E. Ackerman[2,3], Constance M. Lebrun[4], Clare Minahan[5,6], Craig Sale[1], Trent Stellingwerff[7], Paul A. Swinton[8] and Anthony C Hackney[9]

Affiliations

[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, United States

[3] Neuroendocrine Unit, Massachusetts General Hospital and Harvard Medical School, Boston, MA, United States

[4] Department of Family Medicine, Faculty of Medicine & Dentistry, University of Alberta, Edmonton, AB, Canada

[5] Griffith Sports Science, Griffith Health, Griffith University, Gold Coast, QLD, Australia

[6] Australian Institute of Sport, Australian Sports Commission, Canberra, ACT, Australia

[7] Canadian Sport Institute - Pacific, Victoria, British Columbia, Canada

[8] School of Health Sciences, Robert Gordon University, Aberdeen, UK

[9] Department of Exercise & Sport Science – Department of Nutrition, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA

Corresponding author

Professor Kirsty J. Elliott-Sale, Institute of Sport, Manchester Metropolitan University, Manchester, M1 7EL, UK. Email: 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 multi-site team, described herein, to investigate the effects of the menstrual cycle and oral 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.

Background

Whilst 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 (2014) 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, allow cost sharing, and reduce the financial burden on any one centre. Additionally, greater heterogeneity introduced by studying sub-populations from different geographic areas may provide additional insights and potentially increase the generalisability of findings.

Sport science is - or at least was until circa 2020 - predominately 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 (Costello et al., 2014), and when females are used, gold-standard female methodologies are rarely utilised (Elliott-Sale et al., 2021; Smith et al., 2022). The restriction and exclusion of women from sports science research likely reflects: (i) the slower development of sports involving female athletes compared to sports involving male athletes, including at times the discouragement of women to participate in sports; (ii) a lack of qualified researchers with expertise in female endocrinology and exercise physiology; (iii) the higher monetary and time costs often associated with high-quality female-specific research compared to male-specific research (*e.g.,* ovarian hormonal profiling); (iv) reduced funding going towards female-specific research projects compared to research in men; and (v) 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 (*i.e.,* data derived from male participants are frequently applied to women). Whilst 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 are frequently derived 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. (2020) and McNulty et al. (2020). 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 cis-gender women (*i.e.,* an adult who was assigned female at birth and whose gender identity is female). 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 ($\geq$18 and $\leq$ 40 y) 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. (2022) and Decroix et al. (2016).

Our intent is to investigate the effects of menstrual cycle phases and oral 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 oral contraceptive pill use, on aspects of exercise physiology and sports performance in female athletes (*i.e.*, 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 (see Elliott-Sale et al. 2021) and between oral contraceptive pill phases (*i.e.*, monophasic pill consumption versus 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 (Elliott-Sale et al., 2021). Implementing the same standardised methods, each site is responsible for independent data collection from two groups (*i.e.*, eumenorrheic women and existing oral 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 (*i.e.*, 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: (i) advance knowledge and understanding in female athletes by adding to the international state of the art, which is lacking (*e.g.*, Cowley et al. (2023) showed that only ~6% of sport and exercise science has been conducted in female-only cohorts); (ii) 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 for including women as participants in sport and exercise science see Elliott-Sale et al., 2021); and (iii) leave a research and applied legacy for researchers, practitioners, and athletes, by adopting an open-science approach (*i.e.*, 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 (*i.e.*, a consortium) to work on a project [titled *Feminae* – Latin for female and women] that addresses the quality- and quantity-related issues currently associated with studies on female sport/exercise physiology. To this end, we have adopted a multi-site 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 (*i.e.*, 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; i.e., 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 (*i.e.*, co-authors on relevant publications). They will also participate in disseminating the findings in academic (*e.g.*, conferences) and applied (*e.g.*, practitioner, entourage, and athlete facing workshops and peer to peer social media) settings by providing an athletes voice and 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 section on the anticipated dissemination plan). In brief, Feminae has an innovative biopsychosocial research agenda. The following measures, reflecting physical, psychological, and sociological elements, will be assessed: laboratory and field-based sports performance tests, biochemical markers, symptoms and side effects, lived experiences (*e.g.*, emotional well-being), and details on the athletic training environment (*e.g.*, menstrual cycle tracking practices). Ultimately the project aims to raise standards (*i.e.*, high-quality datasets), increase participation (*i.e.*, women as participants in sport and exercise science-based studies), remove perceived and actual barriers to participation (*i.e.*, 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.

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