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3 Viewpoint

5 Fuelling the Female Athlete

Female athletes want to be the most they can be but highly active women are hungry for nutrition advice, especially as dietary recommendations tend to be geared towards male athletes.

Dr Susan Kleiner covers the most pressing nutritional concerns for women in sport and advocates for change in the industry to better support female athletes.

9 Trust and Transparency in Prenatal Nutrition

What a woman eats before and during her pregnancy may have a profound effect on her own and her child's health, but nutritional recommendations at national level in the European Union differ, leading to uncertainty. As **Katia Merten-Lentz** discusses, unclear food information goes against the general principle of European food law and there's a real need for regulation to cover prenatal nutrition.

15 Resveratrol's Promising Role in Women's Healthy Ageing

Scientific literature has accumulated supporting the use of resveratrol to sustain and support healthy ageing and, as **Clare Panchoo** explains, the potential to help women live better as they age is an exciting opportunity to explore.

20 Designing Clinical Trials for Women

While designing clinical trials for women poses certain difficulties, **Eimhear Campbell** is keen to point out this can be said for every clinical trial as each is different presenting its own unique challenges. As the results of trials conducted on men are subsequently applied to women, the importance of continued research in women cannot be understated.

24 Takeaways



Wonder Women Worldwide

Every woman deserves to be healthy and we are the experts on our own bodies; we know what does and doesn't feel normal, and we know we have different needs to our male counterparts—full stop. We talk about periods and pregnancy and menopause and all those uniquely female experiences, but equally as important are the everyday differences that call for nutrition specific to women.

How many consumers know the symptoms of heart attacks are slightly different for women? Or that autism presents differently in young girls than young boys? And yet, public information films broadcast on television invariably only offer education on male experiences. Then, there are female athletes, who you'd expect would have highly personalised nutritional advice, but as Dr Susan Kleiner explains, even most elite sporting dietary recommendations are geared toward men! In her article on [page 5](#), Dr Kleiner covers the most pressing nutritional concerns for women in sport and advocates for change in the industry to better support female athletes.

Even prenatal nutrition comes with its challenges! What a woman eats before and during her pregnancy may have a profound effect on her own and her child's health, but as Katia Merten-Lentz details on [page 9](#), nutritional recommendations at national level in the EU differ, often leading to uncertainty.

While it's possible to explain the dearth of information on female needs on the difficulties involved in designing clinical trials for women, Eimhear Campbell is keen to point out every clinical trial presents its own unique challenges. In her article on [page 20](#), she explains the common issues that arise for women in clinical trials, and further highlights the importance of continued research on women's health.

Happily, there is scientific literature exploring the health benefits of various ingredients for women; one such ingredient is resveratrol, which can sustain and support healthy ageing in everyone. For women, writes Clare Panchoo on [page 15](#), resveratrol has the potential to support women throughout life—including with menopause—which is an exciting opportunity to explore.

Women's health matters. Dr Kleiner says it best: 'With more female-centric data, we will have more female-centric recommendations and more female-centric products'—and ultimately, healthier happier women! With so much being done to empower women globally in their careers and daily lives, it's time for the health and nutrition industry to play its part, too.



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Fuelling the Female Athlete

by *Dr Susan Kleiner*



Most highly active women are hungry for nutrition advice; especially as most dietary recommendations are geared towards male athletes. Female athletes want to know the differences between how men fuel and how they need to fuel.

Female athleticism and the menstrual cycle

Female athletes often under-fuel, sometimes with the intention of dropping body fat and possibly also putting a halt to their menstrual cycles. The belief has been that this will make you a better competitor. However, research shows women and girls who compete during their periods do not show any performance deficiencies. In fact, a study¹ looking at junior national elite female swimmers during their grueling 12-week competitive season found those swimmers with similar training loads but higher energy availability maintained their full menstrual cycles with measured functional ovarian steroids and metabolic hormones throughout the season. They also significantly outperformed the matched athletes who suppressed ovarian function and menstrual cycles through lower energy availability in the final meets at the end of the season. This study shows the common and widespread practice of under-fuelling and over-training female athletes to halt the menstrual cycle with the goal of enhanced performance is a failed strategy. The low metabolic state and altered hormonal environment negatively impact physical performance. However, female athlete physiology does change throughout the month based on the biology of the menstrual cycle. If you try to fight biology, you might under perform. But if you understand it and work with it, you can maximise your potential. This is the information all female athletes—and coaches and trainers of female athletes—should know.



Female athletes are better than males at burning fats most of the time, but this is particularly true during the luteal phase.

However, reproductive hormones are at work on the athletic body and knowing how and when they are working can offer an advantage to diet and training regimens. Oestrogen and progesterone levels are lower during the follicular phase of the menstrual cycle (days 1 to 14), causing an increase in carbohydrate utilisation. Carbohydrates should be more prominent in the diet, and this is when high-intensity, power and speed training will be advantageous. During the luteal phase (days 15 to 28), oestrogen and progesterone levels rise, maintaining muscle glycogen storage, and preserving liver glycogen and increasing fatty acid oxidation.

Dietary carbohydrate can decrease slightly during this phase, and, to take advantage of better fat burning, the training focus should turn to moderate intensity endurance. Female athletes are better than males at burning fats most of the time, but this is particularly true during the luteal phase. During endurance exercise, females have more efficient access to stored triglyceride droplets within the muscle fibres, which can be transported quickly inside the cell to the mitochondria where energy metabolism and fat oxidation takes place. Females are also better at recovery of these fat droplets from the diet back to the muscle cells after exercise. This explains the success many female athletes have in ultra-endurance events.

However, when females do high intensity training, their need for carbohydrate is equally as high as a male athlete, and they have just as strong a capacity to utilise and store carbs as a male athlete. Carbohydrate and fat recommendations for female athletes should be 'periodised' to reflect not only their training, and the athletes should plan their diet and training with their monthly menstrual cycle as regularly as possible.

The last thing about the menstrual cycle is the discussion of heavy bleeding. It is abundantly clear women with heavy periods are at higher risk for iron deficiency, with or without anaemia. While iron supplementation is helpful, it is not always comfortable due to GI discomfort, and sometimes it is not effective. A focus on dietary solutions is important. Diets including animal sources of heme iron help athletes recover more quickly and successfully compared to plant-only diets containing only non-heme iron.

How to determine energy needs

The classic method to calculate energy needs has been to determine energy balance: the point at which calorie output balances with calorie input—in other words, calories in equals calories out. However, a female athlete may be in energy balance, but this may not reflect her optimal energy needs. When calorie intake is low, a low output reflects the low intake, not necessarily the optimal output. Therefore, energy balance may not be a useful concept for managing a female athlete's diet.

Energy availability (EA) is a better method of calculating individual calorie recommendations. It refers to the leftover energy available to support fundamental physiological processes after the largest load has been spent fuelling exercise training. The body will fuel the highest energy demand first, and then whatever is leftover is the energy available to support all the other important health functions of the body. When that leftover energy is low, it is called Low Energy Availability (LEA). Foundational health must be fuelled to enable the systems that support enhanced training effects and performance improvements.

Carbohydrate and fat recommendations for female athletes

should be 'periodised' to reflect not only their training, and athletes should plan their diet and training with their monthly menstrual cycle as regularly as possible.



Determine Energy Availability: $EA = [\text{dietary energy intake (EI)} - \text{energy expended in exercise (EEE)}] / \text{kg FFM (Fat-Free Mass)}$.

For female athletes, EA should always be greater than 30 kcal/kg FFM, and ideally equal to or greater than 45 kcal/kg FFM

The following complaints usually point to LEA: 'I'm training harder but my performance is worse; I'm eating less but getting softer; I have brain fog; I don't sleep well; I can't focus; I have frequent headaches; I keep getting injured; I don't have any energy; I've got nothing left for my partner and family; my hair is thinning and my skin looks terrible.'

Athletes with low energy availability do not have enough calories for their body's basic needs and ultimately, their performance and health will decline. LEA impairs the body's ability to use glucose effectively; increases fat stores in the body; increases cholesterol; slows the metabolic rate; decreases the body's production of growth hormone; impairs immune function; and impairs reproductive function. In women, LEA may cause periods to cease—which is a main characteristic of the Female Athletic Triad (a syndrome including menstrual dysfunction, low energy availability, and decreased bone mineral density)—and impairs bone health and development. Under-fuelling has no place in the diet of an athlete. When performance is the goal, the athlete must eat enough to fully fuel her training and health.

There's no question women have made great strides in sports since the passage and institution of Title IX in the United States: Title IX of the US Education Amendments Act of 1972 states: 'No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.' Crucially for young athletes in the United States, this includes team sports at school and collegiate level.

The Sex Discrimination Act 1975 in the United Kingdom allows legal challenge of any inequality in programmes including sports and physical education, while the European gender equality laws, which form part of the Lisbon Treaty, reinforce the European Union's declaration that 'curbing and preventing discrimination is part of the social objective of the Community'.



Research from EY² shows girls who play team sports are more likely to graduate from college, find a job, make a generous salary, and be employed in male-dominated industries.

But when it comes to research on injury and performance—the real 'meat' of creating a winning strategy—females comprise only 2 percent and 3 percent of the research subjects. For sports nutrition research studies in general, there is a lack of data on how many subjects are female—while the numbers are undoubtedly growing, until very recently, virtually all sports nutrition recommendations for women were based on data collected on men. Even now, most recommendations still depend on male-focused data.

Why does this matter? Because women are not small men or 'men with hormone issues'! Women and girls have unique anatomy and physiology, and

transferring sports nutrition and training recommendations based on males to females is equally as inappropriate and ineffective—and perhaps dangerous—as the application of male-centric pharmaceutical research results to females.

The void in data on the needs of female athletes has allowed weight-loss marketers to swoop down with information masquerading as sports nutrition for women. Most of this misinformation involves ‘cutting calories’, ‘slashing carbs’, and ‘getting thin.’ Such recommendations often lead to poor sports performance and—for athletically active women—can cause dire health consequences—namely, increased risk for injury and illness, deficiencies in energy and key nutrients such as iron and calcium, and fatigue. Many women athletes shoot for 0 percent body fat, eat zero dietary fat, and avoid carbs. These ‘fat-phobia’ and ‘carb-phobia’ phenomena are due in large part to the emphasis on thinness that is so prevalent today and a reliance on information that comes out of the diet world.

Fortunately, within the halls of science and academia is the beginning of a call for change: institutional review boards are beginning to highlight a requirement for female—as well as male—subjects in study designs; journal editors and reviewers are starting to call foul when studies neglect to include females. Although there are currently a handful of scientists focusing their research on the needs of the female athlete, the majority of these scientists are men. Their contributions are wonderful; they should be applauded for fostering lab environments in which female students are being mentored to take their place among the community of full-fledged faculty members and primary investigators. But we also need more female scientists to be role models to enlarge the ranks of female investigators in the fields of sports science and nutrition. By nature, scientists typically study what they find to be personally interesting, and therefore female scientists will more likely have the desire and drive to study female athletes.

With more female-centric data, we will have more female-centric recommendations, and more female-centric products and guidelines. Athletes want what works. Women and girls know what is out there for them today hardly works, and in more than a few cases can actually hurt their health and performance.

Female athletes also want to be the most that they can be, not the least. Skinny and sexy are not athletic goals, and that messaging repels the athletic female consumer. They want to be stronger, faster, and more powerful—all to support their goals of winning. If accomplishing those goals leads to outcomes that also include being leaner and sexier, that’s okay. But those are generally not the athletic goals they are seeking.

As in science, we need women in decision-making roles in product ownership, research and development, manufacturing, marketing and sales—with a personal interest in athletics and sport—to create the change women desire and the authentic products and stories that appeal to the female athlete consumer. ●

**Some content excerpted from Kleiner, SM and Greenwood-Robinson, M. Power Eating. Fifth Edition, Human Kinetics, In Press.*

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Trust and Transparency in Prenatal Nutrition: An EU Perspective

by **Katia Merten-Lentz**



M Keeping a healthy diet throughout life is important for maintaining optimal health. What a woman eats before and during her pregnancy may have a profound effect on her own and her child's health. Pre-pregnancy and pregnancy require an adequate intake of calories, proteins, vitamins and minerals to meet maternal and foetal needs. Prenatal nutrition corresponds to this set of nutrients obtained through food, necessary for health and growth before birth and during pregnancy.

Prenatal nutrition is of the utmost importance, both for the mother and her baby, as it may predispose offspring to the development of chronic diseases in adulthood¹ and increase the risk of complications during the pregnancy.²

Prenatal nutrition: a confusing landscape for pregnant women

In 2015, 5.1 million children were born in the European Union.³ Each mother received advice about what to eat and what to avoid. But, as a German mother was recommended to eat “moderate amounts of animal-based foods [...], with a preference for low-fat milk and milk products, low-fat meats and oily fish,⁴” her Dutch neighbour was advised to “eat more products from the category meat (and processed meats), fish, chicken, eggs and meat substitutes’.⁵

These divergences in the nutritional recommendations may confuse women and can lead to uncertainty on what they should eat or avoid as part of a safe and healthy diet during their pregnancy.

Unclear food information goes against the general principle of European food law, which requires consumers should be provided with the basis to make informed choices in relation to the food they consume and to prevent any practices that may mislead them.⁶

Although Member States were invited by the Council to “promote policies and initiatives aiming at healthy diet and sufficient physical activity throughout the lifespan, starting from the earliest stages of life, before and during pregnancy⁷”, the protection of pregnant women cannot rely solely on the Member States and requires a durable action at Union level.



EU legislation for women's diets before and during pregnancy

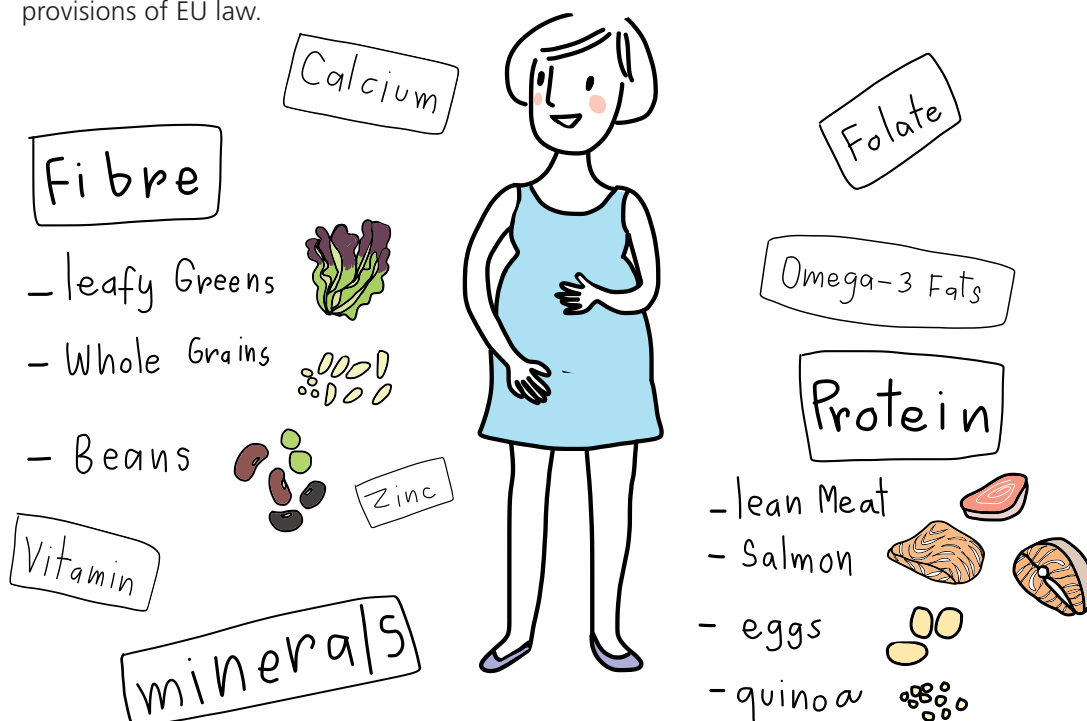
Despite the importance of women's diets before and during pregnancy, there is no EU wide definition of 'prenatal nutrition'. The protection of women during this short, but crucial, period has only been partly embraced by the EU legislator.

In the past, certain foods consumed by pregnant women—such as food supplements—fell within the scope of the PARNUTs Directive 2009/39/CE⁸ concerning foodstuffs for particular nutritional uses.⁹ Because the interpretation and enforcement in Member States was inconsistent, the PARNUTs Directive was deemed to be a source of problems undermining the functioning of the internal market and therefore has been repealed.

Indeed, it can be difficult to distinguish between food intended for the 'normal' population and food intended for a 'specific group' of the population. This has been, for instance, illustrated by the European Commission as part of its Impact Assessment accompanying document to the Proposal to revise the Dietetic Food Framework Legislation:

'How to deal with the following health claim, recently positively assessed by EFSA: 'Folate contributes to normal maternal tissue growth during pregnancy', which, once authorised under the claims Regulation, could be made on food containing folate in certain amounts and could be targeted to women planning to become pregnant and pregnant women? Would a product bearing that claim be considered as a dietetic food because targeted to women that plan to become pregnant or would that be considered as a 'normal' food bearing a health claim addressed to pregnant women?'¹⁰

As of 20th July 2016, the set of rules on dietetic foods has been replaced by Regulation (EU) 609/2013¹¹ which covers food for specific vulnerable population groups needing particular protection. Food for pregnant women no longer falls within the scope of Regulation (EU) 609/2013 and is regarded as 'normal food' regulated under the general provisions of EU law.





Fragmented protection of prenatal nutrition through the general provisions of EU law

Although the general framework applies, the EU often foresees the specific needs of pregnant women.

Accordingly, the use of certain ingredients is restricted or prohibited. For instance, as part of the safety assessment of novel foods, Regulation (EU) 2283/2015¹² explains the European Food Safety Authority (EFSA) should assess all the characteristics of the novel food that may pose a safety risk to human health and consider possible effects on vulnerable groups of the population. As a result, some novel foods are authorised,¹³ provided they meet specific conditions of use. For instance, flavonoids from *Glycyrrhiza glabra*—as a novel food ingredient—will trigger the necessity for the food industry to state the product should not be consumed by pregnant women.

Specific foods may be prohibited, too. For example, total diet replacements for weight control¹⁴—in addition to the mandatory particulars listed under the FIC Regulation—must bear a statement that the product should not be used by pregnant women.

In addition to the general labelling requirements set out under Regulation (EU) 1169/2011¹⁵ on Food Information to Consumers, the EU Regulation foresees specific labelling rules to protect pregnant women. Accordingly, beverages with high caffeine content or foods with added caffeine must bear a specific warning statement indicating the product contains caffeine and is not recommended for pregnant women. Similarly, foods with added phytosterols, phytosterol esters, phytostanols or phytostanol esters must also bear an easily visible statement that the food may not be nutritionally appropriate for pregnant women.

Another important piece of EU legislation for the transparency and trust of pregnant women is the Regulation 1924/2006/EC on nutrition and health claims made on foods.¹⁶ Foods to be consumed by pregnant women can bear specific nutrition or health claims which must comply with the requirements of Regulation 1924/2006/EC. Several health claims targeting pregnant women have been approved, such as 'Folate contributes to maternal tissue growth during pregnancy'¹⁷ or 'Docosahexaenoic acid (DHA) maternal intake contributes to the normal development of the eye of the foetus and breastfed infants'.¹⁸ Similarly, several nutrition claims are relevant during prenatal nutrition such as the 'source of' or 'high in' claims. Indeed, women are encouraged to increase their intake of some vitamins and minerals such as calcium,

vitamin D or folic acid, which plays an important role in the prevention of neural tube defects and other folic acid-sensitive congenital malformations.¹⁹ On the other hand, the excessive consumption of some of these nutrients may be dangerous during the pregnancy. This is the case with vitamin A, for example, because excessive consumption poses a risk of having a child with congenital abnormalities.²⁰

More EU actions advisable in the field of prenatal nutrition

This issue of vitamins and minerals illustrates the limit of the Member States' actions. Indeed, nutritional advice should be personalised, but it is difficult to understand why a mother in the Netherlands should absorb 10 micrograms of vitamin D,²¹ while in Germany, a pregnant woman will be advised to consume 20 micrograms.²² Similarly, in the UK, supplementation is encouraged to obtain the appropriate amount of iron, vitamin C, folic acid and calcium during pregnancy,²³ while in France, food supplements are deemed useless.²⁴

Surprisingly, at EU level, neither Regulation 1925/2006/EC on the addition of vitamins and minerals and certain other substances to foods²⁵, nor the Food Supplement Directive 2002/46/EC²⁶ refer to pregnant women.

As an illustration, Regulation 1925/2006/EC provides for the setting of maximum amounts of vitamins and minerals. To this date, no proposal has been presented, leaving the possibility for Member States to set up their own maximum level in compliance with EU legislation. This is the case in France where the Order of 9 May 2006 on nutrients that may be used in the manufacture of food supplements²⁷ provides for a maximum level of folates. Accordingly, food supplements sold in France must not exceed the daily dose of 200 micrograms of folates where most of the EU countries, as well as the EFSA,²⁸ recommend a daily consumption of at least 400 micrograms of folic acid.²⁹



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One of the objectives of the revision of the PARNUTs Directive was to ensure appropriate consumer information as well as transparency and legal clarity. This is explained by the European Commission in its Impact Assessment 'as the food market evolved so did the EU legislation governing it, in order to ensure the functioning of the internal market and guarantee the same level of protection to citizens across Europe.' It is dubious whether pregnant women are sufficiently well informed before and during pregnancy through transparent and trustworthy information. ●

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pain and lowered sexual desire and activity⁸; loss of skin elasticity and the appearance of wrinkles and age spots¹⁴; and progressive loss of skeletal muscle mass and function.¹⁵

Resveratrol in a healthy lifestyle regimen

Fortunately, in the past couple of decades, awareness of these changes has increased and, in parallel, new nutritional strategies to help manage them have emerged. The inclusion of resveratrol and other polyphenols as part of healthy diet and active lifestyle may be an effective way to tackle some of these menopause-related conditions. Among the dietary interventions supporting healthy aging in women, polyphenols such as resveratrol, soy isoflavones, green tea flavonoids, curcumin and others have gained traction in the past two decades.¹⁶

The anti-ageing effects of resveratrol may be due to several related mechanisms, including: its antioxidant properties; potential role as a dietary phytoestrogen; and possible role in promoting mitochondrial biogenesis,¹⁷ a term that simply refers to the replication of mitochondria in the cell. As we age, the body's ability to grow new mitochondrial cells—which drive energy production in the body—slows down.¹⁸ By promoting mitochondrial cell growth, resveratrol may help return the body's processes to a younger state. This combination of features makes resveratrol a unique compound for anti-ageing activity.

The widespread effects of antioxidants in health science have led researchers to explore the use of resveratrol in a variety of women's health-related applications—including bone health, muscle function, skin and metabolic health, and mood, pain and sexual activity.



Resveratrol and osteoporosis

The delicate balance between bone formation and bone resorption degrades with ageing—when bone resorption overtakes bone formation. The decrease in circulating oestrogen limits the body's ability to remodel bones and increases a postmenopausal woman's risk of developing osteoporosis.¹⁹

The significant decrease in oestrogen may cause bone loss, potentially leading to hip, spine and wrist fractures. In fact, 30 percent of postmenopausal women have been found to have osteoporosis.¹² It is estimated approximately one in two women older than 50 will suffer from an osteoporosis-related bone fracture.^{12,13}

Preclinical data shows promise in the potential of resveratrol to mediate osteoporosis-related outcomes.⁵ Two published studies on osteoporosis have been conducted in overweight and obese men.^{20,21} One study showed supplementation with resveratrol (Veri-te™ from Evolva) leads to a significant dose-dependent increase in bone mineral density.²⁰ Another demonstrated a dose-dependent increase in bone alkaline phosphatase (BAP),²¹ a biochemical marker of bone formation, stimulating mineralisation and increasing bone mineral density. BAP may be a useful marker in the treatment of postmenopausal osteoporotic women.²²

To further elucidate the impact of resveratrol on bone health, additional clinical studies are ongoing. Of note, a current study at the University of Newcastle (Australia) led by Dr Peter Howe is examining the resveratrol and bone health connection in a broader study of health in post-menopausal women.

Although it is difficult to generalise clinical research findings across sexes, both older men and women experience bone loss, yet osteoporosis is often accelerated at an earlier age in post-menopausal women. Given this earlier occurrence, the role of nutritional support with supplements such as resveratrol may be more important for women than men.

Resveratrol and muscle function

The term 'sarcopenia' refers to normal, progressive and age-related loss in muscle mass. There is a large body of evidence that supports the hypothesis that the decline in oestrogen levels surrounding menopause may play a role in the development of sarcopenia in postmenopausal women.¹⁵

A randomised control trial in 30 older adults found the combination of exercise and an oral intake of 500 mg of resveratrol per day significantly improved muscle fatigue resistance compared to the placebo group. Moreover, several parameters related to muscular function (e.g. knee extensor muscle peak torque, average peak torque and power) improved in the group receiving resveratrol, but not the group receiving the placebo. The authors concluded the results from this study suggest resveratrol supplementation combined with exercise may provide an enhanced approach for reversing sarcopenia than exercise alone.²³



Resveratrol and skin health

As we age, the skin does, too. It no longer looks as plump and smooth; it becomes thinner, loses its firmness and can take longer to heal. What was once trouble-free skin develops wrinkles, dark circles and age spots.²⁴

A placebo-controlled, double-blind study involving 50 women and men (aged between 35 and 65) showed after 60 days, supplementation with a dietary supplement blend containing 8 mg of resveratrol significantly decreased systemic oxidative stress, improved skin moisturisation and elasticity, diminished skin roughness and depth of wrinkles, and significantly decreased the intensity of age spots. The authors concluded the specific resveratrol blend may be a promising strategy to reduce skin wrinkling, as well as reducing systemic and skin oxidative stress.²⁵



A randomised

control trial in 30 older adults found the combination of exercise and an oral intake of 500 mg of resveratrol per day significantly improved muscle fatigue resistance compared to the placebo group.

Menopause-related symptoms: mood, pain, and sexual function

Other potential benefits of resveratrol for women's health are related to its effects on mood, pain and sexual function. A recent clinical study in postmenopausal women showed an oral intake of 75 mg of resveratrol twice daily for 14 weeks reduced the perception of pain and improved total well-being. Interestingly, both benefits, including measures of quality of life,

correlated with improvements in cerebrovascular function. The authors concluded the results indicated potential for resveratrol in aiding management of chronic pain associated with age-related osteoarthritis.²⁶

Another study conducted on 60 perimenopausal women experiencing vasomotor symptoms (hot flashes) aimed to evaluate the effect of a resveratrol-containing supplement on sexual function and other menopause-related symptoms. Researchers used two questionnaires to determine the change in sexual function and sexual distress over the course of a six-month study duration. At the six-month follow-up, the sexual function score was significantly higher and the sexual distress score significantly lower compared to baseline scores. Menopause symptoms were also improved in all categories. The authors concluded that the resveratrol-containing supplement improved some peri-menopausal symptoms in women and hypothesised the improvement of the vasomotor function may contribute to the improvement of quality of life and sexual function in this population.²⁷

The available research suggests resveratrol, as a unique antioxidant and phytoestrogen, may be a promising dietary supplement to support several women's health and menopause-related outcomes. In addition, resveratrol's potential role in promoting mitochondrial biogenesis may help slow age-related decline at the cellular level. Furthermore, studies show resveratrol may be a useful supplement for promotion of women's health when combined with an overall healthy diet and active lifestyle. While the function of resveratrol as an antioxidant with anti-inflammatory properties is well known, there is an opportunity for additional research to further demonstrate the role of resveratrol to support women's health specifically. ●

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Clinical Trials for Women's Health

By *Eimhear Campbell, Dr Aoife Hayes and Ursula Leonard*



In recent years, much attention has focused on the lack of clinical trials involving women.

Designing clinical trials for women poses its difficulties, but this can be said for every clinical trial; each trial is different and presents its own unique challenge. It may have been the case for decades that clinical trials excluded women in their recruitment, and the results of the clinical trials conducted in male populations were subsequently applied to female populations. A scientific literature search of clinical trials between the years 1970 and 1990 shows a very low result in relation to women. In the decade following, 1990 to 2000, a dramatic increase of 4,000 results were observed. Thus, the case can be argued that, at present, clinical trials are incorporating women and women's health areas, as well as men. A further search of clinical trials in the past 10 years indicated there are more than double the amount of clinical trials in women than in men. This may be related to limited research in women's health in the past and an attempt to reduce the resulting gender bias present in evidence-based medicine.

Many researchers claim women are excluded from clinical trials because they present several differences at a molecular and cellular level. There is a vast difference in clinical outcomes in comparison to their male counterparts; the differences between the sexes result in varying pharmacokinetics. Women can also develop more side effects such as headaches, nausea and vomiting. In terms of body composition, men tend to have a higher percentage of fat free mass compared to women, who generally have a higher percentage of fat mass. Thus, if a male and female trial subject with the same body surface area—or the same body mass index (BMI kg/m^2)—the likelihood is the female will have a lower muscle mass. Lean soft tissue found in muscle mass is what metabolises most drugs. As the majority of clinical trials administer a standard dose to all subjects, and the lean soft tissue in muscle mass is where most drugs are metabolised, the male is likely to metabolise more of the drug, while the woman will experience a higher level of drug. This area of difficulty is important in dose response trials.



IN THIS ISSUE

Reservatrol **p.15**

Takeaways **p.24**

Table of Contents **p.2**

Hormonal differences between the sexes, including circulating levels of endogenous hormones—for example, testosterone—can affect pharmacokinetic or pharmacodynamic strictures. Women using hormonal contraceptives are often excluded from clinical trials because hormonal contraceptives, including oral birth control pills, may modulate the gut microbiota and alter the population of bacteria originally present. However, the exact mechanism is unclear. Recent studies linked alterations in the gut microbiome to endogenous levels of male sex hormones, which are also known to be altered with exogenous hormone use, which has the potential to result in autoimmune diseases. Another mechanism hypothesised is that oral oestrogen has been shown to alter intestinal permeability. An additional study hypothesised that exposing the body to additional hormones is thought to enhance the development of certain inflammatory diseases. Therefore, sponsors might be reluctant to allow women who use hormonal contraceptives on their clinical trials in areas where the microbiome is analysed.



Women using hormonal contraceptives are often excluded from clinical trials because hormonal contraceptives, including oral birth control pills, may modulate the gut microbiota and alter the population of bacteria originally present.

Some sources argue if women were to take part in a clinical trial, there would be too many costs imparted upon the woman to carry out the clinical trial. Some costs suggested are childcare costs, taking time out from their job, the time it takes to travel to the site of the visit, the travel expenses and parking, to name a few. However, the very same factors apply for men taking part in a clinical trial. If the participant is reimbursed for their participation in the study, then hopefully the expenses related to the trial will be handled. It can also be said people are willing to give their time to science and research and enjoy the experience of a clinical trial. The public is taking an increasingly strong interest in their health, and they feel the supposed costs, burden and effort involved in a clinical trial are 'worth it'. Time and time again, participants are grateful for the knowledge they gained by taking part in a clinical trial and learning about their individual health status. For many, taking part can have a positive effect on their social lives. This can be argued in the case of elderly men and women who might be retired from their career, or raising a child.



Clinical trials aimed at women's health can face challenges due to menstrual cycles and hormones. If anthropometric measurements are taken at intervals during a clinical trial, vast differences can be observed. One difference that may be observed is in body mass and hip-to-waist measurements due to fluctuations in water retention during various stages of a women's menstrual cycle. Another challenge is the conduction of body composition measurements using radiation, such as dual-energy X-ray absorptiometry (DXA) and computed tomography (CT). For safety reasons, clinicians may require woman of childbearing age to be within a certain timeframe of their cycle to ensure that there is the least possible chance of her being pregnant. This can make it difficult for a woman partaking in a clinical trial. The investigator will require her to attend a study visit at one time, and the individual carrying out a DXA or CT scan will require her to attend an appointment at another timepoint, and the woman might then feel that too much of her time is being taken up by the appointments of the clinical trial. This can then result in low compliance and discontinuation of the clinical trial. This area of difficulty is common in weight loss clinical trials.

The stigma associated with women's clinical trials in areas of vaginal health and women's reproductive organs may be related to the apparent lack of research of clinical trials in women. It can be cumbersome and severely uncomfortable—both physically and emotionally—for a woman to present herself for multiple visits for a vaginal exam. It's imaginable that recruitment rates for clinical trials which require a physical exam of the female's reproductive organs would be very slow, and this will subsequently negatively affect the trial budget. Women might also be embarrassed to admit to an investigator that they suffer from symptoms of UTIs or thrush, for example. Also, it can be expensive to carry out a clinical trial in this area involved with the female reproductive organs. General practitioners or qualified medical personnel may be the only individuals permitted to carry out a pelvic exam for a vaginosis study; thus, highly qualified and—therefore expensive—employees would be required. The lab analysis associated with vaginosis can be difficult to carry out, as equipment can be scarce and expensive.



Clinical trials aimed at women's health can face challenges due to menstrual cycles and hormones.

Many research bodies and institutions deem it unjust and unfair to exclude pregnant women from clinical trials. However, it's rare to see medications and food supplements under investigation for pregnant women, even though it is common practice for women to consume supplements and medications prior to and during pregnancy; for example, the widespread use of folic acid in women trying to become pregnant and in the early stages of pregnancy to prevent neural tube defects. It's estimated the total percentage of women who take medications during pregnancy—either prescribed or over the-counter—currently ranges between 64 to 90 percent. A large number of food products and supplements aimed at pregnant women can be found in pharmacies and health care shops, with entire sections devoted to pregnant women alone. Thus, there is a requirement for information leaflets on

supplements and medications to include information for pregnant women. It seems the long-term effect of these supplements on women is null; however, there appears to be little research to conclude whether there is lasting effect on the child. There is outstanding research ongoing in the Cork area of Southern Ireland aimed at helping to reduce infant and maternal mortality and develop optimum nutrition and health for both mother and child.

We have found women show more of an interest than men when applying for clinical trials. This may be due to the fact women tend to take more interest in their health than men. It could also be argued, in some cases, women are more open about sharing their symptoms than men.

In many cases, clinical trials are carried out in men, and results are applied to pre- and postmenopausal women. This poses significant issues, as hormonal levels in a woman are significantly different pre- and post-menopause. An example of this can be seen in cardiovascular disease (CVD), which is the leading cause of death worldwide annually, according to the World Health Organization (WHO). The female sex hormones protect women from CVD onset pre-menopause. However, post menopause, the levels of those hormones diminish, and the woman is less protected against CVD. Women's symptoms of coronary artery disease tend to be more unusual than those recorded in male clinical trials in this area, and a delay in diagnosis can be observed which could cost women their lives. This is one crucial example of how important it is to remove gender bias in research.

More clinical trials are required in women. As there is never enough research published in any health area, the importance of continued research must be recognised for our understanding of healthcare to grow. If the evidence is clear that the differences in sex are clinically significant in clinical trials, we must apply this knowledge. It also cannot be denied there is a stigma associated with clinical trials investigating the female reproductive organs. There is also a reluctance for women to partake in clinical trials if they wish to become pregnant at a point in their lives, or if they are currently pregnant, due to concern over the health of their children. It can also be difficult for researchers, statisticians and medical professionals to account for the differences in men and women. Due to the cascade of hormones present in the female physiology, it can be easier for companies to include exclusively a male population. Thankfully, there are many researchers and companies who are devoting their time, efforts and almost entire careers to women's health, and excellent and ground-breaking research is published daily across all health areas. ●

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Takeaways for Your Business

A According to the Council for Responsible Nutrition 2017 Survey on Dietary Supplements, 50 percent of women reported taking dietary supplements, and cross-sectional studies in Europe confirm dietary supplement users are more likely to be women: 22.9 percent of those women were consistent supplement users, while a further 47 percent were inconsistent users. Depending on her age, a woman's needs vary greatly, and with such a wide range of changing health concerns across the lifespan, female supplement users are moving away from traditional multivitamin formats and choosing multiple, single-ingredient supplements to create their own personalised 'wellness formulas'.

European studies have found physically active women are more likely to use supplements consistently, and Mintel data indicates women are a key target group for sports nutrition; this suggests sports nutrition products tailored to female athletes that include specific additional ingredients for each life stage have great potential. Staying active well into later years is a priority for many ageing women, as maintaining good health into later years leads them to consider natural products and dietary supplements. Products could include protein powder with added resveratrol for postmenopausal women or added calcium, vitamin D and vitamin K2 for 20-something women.

Choosing personalised supplement regimes is indicative of the rise in clean label and free-from; consumers, especially well-informed and invested women, are looking to avoid unnecessary or unnatural ingredients, and choosing the 'cleanest' products to include in their lifestyles. Functional foods and beverages with the fewest ingredients and added functionality will resonate most with millennial women in particular. Data in the *British Journal of Nutrition* found educated women were the most likely to take dietary supplements, and this sector is the most likely to show consistent use, highlighting the importance of tailoring products to the life stages. As consumer education increases, women are taking note of the need to prevent later-life conditions including osteoporosis and skin ageing and are turning to dietary supplements throughout their lives. Younger women understand the need for calcium, phosphorus, magnesium and vitamin D to support bone mass development and cardiovascular health; while women reaching menopause realise the need to maintain bone mass and heart health and choose vitamin K2 to prevent bone density loss.

It is important to also consider women's health needs during pregnancy. As millennial women enter their 'peak reproductive years', the desire for clean label products increases, and supplements with enhanced delivery formats are popular. Research shows omega-3 supplementation during pregnancy could help reduce the incidence of food allergies in infants, while mothers who use probiotic supplements had a 22 percent reduction in the risk of eczema in their children. Manufacturers of prenatal products need to be aware there is no EU wide definition of 'prenatal nutrition' and nutritional recommendations differ at national level.

Data suggests women influence 70 to 80 percent of all household spending, while mothers are particularly discerning consumers and evaluate product labels most carefully. Today's female supplement user is proactive in seeking information and is increasingly educated on an ingredient's health benefits. ●



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