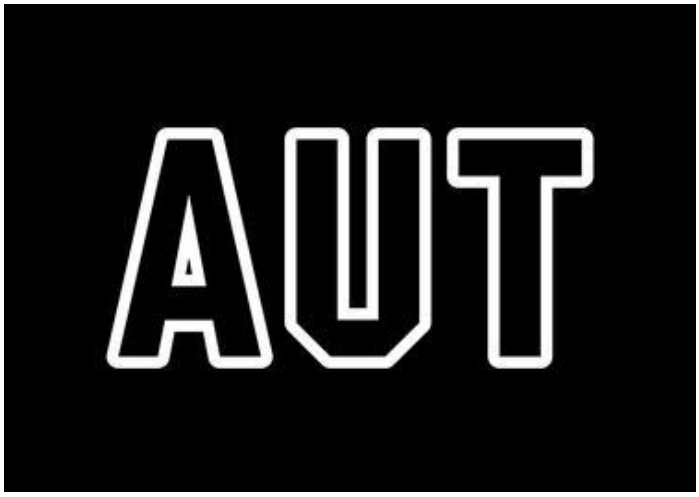

The Effect of a Menstrual Cycle Phase-Based Rehabilitation Programme for Females After Anterior Cruciate Ligament Reconstruction.

Emma O'Loughlin

A thesis submitted to Auckland University of Technology in fulfilment of the requirements for the degree of Doctor of Philosophy (PhD)

2023

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ABSTRACT

Anterior cruciate ligament (ACL) injury rates are rising in females in New Zealand and worldwide. It is well reported that females, overall, have inferior outcomes following rehabilitation compared to men. Specifically, females have reduced quadricep strength recovery as compared to men after anterior cruciate ligament reconstruction (ACLR). Recent research provides support for follicular phase (FP)-based resistance training (RT) for enhancing RT strength outcomes in eumenorrheic females. This research also recommends that, when possible, athletes with an ovulatory menstrual cycle (MC) focus on RT during the FP of their MC. This thesis is, therefore, focused on the development and the evaluation of a novel, MC phase-based rehabilitation (MCPBR) programme for females post ACLR.

In Chapter 2 via a scoping review, the first step was to establish what is known about MC phase-based RT in injured and non-injured females. The authors searched seven databases for primary studies or reviews describing MC phase-based RT programmes. Fourteen studies were included in the final analysis (eight primary studies). No studies were found that investigated MC phase-based RT in females post-ACLR. Studies were limited by methodological issues. However, the results suggest that MC phase-based training may influence outcomes pertinent to females post-ACLR. Furthermore, the results suggested that there is scope to investigate FP-based RT in females following ACLR.

However, it was unclear whether health professionals and athletes routinely and openly discuss this sometimes-sensitive topic in the sports medicine clinic, and if there would be barriers to discussing the MC in the sports medicine clinic. Therefore, Chapter 3 explored different members of the sports medicine community's knowledge, perceptions of, and comfort in discussing the MC. Focus group sessions were conducted with athletes, patients

post ACLR, physiotherapists, and orthopaedic surgeons. Overall, participants described the MC as 'a pertinent and evolving topic in the sports medicine clinic'. Whilst participants reported a dearth of education, perceived lack of MC knowledge, and some hesitancy with discussing the MC in the sports medicine clinic, the participants, specifically health professionals, described pragmatic approaches to tackle these barriers. They described developing trust, giving context, and being aware of athletes' concerns and sociocultural status as important when discussing the MC in the sports medicine clinic. Therefore, it was considered feasible to discuss the MC as part of a study investigating MC phase-based training in the sports medicine clinic.

In Chapter 4, a focus group methodology was also used to develop a novel MC phase-based ACLR rehabilitation (MCPBR) programme appropriate for testing on females following ACLR. Participants reported a preference for a consistent gym-based programme, however they need support from the physiotherapists to attend and engage. In addition, physiotherapists reported that strength is important but challenging to measure. Overall, input from these key stakeholders enabled the development of a new MCPBR programme.

In Chapter 5, a randomised controlled trial assessed the effectiveness of MCPBR versus UC on limb symmetry index (LSI) quadriceps maximum strength and self-reported lower limb function for females following ACLR. Forty one females participated in a 12-week intervention from six to 18 weeks post ACLR. Participants were randomly assigned to one of two groups: MCPBR or UC. Thirty eight females completed the trial, and a further four were excluded in post hoc analysis. Females were highly engaged with both MCBPR and UC. Participants had similar LSIs and self-reported function following MCPBR and UC at 18 weeks post ACLR. Overall, both groups achieved excellent limb symmetry and self-reported functional outcomes. Therefore, this thesis supports twice-weekly, supervised, gym-based

rehabilitation, with targeted quadriceps strengthening and regular strength testing for females following ACLR.

In conclusion, MCPBR and UC following ACLR rehabilitation in this study showed similar but positive results on knee strength and function at 18 weeks post operatively. Future research should investigate MCPBR in a larger cohort of females, including pre and post strength measures of both legs over a longer period. Similarly, it would be pertinent to understand female's experience of MCPBR post-ACLR. Furthermore, this thesis should assist health professionals and researchers in considering female-specific approaches that could improve outcomes for females post-ACLR. Future research should address the thesis limitations and build on the ideas presented in this thesis for a better understanding of the role of the MC hormonal fluctuations, sex-specific considerations, and female outcomes following ACLR.

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ATTESTATION OF AUTHORSHIP

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

18/05/2023

Signature Date

CO-AUTHORED WORKS

Manuscripts Published

1. O'Loughlin, E., Reid, D., & Sims, S. (2023). Discussing the menstrual cycle in the sports medicine clinic: Perspectives of orthopaedic surgeons, physiotherapists, athletes and patients. *Qualitative Research in Sport, Exercise & Health*, 15(1), 139-157. https://doi.org/10.1080/2159676X.2022.2111459
2. O'Loughlin, E., Reid, D., & Sims, S. (2022). Is there a role for menstrual cycle phased resistance training programmes for women post anterior cruciate ligament reconstruction? A scoping review protocol. *Physical Therapy Reviews*, *27*(3), 176-180. https://doi.org/10.1080/10833196.2021.2017613
3. O'Loughlin, E., Reid, D., & Sims, S. The development of a menstrual cycle phase-based rehabilitation programme for women post-anterior cruciate ligament reconstruction: a focus group study. *New Zealand Journal of Sports Medicine 2023;49(2):42-51.*

Manuscripts Accepted for Publication

1. O'Loughlin, E., Reid, D., & Sims, S. The role of menstrual cycle phase-based resistance training for women post anterior cruciate ligament reconstruction: a scoping review. *Physical Therapy Reviews*

Manuscripts Prepared for Submission

1. O'Loughlin, E., Reid, D., Sims, S., & Larsen, P. The effect of menstrual cycle phase-based rehabilitation for females following anterior cruciate ligament reconstruction: a randomised controlled trial. *Prepared for submission to British Journal of Sports Medicine.*

Peer-reviewed Conference Presentations

1. O'Loughlin, E., Reid, D., & Sims, S. (2022). Using focus groups to design and evaluate a rehabilitation programme for women post-anterior cruciate ligament reconstruction. *Proceedings of the Sports Medicine New Zealand Annual Conference.* (pp. 17). Dunedin, New Zealand: Sports Medicine New Zealand. [Abstract]
2. O'Loughlin, E., Reid, D., & Sims, S. (2022, May). *Discussing the menstrual cycle in the sports medicine clinic: Perspectives of orthopaedic surgeons, physiotherapists, athletes, and patients*. Verbal presentation at the British Association of Sport and Exercise Medicine (BASEM) Conference: Positive Health & Performance, Brighton, UK.
3. O'Loughlin, E., Reid, D., & Sims, S. (2022). Using focus groups to design and evaluate a rehabilitation programme for women post-anterior cruciate ligament reconstruction. *Proceedings of the Sports Medicine New Zealand Annual Conference.* (pp. 17). Dunedin, New Zealand: Sports Medicine New Zealand.
4. O'Loughlin, E., Reid, D., & Sims, S. (2021). Knowledge and attitudes to the menstrual cycle in the sports medicine environment: A qualitative study exploring the perceptions of orthopaedic surgeons, physiotherapists, female athletes, and ACL patients in Aotearoa. *New Zealand Journal of Sports Medicine*, *48*(2), (pp. 90-91).
5. O'Loughlin, E. (2021, June). *Menstrual cycle phased rehabilitation for females post ACLR reconstruction: Is it time to play to female strengths?* Verbal presentation at The Female Athlete Conference: Strategies for Health and Performance, Online.

<u>Conference Abstracts Submitted.</u>

1. O'Loughlin, E., Reid, D., Sims, S., & Larsen, P. The effect of menstrual cycle phase-based rehabilitation for females following anterior cruciate ligament reconstruction: a randomised controlled trial. *Abstract submitted to New Zealand*

Manipulative Physiotherapy Association Conference 2023, Rotorua, New Zealand.

STATEMENT OF CONTRIBUTION

Chapter Two

O'Loughlin, E., Reid, D., & Sims, S. (2022). Is there a role for menstrual cycle phased resistance training programmes for women post anterior cruciate ligament reconstruction? A scoping review protocol. *Physical Therapy Reviews*, *27*(3), 176-180. https://doi.org/10.1080/10833196.2021.2017613	Emma O'Loughlin: 80% Duncan Reid: 10% Stacy Sims: 10%
O'Loughlin, E., Reid, D., & Sims, S. The role of menstrual cycle phase-based resistance training for women post anterior cruciate ligament reconstruction: a scoping review. Accepted for publication *Physical Therapy Reviews*	Emma O'Loughlin: 80% Duncan Reid: 10% Stacy Sims: 10%

Chapter Three

O'Loughlin, E., Reid, D., & Sims, S. (2023). Discussing the menstrual cycle in the sports medicine clinic: Perspectives of orthopaedic surgeons, physiotherapists, athletes and patients. *Qualitative Research in Sport, Exercise & Health,* 15(1), 139-157. https://doi.org/10.1080/2159676X.2022.2111459	Emma O'Loughlin: 80% Duncan Reid: 10% Stacy Sims: 10%

Chapter Four

O'Loughlin, E., Reid, D., & Sims, S. The development of a menstrual cycle phase-based rehabilitation programme for women post-anterior cruciate ligament reconstruction: a focus group study. *New Zealand Journal of Sports Medicine, 2023;49(2):42-51.*	Emma O'Loughlin: 80% Duncan Reid: 10% Stacy Sims: 10%

Chapter Five

O'Loughlin, E., Reid, D., Sims, S, Larsen P. The effect of menstrual cycle phase-based rehabilitation for females following anterior cruciate ligament reconstruction: a randomised controlled trial.	Emma O'Loughlin: 75% Duncan Reid: 10% Stacy Sims: 10% Peter Larsen: 5%

We, the undersigned, hereby agree to the contribution percentages to the chapters identified above:

Emma O’Loughlin

Duncan Reid

Stacy Sims

Peter Larsen

ACKNOWLEDGEMENTS

This thesis section is dedicated to the people who have helped me along this PhD journey.

Firstly, thank you to Auckland University of Technology for providing me with the opportunity to complete my PhD degree. To Duncan and Stacy, I could not have asked for a better supervisory team to lead, support, encourage, and help me whenever needed. I have learnt so much from you both, and I will in the future emulate your style of leading projects and guiding others in the same way you have done for me. I hope this is not the end of our work together, and I look forward to collaborating on more projects in the future.

Duncan, my primary supervisor, thank you so much for the time you gave me over these three and a half years. Thank you, especially for all your emails, phone calls, energy, clarity, and feedback you have given me. You were always extremely positive, compassionate, and flexible when we needed to adapt. On another note, thank you for using your research fund to fund much of the project. For that, I am incredibly grateful. Thank you so much. Stacy, thank you for your time over the past three and a half years. Your knowledge and passion for women's health are inspiring, and I feel fortunate to have learned from you over this project. You have always been positive and provided well-needed encouragement, support, belief, and feedback regarding aspects of writing that I found difficult at times.

To the New Zealand Manipulative Physiotherapy Association, thank you so much for funding the focus group project and randomised controlled trial. This funding

enabled our research team to commence the trial and financed many participants' rehabilitation. In addition, to the clinical leaders in ACC, thank you so much for providing me support for my PhD fees over the past three years. Thank you for supporting the research idea and asking me to present my findings as the project progressed. It has been great to share the project process with the team.

I would also like to thank every surgeon who recruited for the trial, every physiotherapist who recruited for the trial and rehabilitated participants as part of the trial. Without you, there would have been no trial. You brought the trial to life with energy, enthusiasm, generosity of time, and caring towards the participants. I will be forever grateful. Furthermore, thank you so much to the women who stepped forward to participate in the trial. I understand it was a big commitment, and I appreciate all the time and energy you gave.

To Peter, thank you for agreeing to help with the RCT statistics and reading my thesis, despite your being sick with Covid(!). Also, thank you for employing me at the University of Otago two years ago. Your daily guidance, problem-solving, and overall presence helped me transition to academia and teaching. Your daily guiding chats are hugely appreciated. Thank you also to the rest of the University of Otago team for being so flexible and supportive.

Jon, thank you for taking care of me throughout this PhD process. Thank you for celebrating during the exciting times, supporting me when it seemed very difficult, and most often just listening when I would continually talk about the project! Secondly, thank you for being so relaxed that our lifestyle changed over the past year or more while I've been writing more and needing to stay home. Most recently, thank you for renovating our house and taking care of the day-to-day household

tasks while I've been working at my desk in the evenings. I am so excited for our next chapter.

Ma and Da, thank you for everything. Thank you for making me read a broadsheet newspaper every day since I was young, which gave me a curiosity about what was happening in the world and a love for reading. Thank you for letting me spend all my childhood money on books. Thanks for driving me to scouts, football, music, drama, and whatever else I wanted to attend growing up. These hobbies have helped me mature into the person I am and how I spend my time today. Thank you for helping me academically by paying for my extra lessons in Dublin and Newbridge when I was at school and supporting me through college. Thank you also for supporting me in moving to Singapore, Switzerland, and New Zealand. I love you both so much. To Hannah, thank you for all your support and help last year. Without you, I'm unsure how I would have gotten through my work and study. Grace and James, I love you both; thank you for your support and encouragement.

ETHICS APPROVALS

Chapter Three and Chapter Four

Ethical approval for this research was obtained from the Auckland University of Technology Ethics Committee (AUTEC); approval number 20/224. (Appendix 1)

Chapter Five

Ethical approval for this research was obtained from the Health and Disability Ethics Committee; approval number 21/CEN/92 (Appendix 2), and AUTEC; approval number 21/203 (Appendix 3). HDEC and AUTEC approved a change of advert for chapter five (Appendix 4 and 5).

ABBREVIATIONS

ACL: Anterior Cruciate Ligament

ACLR: Anterior Cruciate Ligament Reconstruction

FP: Follicular Phase

IKDC: International Knee Documentation Committee Subjective Knee Form

KOOS: The Knee Injury and Osteoarthritis Outcome Score

K-SES: Knee Self Efficacy Score

LP: Luteal Phase

LSI: Limb Symmetry Index

MCPBR: Menstrual Cycle Phase Based Rehabilitation

MC: Menstrual Cycle

OCP: Oral Contraceptive

PASS: Patient Acceptable Symptom State

PROMS: Patient Reported Outcome Measures

RM: Repetition Maximum

RT: Resistance Training

UC: Usual Care

LIST OF APPENDICES

CHAPTER 1: Introduction and Rationale

The Anterior Cruciate Ligament (ACL) & ACL injuries

The ACL is a key ligament within the knee joint with its main purpose to resist anterior tibial translation and rotational loads within the tibiofemoral joint (Duthon et al., 2006). The ACL provides stability and prevents anterior tibial subluxation of the medial and lateral tibiofemoral joints (Duthon et al., 2006). However, an ACL tear is one of the most common knee injuries (Cimino et al., 2010). Most ACL tears are a result of non-contact mechanisms such as sudden changes in direction causing the knee to rotate inward or decelerating while landing from a jump (Kobayashi et al., 2010; Koga et al., 2010). When the knee rotates inward, there is additional strain placed on the ACL (Shin et al., 2009). Therefore, it is no surprise that ACL injuries occur most often in athletes that participate in cutting and pivoting sports, including basketball, volleyball, soccer, netball, skiing, rugby, and Gaelic football (Gianotti et al., 2009; Magnussen et al., 2010).

Females and ACL injury

ACL injury rates are rising in females in the USA, Australia and New Zealand. (Mall et al., 2014; Sutherland et al., 2019; Zbrojkiewicz et al., 2018). Specifically, in New Zealand, the ACLR incidence in women has risen 120% over 10 years (Sutherland et al., 2019). This is similar to Australia, where ACLR increased by 91% between 2000 and 2015 for females under 25 (Zbrojkiewicz et al., 2018). It is also seen in the USA, where the greatest increase in ACL reconstruction (ACLR) incidence from 2002 to 2014 occurred in females aged 13 to 17 years (Herzog et al., 2018). This may be attributable to women playing more sport (Eime et al., 2021). In certain disciplines, such as basketball and soccer, women tear their ACLs at a much higher rate when compared to men; 3.5 times greater in basketball and 2.8 times greater in

soccer (Gornitzky et al., 2015). A recent study found that adolescent girls in particular have higher rates of ACL injury when compared with boys from 12 to 16 years old (Bloom et al., 2020). Extrinsic and intrinsic variables are key factors to this sex difference.

Intrinsic factors

There are intrinsic hormonal and biomechanical differences between male and female athletes (Lin et al., 2018). Specific to females are the cyclical hormonal changes across the menstrual cycle (MC). For eumenorrheic females, the MC is characterised by fluctuations in several hormones, most notably the gonadal steroids, oestrogen and progesterone, and is partitioned into the following phases: early follicular (menses), mid-follicular, late follicular, ovulation, early luteal, mid-luteal and late luteal phases (Fig. 1). The majority of MCs will fall in the midrange of cycle lengths (approximately 26–34 days) (Grieger & Norman, 2020). The first half of the MC is comprised by menses and the mid follicular phase (FP) during which time oestrogen levels are low (early follicular/menstrual) then rise (mid follicular), and peak (late follicular) and ends with the periovulatory phase in which follicular-stimulating hormone and luteinizing hormone reach peak concentrations. After ovulation, the second half of the cycle is comprised by the early luteal (during which time oestrogen level drops and then rises while progesterone rises), the mid-luteal (during which time oestrogen and progesterone levels peak), and finally, the late luteal phase (LP) (during which time oestrogen and progesterone levels fall). See Figure 1 and Table 1 for further information regarding MC hormonal fluctuations.

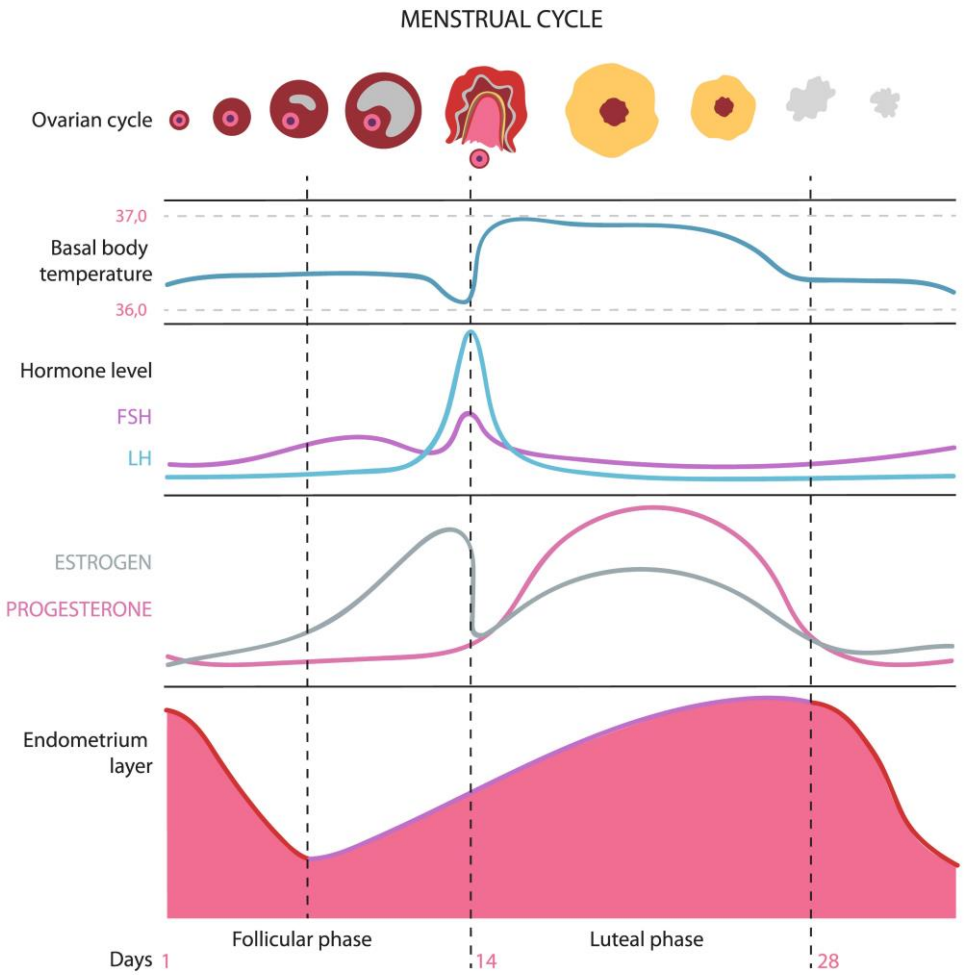

Figure 1. The menstrual cycle. Image used under license from Shutterstock.com using data from Stricker et al., Clin Chem Lab Med (2006);44(7):883–887.

A recent systematic review and meta-analysis reported an association between ACL injury and the ovulatory phase of the MC, compared to the FP of the MC (Herzberg et al., 2017). Similarly, a meta-analysis by Somerson et al. (2019) found that knee laxity had the greatest increase during ovulation. Periodic hormonal fluctuations oestrogen, progesterone, and relaxin have been proposed to cause ligament laxity or stiffness through collagen synthesis and tensile properties of the hormonal receptors on the ACL or through neuromuscular changes which may affect knee alignment (Dragoo et al., 2003).

Biomechanically, females have a narrower femoral intercondylar notch and smaller ACL (Anderson et al., 2001). Females have a larger Q angle (the angle between the patella and the anterior superior spine of pelvis) (Emami et al., 2007), and increased valgus knee position on landing (Mitani, 2017). Females have a greater quadriceps to hamstring strength ratio, leading to an increased generation of an anterior shear force at the knee (Ahmad et al., 2006). In addition, the female centre of mass is higher off the ground than males, and the addition of trunk mass after maturation, leads to the inability to precisely control the trunk in a three-dimensional space (Hewett et al., 2010). Many biomechanical models currently available have less than 50% female representation within their datasets (Norte et al., 2022). As a result, when using reference normative data from these models, caution should be applied when interpretating comparisons. Future investigations should consider matching sex, or consider sex specific biomechanical models (Norte et al., 2022). Furthermore, the results from a nationwide retrospective database study by Wang et al. (2023) demonstrate that significantly more adolescent girls underwent ACLR in the ages immediately following a growth spurt, which may be related to changes in both the physical and hormonal functions of the female body during this stage.

Extrinsic factors

Women may have unique life experiences compared to men, which may result in women experiencing different extrinsic factors which may influence ACL injury rates. For example, girls and boys may be exposed to different experiences as children, such as differences in playing time, which develops different physical skill sets, which may then create altered movement patterns when more mature. Adolescent girls stop playing sport earlier, and play organised sport less than boys, which may reduce the time the ACL is under load. In addition, gyms can be heavily gendered, which may disadvantage women's participation and their willingness to engage in resistance training (RT) (Fisher et al., 2017). These reduced opportunities for load

bearing are of interest as previous evidence has demonstrated that the structure of the ACL can positively change with loading (Myrick et al., 2019; Shultz et al., 2022). Moreover, recent research has demonstrated increased muscle soreness and self-reported physical fatigue for women than men throughout training (O'Leary et al., 2018). These sex differences in responses to high training loads could contribute to the greater rate of injury for females following periods of training. Therefore, overall there may be entanglement of intrinsic and extrinsic factors which may contribute to the higher rates of ACL injury for females (Parsons et al., 2021).

Sex and Gender

As described above, sex and gender can independently influence outcomes following ACL injury. Sex (female) and gender (woman) are two distinct concepts. "Female" generally refers to the distinction from males based on reproductively relevant differences in chromosomes, primary and secondary sex characteristics, and endogenous hormonal profiles (Canadian Institutes of Health Research, 2016). "Woman" is usually the self-perceived identity which is at least partly biologically based and inherent to a person; one's outward expression of one's gender identity - in terms of one's appearance and other behaviours. Woman also refers to the role one is expected to play in society based on one's sex or gender identity - the specifics of which can vary across sociocultural circumstances (Canadian Institutes of Health Research, 2016). Although both sex and gender are certainly relevant to the athletic and medical community at large, the specific issue of ACL injuries in this thesis will be better informed by a restriction to female sex and human sexual differentiation. Therefore, most often 'female' is used to describe sex specific considerations within this thesis. Where "woman/women" is used, it refers to studies in which participants self-identified their gender. However, it is acknowledged that there can often be interaction between sex and gender (Springer et al., 2012), and many examples of this are noted throughout the thesis. As some of the chapters have been previously published as pieces of individual work, there may be some

discrepancy between the published manuscripts and thesis' use of 'female' and 'woman' wording. These have been updated to ensure consistency within the thesis.

ACL rehabilitation pathway & outcomes

Following ACL injury, there are two traditional management pathways; 1) early ACLR surgery and rehabilitation, or 2) non operative management with the option of delayed ACLR if required (Beynnon et al., 2005; Risberg et al., 2004). Most ACL injuries in New Zealand undergo early ACLR surgery and rehabilitation (Fausett et al., 2019). Rehabilitation after ACL injury should always include a pre-operative phase, and criterion based postoperative phases. There are variations in the breakdown of phasing between many protocols, but post operative phases generally consist of an impairment phase, a return to function phase, and a return to play phase (Culvenor et al., 2022; Van Melick et al., 2016)(Figure 2).

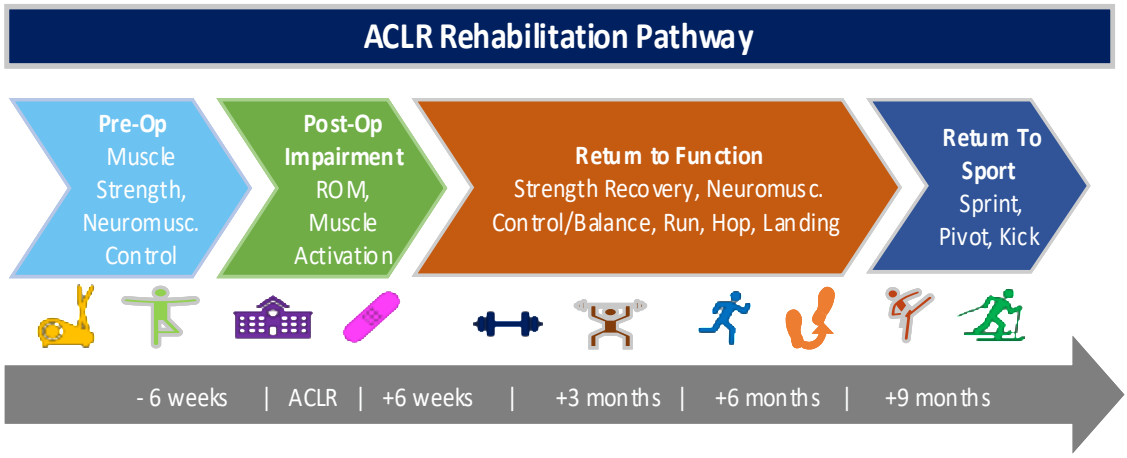

Figure 2. ACL rehabilitation process

Pre-operative rehabilitation consists of 3–6 weeks of muscle strengthening and neuromuscular control exercises to improve self-reported and physical function before ACLR. Following this, post ACLR, during the impairment phase, rehabilitation involves range of movement exercises to ensure equal range of movement of injured versus uninjured knee. In addition, throughout the impairment and sport

specific training phases, patients engage in strength training to achieve equal, or at least >90% equal strength, or symmetry, of strength between the injured and non-injured limbs (Van Melick et al., 2016; Whittaker et al., 2022). Recent consensus statements recommend isometric quadriceps strength exercises to commence one-week post operatively, with the use of neuromuscular electrical stimulation also recommended to improve quadriceps strength outcomes (Culvenor et al., 2022). Following this, three weeks after ACLR, eccentric quadriceps training is recommended to improve quadriceps strength recovery. Open versus closed kinetic chain exercises have been found to be similarly effective for quadriceps strength, self-reported function, and knee laxity and therefore both are recommended (Culvenor et al., 2022; Van Melick et al., 2016). However, there is a lack of high quality knee injury rehabilitation trial research, and therefore researchers and clinicians recommend using evidence based exercise training principles to prescribe exercise for ACLR patients (Culvenor et al., 2022). Therefore lower limb strengthening with high repetition low load exercises should be gradually replaced by low repetition, high load exercises to target hypertrophy and strength gains over time in line with in line with ACSM Position Stand Progression Models in RT for Healthy Adults (Culvenor et al., 2022; Kraemer et al., 2002; Van Melick et al., 2016). Neuromuscular and proprioceptive training, which address several aspects of sensorimotor function and functional stability to improve function and alleviate symptoms, are also recommended during this phase to optimise self-reported outcome measurements (Gokeler et al., 2017; Kruse et al., 2012).

Once the patient has reached their strength goals within the impairment phase, return to play training commences. Return to play rehabilitation includes interval training programmes, running patterns in football, sprinting, change of direction drills, pivoting, and kicking. The patient's readiness to return to sport should be assessed using a battery of tests including hop tests, strength tests, vertical jump

tests, and patient reported outcome measures (Capin et al., 2019). In addition, best practice rehabilitation following ACL injury should be a biopsychosocial rehabilitation programme which includes patient education and addresses psychological barriers (Ayers et al., 2013; Filbay & Grindem, 2019). It is important to note here, that in an ACLR rehabilitation setting, motivation also plays a pivotal role (Walker et al., 2020). Moreover, athletes who have undergone ACLR tend to achieve successful return to pre-injury sport when they exhibit elevated levels of motivation during rehabilitation (Sonesson et al., 2017).

It is important to state that females are under-represented in ACLR research and most ACLR rehabilitation evidence is based on findings from male data (56%–95% male participants throughout ACLR trials) (Culvenor et al., 2022; Mok et al., 2022). Considering research underpins recommendations for treatment and recovery, it is unsurprising that there are currently no female specific approaches or guidelines to specifically approach their rehabilitation (Filbay & Grindem, 2019; Van Melick et al., 2016; Whittaker et al., 2022). It is unknown how women engage throughout the rehab process, and how they specifically respond to ACL rehabilitation interventions. As previously mentioned, there are biomechanical, hormonal, and gendered factors which may be associated with the higher rates of ACL injuries in females, which may also be pertinent to consider within the rehabilitation environment.

Sex differences in outcomes post ACLR

Although it is unknown how women respond to specific rehabilitation interventions, it is well reported that women, overall, have inferior outcomes following rehabilitation compared to men (Beischer et al., 2019; Cristiani et al., 2020; Tan et al., 2016; Webster & Feller, 2017). A systematic review by Tan et. al (2016) concluded there

were comparable or inferior results for women compared to men in all outcomes studied in 135 studies. None of these 135 studies demonstrated results where men had poorer outcomes compared with women. It was also noted these inferior outcomes were irrespective of the graft choice (De Valk et al., 2013). Within these studies, women have greater anterior-posterior laxity after ACLR in clinical examination and instrumented testing (Paterno et al., 2012). Secondly, women report higher levels of self-reported locking, instability, pain and swelling, and inferior pre- to post-operative self-reported activity levels (Tan et al., 2016). This is in line with women's noted bilateral quadriceps weakness and slower rate of quadriceps' torque development compared to men (Kuenze, Lisee, et al., 2019). It is also not surprising that in the longer term, less women return to sport and those who do return, do so after more time than men (Ardern et al., 2014; Tan et al., 2016). However, in contrast, data is conflicting regarding the ACL re-injury rate; the ACL injury rate is higher for females compared to males in some data, but not all (Nawasreh, Logerstedt, et al., 2018). Women are however, more likely to injure their contralateral leg following initial ACL injury compared to males (Nawasreh, Adams, et al., 2018).

Quadricep strength recovery importance

It is known that women post-ACLR have reduced quadriceps strength recovery and worse self-reported knee related function compared to men (Kuenze, Pietrosimone, et al., 2019; Maguire et al., 2021). Recent literature examined the effect of patient demographics on quadriceps strength, rate of torque development and knee function in the first year following ACLR (Kuenze, Lisee, et al., 2019). Near equal numbers of males and females were examined (29 versus 31) and it was reported that females displayed bilateral quadriceps weakness and slower rate of torque development of the involved limb quadriceps compared to males of similar demographics and time since surgery (Kuenze, Pietrosimone, et al., 2019).

Similarly, Kuenze et al. examined 230 athletes (146 male and 162 female) and determined that females demonstrate significant quadriceps weakness in the involved limb and diminished quadriceps strength symmetry during the first 12 months following ACLR (Kuenze, Pietrosimone, et al., 2019). Similarly, in the presence of quadriceps dysfunction, female participants experienced greater-magnitude reductions in quadriceps function after 30 minutes of exercise than male participants, which indicates a reduced ability for females to absorb knee-joint loads (Kuenze et al., 2014). Patients with ACL injury suffer from quadriceps strength deficit due to disuse atrophy or arthrogenic muscle inhibition (Pietrosimone et al., 2022; Thomas et al., 2016). These results may indicate a potential sex difference in the quadriceps structural response to ACLR that may be leading to disparities in quadriceps strength and torque (Kuenze, Lisee, et al., 2019). The authors suggested that these differences may also be influenced by the pre-surgical levels of quadriceps strength present in males and females (Kuenze, Pietrosimone, et al., 2019).

These quadriceps deficits are of particular importance because, firstly, much evidence has reported an association between reduced quadriceps strength and poor self-reported function and functional performance (Schmitt et al., 2012). Secondly, reduced quadriceps strength has been known to put ACLR athletes at a higher risk of further subsequent ACL injuries (Grindem et al., 2016). Finally, of more concern, persistent quadriceps weakness after ACLR has been linked to early-onset post-traumatic osteoarthritis (Palmieri-Smith & Thomas, 2009; Wang et al., 2020). The quadriceps distribute load across the articular surface and stabilize the knee joint, working as shock absorbers and dynamic stabilizers (Abulhasan & Grey, 2017). This quadriceps weakness may alter loading at the joint, which may commence a process of degeneration (Jeon et al., 2017; Thomas et al., 2017). This

is of concern as knee osteoarthritis can lead to significant levels of pain and mobility disability (Vos et al., 2012).

Therefore, considering their weak bilateral quadriceps post operatively, it is specifically recommended for women to engage in targeted rehabilitation to restore quadriceps muscle size and enhance quadriceps neural drive in ACLR patients (Kuenze, Lisee, et al., 2019). Specific approaches that have been recommended and are evidence based include heavy strength training and eccentric exercises (Kuenze, Lisee, et al., 2019). Both of these approaches have been shown to increase muscle hypertrophy and enhance neural drive to the quadriceps (Aagaard et al., 2002). As it is a bilateral problem, bilateral quadriceps strengthening programmes are recommended (Kuenze, Lisee, et al., 2019).

Resistance Training & Hormone Effects

Overall, females need to engage in high quality RT post ACLR to stimulate quadriceps strength recovery post ACLR. Resistance exercise stimulates muscular adaptation by commencing the process of muscular damage, inflammation, leukocyte infiltration, activation and proliferation of muscle satellite cells, repair signalling, collagen synthesis, and consequent muscle repair (Hackney, 2017; Tidball, 2005). The individual response to resistance exercise and the subsequent sequelae including muscle fibre breakdown and repair depends on diet, sleep, training status and hormone responses (Tidball, 2005). These acute hormone responses include changes in testosterone, growth hormone, dehydroepiandrosterone sulfate (DHEA), and insulin-like growth factor-1 (IGF-1) (Consitt et al., 2002; Hackney, 2017). In addition, for females specifically, the sex hormones oestrogen and progesterone play a role in muscle recovery and repair following resistance exercise (Hackney, 2017).

Oestrogen refers to a group of similarly structured steroid hormones made up of estrone (E1), estriol (E3), and 17-β-oestradiol (E2) (Wierman, 2007). Estrone and estriol are mostly produced locally in target tissue such as adipose cells whereas oestradiol-β-17 is primarily produced at the ovaries. E2 is the specific hormone responsible for primary and secondary female sex characteristics, and therefore is the main oestrogen referred to in this thesis. These oestrogens have many physiological roles, but specifically, oestradiol is known to have an anabolic effect on muscle by increasing satellite cells and reducing oxidative stress following RT(Oosthuyse et al., 2022).

Progesterone is the second major reproductive hormone for females. Progesterone is the major progestogen and is produced predominately by the ovaries, but it is also produced locally in some tissues (Hackney, 2017). However, in contrast to oestradiol, progesterone supresses oestrogen's satellite cell activation in response to resistance training, promotes protein oxidisation, and is thought to be catabolic (Lamont et al., 1978; Oosthuyse et al., 2022).

The Menstrual Cycle & MC Phase-Based Resistance Training

Both oestrogen and progesterone are released from the ovary as a result of the hypothalamic-pituitary-ovarian (HPO) axis (Hackney, 2017). Initially, gonadotropin-releasing hormone is released by the hypothalamus into the blood stream and travels to the pituitary gland. Subsequently, the pituitary gland releases gonadotropin hormones luteinizing hormone and follicle stimulating hormone in females. Following this, FSH and LH then bind to their respective ovarian receptors, which initiates the production and secretion of both oestrogen and progesterone in

predicable volumes across each MC in naturally cycling females (Filicori, 1999; Hillier, 1987) (see Figure 1). As mentioned previously, hormonally, the MC consists of several distinct phases with different hormonal profiles (see Figure 1 & Table 1) (Stricker et al., 2006). Subsequently, these different hormonal profiles and the antagonist relationship of oestrogen and progesterone affect women's responses to muscle strengthening and hypertrophy effects over the course of this monthly MC (Kreamer et al., 1995; Markofski & Braun, 2014; Oosthuyse et al., 2022).

Table 1. Oestrogen and progesterone reference values throughout the menstrual cycle.

Menstrual cycle phase:	Early Follicular	Mid - Follicular	Ovulatory	Mid Luteal	Late Luteal
Oestrogen	149.74	450.49	671.06	495.85	327.36
Progesterone	0.64	0.64	2.54	14.63	13.99

References values from Stricker et al. (2006). "Establishment of detailed reference values for luteinizing hormone, follicle stimulating hormone, estradiol, and progesterone during different phases of the menstrual cycle on the Abbott ARCHITECT analyzer". Clin Chem Lab Med 2006;44(7):883–887

Recent research has demonstrated oestrogens influence over the satellite cell response to exercise induced muscle damage is more noticeable during the mid FP compared with the mid LP after unilateral eccentric knee extensor exercise (Haines et al., 2018). Specifically, these authors found oestrogen receptor muscle content and oestrogen receptor DNA binding after exercise to be greater in the mid follicular than mid luteal phase (Haines et al., 2018). In addition, the increase in expression of myoblast determination protein (Myo-D), which regulates muscle differentiation and reflects satellite cell activation, was significantly greater in the mid FP than mid LP after eccentric exercise (Haines et al., 2018). In this study, serum oestrogen concentration was similar between mid-follicular and mid luteal phases. Therefore, the noted difference in oestrogen receptor and satellite cell activity occurred without a difference in muscle oestrogen concentration. This suggests that progesterone, present in the mid LP, suppressed oestrogen satellite cell engagement and muscle

regeneration following exercise induced muscle damage (Oosthuyse et al., 2022). This progesterone antagonism of oestrogen is thought to be due to inhibition of oestrogen receptor expression and protein content (Ekenros et al., 2017; Jayaraman & Pike, 2009).

Therefore, considering this superior response to resistance exercise in the FP, it would appear possible that training programs for eumenorrheic women could be timed in accordance with the MC to maximize anabolic effects. Studies have investigated this concept, by investigating RT programmes where the weekly frequency of RT is increased in the FP (FP-based training), as compared to increased frequency of training sessions in the LP (LP-based training), or equal numbers of training sessions per week (regular training) (Figure 3). Researchers have demonstrated greater muscle strength gain, greater muscle diameter gain, and an increase in the nuclei to fibre ratio in the limb trained in the FP, which suggests superior satellite cell recruitment in the FP. Other studies, but not all, have demonstrated increased strength outcomes for females participating in FP-based RT programmes (Reis et al., 1995; Sakamaki-Sunaga et al., 2016; Wikström-Frisén et al., 2017). Considering the overall research available, whilst noting the methodological limitations and small sample sizes of previous studies, recent systematic and expert reviews concluded that the very limited research to date suggests that follicular-phase-based RT may be beneficial to improve strength outcomes for females. They recommended that, based on the evidence currently available, athletes should periodize their strength training sessions in the FP to benefit from greater muscle strength gains likely owing to oestrogen activation of satellite cells that is supressed by progesterone in the LP (Oosthuyse et al., 2022; Thompson et al., 2020) (see Figure 3). These reviews also recommend that further high quality research trials are needed.

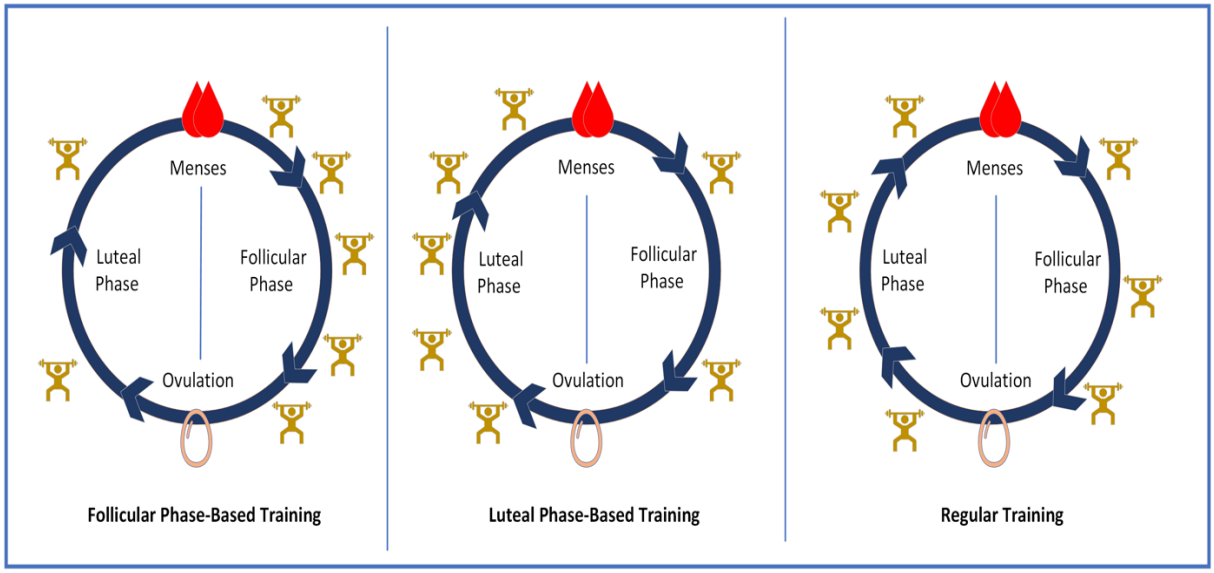

Figure 3. Menstrual cycle phase-based resistance training.

Menstrual Cycle Tracking Methods

To carry out MC phase-based RT, accurate identification and verification of each new MC, ovulation, and when the female is in the correct MC phase is necessary. Firstly, each new MC, the early FP, is easily identified by the onset of menstruation. Therefore, calendar tracking, whereby individuals keep a record of the start and end dates of each menstrual period on a calendar or in a dedicated MC tracking app or journal, works well for this task, and has been used historically (Prior et al., 1986). There is minimal cost and participation burden for the calendar tracking method. However, calendar tracking does not provide insight into length of different menstrual phases, ovulation, or luteal function. Ovulation prediction kits identify luteinising hormone in urine samples, and predict that ovulation will occur in the next 24 hours (Guida et al., 1999). Basal body temperature testing can also identify ovulation. Basal body temperature refers to the body's resting temperature, which is typically taken in the morning before getting out of bed, eating, drinking, or engaging in any physical activity. Basal body temperature is influenced by hormonal changes, particularly the rise in progesterone that occurs after ovulation. Therefore, after ovulation, there is a noticeable increase in basal body temperature due to the influence of progesterone. Basal body temperature testing has a moderate level of

burden on the participant and has minimal cost, but has a failure rate of approximately 20% (Moghissi, 1976). Overall, in isolation, these methods may have significant limitations, especially for active females, who may experience anovulation or LP deficiency (Wideman et al., 2013).

Direct methods such as ultrasound, biopsies and frequent measures of blood serum ovarian hormone concentrations can identify follicular and luteal menstrual phases (Ecochard et al., 2001; Elliot Sale et al., 2021). These methods are valid & reliable; however these methods are time-consuming, costly and invasive. Thus, these methods may increase the timescale of sports and exercise studies to recruit participants, and they may increase study costs (Elliot Sale et al., 2021). Subsequently, recent research recommends a three-step method comprising MC mapping (to confirm a new cycle), home urinary ovulation prediction testing (to confirm ovulation), and a once monthly serum plasma hormone measurement (to confirm the mid LP progesterone peak) (Schaumberg et al., 2017). The serum plasma measurement is recommended seven to nine days following positive ovulation prediction testing, or 20–22days following onset of menstruation, to confirm mid LP progesterone. Once LP deficient participants are excluded, the method is successful 90% of the time in normally-menstruating women. Therefore, this is the recommended three step method for sports medicine research.

However, it is unclear whether these three step guidelines, which still include costly blood serum verification are practicable in a sports medicine environment. On balance, with MC verification methods, there is a need to consider accuracy, cost and participant burden when designing a research trial (Allen et al., 2016; Elliot Sale et al., 2021). Furthermore, more recently, mobile phone applications, using provider

inputted data and machine learning artificial intelligence, track MC phases, and may be an option for future research trials (Bull et al., 2019).

MC Phase-Based Training in the ACLR Rehabilitation Environment

Currently, it is unknown whether FP-based RT has been trialled within an ACLR rehabilitation context. Females carrying out RT following ACLR would benefit from improved strength outcomes from RT and their quadriceps musculature would respond in a similar manner to strength stimuli across the MC. This training therefore has potential to improve strength recovery outcomes during rehabilitation. However, carrying out this type of training following ACLR would require physiotherapists and athletes to understand MC phases and MC tracking. However, it is unknown what knowledge physiotherapists, female athletes and women post ACLR have of the MC. Similarly, this type of training would require the physiotherapist and athlete to discuss MC phases in the sports medicine clinic to periodise exercise based on their individual patient's MC phase. it is unknown whether doctors, physiotherapists, and athletes currently discuss, or are comfortable discussing the MC in clinic. The MC can be a sensitive topic, and previous research within New Zealand, and internationally shows that the MC can be considered a social stigma, and is taboo with sports settings (Schofield et al., 2021; Thorpe et al., 2020).

Furthermore, females are not just their hormones, and may have particular preferences for a newly designed rehabilitation programme designed for them – i.e. gym or home based (Parsons et al., 2021). Physiotherapists and sports/orthopaedic doctors may have concerns or ideas for such an approach to be considered within their treatment environment. Therefore, any MC phase-based RT programme, adapted to the ACLR rehabilitation would need consultation with relevant

stakeholders including ACLR patients, athletes in high-risk sports, physiotherapists, and sports medicine doctors.

Variations

However, it is important to note that this type of training would not be appropriate for all females post ACLR. Women using oral contraceptive pills (OCP)s will not have natural MC hormonal fluctuations. OCP use down-regulates endogenous oestrogen and progesterone synthesis so the hormonal fluctuations across the MC are significantly more subtle, and the OCP replaces endogenous hormones with considerably reduced levels of oestrogen and progesterone circulating in the blood (Elliott-Sale et al., 2013). The OCP down regulates endogenous through several inhibitory feedback mechanisms. The synthetic progestogen prevents the hypothalamus from releasing GnRH and the pituitary from releasing LH and FSH; therefore, it prevents the ovarian cycle from entering the menstrual phase and prevents follicle development and ovulation. The withdrawal bleeding these women experience is not a physiologic menstrual period (Sulak et al., 1997). This withdrawal bleed occurs due to the drop in exogenous hormone levels which causes the endometrium to shed and it is not indicative of hormone interactions (Sulak et al., 1997). Furthermore, OCPs increase oxidative stress and inflammatory responses which may inhibit adaptations to workloads (Bozzini et al., 2021).

The New Zealand Health Survey 2014/15 reported 26.3% of females who had sex in the previous four weeks used the OCP. However, in addition, seven per cent of females were using an intrauterine device (IUD) (Ministry of Health, 2019). Two types of IUDs are available: copper-containing and hormonal (slow-release progestin). Both IUDs work by preventing fertilisation. Copper IUDs do not affect a females' endogenous hormone cycle and therefore this type of training may be

appropriate for these women. As the progestin amount is relatively small in hormonal IUDs, many females using a hormonal IUD will have a natural ovulatory MC and associated hormonal fluctuations. Similarly, individual variations occur frequently within and between a woman's own MCs. it is noted that even though MCs usually have FP, ovulation and LPs as mentioned above, many athletes may have a shortened LP due to insufficient progesterone exposure to maintain a normal secretory endometrium (Balasch et al., 1985; De Souza, 2003; McNeely & Soules, 1988).

Purpose of research

Therefore, the overall purpose of this research was to establish the effect of a female-specific, MC phase based, ACLR rehabilitation programme on strength recovery and self- reported functional outcomes for females after ACLR. The primary hypothesis was that the intervention group will achieve a greater quadriceps strength recovery following FP-based RT programme, as part of rehabilitation, compared to the control group. The secondary hypothesis was that the intervention group will have greater self-reported functional outcome changes compared to the control group. The thesis had four sub aims which together, formed the overall purpose.

Sub aims:

- Review the available evidence regarding MC phase-based RT programmes and establish if there is a role for MC phase-based RT for females post ACLR.
- Explore key stakeholders' knowledge of the MC, establish whether they discuss the MC, and explore how comfortable they are discussing the MC in the sports medicine environment.

- Establish what aspects of current ACLR rehabilitation work well for females, and their preferences for adapting a MC phase-based RT approach for the rehabilitation environment; to inform the design of a MCPBR programme for women after ACLR.
- Evaluate the effect of MC phase based strengthening rehabilitation programme on maximum isometric knee strength and self-reported knee function for females post ACLR.

Significance of research

The results of this research are beneficial to ACL rehabilitation and female exercise physiology research in New Zealand and internationally. Firstly, this thesis provided a detailed picture of MC phase-based resistance training, whether this had been studied before, whether there was a role to investigate this in ACL populations. This research was the first to review the methodologies of current MC phase-based RT programmes whilst considering if their design was suited to an ACLR rehabilitation environment.

Secondly, the thesis explored health professionals and female's knowledge about the MC, and how comfortable they were talking about the cycle. There has been a proliferation of MC related sports medicine and performance research regarding heavy menstrual bleeding (Bruinvels et al., 2016), relative energy deficiency in sport (Mountjoy et al., 2018), MC tracking (Heather et al., 2021), and menopause symptoms (Capel-Alcaraz et al., 2023). However, it was unknown whether any of the clinical recommendations from this research were being spoken about in the sports medicine clinic within New Zealand. The discussion of one's MC depends on health professionals and non-health professionals' knowledge, perceptions and comfort initiating and partaking in discourse regarding the cycle. Understanding

different members of the sports medicine community's knowledge and comfort discussing the cycle helped understand the extent to which they discuss these issues in clinic. Therefore, this understanding also offered scope to recommend practical approaches to enable unrestricted conversations about the MC in clinic.

Thirdly, this thesis benefits the ACL research literature by providing an insight into women's preferences for ACL rehabilitation programmes. The specific contexts of women's lives may create different possibilities and restrictions to engage and complete ACLR rehabilitation (Parsons et al., 2021). This study specifically recruited women post ACLR to draw upon their perspectives as to their preferences and specific requests for a newly designed ACLR rehabilitation programme. Secondly, this co-design approach to development of a new approach ensures this programme met the needs of physiotherapists and surgeons. To the authors knowledge, this is the first time key stakeholders developed a MC phase based programme, designed to utilise female sex hormone fluctuations, to recover better from rehabilitation exercises. The results of this informed not only a MC specific programmes, but also provides insight to inform other future rehabilitation trials regarding women specific preferences for rehabilitation.

Fourthly, this thesis provided data regarding the effectiveness of MC phase-based RT to improve maximum quadriceps strength and self-reported functional outcomes for females. Females are under-represented in ACLR research and most ACLR rehabilitation evidence is based on findings from male data (Bruder et al., 2023; Tan et al., 2016). To the best of the author's knowledge, there are no female specific approaches to rehabilitation currently (Culvenor et al., 2022). Therefore, this study provided much needed data regarding the effect of specific interventions and rehab approaches for women post ACLR. In addition, these results may be applicable to

other areas; for example, building rotator cuff muscle strength following rotator cuff surgery or hamstring muscle strength following a muscle tendon injury.

Structure of the thesis

The project was divided into three sections to answer the overall research question (see Figure 4). The PhD used quantitative and qualitative methodology and followed a thesis by publication pathway. Firstly, Chapter 2 provides an overview of what has been studied previously in terms of MC phase-based resistance training, and why it should be applied to females undergoing ACLR rehabilitation. An overview of current research methods, designs, and results regarding the topic is included. Chapter 3 establishes physiotherapists, sports/orthopaedic doctors, ACLR patients and athletes' knowledge of the MC. It also establishes how regularly they discuss the MC in clinic, and how comfortable they are discussing this topic in clinic. Thirdly, Chapter 4 also uses qualitative research methods to identify pertinent themes via focus groups interviews with health professionals, ACLR patients and female athletes. These stakeholders outline how to adapt a MC phase-based training programme to an ACLR environment, in line with key stakeholders' preferences. This feedback assists with final design for the main study, ensures the best pragmatic approach, and improves compliance.

Subsequently, Chapter 5 outlines the effects of a MCPBR programme on strength outcomes and self-reported function for women post ACLR. Quantitative research methods are used here to evaluate this multi-centre randomised controlled trial. Chapter 6 outlines a summary and discussion of the results from the above three studies, and advises practical implications, limitations, and future research directions for the trial. Chapter 2 part i is published in Physical Therapy Reviews, Chapter 2 part ii is submitted to Physical Therapy Reviews. Chapter 3 is published in

Qualitative Research in Sport, Exercise and Health, and Chapter 4 is published in New Zealand Journal of Sports Medicine. Each chapter commences with a brief prelude that provides clear links between the different chapters, which form a consecutive, coherent thesis. As this thesis uses a publication pathway, there is repetition expected between chapters.

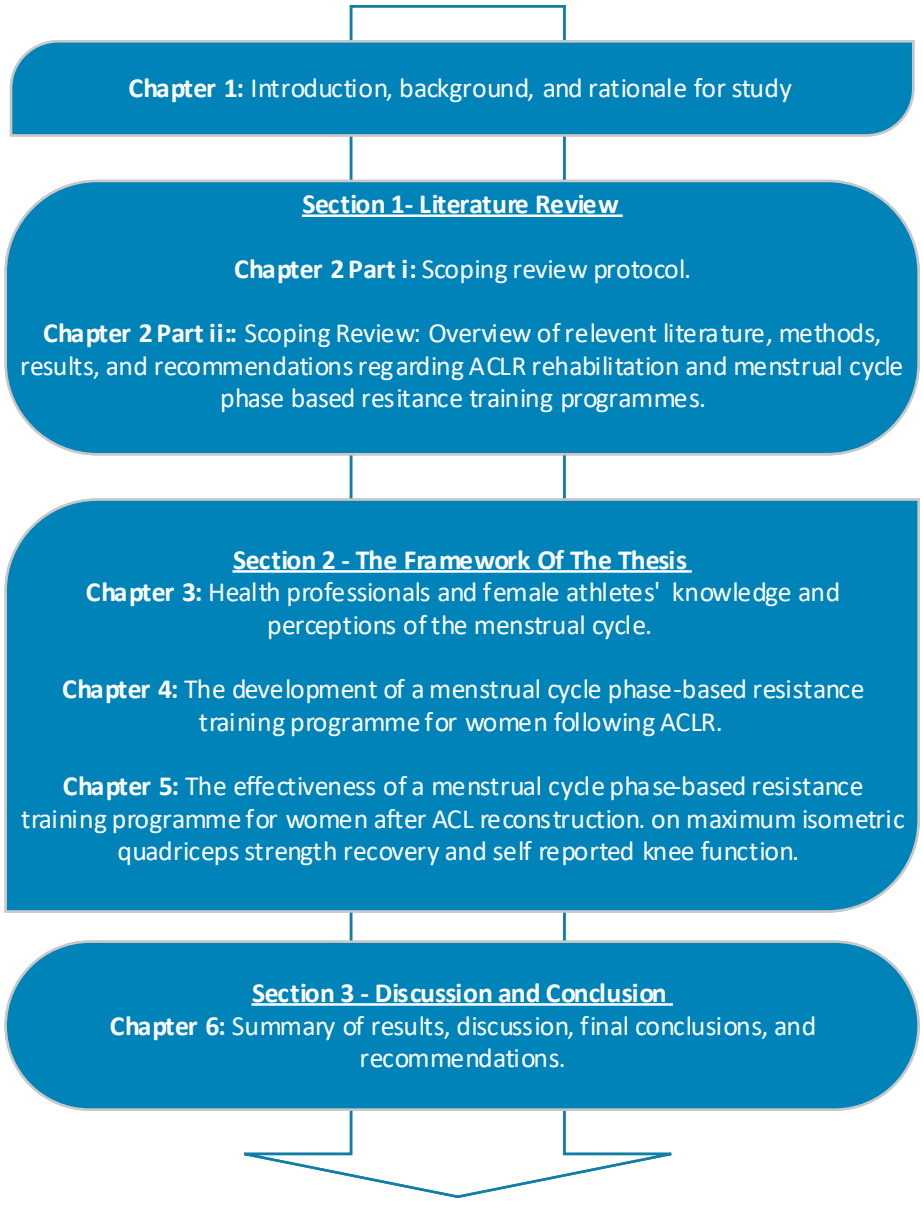

Figure 4. An overview of thesis structure

SECTION 1: LITERATURE REVIEW

CHAPTER 2: Is there a role for menstrual cycle phased resistance training programmes for females post anterior cruciate ligament reconstruction? A scoping review protocol & scoping review

Part i: A scoping review protocol

This first section of the chapter contains the following paper published in *Physical Therapy Reviews.*

Reference

O'Loughlin, E., Reid, D., & Sims, S. (2022). Is there a role for menstrual cycle phased resistance training programmes for women post anterior cruciate ligament reconstruction? A scoping review protocol. *Physical Therapy Reviews*, *27*(3), 176-180. doi: 10.1080/10833196.2021.2017613

Prelude

As discussed in chapter one, females need to engage in effective quadriceps RT programmes following ACLR. Recent research has supported FP-based RT for enhancing RT strength outcomes in eumenorrheic females. It is unclear whether research had investigated MC phased RT programs in eumenorrheic females post-ACLR or whether there was a gap for further research in this area. This scoping review protocol planned the design of the scoping review.

Introduction

Injury to the anterior cruciate ligament (ACL) of the knee is common in an active population (Gianotti et al., 2009). There has been an increase in the number of ACL injuries in female athletes, which may be linked to females' increased participation in sports (Mall et al., 2014). Quadriceps weakness is common among those with ACL

reconstruction (ACLR) (Thomas et al., 2015). Reduced quadriceps strength is associated with poor self-reported function and functional performance (Schmitt et al., 2012) and a higher risk of subsequent ACL injuries (Grindem et al., 2016). Females have reduced quadriceps strength recovery post ACLR despite similar age, time since surgery, pre-injury activity level, and graft source compared to men (Kuenze et al., 2014). Recent consensus statements recommend progressive quadriceps resistance training (RT) programmes to commence six weeks post ACLR to target these strength deficits (Adams et al., 2012; Van Melick et al., 2016).

These post-operative RT programmes provide a stimulus for quadriceps muscular adaptation. Many mechanisms mediate muscular adaptation, including the type of exercise completed, patient's nutrition, sleep, and acute and chronic hormonal responses to RT (Douglas et al., 2017; Hawley et al., 2011; Lamon et al., 2021). Hormonally, in naturally cycling females, despite intra- and inter-individual variation (Rocha-Rodrigues et al., 2021), the steroid hormones oestrogen and progesterone fluctuate fairly predictably throughout the menstrual cycle (MC). Oestrogen is known to have an anabolic effect on skeletal muscle (Lowe et al., 2010) and can affect mood (Le et al., 2020). In contrast, progesterone has been shown to oppose oestrogen (Frankovich & Lebrun, 2000), and is thought to be catabolic (break down substances within the body) (Kriengsinyos et al., 2004).

Previous research has investigated these hormonal fluctuations' chronic effects on muscular adaptation (Reis et al., 1995; Sung et al., 2014). Studies have investigated follicular phase (FP)-based training, where women track their MCs and carry out a higher frequency of RT in their FP. FP-based training targets RT skeletal muscle responses when oestrogen levels are rising and progesterone is low. A recent systematic review, whilst noting methodological limitations and small sample sizes of previous studies, provided support for FP-based training for enhancing RT

strength outcomes in eumenorrheic females (Thompson et al., 2020). The review also recommended that, when possible, athletes with an ovulatory MC focus on RT during the FP of their MC.

However, this review did not include injured participants or discuss recommendations for MC phase-based approaches for female athletes completing RT programmes as part of post-operative rehabilitation programmes. Therefore, it is unclear from the literature whether previous research has investigated MC phased RT programmes in females post ACLR. It is also unclear whether the methodologies and effects of MC phased RT programmes with non-injured participants are transferable or applicable to females post ACLR. Given females' need for maximum quadricep strength improvements post ACLR, it would be pertinent to investigate whether MC phased RT programmes may be warranted to research in this population.

For these reasons, a scoping review was proposed to establish what is known in the literature in this area, identify any existing gaps in knowledge, and propose future research. A scoping review was deemed most appropriate here as scoping reviews are exploratory and aim to map key concepts underpinning a complex research area (Mays et al., 2001).

Plan for Scoping Review: Review question

The overarching research question was: Is there a role for MC phased RT programmes for females post ACLR?

More specifically, the review aimed to address the following questions:

(1) Have MC phased RT programmes been investigated in females post ACLR?
(2) What is known about the methodologies of MC phased RT programmes?

(3) What is known about MC phased RT effects on strength outcomes and motivation for training?
(4) Do these findings provide a gap for future experimental studies in an ACLR rehabilitation context?

Materials and Methods

Plan for Scoping Review: Eligibility Criteria

Participants must have been pre-menopausal women of any age (injured or non-injured). Similarly, the review included studies which investigated both MC phase-based RT and oral contraceptive pill (OCP) phase–based RT (i.e., exercises periodized to the sugar pill week versus the rest of the month). These studies were included as they provide information regarding MC phase-based training (Wikström-Frisén et al., 2017). Included studies must have reported outcomes following a MC phase-based RT programme, whereby females carried out a higher frequency of RT in a particular phase of the MC. The programme must have been at least one MC length of 28-40 days duration. RT programmes may have been completed in rehabilitation gyms, commercial gyms, laboratory settings, or home-based gyms. The review included MC phased training versus OCP phased training comparisons as these may provide insights into the conduct and effects of MC phased strengthening and inform future research, in line with this review aim. The review excluded OCP versus OCP comparisons as these did not examine MC phased RT or align with the research aims.

This scoping review considered designs including primary research studies (cross-sectional, longitudinal design, intervention, or pre-post measures). In addition, the review included narrative reviews, systematic reviews, scoping reviews and meta-analyses describing methodologies or effects of a MC phase-based RT programme. All included studies were published in peer-reviewed academic journals. Studies

must also had to have been published in English to be reviewed by the researcher and assessed for suitability. The review did not use date restrictions. The review excluded evidence types, including guidelines, dissertations and editorials, opinion pieces, magazine and newspaper articles, and unpublished trials.

The research team conducted the proposed scoping review following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for scoping reviews (Tricco et al., 2018) and the Joanna Briggs Institution review manual (Peters et al., 2021) based on the original scoping review methodology with five stages as described by Arksey and O'Malley (2005). This scoping review protocol was registered on the Open Science Framework (https://doi.org/10.17605/OSF.IO/9FNJP).

Plan for Scoping Review: Search strategy

The research team developed a four-step search strategy in consultation with a librarian knowledgeable in medical science. Initially, in March 2020, the research team and an experienced librarian performed a pilot test of study selection procedures. This exercise tested the literature search strategy and proposed study selection criteria. The primary researcher and an experienced librarian conducted three electronic database searches on 18th March 2020 for studies investigating MC phased RT programmes for females following ACLR or any orthopaedic injury (Appendix 30). Zero studies met the criteria after abstract review.

Consequently, the search strategy was informed to include studies examining MC phased RT programmes in non-injured women, in line with the iterative process of a scoping review (Arksey & O'Malley, 2005). The second step was to conduct a search across five databases using the refined search strategy. The databases

searched were EBSCO Health Database (CINAHL, Medline, SportsDiscus), Web of Science, Scopus, Google Scholar and the Cochrane Library. Thirdly, the reference list of all included sources of evidence were screened for additional studies. Finally, a citation search of all included sources of evidence was carried out.

Plan for Scoping Review: Study/Source of Evidence selection

Following the search, all identified citations were collated and uploaded into EndNote V17 (Clarivate Analytics, PA, USA) and duplicates were removed. Relevant titles and abstracts were evaluated against the eligibility criteria by one reviewer (EOL). A second reviewer will (DR) completed the same process on a random sample of 10% of titles and abstracts. If there was no consensus regarding inclusion or exclusion decisions, the study proceeded to full-text review.

Potentially relevant sources were retrieved in full. The full text of selected citations were assessed in detail against the inclusion criteria by two reviewers. The scoping review recorded and reported reasons for excluding sources of evidence in the full text that did not meet the inclusion criteria. Disagreements that arose between the reviewers at each stage of the selection process were resolved through discussion or with an additional reviewer (SS). The search results and the study inclusion process were reported in full as a narrative in the final scoping review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping review (PRISMA-ScR) flow diagram (Page et al., 2021).

Plan for Scoping Review: Data Extraction

Two or more independent reviewers extracted data from papers included in the scoping review using a data charting form (Appendix 31). The data extracted included specific details about the participants, concept, context, study methods and

key findings relevant to the review questions. The draft data extraction tool was modified and revised as necessary while extracting data from each included evidence source. The scoping review detailed all modifications. Any disagreements that arise between the reviewers was resolved through discussion or with an additional reviewer/s. If appropriate, the research team contacted authors of papers to request missing or additional data, where required. If the author failed to respond within two weeks, the scoping review reported this as missing data.

The data charting form gathered information from the studies based on study characteristics (author, date of publication, population, study type, location), training status of participants, duration of the training programme, MC verification methods, strength outcomes and measures of motivation for training. The research team modified the charting form as necessary in line with the iterative process of a scoping review. In line with guidelines for scoping review methodology, the review did not conduct a methodological quality appraisal of the included studies (Tricco et al., 2018). This scoping review covered a broad topic and proposed new research, not practical advice or clinical guidelines (such as in a systematic review). Therefore, it was not necessary to include a quality assessment.

Plan for Scoping Review: Data Analysis and Presentation

The review presented all results in table format (Appendix 32). A narrative summary accompanied the tabulated results and described how the results relate to the review objective and question/s. The table described individual study characteristics and results.

Plan for Scoping Review: Expected Outcome and Impacts

This project will provide an up-to-date overview of the methodologies, and the effects of MC phased RT programmes. This review will also identify gaps in the literature and identify if there has been an adequate representation of females who complete RT programmes as part of post-operative rehabilitation plans. This information will help to develop future research questions regarding MC phase-based RT programmes.

Part ii: The role of menstrual cycle phase-based resistance training for females post anterior cruciate ligament reconstruction: a scoping review.

This second section of the chapter contains the following paper submitted to *Physical Therapy Reviews.*

Reference

O'Loughlin, E., Reid, D., & Sims, S. The role of menstrual cycle phase-based resistance training for females post anterior cruciate ligament reconstruction: a scoping review. *Physical Therapy Reviews*

Prelude

Research has provided support for FP-based RT for eumenorrheic females. Females perform RT following ACLR. This study aimed to describe what is known about MC phase-based RT in injured and non-injured females. No studies were found that investigated MC phase-based RT in females post anterior ligament reconstruction. Six primary studies supported FP-based training to enhance responses, including superior strength, power, lean mass gain, and reduced dysmenorrhea symptoms. One study reported no difference in strength gain between follicular and luteal phase-based RT, and another study reported that underweight participants obtained superior strength gain following LP-based resistance training. Studies were limited by methodological issues and small sample sizes. In addition, these studies had a risk of bias, including a lack of information regarding co-intervention. However, overall, the results suggest that MC phase-based training may influence responses pertinent to post-anterior cruciate ligament reconstruction in females. Overall, the studies support that there is scope to investigate FP-based RT in females following ACLR.

Introduction

After undergoing anterior cruciate ligament reconstruction (ACLR), athletes typically engage in rehabilitation sessions with physiotherapists. These sessions serve several purposes: they address postoperative deficits, prepare for return to sports, and aim to reduce the risk of reinjury (Culvenor et al., 2022). Among common post-surgery challenges, athletes often encounter strength deficits in the quadriceps and hamstring muscle groups (Thomas et al., 2016). Specifically, research has found that females tend to experience inferior recovery of quadriceps and hamstring strength in their injured leg post-ACLR when compared to males. This sex difference is maintained even when considering similar post-surgery timelines, pre-injury activity levels, and graft sources (Kuenze, Pietrosimone, et al., 2019; Maguire et al., 2021). Of particular concern is the slower recovery of quadriceps strength, as persistent weakness in quadriceps strength is associated with less favourable patient outcomes, including reduced lower limb function, lower activity levels, and higher rates of reinjury (Cristiani et al., 2019; Grindem et al., 2016).

Consequently, this inferior recovery of quadriceps strength in females may be linked to their noted poorer knee function, decreased activity levels, and a decreased likelihood of returning to sports following ACLR compared to their male counterparts (Kuenze, Lisee, et al., 2019). As a result, restoring lower limb strength, especially quadriceps strength, is a rehabilitation priority for female ACLR patients (Kuenze, Lisee, et al., 2019). Current best practice guidelines recommend initiating resistance training (RT) programs commence six weeks after ACLR surgery to address these strength deficits (Van Melick et al., 2016).

These postoperative RT programs play a crucial role in stimulating muscular adaptation. Various factors influence these adaptations, including the physical stress applied to the body (in terms of training volume, loading, and frequency), recovery,

diet, sleep, and hormonal responses to RT (Hawley et al., 2011; Lamon et al., 2021; Tan et al., 2016). In eumenorrheic females (those with regular MCs), the MC (MC) plays a significant role. Throughout the MC, the steroid hormones oestrogen and progesterone fluctuate predictably. Oestrogen is known for its anabolic effects on skeletal muscle including antioxidant properties, membrane stabilization, neuro-excitatory effects, and satellite cell activation and proliferation (Lowe et al., 2010; Strehlow et al., 2003). In contrast, progesterone has anti-estrogenic effects and is considered catabolic (Enns & Tiidus, 2010). Additionally, hormonal variations in oestrogen can influence motivation and mood, potentially impacting training motivation (Kriengsinyos et al., 2004).

Prior research has investigated the chronic effects of hormonal fluctuations on RT adaptations, specifically phase-based RT programs that align with different phases of the MC (MC). FP-based RT, where females increase RT frequency in the FP of the MC, has been compared to linear/unilateral training, were females exercise consistently across the MC, and LP (LP)-based RT, where females carry out a higher volume of training in the LP. During MC phase-based RT, females track their MC using various methods such as calendar tracking, basal body temperature testing, urinary ovulation kits, and serum blood analysis. A recent systematic review which investigated the effect of the MC on chronic responses to RT reported a small number of studies, small sample sizes and methodological limitations. However, the review supported that FP-based RT may be beneficial for improved strength outcomes in eumenorrheic females (Thompson et al., 2020). The review suggested that athletes with regular MCs should focus on RT during the FP (Thompson et al., 2020).

Materials and Methods

This scoping review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for scoping reviews (Tricco et al., 2018)] and the Joanna Briggs Institution review manual (Peters et al., 2021) based on the original five stages scoping review methodology (Arksey & O'Malley, 2005). An a priori scoping review protocol was developed and is registered on the Open Science Framework (https://doi.org/10.17605/OSF.IO/9FNJP) and has been previously published (O'Loughlin et al., 2022). The scoping review has one variation from the protocol. The authors broadened the scope of the third review question from “what is known about MC phased RT effects on strength outcomes and motivation for training?” to “what is known about the effects of MC phase-based RT?". The authors broadened the question as more results from included studies were considered relevant for females post ACLR (pain symptoms, fat-free mass, adherence to exercise, participant preference).

Eligibility criteria

The review included any primary research study which reported outcomes following MC phase-based RT of at least one MC duration. Initial searching did not find any studies investigating MC phase-based RT in injured females; therefore, the final search strategy included naturally cycling females regardless of injury status. Similarly, the review included studies which investigated both MC phase-based RT and OCP phase–based RT (i.e., exercises periodised to the sugar pill week versus the rest of the month). These studies were included as they provide information regarding MC phase-based training (Wikström-Frisén et al., 2017). In addition, the review included narrative, systematic and scoping reviews and if they discussed methodologies or effects of MC phase-based RT. Studies must have been published in English to be reviewed by the research team (EOL, DR, SS) and assessed for suitability. The review did not use date restrictions, but studies must have been

published in peer-reviewed academic journals to ensure a minimum quality standard. The review excluded studies that specifically investigated the effect of the OCP on RT responses, as females taking the OCP have different hormonal profiles from those with a natural MC. This review aimed to investigate the effect of the endogenous MC only.

Search strategy

In March 2020 and October 2021, the primary author (EOL) and an experienced librarian, Michael Fauchelle (MF), performed pilot tests of study selection procedures (Appendix 30). These searches tested the literature search strategy and proposed study selection criteria. The results, keywords, and index terms were reviewed by the primary author (EOL) and the librarian (MF). No studies were found that investigated MC phase-based RT for females following an ACL injury. Zero studies met the criteria after abstract review. This pilot exercise informed the development of the complete search strategy by the librarian (MF) and the primary author (EOL) to include broader search terms. These broader terms aimed to find studies examining MC phase-based training in females regardless of injury status. Searching was then undertaken in the following databases: CINAHL, Medline, SportsDiscus, Web of Science, Scopus, the Cochrane Central Library, and Google Scholar (Appendix 34). Following the search, all identified citations were collated and uploaded into EndNote V17 (Clarivate Analytics, PA, USA), and duplicates were removed.

Study/Source of Evidence selection

Relevant titles and abstracts were independently evaluated against the eligibility criteria by two authors (EOL, DR). If there were no consensus regarding inclusion or exclusion decisions, the study proceeded to a full-text review. However, there was a consensus between both authors. Potentially relevant sources were retrieved in full.

The full text of selected citations was assessed in detail against the inclusion criteria by two authors (EOL, DR). The primary author sent each screening step's Endnote Library (Clarivate Analytics, PA, USA) to the other authors (SS), who agreed with all included studies. Thirdly, reference list and citation searching were carried out on Ovid. All potentially relevant citations were collated and uploaded into EndNote V17 (Clarivate Analytics, PA, USA). Relevant titles and abstracts were evaluated against the eligibility criteria by two authors (EOL, DR), and two authors (EOL, DR) assessed relevant full texts. Initial searching took place between 6/12/21 – 14/12/21, and the search was updated during the manuscript peer review on 22/12/22.

Data Extraction

The authors adapted the data charting form used in this review from the Joanna Briggs Manual template (Appendix 35) (Peters et al., 2021). The primary and secondary authors (EOL, DR) independently extracted the data from all studies. In line with guidelines for scoping review methodology, the review did not conduct a methodological quality appraisal of the included studies (Tricco et al., 2018). This scoping reviews a broad topic and will propose new research, not practical advice or clinical guidelines. Therefore, it was unnecessary to include a quality assessment.

Results

A review flow diagram summarises the results from the search process (Figure 5). The initial database search results yielded 1,250 records after duplicates were removed. 1,196 of these records were excluded following title/abstract screening leaving 54 studies for full-text screening. A further 41 reports were excluded at full-text screening. The excluded studies' names and reasons for exclusion are reported in Appendix 36. With the addition of one extra study identified from reference list screening & citation searching, the final number of included studies was 14 (see

Figure 5 and Appendix 37). These 14 studies included eight primary research studies and six review articles. All eight primary studies compared FP-based RT to LP-based RT or regular resistance training. One systematic review and five narrative reviews were also included. Results are summarised as to the research questions and in Table 2.

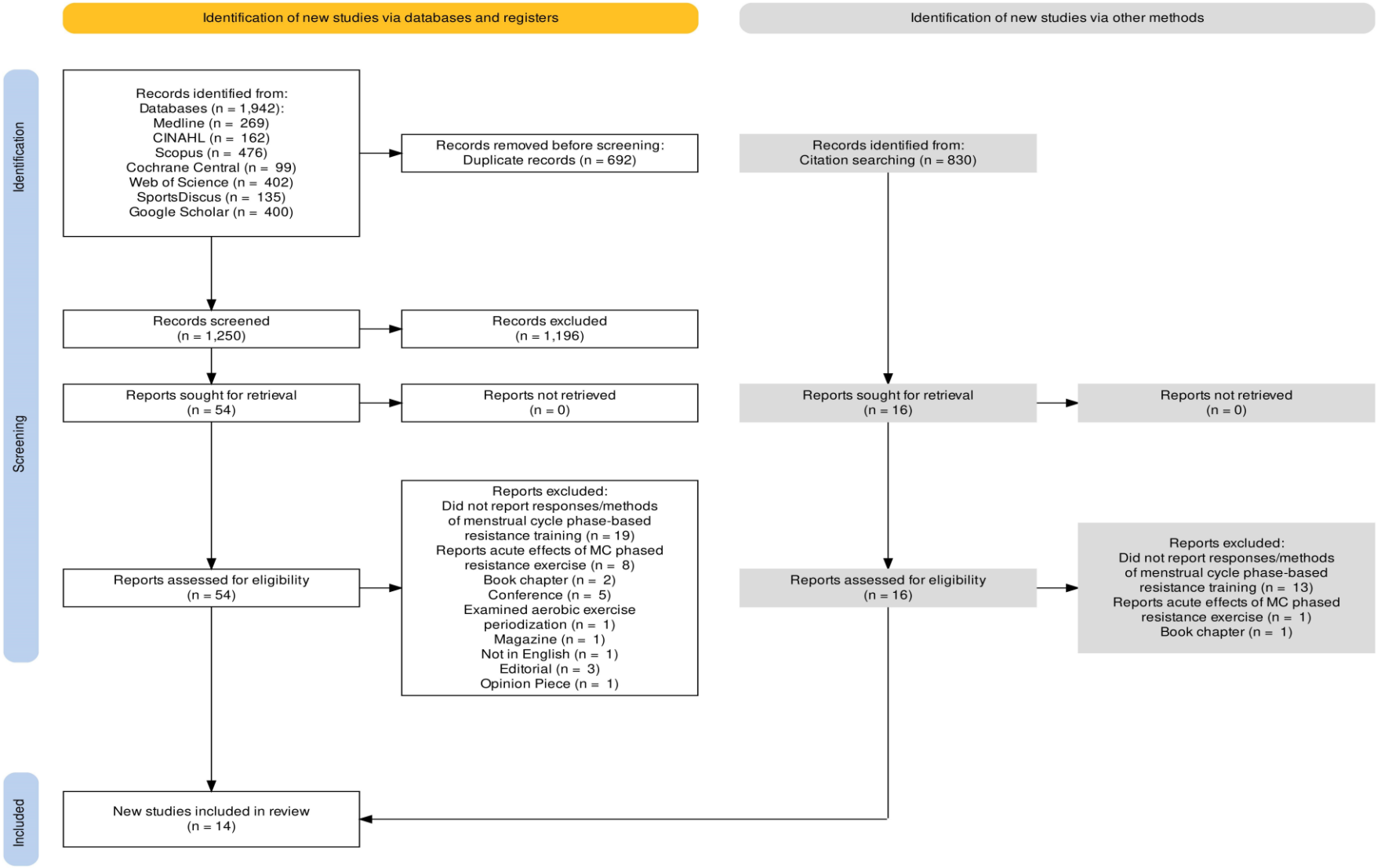

Figure 5. PRISMA flow diagram

Table 2. Study characteristics of primary studies and reviews that met inclusion criteria.

Author, Year, Location	Study Design & Duration	Population	Study Design/Review Aim	Comparison	MC Verification	Results	Conclusions
Reis et al. 1995 Germany	Non-randomised controlled trial. 8 weeks	N =7 students. Training status not noted. Non-injured. Age: 24±3.5 years	Lower limb unilateral knee extension RT every second day in the FP. Rest or x1/week in LP.	Opposite leg carried out lower limb unilateral knee extension RT every third day throughout the MC (regular training).	BBT, ovulation kits, & blood serum analysis. N=1 excluded by blood analysis.	20% increase maximum knee extension strength difference in FP-based RT group.	FP based RT is superior for strength development.
Sung et al. 2014 Germany	Randomised controlled trial. 12 weeks	N= 20 untrained students. Non-injured. Age: 25.9 ± 4.5 years	8 lower limb unilateral leg press RT sessions in FP & 2 in LP per MC.	Opposite lower limb completed 8 lower limb unilateral leg press RT sessions in LP & 2 in FP per cycle.	Calendar tracking, BBT, & blood serum analysis N=4 excluded by BBT analysis	29% increased maximum knee extension strength in FP-based RT group. FP-based RT group also showed a higher increase in muscle CSA than LT. Increase in fibre diameter of type II fibres and in cell nuclei-to-fibre	FP based RT is superior for strength development & muscle CSA.

						ratio only after FP-based RT.	
Wikström-Frisén et al. 2017 Sweden	Randomised Controlled trial 16 weeks	N= 59 N= 32 using OCP, N=27 no OCP. x3/week > 2 months RT experience. Non-injured. Age: 25 ± 4 years	Group 1: Leg press and leg curl RT x5/week in FP. 1x/week in LP. Group 2: Leg press and leg curl RT 5 days/week in LP. x1/week in FP.	Control group: Leg press and leg curl RT 3days/week during MC.	Calendar tracking Exclusion if cycle >35 days. n=2 excluded.	Increased squat jump and muscle strength for FP based RT compared to LP. Control group greater strength compared to LP based RT. Increased LBM in FP group only.	High volume FP based RT is superior to optimize results compared to LP-based RT. FP based RT also resulted in larger LBM compared to regular training.
Wikström-Frisén et al. 2016 Sweden	Randomised Controlled trial 16 weeks	N= 59 N= 32 using OCP N=27 no OCP x3/week > 2 months RT experience. Non-injured. Age: 25 ± 4 years	Group 1: Leg press and leg curl RT x5/week in FP. 1x/week in LP. Group 2: Leg press and leg curl RT 5 days/week in LP. x1/week in FP.	Control group: Leg press and leg curl RT 3days/week during MC.	Calendar tracking. Exclusion if cycle >35 days. n=2 excluded.	No negative impact on sex and growth hormones, body fat, bone mineral density in either group. Participants' preferred FP based RT.	FP based RT was not associated with negative hormonal consequences & is well accepted by participants.
Sakamaki-Sunaga et al. 2016 Japan	Non-randomised controlled trial 12 weeks	N= 14 Untrained, uninjured. Age: 21 ± 2 years	Upper limb unilateral dumbbell curls RT 3days/week in FP, and 1 day/week in LP.	Opposite arm unilateral dumbbell curls RT 3days/week in LP and 1	BBT. No exclusion criteria.	No difference in maximum voluntary contraction or muscle CSA.	No difference between FP and LP based RT adaptations.

				day/week in FP.			
Sung and Kim. 2019 Korea	Non-randomised controlled Trial 12 weeks	N= 36 sedentary or recreationally active. Non-injured. Age:25±7 years	Intervention group: Leg extension RT x8 times in FP and x2 times in LP.	Control group: Leg extension RT x8 times in LP and x2 times in FP.	BBT. No exclusion criteria.	Max leg extension strength increased for FP and LP based RT groups. Sig greater max isometric force increase for LP based RT for underweight group.	LP based RT can influence muscle strength results for underweight females.
Zainab et al. 2021 India	Randomised controlled trial 12 weeks	N= 150 students with primary dysmenorrhea. Training status not noted. Age= 18-22 years	Group A: N=75. Performed RT (10 core exercises) daily in FP	Group B: N=75 Performed RT (10 core exercises) daily in LP	No MC verification. No exclusion criteria.	Group A had decreased WALIDD score, & increased QoL more than Group B	Completing core RT during the FP is more effective as compared to LP based RT.
Vargas-Molina et al. 2022 Spain	Pilot Study 8 weeks	N= 14. 2 years of RT experience. Non injured. Age: 26.6 ± 3.0 years	Group 1: N=7 Strength training during the FP, hypertrophy training during ovulation, muscular endurance during LP, and recovery during the	Group 2: N=7 Undulating training divided into 4 phases per month: strength, hypertrophy, muscular endurance,	Urinary ovulation testing	Strength increases were observed for both groups, with bench press favouring Group 1. Only Group 1 showed differences in CMJ. A	The MC tailored program benefited bench press and CMJ performance. Limited by small sample. Future studies should seek to investigate the

			premenstrual phase.	and recovery.		significant increase in LBM was observed for Group 2, however absolute changes favoured Group 1.	topic employing a larger sample.
Knowles et al. 2019	Narrative Review	No inclusion criteria	Overview the current research regarding RT performance and muscle adaptation in females, focused on hormonal variables that may influence RT outcomes.	N/A	N/A	Muscle adaptation may be optimised by emphasizing FP based RT, or with combined strength/power training through the MC.	Current evidence suggests possible RT practices that could optimize performance outcomes in females, although further research is warranted.
Thompson et al. 2020	Systematic Review	N= 17 included studies (n=418 females) Age: 18–38 years.	Identify and critically appraise current studies on the effect of the MC and OCP on responses to RT.	N/A	N/A	Conflicting findings, small participant numbers & methodological issues.	Results appear to suggest that female hormones may affect RT responses.

Randell et al. 2021	Narrative Review	No inclusion criteria	Discuss research addressing other major topics relating to females soccer players.	N/A	N/A	Greater responses to training have been observed in studies when higher frequency RT was performed in the FP compared to the LP or compared to regular training	Phase-based RT is a promising area to maximize responses. Further research is required before implementation, noting the logistical challenges of personalizing loads in squads.
Hansen et al. 2018	Narrative Review	No inclusion criteria	Aim: Review the literature regarding the effect of female hormones on muscle and tendon collagen protein turnover and mass.	N/A	N/A	Future trials are needed to clarify the effects of the oestrogens on muscle biology under different conditions, e.g., phase of MC.	The number of studies within the area is still limited.
Gharahdaghi et al. 2020	Narrative Review	No inclusion criteria	Aim: Provide an update on advances in RT induced hormonal responses and their impact on muscle adaptation.	N/A	N/A	RT in late FP appears to result in increased fibre type II CSA, nuclei to fibre ratio and muscle mass, compared to RT during LP. This has not been confirmed.	Future trials are needed to clarify the effects of the oestrogens on muscle biology under different conditions, e.g., phase of MC.

Oosthuyse et al. 2022	Invited Review	No inclusion criteria	Aim: Outline recent advances in ovarian hormone molecular signalling that elucidates the mechanisms for menstrual phase variability in exercise metabolism.	N/A	N/A	Progesterone increases protein catabolism during the LP by indeterminate mechanisms. Satellite cell function supported by oestrogen-targeted gene expression is countered by progesterone, which explains greater muscle strengthening from FP-based RT.	Causative effects are provided by the review. The review also highlights research opportunities and evidence-based relevance for females athletes, including FP-based RT.

MC: Menstrual Cycle*. OCP:* Oral Contraceptive Pill*. LP:* Luteal Phase. *FP:* Follicular Phase *RT:* Resistance training *BBT:* Basal Body Temperature. *LH:* Luteinising Hormone. *N/A:* Not Applicable*. N=:* Number of Participants *1RM:* 1 Repetition Maximum Test. *LBM:* Lean body mass. *CMJ:* Counter Movement Jump

Participants

No females with ACL injuries were included as participants in any of the included studies. All studies included non-injured participants. However, Zainab et al. (2021) included 150 university students with moderate to severe primary dysmenorrhea. Many primary studies had low participant numbers (median n= 20, minimum n= 7, maximum n=150). Three of the six original research studies included non-resistance-trained participants (Sakamaki-Sunaga et al., 2016; Sung et al., 2014; Sung & Kim, 2019). Two more did not report the training status of the participants on entry to the programme (Reis et al., 1995; Zainab et al., 2021). In addition, Sung and Kim (2019) did not report the number of participants in each training group or how they distributed subgroups of participants with different BMI levels between phase-based training groups. Wikström-Frisén et al. (2017) included 59 participants who had previous experience with RT for leg press & leg curl for a minimum of two months, three times per week before the start of the study. In this study, MC-phase and OCP-based training were combined, with OCP users (n=32) and non-OCP users (n=27) distributed evenly throughout the three groups. Vargas-Molina et al. (2022) included females with two months of three times weekly RT experience for two months or more. Three studies included participants who served as their own control (Reis et al., 1995; Sakamaki-Sunaga et al., 2016; Sung et al., 2014), whilst the other four utilised a control group (Sung & Kim, 2019; Wikström-Frisén et al., 2016; Wikström-Frisén et al., 2017; Zainab et al., 2021).

Resistance training programme design

Three studies included RT programmes lasting twelve weeks (Sakamaki-Sunaga et al., 2016; Sung et al., 2014; Zainab et al., 2021), two studies reported eight-week RT programmes (Reis et al., 1995; Vargas-Molina et al., 2022), and Wikström-Frisén et al. (2017) described a sixteen-week RT programme. Four studies included

lower limb resistance training, including knee extension exercises (Reis et al., 1995; Sung & Kim, 2019), leg press (Sung et al., 2014; Wikström-Frisén et al., 2017) and leg curls (Wikström-Frisén et al., 2017). Sakamaki-Sunanga et al. (2016) included arm curls, Vargas-Molina et al. (2022) included a mix of upper and lower limb exercises, including bench press and squat training, whilst a study by Zainab et al. (2021) included core resistance training, including crunches, pelvic bridges, superman exercise, and bilateral single-leg raises, forearm planks, side planks, and cat and camel exercises.

Most studies provided guidance on RT parameters, including exercise session frequency and progression protocols. Six studies recommended two to three sets of eight to fifteen repetitions, either of 80% repetition maximum (RM) (Reis et al., 1995; Sung et al., 2014; Sung & Kim, 2019), or at eight to twelve RM (Sakamaki-Sunaga et al., 2016; Wikström-Frisén et al., 2017). Zainab et al. (2021) recommended ten reps of each exercise prescribed per day. Interestingly, only Vargas-Molina et al. (2022) prescribed the same number of sessions per week but varied the RT session to participants' MC phase. Vargas-Molina et al. (2022) prescribed strength training during the FP (3-5 RM load until one or two reps before failure, then a three-minute break between sets), hypertrophy training during the ovulatory phase (eight to ten RM load until failure, then a 90-second break between sets), muscular endurance during LP (20-25 RM load until failure, then a 45-second break), and recovery (12 – 15 repetition load), during the premenstrual phase.

Four studies provided participation adherence rates; Sung et al. (2014) reported 92% adherence, Sakamaki-Sunaga et al. (2016) reported 100% adherence, and Vargas-Molina et al. (2022) excluded two participants due to non-adherence to training. Wikström-Frisén et al. (2017) reported that participants in both groups had equal adherence as per participant training logs.

MC verification methods

All primary studies used different methods to track and verify participants' MC phase and status. Only Reis et al. (1995) used a three-step method, including basal body temperature testing, ovulation prediction kits and blood serum analysis to confirm the MC phase. Similarly, Sung et al. (2014) used calendar tracking, basal body temperature and serum blood analysis to verify participants' MC phase. In contrast, Sakamaki-Sunaga et al. (2016) and Sung and Kim (2019) used basal body temperature only to verify the MC phase, whilst Wikström-Frisén et al. (2017) used calendar tracking only, and Vargas-Molina et al. (2022) utilised ovulation testing only. Zainab et al. (2021) did not report any MC verification method. Four studies excluded participants who did not meet stipulated MC criteria (Reis et al., 1995; Sung et al., 2014; Wikström-Frisén et al., 2016; Wikström-Frisén et al., 2017).

Effects of MC phase-based resistance training

Six primary research studies reported the effect of MC phase-based RT on strength measures. Four studies reported superior strength changes for participants who engaged in predominantly FP-based RT compared to participants who engaged in predominantly LP-based RT (Sung et al., 2014), regular RT (Reis et al., 1995), or an undulating RT programme (Vargas-Molina et al., 2022). Wikström-Frisén et al. (2017) also reported that participants in the control group, who carried out regular resistance training, gained significantly more strength than the LP-based RT group. In contrast, Sakamaki-Sunaga et al. (2016) recorded no significant differences in strength change between their FP-based and LP-based RT groups. Sung and Kim (2019) divided their participants' results into three groups: an underweight group, a group within the normal range BMI score, and an overweight group. This study

reported that the underweight participants gained significantly more strength in the LP-based RT group.

The included studies also recorded several other outcomes applicable to females post ACLR. Firstly, Sung et al. (2014) reported an increase in the quadriceps muscle cell nuclei-to-fibre ratio following FP-based RT only, as compared to the LP-based training group. Secondly, Wikström-Frisén et al. (2017) and Vargas-Molina et al. (2022) reported increases in power measures such as squat jump and countermovement jump compared to LP -based or undulating resistance training, respectively. Thirdly, Wikström-Frisén et al. (2017) reported that only FP-based RT increased participants' lean body mass. Likewise, Sung et al. (2014) reported a superior increase in muscle diameter following FP-based training compared to LP-based resistance training. Moreover, a pilot study by Vargas-Molina et al. (2022) noted that although significant increases in lean body mass were observed for their undulating training group, absolute changes favoured MC phase-based resistance training.

In addition, Wikström-Frisén at al. (2017) reported that participants experienced the FP-based RT program as positive, but participants in LP-based RT or the control group did not. Similarly, Zainab et al. (2021) also reported that their FP-based RT group reported reduced dysmenorrhea symptoms and increased quality of life compared to the LP-based RT group.

Other reviews

A systematic review by Thompson et al. (2020) aimed to identify and critically appraise studies examining acute and chronic effects of the MC on responses to resistance training. This review included 17 studies and four original research

articles in this scoping review (Reis et al., 1995; Sakamaki-Sunaga et al., 2016; Sung et al., 2014; Wikström-Frisén et al., 2017). The authors reported conflicting findings, small participant numbers and methodological issues. They concluded that female hormones might affect RT responses & advocated for further experimental studies in the area. A narrative review by Knowles et al. (2019) noted that females may be able to optimize performance or muscle adaptation by emphasizing RT frequency during the FP of the MC or with combined strength/power training throughout the cycle. Another narrative review by Randell et al. (2021) discussed major research topics relating to soccer players. They reported that phase-based RT is a promising area with the potential to maximize training responses in soccer players. The authors advised further research before implementation due to the logistical challenges of personalizing training loads in squads. In addition, two narrative reviews recommended further research in this area due to the small number of trials and to clarify effects (Gharahdaghi et al., 2021; Hansen et al., 2011).

Regarding effects, a recently published mechanistic review paper by Oosthuyse et al. (2022) described the signalling pathways of oestrogen and progesterone and discussed the effects of the MC on muscle regeneration and strength training. Oosthuyse et al. (2022) concluded that by unknown mechanisms, progesterone increases protein catabolism during the LP. In addition, Oosthuyse et al. (2022) noted that muscle regeneration and strengthening are mostly greater during the FP when oestrogen is present alone without progesterone. Subsequently, Oosthuyse et al. (2022) outline that when females train during the FP when oestrogen is high, superior muscle strengthening results from oestrogen-activated superior satellite cell function. Whereas, when females train during the LP, that progesterone counters this activation of satellite cells. Therefore, Oosthuyse et al. (2022) recommend that

females plan RT sessions during the FP because progesterone is less active and will not suppress the activation of satellite cells.

Discussion

This review aimed to establish what is known from the literature about MC phase-based RT research for females post ACLR. Furthermore, it aimed to establish any gaps in this literature. No original studies were found that investigated MC phase-based RT in females with ACL injuries. Six out of eight included primary research studies provided support for FP-based resistance training.

Participants

Considering the results above, it is worth noting that many of the included experimental studies had low participant numbers (median n= 20, minimum n= 7, maximum n=150). Females have significant inter-and intra- individual variations in reproductive hormone status, which, combined with low participant numbers, may lead to underpowered studies (Elliott-Sale et al., 2021). Therefore, there is a need for future research in this area to recruit and maintain more significant participant numbers. Similarly, participant training status is a pertinent concept that may have implications for research in this area. Three (Sakamaki-Sunaga et al., 2016; Sung et al., 2014; Sung & Kim, 2019) out of eight primary studies included non-resistance-trained participants, and two did not note RT status (Reis et al., 1995; Zainab et al., 2021). When studies do not use resistance-trained participants, the initial training effect may be more significant than the MC hormonal training response. In an ACLR environment, many sporting females may engage with RT regularly as part of their sporting programme. Parsons et al. (2021) noted that some females post-ACLR may have reduced familiarity with gym environments due to factors including expectations of weightlifting as masculine. Consequently, there may be a proportion

of females who may be more likely to be non-resistance trained on entry to RT programmes or likewise when commencing rehabilitation post-ACLR. Rather than excluding non-resistance-trained females from future trials, participants' allocations could be matched for their initial hormonal and training status to guarantee a homogenous distribution between groups in future research.

Three studies included participants who served as their own control (Reis et al., 1995; Sakamaki-Sunaga et al., 2016; Sung et al., 2014). With this method, the cross-transfer effects of unilateral training would influence these results (Green & Gabriel, 2018). Therefore, future research should investigate participants who do not serve as their own control. Participants not serving as their own control would be especially pertinent in a cohort following ACLR, considering the underlying strength asymmetry between bilateral lower limbs postoperatively. In addition, Wikström-Frisén et al. (2017) used control groups that distributed OCP and non-OCP users evenly throughout three groups and compared the results across these three groups. These females using the OCP would not have had natural MC hormonal fluctuations. Nevertheless, they were grouped randomly with naturally cycling females, making it challenging to establish the hormonal effects on the RT responses of those in this study with a regular MC taking the OCP (Sims & Heather, 2018). Elliot-Sale et al. (2021) have provided methodological guidance regarding using OCP groups as control or experimental groups, guiding future research in this area.

Resistance training design

Six out of eight primary studies included RT protocols which guided training frequency, intensity, volume, progression, and duration of the training period (Reis et al., 1995; Sakamaki-Sunaga et al., 2016; Sung et al., 2014; Sung & Kim, 2019; Wikström-Frisén et al., 2016; Wikström-Frisén et al., 2017). The guidance is in line

with recommendations of a systematic review investigating RT documentation after ACLR (Augustsson, 2013). Therefore, the reported training protocols would be considered adequate in detail to apply and relate to a post-ACLR environment. Similarly, the primary research studies included RT programmes between eight- and sixteen weeks. This duration range is in line with recommended RT hypertrophy and strength recovery timeframes post-ACLR, following an initial five to six weeks of postoperative recovery (Buckthorpe et al., 2019). Therefore, the reported training protocols would also be considered similar in duration to apply and relate to a post-ACLR environment.

In addition to the training detail and duration, participation adherence rates are also pertinent to record to establish between and within group differences in outcome measures related to participants' participation in the RT programme (Walker et al., 2020). Furthermore, females post-ACLR must also complete cardiovascular, neuromuscular and agility training as part of their rehabilitation. In line with this, Wikström-Frisén et al. (2016) recommended that participants engaging in FP-based RT include these other exercise modalities during training sessions in the LP.

MC verification methods

One of the challenges in MC phase-based research is establishing the MC phase and status of participants. This challenge is due to incidences of anovulation and LP insufficiency in athletic females. Recent research recommends a three-step gold standard, which includes MC calendar mapping, urinary ovulation prediction kits and blood serum analysis to verify ovarian hormone status (Schaumberg et al., 2017). Only one primary study reported using the gold standard three-step method for MC verification (Reis et al., 1995). Furthermore, recent research recommends that if participants do not meet the theoretical or stipulated hormonal concentration

requirements, researchers should exclude this data from the study (Elliott-Sale, Minahan, Janse de Jonge, et al., 2021). Only Sung et al. (2014) and Reis et al. (1995) used blood serum analysis post hoc to confirm hormone levels to exclude participants, whilst Wikström-Frisén et al. (2017) excluded participants whose MC was longer than 35 days.

Consequently, as a recent methodological paper recommended, further research is needed in this area to establish the effect of the MC on chronic RT responses using a robust methodology, including gold-standard three-step MC verification and post hoc data exclusion (Elliott-Sale, Minahan, Janse de Jonge, et al., 2021). Regarding the feasibility of tracking the MC in cohorts post ACLR, it is worth noting that recent research reported that fifty per cent of elite females athletes in New Zealand record their MC (Heather et al., 2021). Furthermore, whilst there is intra-individual variability between female's cycles (Fehring et al., 2006), a recent retrospective study by Francis et al. (2023) demonstrated that mid-follicular through mid-luteal patterns are very stable. In addition, rehabilitation post-ACLR is a solitary endeavour, and injured females would not be restricted by the logistical challenges of MC tracking and personalizing training loads in large squads. Therefore, further research to establish the effect of the MC on chronic RT responses, incorporating a robust MC verification methodology, could be conducted in sporting or rehabilitation environments.

Effects of MC phase-based resistance training

Overall, the two studies that confirmed MC phases by blood serum analysis (Reis et al., 1995; Sung et al., 2014) concluded that FP-based RT resulted in superior strength gain than regular and LP-based RT by 20% and 29%. Therefore, overall, in line with the systematic review by Thompson et al. (2019), the studies included in this review with the recommended hormone verifications suggest that female

hormones may affect RT strength responses. This potential effect of FP-based RT on strength outcomes for participants is especially relevant to investigate for females post ACLR. As previously discussed, persistent impairments in strength are associated with reduced patient outcomes, including reduced function, inferior activity levels and increased reinjury rates (Cristiani et al., 2020). It is also important to note that even minimally superior gains in strength can positively influence recovery post-ACLR (Grindem et al., 2016).

Several other reported results are applicable to females' recovery post-ACLR. Firstly, the higher increases in squat and countermovement jump power measures reported by Wikström-Frisén et al. (2017) and Vargas-Molina et al. (2022) apply to females post ACLR. Sports such as netball and skiing, which have high rates of ACL injuries, often include jumping and landing. Therefore, females engage in plyometric training to increase their proficiency in these functional movements during ACL rehabilitation. Furthermore, vertical and countermovement hop tests are part of the battery of tests used to clear females back to sport following ACLR (Grindem et al., 2016).

Secondly, Wikström-Frisén et al. (2017), Sung et al. (2014), and Vargas-Molina et al. (2022) reported lean body mass changes favoured MC phase-based resistance training. On this note, Sung et al. (2014) reported that females' quadriceps nuclei to cell ratio increased after FP-based training only. As mentioned in the mechanistic review from Oosthuyse et al. (2022), these results suggest increased satellite cell recruitment for females who resistance train in the FP of their MC. Increased satellite cell recruitment can lead to several benefits, including reduced muscle atrophy and improved muscle repair and growth. These superior lower limb muscle mass and increase in nuclei-to-cell ratio results are pertinent for females post ACLR. Disuse atrophy of the quadriceps is common post-ACLR, and recent research has

recommended further research into establishing optimal methods to tackle postoperative atrophy (Thomas et al., 2016).

Considering the physical differences noted above, it is also pertinent to consider if females engage in and prefer this type of training. The included studies reported no differences in adherence for different training types. However, Wikström-Frisén et al. (2016) reported that more participants experienced FP-based RT as positive, compared to regular or LP-based training, indicating that FP-based training may be favourable for females. It is unknown whether this noted preference for FP-based training may relate to MC phase differences in mood or motivation. Mood or motivation for training was not reported or monitored in any of the included studies despite recent research reporting that hormonal fluctuations can affect both factors (Cook et al., 2018; Prado et al., 2021). Motivation for training is essential in a rehabilitation environment (Walker et al., 2020), and for athletes post ACLR, higher motivation during rehabilitation is associated with returning to pre-injury sport (Sonesson et al., 2017). Therefore, there is a role for future research to investigate this topic and explore the rationale for participants' preference for FP-based resistance training, which is also relevant for females post ACLR.

Likewise, Zainab et al. (2021) reported a superior reduction in pain symptoms for their FP-based RT participant group with dysmenorrhea. The impact of RT on pain symptoms is also applicable and relevant to females post ACLR, as pain symptoms may affect their ability to engage in RT following ACLR.

Limitations

This review is the first to consider the methodologies of MC phase-based RT and identify an opportunity for future research in a population group that needs efficient

and effective RT approaches. There are several limitations to consider. The review is limited to the available research. This review identified several studies with small sample sizes and methodological issues. In addition, this review did not undertake any formal methodological quality assessment. Because the aim was to provide a general overview of existing literature, there is no synthesised result or answer to any question. Furthermore, this scoping review is at risk of bias from different sources, including selection bias. However, the complete search strategy, including the iterations, was all documented to acknowledge and mitigate this risk of selection bias. Similarly, as the Open Science Framework does not permit modifications to registered protocols, the changes made to this study may not be apparent to other researchers. However, all protocol changes were noted in the Material and Methods section to ensure transparency and reliability.

Conclusion

This scoping review provides an overview of current literature relating MC phase-based RT for women, providing implications for future research for post ACL rehabilitation. To date, there are no current published studies investigating the effects of MC phase-based RT following ACLR. This review included eight original research studies, six supporting FP-based RT to enhance training responses. The included studies described RT protocols and results relevant and applicable to females post ACLR. Specifically, the studies that confirmed MC phases by blood serum analysis concluded that FP-based RT resulted in superior strength gain than regular and LP-based resistance training. In addition, studies reported superior training results for FP-based resistance training, including increased lean body mass, nuclei-to-cell ratio, superior power measures, participant preference, quality of life, and symptom improvement measures. These results support that these described FP-based training protocols influence responses relevant to females post ACLR. However, these studies were limited by small sample sizes, methodological

issues including differing MC verification methods. Furthermore, these studies had a risk of bias, including a lack of information regarding co-intervention. Overall, this review supports future research which examines how FP-based RT affects naturally cycling females following ACLR. Researchers should conduct all future research in line with up-to-date methodological recommendations.

SECTION 2: THE FRAMEWORK OF THE THESIS

CHAPTER 3: Discussing the menstrual cycle in the sports medicine clinic: perspectives of orthopaedic surgeons, physiotherapists, athletes, and patients.

This chapter contains the following paper published in *Qualitative Research in Sport, Exercise and Health.*

Reference

O'Loughlin, E., Reid, D., & Sims, S. (2023). Discussing the menstrual cycle in the sports medicine clinic: Perspectives of orthopaedic surgeons, physiotherapists, athletes and patients. *Qualitative Research in Sport, Exercise & Health,* 15(1), 139-157. doi:10.1080/2159676X.2022.2111459

Prelude

In Chapter 2, the review findings support future research which examines how FP-based RT affects naturally cycling females following ACLR. However, it is unclear whether health professionals and athletes routinely and openly discuss this sometimes-sensitive topic in the sports medicine clinic, and if there would be barriers to discussing the MC in the sports medicine clinic. This study explored different members of the sports medicine community's knowledge, perceptions of, and comfort in discussing the endogenous MC. Five semi-structured focus group sessions were conducted with 18 participants (2 orthopaedic surgeons, 9 sports physiotherapists, 3 patients, and 4 athletes) in New Zealand. Reflexive thematic analysis revealed an overarching theme which described the MC as 'a pertinent and evolving topic in the sports medicine clinic'. The first theme, 'A dearth of education and discussion has given rise to a perceived lack of MC knowledge', reflects the participants' consensus regarding a lack of knowledge of the MC. In contrast, 'Different (mismatched) concerns of health professionals and non-health professionals' describes the different groups' differing MC-related concerns. The third theme, 'Health professionals have specific strategies to enable comfortable MC

conversations,' describes that the broader sports medicine community does not routinely discuss the MC in the clinic. In addition, it describes common barriers to in-clinic MC discussions, including athlete and health professional age, gender and culture. Finally, the study describes pragmatic approaches health professionals frequently take to tackle these barriers. This study highlights the importance of developing trust, giving context, and being aware of athletes' concerns and sociocultural status when discussing the MC in the sports medicine clinic. These strategies can be used when designing and implementing a study investigating MC phase-based training in the sports medicine clinic.

Introduction

The number of females participating in exercise and sport has risen in the previous multiple decades (Acosta & Carpenter, 2015), and recent reports demonstrate these participation rates are continuing to rise (Sport England, 2020). Females have unique anatomy and physiology, which is pertinent for the sports medicine health professional to consider (Regitz-Zagrosek, 2012). Physiologically, the female hormones, oestrogen and progesterone, fluctuate somewhat predictably across the monthly menstrual cycle (MC) in naturally cycling females. The MC comprises a follicular phase (FP) (begins at menses, low levels of oestrogens and progesterone), ovulation (approximately day 14, preceded by an oestrogen surge), and a luteal phase (post-ovulation, high levels of oestrogen and progesterone). Complex relationships exist between these MC hormonal fluctuations and mood (Prado et al., 2021), exercise performance (McNulty et al., 2020), and recovery (Thompson et al., 2019). Recently, there has been a global increase in female-based sports performance and medicine research related to the MC.

Firstly, much research has described the effects of 'Relative Energy Deficiency Syndrome in Sport' (RED-S) (Mountjoy et al., 2018; Thorpe et al., 2020), whereby low energy availability can result in amenorrhea and bony stress fractures. In contrast Bruinvels et al. (2016) have described the impact of heavy menstrual bleeding on sportswomen, including anaemia, iron supplementation and slower performance times. Similarly, athletes have reported dysmenorrhea symptoms to impact their training and competition performances (Findlay et al., 2020). Physiotherapy researchers Zainab et al. (2021) recently reported that RT in the MC's FP was most effective in reducing dysmenorrhea symptoms compared to training in the luteal phase. These results align with a recent review, which, whilst noting the methodological limitations and small sample sizes of previous studies, recommended for eumenorrheic women, where feasible, to target their resistance training (RT) to the FP of their MC (Thompson et al., 2020).

Moreover, recent research has demonstrated increased muscle, tendon and ligament injury rates in the late FP of a female's MC, or when women's cycles are 'overdue' (Martin et al., 2021). This reported increased rate of injury is in line with previous musculoskeletal research, which has identified an increased incidence of anterior cruciate ligament (ACL) injuries in the late FP of the MC (Herzberg et al., 2017). The impact of ACL injury is particularly significant, as the incidence of ACL reconstruction (ACLR) in females has increased by 120% in New Zealand (Sutherland et al., 2019) and worldwide (Zbrojkiewicz et al., 2018). The return to sport rate following ACL injury is lower for females (Mok et al., 2022), and there is a high risk of subsequent ACL injuries (Webster et al., 2021). Current research is investigating whether there is a role for MC phased RT programmes for females to improve quadriceps strength recovery post ACLR (O'Loughlin et al., 2022).

Concurrently, MC tracking applications have recently become prominent, allowing females to track their cycles and predict their menstruation dates (Worsfold et al., 2021). A recent study carried out in New Zealand reported that over half of elite sportswomen track their MCs (Heather et al., 2021). Females track their MC to become aware of their general health, understand their body's reactions to different phases of their cycle, prepare menstrual hygiene materials, plan life events, aid becoming pregnant, and to inform conversations with healthcare providers (Epstein et al., 2017). MC tracking apps are now considered essential for advancing epidemiologic research on menstruation (Schantz et al., 2021).

Much of this bio-medical research and dialogue focuses on the MC's quantitative physiological and biological aspects. However, female athletes experience the MC and its hormonal fluctuations and manifestations within a broader sociocultural context (Bobel, 2015) and through their unique lived experiences. The MC is considered a social stigma (Johnston-Robledo & Chrisler, 2011) and is a taboo subject that must be physically and verbally hidden (Bobel, 2015; Kissling, 2002). There are many recent examples of how this taboo shapes how women talk and share information regarding the MC in New Zealand sporting culture. Dykzeul (2016) reports that menstruation is concealed and remains absent from talk in adventure racing dialogue and action. Similarly, Schofield et al. (2021) used a feminist conversational analytical approach to provide examples of New Zealand track cyclists using silencing, laughter to lighten the tension, and deflection techniques when discussing the MC. In addition, Thorpe et al. (2020) described how New Zealand Rugby Sevens players of Māori and Samoan descent use culturally specific euphemisms such as 'getting your mate' to describe menstruation. In a non-sporting environment, Wootton & Morison (2020) describe the current discourse of disgust surrounding menstruation in low-income schoolgoers. Therefore, overall, evidence

from New Zealand is in line with previous research, which indicates that many females are embarrassed about discussing their MC (Chrisler, 2013).

As discussed above, recent sports medicine research gives reason for sports medicine health professionals to screen for, diagnose, and treat a range of MC-related injuries and conditions in their clinics. However, recent qualitative research has identified barriers to athletes communicating with support staff regarding their MC in the United Kingdom (Findlay et al., 2020) and in New Zealand (Heather et al., 2021). Likewise, focus group research, which investigated the lived experiences and perceptions of the MC in elite rugby athletes, reported that sporting athletes prefer taking their MC concerns to non-sports medical staff. These findings highlight issues for athletes discussing menstrual health within their sporting environment (Findlay et al., 2020). Consistent with these noted communication barriers described by athletes, the British Association of Sport and Exercise Sciences released a recent expert statement which advocated for a cultural shift away from MC-based silencing and towards unrestricted, irreproachable conversations about MCs in order to "advance female-athlete based research and implement research into practice" (Elliott-Sale, Ross, et al., 2021).

Sports medicine health professionals' knowledge, perceptions, and comfort in discussing the MC in the sports medicine clinic are unknown. It is also unclear whether health professionals routinely broach the MC subject in the sports medicine clinic as part of a typical consult. The discussion of one's MC in the clinic depends on health professionals and non-health professionals' knowledge, perceptions, comfort initiating and partaking in discourse regarding the MC. Understanding the different members of the sports medicine community's knowledge, perceptions, and comfort discussing the MC may help understand the extent to which health professionals and non-health professionals discuss MC-related issues in the sports

medicine clinic. This understanding may also offer scope to recommend practical approaches to enable unrestricted conversations about the MC in the sports medicine clinic.

The size and members of the sports medicine team depend on the setting. For example, in a local sports club, the sports medicine team may consist of a physiotherapist alone, while a larger team consists of many professionals. This study included physiotherapists as representative members of a core sports medicine team and sports orthopaedic surgeons as representative members of the broader sports medicine team. Thirdly, the study included patients (athletes post ACLR) who have extensive experience in the sports medicine environment. Finally, the study also included athletes who did not have specific injury experience. The study included these athletes to give a different perspective of their expectations for, rather than previous experiences of, MC-related conversations within the sports medicine environment.

Thus, the objective of this qualitative study was to 1) explore sports orthopaedic surgeons, physiotherapists, female athletes, and patients' knowledge and perceptions of the MC, and 2) explore the comfort of orthopaedic surgeons, physiotherapists, female athletes, and patients in discussing the MC in the sports medicine clinic. A critical realist approach was deemed appropriate to explore perceptions of, knowledge of, and comfort discussing the MC. Previous studies utilised feminist (Schofield et al., 2021), feminist standpoint, and feminist postcolonial science theories (Thorpe et al., 2020) to frame their discussions. These theories will also inform the study by acknowledging and considering participants' gender, ethnicity, age groups and when analysing the text. To answer these research objectives in line with a critical realist approach, these research questions were developed by discussion and iteration within the research team:

What do orthopaedic surgeons, physiotherapists, female athletes, and patients know and think about the MC?

Do/would orthopaedic surgeons, physiotherapists, female athletes, and patients discuss the MC in clinic? and

How comfortable are orthopaedic surgeons, physiotherapists, female athletes, and patients discussing the MC in the sports medicine clinic?

Materials and methods

Study Design

This study utilised an interpretive descriptive study design, via focus groups to investigate the knowledge of and perceptions of the MC, and to inform practical recommendations. The data for this analysis were drawn from a wider qualitative study developing a MC phased ACLR rehabilitation programme for women. For the purposes of this paper, only data related to the participants' knowledge, perceptions of, and comfort discussing, the MC will be used. Focus groups were chosen as focus group interviews are a social experience in which individuals participate in discussions, develop and elaborate on each other's statements to bring out key points, ideas, and themes (Kevern & Webb, 2001; Kruegar & Casey, 2000). Also, focus groups were specifically decided to be appropriate to answer our research question, as it was considered that group dynamics and the role played by less inhibited participants could help shyer members to discuss the sensitive subject of the MC (Liamputtong, 2011). It was also considered that a focus group design would provide respondents with a safe environment where they can articulate their experiences, opinions and beliefs in the company of people who share similar experiences and hold similar beliefs, i.e., people of the same profession (Liamputtong, 2011). Videoconferences were also considered appropriate here for

health professionals and patients who were geographically dispersed (Flynn et al., 2018).

Māori participants were not specifically targeted, however it was considered that it was likely that some participants may identify as Māori or Samoan. Māori traditionally believed in specific “tikanga”, custom or habits, around the time of menstruation (Murphy, 2011). Considering this may affect the potential participants knowledge and perceptions of the MC, a specific question regarding cultural beliefs and practices surrounding the MC was added to the focus group questions asking “do you have any specific cultural considerations re the MC?’. Furthermore, as it was expected there would be different levels of knowledge of the MC between the health professional and non-health professional groups, the information sheets for the different groups were worded in more (health professional questions) and less (non-health professionals) medical language. Furthermore, advice was provided in the information sheet to potential participants that they will be questioned about their MC. The New Zealand Ministry of Health and Disability Ethnicity Data Protocols standard ethnicity collection question was used to collect ethnicity data (Ministry of Health, 2004). Auckland University of Technology Ethics Committee approved this study (approval #20/224).

Participants

The participants were grouped into four separate cohorts (Table 3). Two cohorts comprise health professionals: orthopaedic surgeons practising sports medicine (n=2; age: 45 ± 0.5 years; ethnicity: New Zealand European, n=1 Samoan/Nuean) and sports physiotherapists (n=9; age: 33 ± 15 years; ethnicity n= 1 Indian, n=1 Irish, n=7 New Zealand European). The third cohort comprises patients post ACLR (n= 3; age: 30 ±6 years; ethnicity: n= 1 New Zealand European, n= 1 European, n=

1 British), and the fourth cohort comprises female athletes (n= 4; age: 35 ± 15 years; ethnicity: n=2 New Zealand European, N=2 British). One of the orthopaedic surgeons is dual qualified as a sports medicine doctor. Health professionals were contacted by email-based upon contact information available online. In the email to physiotherapy clinics, the primary researcher requested the physiotherapists share the patient focus group study advertisement to patients who were post ACLR. The primary researcher emailed the focus group study advertisement to sports teams based upon contact information available online. Subsequently, interested participants emailed the primary researcher to express interest. The primary researcher carried out screening questions and sent information sheets regarding the research study. This study used purposive and convenience sampling to select participants. Of the total eligible participants, three withdrew from the study without reason. All participants gave written informed consent on the focus group day.

Table 3. Demographic characteristics of participants

Interviews	Location	N	Participants	Sex	Age, years	Ethnicity	Sports
Focus Group 1	Online	2	Orthopaedic Surgeon 1	Male	44	NZ European	-
			Orthopaedic Surgeon 2	Male	45	Samoan/Nuean	
Focus Group 3	Online	3	Physiotherapist 1	Female	42	NZ European	
			Physiotherapist 2	Female	34	Irish	
			Physiotherapist 3	Female	37	NZ European	
Focus Group 2	Face to face	6	Physiotherapist 4	Male	44	Indian	-
			Physiotherapist 5	Male	30	NZ European	
			Physiotherapist 6	Female	22	NZ European	
			Physiotherapist 7	Female	24	NZ European	
			Physiotherapist 8	Female	39	NZ European	
			Physiotherapist 9	Female	31	NZ European	
Focus Group 4	Face to face	4	Athlete 1	Female	30	British	Cycling
			Athlete 2	Female	26	British	Squash
			Athlete 3	Female	58	NZ European	Netball
			Athlete 4	Female	27	NZ European	Hockey
Focus Group 5	Online	3	Patient 1	Female	37	NZ European	-
			Patient 2	Female	25	British	

Patient 3	Female	29	European

Data Collection

Five focus group sessions took place. Two focus groups took place face-to-face in an office in a sports arena in Wellington [physiotherapists based in Wellington, New Zealand, and female athletes). Otter audio recording technology (Otter.AI, Mountain View, CA, USA) was used to record the face-to-face focus groups. The other three focus groups took place over Zoom (Zoom Video Communications, Inc; San Jose, CA USA) and were video recorded (physiotherapists residing in different geographical locations within New Zealand, orthopaedic surgeons, and patients). The primary researcher conducted all focus groups during which field notes were taken, and the sessions lasted no longer than one hour. The secondary author, an experienced physiotherapy professor, attended two focus groups (orthopaedic surgeons, patients) and took notes. Nobody else was present. All focus groups contained the same protocol as outlined in Appendix 6 “Focus Group Protocol”. The focus groups included five questions; 1) What knowledge do you have of the/your monthly MC?, 2) Do you have any experience or knowledge of tracking the/your MC?, and 3) How comfortable do/would you feel talking about your MC in clinic with your physiotherapist/surgeon/patients? 4. Do you have any cultural beliefs of practices surrounding your MC? 5. Have you ever discussed your MC with you patients/a health professional before? These questions were not pilot tested but were discussed and underwent iteration amongst the research team to ensure they could answer the research objectives and questions. Repeating and summarising were used as a form of informal member checks during the focus groups. Transcripts were not returned to the participants for comment, but a one-page result sheet was sent to the participants with an invitation to comment if there were any questions regarding the results, as another form of member check. Participants did not ask any questions regarding the results. No repeat interviews were carried out.

Data Analysis

Data analysis was supported by NVivo software (V.12.1.0; NVivo 12, QSR international Pty, Australia). Focus group discussions were voice recorded and transcribed verbatim by the primary researcher. Braun and Clarke's six-phase framework for doing a reflexive thematic analysis in sport and exercise science was used (Braun & Clarke, 2006; Braun et al., 2016; Clarke & Braun, 2013) because of its flexibility and potential to deliver rich understandings. An inductive, semantic and (critical) realist approach of reflexive thematic analysis was used to answer the research questions. The critical realist ontological approach which informed the research team's thematic analysis by retaining focus on the limits of reality, i.e., the participants' descriptions of the MC. However, concurrently, the analysis acknowledged participants' meanings and experiences of the MC, and the ways the broader social context impinges on those meanings (Willig 2013). Mostly semantic codes (i.e., surface, obvious) were constructed from the data, but latent codes (i.e., implicit, informed by underlying concepts) were also considered. This semantic coding approach was deemed appropriate for answering the research questions and investigating the concepts directly reported by participants. In addition, quality guidelines from Braun & Clarke (2021) informed the analysis and report writing, in line with the study's critical realist approach and descriptive purpose, to be an interpretive activity and tell the research team's story of the data.

The primary researcher familiarised herself with the data, reading and re-reading the transcripts, and taking casual notes about their content; subsequently carried out reflexive, inductive, and research question informed coding. This process was recursive, and codes were returned to and revised multiple times. Themes were then established from these codes initially by clustering codes together and establishing candidate themes. The primary researcher tested these primarily descriptive candidate themes by establishing if they could tell the story of the data.

All authors discussed the codes, themes and theme names using thematic maps to gain familiarity with the central ideas. This theme construction phase was iterative and consultative, with the primary author consulting with the second and third authors in regular meetings to test how well the themes told the story of the data, and to test the interpretation of the data. Themes and subthemes were also returned to and revised multiple times. These themes were then reviewed and finalised. Initially, four focus groups were planned, in line with standard recommendations of three and six focus groups (Guest, Namey, and McKenna 2016). After data analysis, the authors deemed the data analysed to be of adequate richness, depth, complexity, and diversity to answer our research question. Therefore, no further focus groups were conducted. In terms of transcription notation, [...] indicates omitted data.

Results

Reflexive inductive thematic analysis, using verbatim transcripts of discussions from both focus groups and comprehensive notes, resulted in one overarching theme and four key themes (Appendix 38). The overarching theme titled ‘The MC is a pertinent and evolving topic in the sports medicine clinic’ captured the way focus group participants continually identified the MC as a topic that is relevant and currently developing within the sports medicine clinic environment. This overarching theme was identified within and across three distinct themes. Within the first theme, ‘A dearth of education and discussion has given rise to a lack of MC knowledge,’ participants described their perceived lack of knowledge and outlined the potential value for sports medicine professionals to learn further about the MC. In the second theme, ‘Different (mismatched) concerns regarding the MC’, participants described varied MC-related concerns, which were all relevant to the sports medicine environment. The third theme, ‘Strategies to enable comfortable MC conversations’ details health professionals’ commitment to discuss the MC by outlining several

ways health professionals can combat barriers to these discussions. Finally, the theme 'The MC is a gendered topic in the sports medicine clinic' describes participants' reports of traditional gendered expectations regarding knowledge and discussion of the MC and how they pertain to the sports medicine environment. An overview of the four themes will now be discussed.

A dearth of education and discussion has given rise to a current lack of MC knowledge.

The first theme, 'A dearth of education and discussion has given rise to a current lack of MC knowledge' reflects participants' general concurrence regarding their lack of current knowledge regarding the MC. In the first subtheme, participants reported a lack of structured education regarding the MC. The second subtheme reveals several examples where participants physically or verbally concealed the MC as it was considered taboo. The third subtheme reflects the general rhetoric that health professionals identified a need for further education regarding the MC. Also, within this subtheme, health professionals acknowledged that further education would enable improved sports medicine practice around the MC in the future.

Lack of education

Many participants identified a lack of consistent, structured education and training regarding the MC. This lack of education, resulting in a current lack of knowledge of patients, was noted by an exchange between physiotherapists in Focus Group 2:

> *For young girls, like there's no education around their period, at all…they just don't have an idea that it's even bad to not like stop getting your period (Physiotherapist 8, F, 39)*
>
> *Yea, especially like for young girls, there's no education around their period at all. Especially in athletes, like they just don't have an idea that it's bad to*

not, like stop, getting you period […] My client's like I haven't had mine in three years and I'm like woah (Physiotherapist 7, F, 24)

Similarly, athletes reported that education, including whether they received teaching about the MC and how in-depth this teaching was, depended on their school or teacher.

It depends on the school for your experience, or location as well. But you'd think that they would be, a bit more yeah, up to date (Athlete 4, F, 27)

Or even individual differences of who is teaching that individual year (Athlete 1, F, 30)

Yeah (Athlete 4, F, 27)

Because there's so much individual variability (Athlete 1, F, 30)

Yeah (Athlete 2, F, 26)

In addition, one surgeon noted his own lack of education regarding the MC:

I would have to be honest with you and say it, it's not something I've read a lot about or understand a lot about (Surgeon 2, M, 45)

Participants reported a traditionally gendered expectation that students learn more about the MC in an all-girls school. Furthermore, health professionals noted that their children's sex and/or gender may affect their education and adult learning regarding the MC. Examples of these narratives include the following:

With an all-girls school you should nearly talk about it more (Athlete 4 F, 27)

As a male physio, I can explain the basics, but I am quick to refer on… (Physiotherapist 4, M, 44)

I have three sons whereas [the other surgeon] has a daughter. So he's going to learn all about this (Surgeon 1, M, 44)

Considered a taboo subject

Physiotherapists, patients, and athletes all noted experiences where the MC topic was taboo. Participants provided examples of their family physically concealing the MC within their family home. Similarly, participants also described the MC as sometimes verbally hidden within university living environments and the sports medicine environment. Furthermore, a participant identified certain tikanga (customary practices or behaviours) as taboo within traditional New Zealand Indigenous Māori culture. The following excerpts illustrate the taboo nature of the MC:

My mom used to put like a mark on the television […] But it wouldn't be [written down as] like, period, it would be written as something else (Athlete 4, F, 27)

Growing up, like in my family, we didn't talk about it. Uni and after uni living with guys, we didn't talk about it. Like it's only since actually moving to Wellington, living with girls that I do talk about it (Athlete 2, F, 26)

We had quite a few girls that had various issues with the MC individually. It was like, right. The actually needs to be dealt with instead of being swept under the rug (Physiotherapist 1, F, 42)

I was an early childhood teacher, so we tried to, like tikanga Māori. So it's like, there was a cemetery across the road, so if you were in the middle of

your period you wouldn't go. If you had your period, [or] you were hapu, pregnant, you're not meant to go [to the cemetery] (Athlete 4, F, 27)

Need for more education.

It was identified within the health professional focus groups that there is an opportunity for further education to be provided to sports medicine health professionals. Participants identified this further education would enable health professionals to collect relevant information from patients and athletes within the medical exam. This desire for further education was illustrated within discourse between physiotherapists during Focus Group 3:

I think the MC side of things is probably incredibly under cooked but it's definitely an area that there's value in knowing more about […] (Physiotherapist 4, F, 34)

I think there's quite a lot of scope to get more education into our support staff and physios in clinics […] because there's heaps and heaps of information that we seem to be getting from teenagers, especially when it's related to stress fractures and, and things like that that we could be doing and doing well. So I think we've got a really good, seem to have a really good role to play (Physiotherapist 3, F, 37)

In line with this, male participants reported a gender-specific lack of education and expressed a need for future education regarding the MC for male health professionals in sports medicine.

One of the things that we need from this is there's more practical education for the male physios to be able to address these issues (Physiotherapist 4, M, 44)

Health professionals and non-health professionals have different (mismatched) concerns regarding the MC.

Whilst the first theme acknowledged a dearth of knowledge, this second theme reflects health professionals and non-health professionals different interests regarding the MC. As outlined in the first subtheme, patients and athletes described knowledge, interest and tracking the regularity and symptoms of their MC. In contrast, health professionals, in the second subtheme, described knowledge and interest with MC-related injury risks and performance. The third subtheme describes physiotherapists' lack of questioning about females' tracking habits and insights, unless they are situated within a high-performance environment.

Symptoms & regularity

When asked about their knowledge and perceptions of the MC, patients and athletes reported knowledge and interest with the regularity and symptoms of their MC. Several female athletes and patients reported discomfort exercising during menses. An excerpt of Focus Group 5 provides an example of such discussions:

> *I'm on the contraceptive pill. So for me it's much more about sort of just convenience and just, I brought a couple of packs together because I want to avoid it as much as possible. And yeah, if I had sport on at the same time, it's a total pain (Patient 2, F, 25)*
>
> *Yeah, I think it's quite similar. Like it's, everything is more painful when you actually get your period so trying to get workout in is quite dreadful, yeah, I'm just, I'm very irregular in my periods. I'm never really sure when it's going to pop up and it's usually more a physical feeling where I'm like, I feel quite, quite tired (Patient 3, F, 29)*

Most female participants reported tracking their MCs on smartphone applications to understand and monitor their regularity and symptoms. Only one athlete reported she had never heard of tracking the MC via a smartphone application. The rationale for, and interest in, MC tracking is demonstrated here in an excerpt from Focus Group 4:

> *I mean, I track mine on like a period app, so... That's how I know when I'm meant to get it or not in between cycles and in between so I can track or symptoms of the cycle and everything like that (Athlete 4, F, 27)*
>
> *That's totally new to me, I didn't know you could do that. I didn't know you could track via an app and hadn't really thought about it to be honest (Athlete 2, F, 26)*
>
> *I do track my cycle on an app, I've tracked it also on Fitbit. So both apps will be like your period is about to start and I'm like yea I know. I've been monitoring to see, see how regular it is […]. It's starting to become regularish, not three-month gaps or anything (Athlete 4, F, 27)*

Risk of injury

In contrast, health professionals reported knowledge and interest with MC related injury risks and medical conditions. Specifically, orthopaedic surgeons and physiotherapists reported interest in ligamentous injury risk associated with specific MC phases. Surgeons and physiotherapists also reported regularly monitoring patients for signs of RED-S. The following examples illustrate health professionals' interest in MC-related injury risk and performance:

My interest came in 2005 where someone did rupture her ACL. So, my research was, I guess, that she got injured around that (Physiotherapist 4, M, 44)

In certain phases of the cycle, depending on the oestrogen and progesterone levels, there was increased rates of [ACL] rupture (Orthopaedic Surgeon 1, M, 44)

We're always looking out for, you know, relative energy deficiency syndrome (Physiotherapist 2, F, 34)

Physiotherapists do not usually inquire about tracking.

Physiotherapists noted the possibility of MC tracking information as useful and reported advising their patients to monitor their MCs. Nevertheless, they reported that normally, they do not usually ask their patients about this tracking information. Physiotherapists in Focus Group 2 discussed as follows:

I have started asking my ACL patients to record their periods, to state whether they've got them or not. But I haven't gotten to the point where I have made any changes, other than I do a bit of general advice (Physiotherapist 8, F, 39)

For any sort of high-level athlete, even if they're moderately fit, I advise and I suggest [MC tracking] to them. Even if they're not going to use that information, its good information to store (Physiotherapist 7, F, 24)

Physiotherapists reported only using this tracking data in high-performance sports environments. Within these high-performance environments, health professionals used MC tracking information to establish athletes' standard cycles, assist with exercise programming, and refer athletes for specialist medical intervention when

indicated. This use of menstrual tracking information is described in the following excerpt from Focus Group 3:

> *With the woman's team, we tracked the MC for probably the last three years prior to the [international named] campaign... Then people that needed help from, you know, sports med intervention or an endocrinologist intervention and then there were those whose programs we just adapted accordingly (Physiotherapist 1, F, 42)*

Strategies to enable comfortable MC conversations.

Despite a reported lack of knowledge and noted different concerns and interests regarding the MC, participants generally concurred in this first subtheme that there is a relative comfort discussing the MC in the sports medicine clinic. However, it was acknowledged that there are many individual barriers to these discussions. The second subtheme reflects several participants' comments which outlined the need to educate patients and contextualise the MC's relevance to sports medicine when discussing this sensitive conversation topic in the sports medicine clinic. Finally, the third subtheme outlines the reported importance of building trust and rapport between health professionals and patients to enable discourse regarding this sometimes-delicate topic.

Comfort discussing the MC…it depends.

Most of the participants reported a general comfort discussing the MC in clinic. Many patients and athletes noted that this was a hypothesised comfort, as their physiotherapist or sports medicine doctor had never discussed this topic with them. An athlete and a patient describe their perceived comfort:

I'd talk to whoever, I don't really mind. It's a thing we've all got, so (Athlete 4, F, 27)

I'd be reasonably comfortable talking about, it if it was for my own physical benefit and it was going to help me then. Yeah. I wouldn't have a problem with it. Yea but never brought up, not once (Patient 2, F, 25)

Whilst the young age of a patient was considered a barrier, a participant recommended including parents in the discussion when the patient or athlete is young to enable comfortable and open conversations:

Potentially you could talk to young, young female athletes, but the ones at risk, the young females playing soccer, it's not a conversation that orthopaedic surgeons are very good at having […]. It's harder if they're there on their own, but if they've got mum or dad there, usually mum, it's a lot easier (Surgeon 1, M, 44)

Similarly, health professionals also recognised it might be challenging to talk to people of specific cultures regarding the MC. However, several participants reported experience in this area and advised non-confronting methods to obtain MC information. For example, surgeons and physiotherapists identified screening tools and questionnaires that may help provide context and enable the discussion in a roundabout way in the sports medicine clinic:

A lot of people, especially culturally, they might not say it to your face, but that'd be quite happy to do it in a survey type form or medical questionnaire if they think it's all part of the team. So, there's quite a lot of ways that we can get information that doesn't have to be confronting (Physiotherapist 3, F, 37)

In addition, surgeons, physiotherapists, athletes, and patients reported that sex and/or gender of both the health professional and athlete was pertinent when discussing the MC in the sports medicine clinic. Several excerpts revealed a traditionally gendered expectation that women find it less challenging and would be more comfortable discussing the MC.

> *It was never broached despite having numerous female physios as well, who you would assume would be more comfortable talking about it (Patient 2, F, 25)*

> *[Him] and I are both males and it's probably harder to bring it up than if we were females (Surgeon 1, M, 44)*

Develop trust

Furthermore, participants recognised a lack of trust between the health professional and athlete was also a potential barrier to discussing the MC in the sports medicine clinic. Therefore, physiotherapists recommended delaying discussing the topic, if possible, to allow the athlete and health professional to develop rapport and trust:

> *There's that element of you got to develop trust with your patients, getting into the nitty gritty of it, maybe in the second or third session, when you know them a little bit better and they feel more comfortable (Physiotherapist 2, F, 34)*

Developing trust was also deemed to be especially pertinent between different genders in the sports medicine clinic. This was illustrated by an athlete in the fourth focus group:

> *To be honest it depends how comfortable I am with them. Like, to be honest, I'd be less comfortable if it was a guy, but it depends on how my interactions*

are with them. Like if they seem, I don't know, creepy or something, I probably wouldn't really want to be talking about my full MC and the rest of it. But if I got really comfortable with them, then I would probably just go and tell them (Athlete 4, F, 27)

Patients may not understand the why.

Finally, several athletes and patients communicated that they would not initially understand why questions would be asked about their MC when presenting to a sports medicine clinic. Physiotherapists also identified that they had experienced this lack of understanding in their practice and acknowledged that this could be a barrier to discussing the MC in the sports medicine clinic. To combat this, both athletes and physiotherapists recommended informing all athletes of the rationale and research underpinning the need to discuss this topic in the sports medicine environment:

I don't even know, but if there was someone saying, saying we're trying to make some connections. I will ask you about this and here's the pamphlet to support it, that would be sweet. But might be a bit random if not (Athlete 3, F, 58)

They're kind of confused as to why you would want to know that. I generally always say why I'm asking, you know. There's research behind this (Physiotherapist 5, M, 30)

Discussion

A dearth of education and discussion has given rise to a current lack of MC knowledge.

Participants noted they had a lack of structured education at school. These results agree with previous research that reported a quarter of girls felt unprepared for their period, and their school education lacked basic information about their bodies' anatomy and the use of sanitary products (Tingle & Vora, 2018). Recent qualitative research reported this lack of knowledge and freely available information in New Zealand, where this study is also based. Almost one in three elite female athletes reported having never received any female health-related information. These results were despite being a cohort of predominantly professional athletes with access to a range of embedded health care professionals (Heather et al., 2021). These results also align with international research. For example, college students enrolled in Women's Psychology classes reported that much of what they "knew" about the MC came from popular culture and was considered based on stereotypes (Chrisler, 2013). Furthermore, this lack of structured education was reported to be exacerbated for boys and men. This is unsurprising, as recent reports from the UK note up to one third of students are split by gender when learning about the MC in school (Brown et al., 2022). Practically, sports medicine clinicians may have difficulty searching for and interpreting research in this area if they are uneducated. At the same time, this reported lack of education outlines the importance of health professionals not assuming athletes have a high level of knowledge or understanding when discussing the MC in clinic. Similarly, within our interprofessional extended sports medicine teams, it cannot be assumed that all health professionals have a similar level of knowledge if referring to another member of the team for MC related issues.

Similarly, participants in this study noted experiences where the MC was a taboo subject at home, culturally, in living environments with men, and in the sporting environment. These reported taboos are in line with Dykzeul (2016), who reported that athletes silenced their menstrual-related pain and used the oral contraceptive pill (OCP) to manipulate when (or if ever) they bled while being the sole woman in a mixed gendered adventure racing team. Relevant to New Zealand, in Māori culture, the concept of tapu means to be sacred or restricted, and this concept relates to the MC (August, 2005). Thorpe, Brice, and Rolleston (2020), noted that Māori and Samoan members of the Black Ferns might follow specific MC-related protocols, such as not using the ice bath for recovery when menstruating. While not using the ice baths was not discussed within the team or with support staff, Thorpe described a shared knowledge and understanding of cultural traditions and menstruation in the team. However, many of these experiences noted by participants were in the past. In broader society, breaking the taboo nature of the MC seems to be gaining momentum. In New Zealand, period products are now freely available for students at school. One physiotherapist noted the role sports medicine professionals could also take to break this taboo by asking their teams to input their information, in a culturally appropriate, non-confronting way, into a wellness application to stop this subject 'being swept under the rug'.

Considering this lack of structured education and the taboo environment in which the participants did not discuss the MC at home or amongst peers, it is not surprising that the participants in this study have requested further education regarding the MC. Specifically, a physiotherapist and a surgeon both advocated for more education regarding the MC for men in sports medicine. These results underline the previously noted need for increased MC education for sports medicine support staff (Findlay et al., 2020), but also add that professional training programmes or postgraduate continuing professional development programmes

within sports medicine should be not only targeted towards females in these medical teams, but open for all, with males encouraged to attend.

Health professionals and non-health professionals have different (mismatched) concerns regarding the MC

Athletes and patients reported they are concerned with the regularity of the MC and menstrual symptoms' impact on their sports. These findings align with a previous study that reported heavy menstrual bleeding impacted female athlete's performance (Bruinvels et al., 2016) and another that reported the impact of MC knowledge, symptomology, and perception of menstruation on sports performance (Heather et al., 2021). In the current study, most patients and athletes reported using a smartphone application to track their MC regularity and symptoms, further demonstrating their curiosity in understanding the regularity, mood, and symptoms across the MC. Interestingly, no female athlete or patient noted that they tracked their cycle to avoid musculoskeletal injuries associated with extended cycles, track for signs of RED-S (i.e., missing periods), or guide when to carry out resistance training, indicating that women are either not interested in these more medical and performance applications, or are simply unaware of these applications.

In contrast, health professionals only reported being concerned with the risk of injury and medical conditions associated with the MC. No health professional, male or female, described any concern regarding patients' MC day-to-day symptoms or the impact on their sport. This lack of noted concern indicates that surgeons and physiotherapists may not ask patients about their day-to-day MC symptoms, despite this being a concern to the patients themselves. Whilst it is not considered necessary for every health care professional to discuss the MC at all appointments, at least one member of the sports medicine team should ask the athlete to identify

any concerns. The most appropriate member could ask the athlete, and relevant information can be shared with other team members as needed. Reporting MC symptoms is a step that is usually reluctantly taken by women (Santer et al., 2008), with patients tending towards an 'accepting mentality' (Findlay et al., 2020). Women's response to MC symptoms tends to take place with a moral framework, and that the only 'virtuous' response is to be stoic (Santer et al., 2008). Consequently, if a clinician does not ask explicitly, this may impede the ability for athletes' symptoms to be actively managed with appropriate pharmacological or multi-disciplinary non-pharmacological interventions such as nutritional strategies, exercise modes such as yoga, and extending sleep (Bruinvels et al., 2022).

Physiotherapists reported advising recreational and elite female patients to track their cycle for their reference. Still, they reported utilising or enquiring about this information regarding performance and training in high-performance environments only. Whilst this indicates a growing awareness of the implications of irregular cycles and symptoms on sports performance, it is of concern that health professionals do not carry over the utilisation of tracking information to non-elite populations. This lack of utilisation of available tracking information is despite robust evidence to show that issues like heavy menstrual bleeding (Bruinvels et al., 2016), low energy availability (Black et al., 2018), and clinical issues such as polycystic ovary syndrome (Awdishu et al., 2009) are highly prevalent in the recreational female athlete population. For non-elite athletes in areas with low resources, tracking allows patients to monitor their cycle and symptoms. At the very least, this tracking information may provide regularity, mood, and symptom insights to the patients. Accordingly, these results highlight the importance of questioning patients in the sports medicine clinic about their MC tracking data insights regardless of whether they are recreational or elite athletes.

Specific strategies to enable comfortable MC conversations.

Most participants reported a general comfort when asked about discussing their MC. However, patients and athletes described this as a hypothesised comfort and indicated they were not used to discussing this or would expect to discuss the MC in clinic. Several factors were noted to affect this comfort. Firstly, age of the health professional was noted as a potential barrier to these discussions, which may be due to a lack of education at the time of training and the limited professional, and life experience of the young health professional. Age of the athlete was also noted as a potential barrier by health professionals. Discussing sensitive topics with adolescents may be difficult as young women in New Zealand "learn simultaneously that menstruation is important and natural and that they should hide and ignore it" (Wootton & Morison, 2020). The inclusion of a parent, particularly the mother, was acknowledged as a mitigating factor here. Discussing adolescent health topics with both the parent and adolescent has been recommended by previous research, as both parents and clinicians can participate in these environments and can improve parents' knowledge (Jones et al., 2021). This piece of advice is in line with research that reports that mothers are the preferred source of information for young girls regarding puberty, menarche and the MC (Sooki et al., 2016).

Cultural considerations were identified as 'another layer' when considering MC conversations. As discussed previously, Māori and Samoan cultures have their own considerations regarding the MC. However, recent research (Thorpe et al., 2020) reported within a high performance sports environment Māori athletes saw menstruation primarily through a Western, medicalised view. Overall, they concluded that is player specific as to whether Māori or Samoan cultural ideas guide athletes around menstruation. These results together support that health professionals should be mindful of patients' sociocultural status when discussing the MC, but their patients should ultimately guide the direction of this discussion.

Likewise, male health professional participants noted that it was more challenging for them to discuss the MC. Similarly, athletes and patients assumed it would be easier for women to discuss the MC. This is in line with previous literature, which noted that most conversations about menstruation are heavily gendered (Tingle & Vora, 2018). The lack of comfort in discussing menstrual issues with males is in line with recent research on female athletes (Findlay et al., 2020). This discomfort of discussing the MC is a pertinent issue in the sports medicine clinic, as most sports medicine physiotherapists (MacLean & Rozier, 2007; Öhman et al., 2001), orthopaedic surgeons (Bernstein, 2013), and sports medicine doctors are male (O'Reilly et al., 2020). The current study provides insight that medical staff, and many female athletes, may feel uncomfortable with mixed sex/gender conversations around female health issues pertaining to the MC. Female athletes should have the choice to discuss the MC with someone they feel comfortable with, and so within a wider sports medicine team, this may be worth considering.

In general, health professionals reported that developing trust with the patient enabled patients to feel comfortable in the clinic and develop rapport with the health professional before discussing the MC. The importance of developing trust is in line with previous literature (Findlay et al., 2020). This study extends this knowledge by noting that females stressed that trust was especially important when discussing the MC with men. A lack of trust was the only noted barrier to mixed sex/gendered conversations, and similarly, gaining trust was the only noted enabler to these mixed sex/gendered conversations.

Finally, many participants noted that patients would not usually understand why a sports medicine health professional would want to discuss their MC. This lack of

understanding aligns with athletes' previously noted lack of awareness regarding MC-related medical and performance research. In line with this, health professionals should explain to the athlete why this MC discussion is appropriate in the sports medicine environment. This lack of understanding also underlines the recommendation that consults between sports medicine health professionals and athletes are opportunities to disseminate this MC-related medical and performance research.

Methodological considerations and limitations

The inclusion of orthopaedic surgeons, physiotherapists, patients, and athletes provided a comprehensive overview of perspectives regarding the topic of the MC in the sports medicine environment. The interpretive descriptive methodology allowed the study to provide practical recommendations to health professionals. However, we acknowledge several limitations. There may be an underestimation of participants who are uncomfortable discussing the MC, as this study utilised purposive sampling, and those who may have been uncomfortable may not have expressed interest in the study. All participants were living and working in New Zealand. Thus, specific cultures relevant to New Zealand may have played a role in our findings. Considering that point, it is worth noting that no Māori participants took part in the study. Māori athletes and health professionals would likely have specific cultural knowledge, perceptions and comfort discussing the MC, which this report would not have captured. Moreover, only physiotherapists and orthopaedic surgeons (albeit one who is also dual qualified as a sports medicine doctor) were represented. There was no representation of other sports medicine team members apart from physiotherapists and orthopaedic surgeons. However, this report has the potential to display transferability to other members of the sports medicine team and the broader sports and exercise community. Through the rich testimony given by our diverse group of participants and the research team's interpretations of these, this report invites readers to reflect on their knowledge, perceptions, and comfort in

discussing the MC. Readers may connect with the MC situations and interpretations' recognizable' to them (Smith, 2018).

Implications

Previous literature has examined MC-related symptoms, ACL injury rates and exercise adaptations relevant to the sports medicine environment. However, literature has also identified barriers to female athletes discussing the MC in the sports medicine environment and recommended that athletes and coaches need further education regarding the MC. Whether athletes and sports medicine health professionals routinely discuss the MC in the sports medicine environment was unknown. In this study, no athlete or patient had previously discussed the MC in the sports medicine environment. Physiotherapists reported advising athletes to track their cycles, in line with previous research recommendations (Elliott-Sale, Ross, et al., 2021; Findlay et al., 2020). However, physiotherapists only utilised this tracking data in high-performance environments. Therefore, this study extends the previous guidance and suggests that, where possible, health professionals ask patients about this tracking information.

Overall, these results indicate that the broader sports medicine community does not routinely discuss the MC in the clinic. However, the overarching theme described that the MC is considered a relevant and evolving topic within the sports medicine clinic environment. Many participants reported a lack of structured education regarding the MC, especially the males. Previous literature has recommended educational workshops for support staff where necessary (Findlay et al., 2020). As per the request of males in this study, this study recommends that this education should specifically target young and male sports medicine professionals. Likewise, as per the lack of structured education described by the participants, this study

recommends that health professionals do not assume that their athletes or colleagues have a particular level of knowledge regarding the MC when they present to the clinic.

This study also established that health professionals regularly screened for extended cycles and RED-S, but did not tend to ask regarding day-to-day MC-related symptoms. There is an opportunity for health professionals to ask athletes about their symptoms and associated perceived impacts on health and sport, as previously suggested by Findlay et al. (2020). Similarly, athletes did not describe any knowledge of RED-S, risk of injury during extended cycles, or MC phased resistance training, which indicates a further need for sports medicine professionals to inform their athletes of recent research applications. Finally, this study described specific barriers to these discussions, including age, sex/gender, culture, lack of trust, and understanding of the rationale for the discussion. Considering that specific cultures were described here as a potential barrier for discussing the MC, this study suggests that health professionals be aware of their patients' sociocultural status. This recommendation aligns with Thorpe et al. (2020) who argue that greater cultural competence is required in sporting environments. These noted results and barriers form the basis of several practical recommendations for health professionals working in the sports medicine environment. Applying these recommendations may help a) improve health professionals' and non-health professionals' knowledge of the MC and b) enable open, comfortable conversations about the MC in the sports medicine clinic environment:

- Engage in ongoing education regarding the MC
- Enquire regarding the level of knowledge individual athletes have regarding the MC
- Be aware of the patient's perspective and concerns regarding their MC.

- Discuss patients' MC-related symptoms and whether they impact their life and sports.
- Ask the patient about their menstrual tracking insights
- Be aware of the patient's sociocultural status when discussing the MC.
- Consider having parents present when discussing the MC with young patients.
- Give context and rationale to the patient as to why this MC discussion is appropriate.
- Develop trust with the patient by building rapport before discussing the MC.

Conclusion

This qualitative study explored health professional and non-health professional members of the sports medicine community's knowledge and perceptions of the MC. This study also explored health professionals and non-health professionals' comfort in discussing this topic in the sports medicine clinic. Overall, the overarching theme demonstrated that participants considered the MC as an evolving and pertinent topic for the sports medicine environment. Consistent with this, health professionals and non-health professionals in this study identified several interests and concerns regarding MC information and advocated for further education regarding this topic. While many participants described general comfort discussing the MC, participants identified several factors affecting this, including health professional and non-health professional age, culture, sex, and/or gender. This study highlights the importance of developing trust, giving context, using screening tools, and being aware of each patient's sociocultural status when discussing the MC in the sports medicine clinic. These strategies may encourage a shift away from MC-based silencing to open and comfortable conversations about the MC in the sports medicine clinic.

CHAPTER 4: The development of a menstrual cycle phase-based rehabilitation programme for females post-anterior cruciate ligament reconstruction: a focus group study.

This chapter consists of the following paper published in *New Zealand Journal of Sports Medicine.*

Reference

O'Loughlin, E., Reid, D., & Sims, S. The development of a menstrual cycle phase-based rehabilitation programme for women post-anterior cruciate ligament reconstruction: a focus group study. *New Zealand Journal of Sports Medicine 2023;49(2):42-51.*

Prelude

As discussed in Chapter 2, research has recommended FP-based RT for women to enhance RT responses. In Chapter 3, health professionals and non-health professionals noted that the MC is a pertinent topic for the sports medicine clinic, and there are strategies to enable comfortable discussions in the sports medicine clinic. However, FP-based RT has not been adapted for women following ACLR. This study aimed to develop a novel MCPBR programme appropriate for testing on women following ACLR. This chapter consisted of two phases: i) Focus groups with orthopaedic surgeons, physiotherapists, patients, and athletes, ii) the development of a MC phase-based ACLR rehabilitation programme. Three themes were constructed from the focus group data: (1) Preference for a consistent gym-based programme – referring to females' reported desire for frequent rehabilitation sessions in a gym; (2) Females need support to attend and engage –highlighting the different support structures women need to take part in a rehabilitation programme; (3) Strength is important but challenging to measure – outlining the difficulties health professionals have measuring strength in this

population. Overall, input from key stakeholders enabled the development of a new MCPBR programme that will undergo further testing in Chapter 5.

Introduction

In recent years, rates of anterior cruciate ligament (ACL) injuries and anterior cruciate ligament reconstruction (ACLR) in females have increased in New Zealand. Young females are the fastest growing subgroup for incidence of ACLR in the previous ten years (Sutherland et al., 2019). Females are three to six times more likely to sustain an ACL injury than men, possibly due to various anatomical, biomechanical, physiological and gendered environmental factors (Hewett et al., 2006; Parsons et al., 2021). However, after ACLR, females do not return to the same activity level and do not return to sport as often as men (Bruder et al., 2023; Tan et al., 2016). Females engage in rehabilitation with the assumption they are receiving evidence-based treatment. However, the most recent, up-to-date consensus statements on rehabilitation post ACLR do not have any specific recommendations regarding a female-specific approach to rehabilitation (Culvenor et al., 2022). This lack of female-specific guidelines is in line with a dearth of research on female athletes; 8-14% of sports medicine research studies are conducted on females only (Costello et al., 2014). Females have notable female-specific physiological, biomechanical, and endocrinological differences pertinent to consider post-ACLR.

More specifically, females have reduced quadriceps strength recovery of the injured limb postoperatively compared to males (Kuenze, Pietrosimone, et al., 2019; Maguire et al. 2021). Persistent quadriceps deficits are associated with inferior postoperative outcomes (Lepley, 2015). Research recommends a nine-month phase-based

rehabilitation process including range of movement, strength, power, agility and sport-specific exercises (Van Melick et al., 2016). Activation exercises initially commence postoperatively, and then progressive RT programmes commence once patients obtain full range of movement and restore balance and walking confidence.

Meanwhile, non-injured, naturally cycling females have been advised, where possible, to concentrate their resistance training (RT) in the FP of their menstrual cycle (MC) to potentially benefit from rising levels of oestrogen and low levels of progesterone (Thompson et al., 2019, Oosthuyse et al., 2022). These recommendations were based off previous studies which investigated FP-based training, where females track their MCs and periodise resistance exercise to their FP. There are limited number of previous studies in this area, with small sample sizes and methodological limitations. Oestrogen is known to have an anabolic effect on skeletal muscle via satellite cell activation (Strehlow et al., 2003). In addition, oestrogen correlates with and interacts with growth hormone in healthy adult females (Frantz & Rabkin, 1965; Hamilton et al., 2017). In contrast, research has also shown that females have greater amino acid oxidation during the LP compared to the FP after exercise and at rest (Kriengsinyos et al., 2004). However, these studies did not investigate this training approach in females following ACLR injury.

In the absence of such an insight, there is a gap in the literature as more efficient quadriceps strength recovery for females after ACLR leads to better postoperative outcomes. As mentioned, quadriceps strength deficits are associated with several adverse outcomes, including poor self-reported function, poor functional performance and a higher risk of subsequent ACL injuries (Grindem et al., 2016, Lepley, 2015; Palmieri-Smith & Lepley, 2015; Pietrosimone et al., 2016). Even small gains in

quadriceps strength result in improved outcomes for females following ACLR (Grindem et al., 2016). Therefore, MC phase-based quadriceps RT should be investigated in females post ACLR.

However, there are several other considerations when developing a MC phase-based rehabilitation (MCPBR) programme that would be practical to research in the physiotherapy clinic. A MCPBR programme would have to consider the pragmatics of rehabilitation environments. These practical considerations include postoperative rehabilitation protocols, scheduling considerations, and the practicalities of measuring improvements in strength and function in postoperative patients. Similarly, as this will be a programme designed specifically for females, the specific context of females' lives should be considered. The specific context of females' lives may create different opportunities and constraints to complete effective ACLR rehabilitation and, subsequently, any MCPBR programme (Parsons et al., 2021). Therefore, females' perspectives and preferences for ACLR rehabilitation must be taken into account. In addition, a co-design approach with relevant health professionals such as experienced sports physiotherapists and orthopaedic or sports physicians is appropriate to ensure the design and adaptation of a MC phase-based programme for research also meets the needs of the involved health professional groups.

Overall, this focus group study aimed to guide the design and development of a novel MCPBR programme that that will undergo further testing prior to a programme for release to practitioners. This MCPBR programme aims to be accessible for females and achievable to research in physiotherapy clinics. The research team developed these research questions to answer the research aims above:

1. What aspects of ACLR postoperative rehabilitation currently work well for female athletes, ACLR patients, physiotherapists, and surgeons?
2. How could previously designed MC phase-based RT programmes be adapted to suit females after ACLR injury?
3. Are there any specific aspects of the newly designed MCPBR programme to consider to increase compliance?

Methods

Study Design

This interpretive descriptive study, using focus groups was drawn from a wider programme of research developing and testing the effects of a novel MC phase-based ACLR rehabilitation programme. Focus groups were chosen to let participants participate in group-specific discussions and bring out key ideas and themes (Kevern & Webb, 2001; Kruegar & Casey, 2000). In addition, the research team considered that focus group discussions would provide insights into the relative norms, agreements, and points of disagreement of the different groups, such as health professionals versus non-health professionals. Auckland University of Technology Ethics Committee approved this study (approval #20/224).

Participants

The participants were grouped into four separate cohorts, as shown in Table 4. Two cohorts comprised health professionals: orthopaedic surgeons practising sports medicine and sports physiotherapists. The third cohort comprised patients post ACLR, and the fourth cohort comprised athletes. This study used purposive and convenience sampling to select participants. Firstly, health professionals were contacted by email based on online contact information. The primary researcher also requested that the physiotherapists share the study advertisement with ACLR patients. Subsequently, the

primary researcher emailed the focus group study advertisement to sports teams based on online contact information. Following this, interested participants emailed the primary researcher to express interest. The primary researcher asked screening questions to all interested participants and then sent information sheets regarding the research study. Three eligible participants withdrew from the study without reason before the focus group day. All participants gave written informed consent on the focus group day.

Table 4. Focus group participants

Interviews	Location	N	Participants	Sex	Age, years	Ethnicity
Focus Group 1	Online	2	Orthopaedic Surgeon 1	Male	44	NZ European
			Orthopaedic Surgeon 2	Male	45	Samoan/Nuean
Focus Group 3	Online	3	Physiotherapist 1	Female	42	NZ European
			Physiotherapist 2	Female	34	Irish
			Physiotherapist 3	Female	37	NZ European
Focus Group 2	Face to face	6	Physiotherapist 4	Male	44	Indian
			Physiotherapist 5	Male	30	NZ European
			Physiotherapist 6	Female	22	NZ European
			Physiotherapist 7	Female	24	NZ European
			Physiotherapist 8	Female	39	NZ European
			Physiotherapist 9	Female	31	NZ European
Focus Group 4	Face to face	4	Athlete 1	Female	30	British
			Athlete 2	Female	26	British
			Athlete 3	Female	58	NZ European
			Athlete 4	Female	27	NZ European
Focus Group 5	Online	3	Patient 1	Female	37	NZ European
			Patient 2	Female	25	British
			Patient 3	Female	29	European

Data Collection

Five focus group sessions took place. Two focus groups took place face-to-face in an office in a sports arena in Wellington (Table 4). Otter audio recording technology

(Otter.AI, Mountain View, CA, USA) was used to record the face-to-face focus groups. Three other focus groups took place over Zoom (Zoom Video Communications, Inc; San Jose, CA USA) and were video recorded. The primary researcher conducted all focus groups, and the sessions lasted no longer than one hour. The secondary author attended two focus groups (orthopaedic surgeons and patients) and took notes. Nobody else attended.

The primary researcher opened all focus groups by introducing the research team and providing an explanation of the focus group session. Each participant introduced themselves and were given time to ask questions about the session. The researcher then opened the focus group discussion with the first question (Table 5). Following this, the researcher described the general design of previous MC phase-based RT programmes. The primary researcher then asked a series of questions regarding the feasibility of the proposed programme (Table 5). These questions were discussed and underwent iteration amongst the research team to ensure they could answer the research questions. Repeating and summarising were used as informal member checks during the focus groups. The primary researcher closed the session once all questions were asked and participants had expressed all of their opinions. The primary researcher sent a one-page result sheet to the participants with an invitation to comment.

Table 5. Focus group protocol

Initial Question
What works well/ doesn't work well/ would you expect in ACLR rehabilitation programmes?
Researcher Outlines Previous MC Phase-Based RT Programmes
▪ Levels and roles of oestrogen & progesterone ▪ Only females with an ovulatory cycle (naturally cycling) included ▪ Lower or upper limb exercises ▪ Usual programme duration 8 – 12 weeks ▪ High frequency training in the first two weeks, low frequency training second two weeks ▪ Strength tested at the start and end of trial
In your opinion, would a periodised programme similar to this be workable to run/engage with in clinic?
Are there any barriers or difficulties identified with this programme in an ACLR rehab environment?
Is this programme similar or different to usual care provided/ rehab you engaged with?
How achievable would it be to fill in a data collection sheet recording MC and rehabilitation information?
Medical Professionals
Are there any barriers to changing appointment scheduling to align with the MC?
What would be the maximum number of sessions you would book participants per week into your clinic?
Current ACLR Patients/ Athlete Specific
How would you feel about tracking your MC for a few months?
How would you feel about using a home urinary testing kit as part of your rehabilitation?
What would be the maximum number of sessions you would attend per week?
Would you like some days to be a home-based programme instead of in clinic?

Data Analysis

Data analysis was supported by NVivo software (V.12.1.0; NVivo 12, QSR International Pty, Australia). Focus group discussions were voice recorded, and the primary researcher transcribed them verbatim. Braun and Clarke's six-phase reflexive thematic analysis was used (Braun & Clarke, 2019; Braun et al., 2016; Clarke & Braun, 2013). The researchers used a realist and indictive approach of reflexive thematic analysis to answer the research questions. The realist ontological approach informed the research team's thematic analysis by retaining focus on the limits of reality, i.e. the participants' preference for gym-based rehabilitation. The use of an inductive approach to thematic analysis meant that the research team developed codes and themes from the data content (Clarke & Braun, 2013). Practically, a mostly semantic coding approach (i.e. surface and obvious) was considered appropriate to investigate the concepts directly reported by participants. The primary researcher read and reread the transcripts, making notes about their content to become comfortable with the data. The primary researcher then commenced reflexive, inductive, and research question-informed coding. The primary researcher returned to codes and revised them multiple times. Subsequently, candidate themes were established. By determining if they could communicate the story of the data, the primary researcher explored these potential themes. The research team discussed the codes, themes, and thematic definitions. This theme construction phase was iterative, with the primary author consulting with the second and third authors in regular meetings. Themes were also returned to and revised several times. Following data analysis, the authors concluded that the data were sufficiently rich, complex, and diverse to answer our research question. As a result, no additional focus groups were held. In terms of transcription notation, [...] indicates omitted data.

Findings

Thematic analysis resulted in three key themes. The first theme outlines physiotherapists' (n=9), orthopaedic surgeons' (n= 2), female athletes' (n=4), and ACLR patients' (n=3) preference for a MCPBR programme's design to be consistent in design and implementation. The second theme outlines the support patients, athletes, & health professionals identified they would need to successfully carry out and engage with this specific MC programme in the clinic. Finally, the third theme describes that objective measure change is necessary for patients' progress during ACLR rehabilitation. However, it also describes health professionals' challenges with carrying out specific objective testing at certain time points in this population.

Preference for a consistent gym-based programme

Physiotherapists and surgeons agreed that participants commence the training programme at the same time post-ACLR (six weeks post-surgery). They noted that the participants' MC phase should not affect commencing the programme. Therefore, this would ensure consistency regarding taking outcome measures and strengthening relative to their operation date.

> *Could they not start in the phase that they're in? So could they, if they were in the luteal phase, just after that six week mark, would they not start low frequency, so just slot into the rehab? Because I would be really wary of holding someone back for another two and a half, three weeks. (Physiotherapist 3, F, 37)*

Athletes and patients strongly preferred gym-based sessions for their ACL rehabilitation. Participants reported that attending a gym provides structure and routine to their rehabilitation journey. Patients post ACLR valued learning how to use gym equipment properly with their physiotherapist. In addition, patients described their preference to have a time where they had to attend a specific place, which provided a welcome rigidity to their rehabilitation. It put the responsibility on them to attend their rehabilitation. Two ACLR patients discussed as follows:

> *I think the fact that you need to go to the gym is actually really like helping with getting a routine as well in your rehab. So yeah, I think, I think the gym is, is probably the safest way to do it. (ACLR Patient 3, F, 29)*

> *I do prefer the gym because there is that strictness …that was definitely the preference because it was, you know, accountability. You do need to be here at this time and do that, do that sort of thing (ACLR Patient 2, F, 25)*

Similarly, ACLR patients and athletes outlined their preference to attend multiple rehabilitation sessions weekly. They reported that they preferred to attend multiple sessions so they could be sure to complete their rehabilitation multiple times per week in a structured manner. However, they noted that this frequency might depend on their other responsibilities. These patients and athletes described work, children, and pets as responsibilities that could affect their, or other females, ability to attend frequently.

I'd say probably three to four sessions a week to, to really smash it out and get it done (ACLR Patient 1, F, 37)

Yeah. I think more or less the same for same. I don't have a baby. I don't even have a puppy, so I don't have any responsibility. So I think it would be really like, yeah… So as many sessions as I can fit in in a week. (ACLR Patient 2, F, 25)

However, physiotherapists and athletes agreed that participants should attend an equal volume of sessions every week, no matter the MC phase. They noted that an equal number of weekly sessions is more appropriate for ACLR rehabilitation, as females want to attend rehabilitation consistently. There can also be challenges in booking physiotherapists' calendars with short notice. Both groups advised that exercises completed within these sessions could be specific to a MC phase.

Maybe if it's more like this is the principle for this bit of the cycle, and that's the principle for the other bit of the cycle (Physiotherapist 4, M, 44)

I'd rather just go consistently more for weeks and weeks. Even if I felt not as strong or not as capable, I would still rather keep up that consistency (Athlete 4, F, 27)

Finally, physiotherapists generally agreed that they were not experts in general RT programming, especially if they had not worked in a strength and conditioning area or with strength and conditioning coaches. In addition, they acknowledged a wide variation in training protocols used by physiotherapists. They expressed a need for guidance in

the form of an exercise protocol and a progression framework for physiotherapists carrying out a structured, MC phase-based RT programme.

> *There's a lack of understanding if you're not involved or you haven't worked in the strength and conditioning…we're trying to provide education to providers to try and bring up that standard and just get them to meet basic strength and conditioning guidelines.. There'll be no consistency between the groups, unless you provide some form of a framework for them to work on. (Physiotherapist 2, F, 34)*

Females will need support to engage with a MC phase-based rehab programme

ACLR patients consistently reported that they needed supervision and support from their physiotherapist to help them engage and carry out the day-to-day processes of engaging with the rehabilitation programme. One participant felt that physiotherapists needed to engage more with the patient so that the patient could get more from their rehabilitation process. ACLR patients reported that their experiences of being given information such as a home exercise sheet were insufficient to meet their needs. Instead, they preferred having clear ongoing support to attend and carry out their exercises in the clinic with their physiotherapist.

> *One thing that didn't work for me right at the start was like… here's all the information and now it's over to you and you can either do it or not do it and it's up to you.. My physio was just like, well, here's the information, you know, I'm just going to see what you do. And then we had a big chat and I was like I actually need your help to get me to do this. Like tell me how to make me do it, make me do it. And now it's working for me. (ACLR Patient 1, F, 37)*

In particular, this new mother noted that caring for a young child while engaging with ACLR rehabilitation meant she needed extra support and the ability to have an individualised, adaptable approach from her physiotherapist.

> *It has been a bit tricky, especially with a baby kind of getting in the way of just everything… I found my physio just recently to be like really adaptable. Like I was kind of expressing how hard it was to, you know, fit it in around baby or whatever. And, and he was able to just kind of see that from my perspective and say, okay, well, you know, what can we do to make this work for you? (ACLR Patient 1, F, 37)*

Similarly, athletes, patients, and physiotherapists advised that a centralised data system would be helpful for the proposed programme. Specifically, participants noted that having one centralised datasheet which has both their MC information and their physiotherapy information would make it easier for patients and physiotherapists to engage in the planned MCPBR programme.

> *It would be really handy to have all of those, all of three of those things and physio*
>
> *Appointments in one in one place (Athlete 4, F, 27)*
>
> *The only thing that I would recommend is having some sort of centralised system to manage the admin side. (ACLR Patient 2, F, 25)*

Finally, athletes noted they would appreciate some education regarding the MC to partake in the programme. However, athletes advised that this would not have to be detailed, and optional information could be available for those interested in learning more. This further education could be in multiple media formats, including written information, videos, or links to internet resources.

> *The people who want to really delve hot out into it and just look at links and videos or read about it, and then the people that don't really want, or care, you can say [some education] but it's not too much information. (Athlete 4, F, 27)*

In addition, physiotherapists advocated that a lack of funding could be a barrier to attending a rehabilitation programme multiple times per week. Physiotherapists advised that there would have to be funding available for patients to attend a gym-based MC phase-based programme multiple times per week. However, the athletes or patients did not discuss funding when they discussed their preference for multiple sessions per week.

> *If they were funded, they could come in as much as they wanted then. (Physiotherapist 4, M, 44)*

Testing strength and function is essential but challenging

There was an agreement between all focus group participants that measuring strength and function is an integral aspect of ACLR rehabilitation. Athletes expected initial and ongoing objective measurements as part of the rehabilitation process following an ACL

injury. Similarly, previous patients with experience in ACLR rehabilitation reported how objective measures were essential to see real change throughout their rehabilitation. In addition, physiotherapists and surgeons reported that they routinely use objectively measured data to demonstrate deficits in the strength and function of their patients. They noted that when they give this data to patients, their patient's compliance with the rehabilitation process improves.

> *Measurable standards of improvement where I could say, hey, look, I can do, I couldn't do this last week, I can do it this week. (ACLR Patient 3, F, 29)*

> *Objective measures work well. They improve patient compliance. The more objective data you can give these people, the more they mind. (Physiotherapist 4, M, 44)*

Physiotherapists reported testing strength in patients post-ACLR via repetition maximum (RM) testing and handheld dynamometry. They also reported testing functional movement symmetry including single-leg squats and bridging exercises. However, physiotherapists acknowledged that strength testing approaches are not well standardised across physiotherapists in general. Therefore, they advised the MC phase-based programme to define a testing protocol for measurements at the start and end of the programme.

> *Lifting symmetry and then quads, like a leg press, hamstring curl, handheld dynamometer, hamstring bridging on a chair, endurance, single leg squat, knee extension. (Physiotherapist 5, M, 30)*

I think the other problem is… it's very therapist dependent also (Physiotherapist 1, F, 42)

Furthermore, the physiotherapists and surgeons explained that most quadriceps strengthening programmes commence four to six weeks after surgery. At this point, anterior and intra-articular knee pain inhibits patients' ability to complete repetition maximum testing. Therefore, they noted that patients post-ACLR would be unable to carry out a reliable strength test when commencing a MC phase-based quadriceps loading programme due to pain.

You just won't be able to do [strength testing] at six weeks because pain would be higher, even if it's pain from the graft, it's just pain. It'll just, it'll give you nothing. (Physiotherapist 2, F, 34)

Similarly, physiotherapists and surgeons reported that orthopaedic surgeons would not support hop testing before six months post-ACLR. Therefore, participants suggested using a validated patient-reported outcome score to establish the effect of a MC phase-based RT programme on patients' knee function from the early to the middle phase of ACLR rehabilitation.

I normally don't get people jumping on one, you know, doing the plyometric stuff or the hop test or hop training or jump training until six months onwards. (ACLR Surgeon 1, M, 44)

Discussion

Preference for a consistent gym-based programme

The focus group participants have noted that it would be pragmatic to commence the MC phase-based ACL rehab programme at a specific time point postoperatively, approximately six weeks post ACLR. Participants enter at whatever MC phase they are in at this six-week postoperative time point. Therefore, at this point, participants would be, in general, at a similar starting point of postoperative healing when commencing the programme. This approach is in contrast to previous studies investigating MC phase-based RT programmes, where participants commenced the training programme at a specific point in their cycle, for example, on day seven (Wikström-Frisén et al., 2017).

Similarly, focus group participants also described a preference for an equal volume of weekly rehabilitation sessions, noting that they prefer to attend physiotherapy regularly. It is also challenging to change bookings at short notice with physiotherapy clinics. This preference is also in contrast with previous MC phase-based RT programmes. In previous programmes, participants usually engaged in high-frequency, low-frequency programmes (Wikström-Frisén et al., 2017). In these high-frequency, low-frequency programmes, participants engaged in approximately five RT sessions per week in their FP and approximately once weekly in their LP(Wikström-Frisén et al., 2017). However, there are high intra and inter-individual variation in MCs. Subsequently, there may be short notice when someone switches from follicular to LP and vice versa. Patients book rehabilitation sessions in advance, and so there is less ability to arrange sessions at short notice with physiotherapists. Therefore, equal weekly volumes and periodizing the content of these sessions to the specific MC phase is more practical for a rehabilitation environment. Therefore, patients will commence their phase-specific training session

when they reach six weeks postoperatively (see Figure 7). MC phases will be determined by the patients, using calendar tracking, basal body temperature recording and urinary ovulation kits. The patients will note their MC phase on their individual data sheet, also available for the physiotherapist to see before each patient visit. RT is carried out in the FP-based sessions. Furthermore, best practice guidelines recommend neuromuscular and cardiovascular exercises alongside quadriceps strengthening programmes post ACLR (Van Melick et al., 2016). Therefore, neuromuscular & cardiovascular exercises are included during the LP as part of the MCPBR programme.

Similar to previous MC phase-based programmes, which consisted of gym-based exercises, athletes and patients in this study both described a clear preference to attend gym-based ACL rehabilitation. This preference contrasts with previous research, which reported that not having access to facilities and equipment was not regarded as a barrier to ACL rehabilitation (Walker et al., 2020). This preference is vital to note, as gyms can be heavily gendered, which may disadvantage females' participation (Fisher et al., 2017; Parsons et al., 2021; Rapport et al., 2018). Females in this study did not mention any difficulty or barriers to attending the gym. However, it is possible that the participants in this study were more comfortable in gym environments due to previous sporting involvement, and others may feel uncomfortable in these environments. In addition, there are geographic constraints that may prevent some ACL patients' access to appropriate facilities (Walker et al., 2020). Therefore, whilst the protocol includes gym-based exercises (leg press, squat, and knee extension), modifying and adapting said exercises will be available if a participant does not want to or cannot attend a gym facility consistently. In addition, females will be fully supervised by a physiotherapist, as described in Theme Two.

Athletes and patients also described their preference to attend these gym sessions multiple times per week. This preference to attend weekly is not in line with the average twelve ACLR postoperative rehabilitation sessions in New Zealand (Fausett et al., 2019). This mismatch suggests that physiotherapists may not schedule patients as frequently as patients would like. A recent scoping review by Walker et al. (2020) examined barriers to and facilitators of ACLR rehabilitation. Walker et al. (2020) reported that the optimal frequency of supervised rehabilitation, and whether this varies between stages of rehabilitation, is yet to be determined. In addition, the authors noted none of the included studies in the review which examined the frequency of supervised rehabilitation included a cost benefit analysis (Walker et al., 2020) . Rehabilitation needs to be effective and economical, to ensure that patients have access to appropriate rehabilitation to achieve their goals but also reduce financial impact on the individual and health care system (Walker et al., 2020).

However, it is worth noting that female participants in this study were clear regarding their preference for multiple supervised sessions per week. Previous research has described how women, specifically, juggle other pressures such as routine and rigid familial and domestic labour which affects their ability to engage in physical activity (Doan et al., 2022; Moreno-Colom, 2015). These other pressures may make it hard to prioritise non-supervised, home based rehabilitation, and therefore create a need for frequent structured times and place for rehabilitation, as described by our focus group participants. Although, concurrently, these pressures could also affect their ability to attend supervised rehabilitation. This was as noted by an athlete who described attending physiotherapy whilst ‘managing everything else as well’ could affect her ability to attend. Therefore the MCPBR programme includes multiple supervised weekly sessions. However, as suggested, adaptions such as telehealth sessions or alternative

exercises will also be provided for days when these women have other commitments. Similarly, attendance to the programme will be monitored to understand further if specific groups of females do or do not attend physiotherapy consistently, and whether their adherence affects their outcomes.

Finally, physiotherapists acknowledged the importance of RT but noted they were not experts in resistance programming and progressions. This lack of knowledge is in line with recent New Zealand-based research, which has demonstrated deficits in physiotherapy strength and conditioning knowledge and recommended liaison with trained strength and conditioning professionals (Nichols et al., 2021). In addition, physiotherapists did not discuss any differences regarding current RT prescription differences in clinic for males and females. It is assumed that males and females are prescribed RT following ACLR. However, male and female coaches have been found to differ in the activities they programme for their athletes, and gender bias has been shown to affect treatment prescription in orthopaedic medicine (Borkhoff et al., 2008; Judge & Burke, 2010). Therefore, it is plausible that physiotherapy exercise prescription, including explanation, support, and interaction regarding these exercises, could be different for male and female patients. Physiotherapists in these focus groups recommended that the programme design include specific exercises and a progression framework to carry out as part of the programme. Therefore, a protocol was developed with resistance exercises targeting the quadriceps muscles, including leg press, knee extension, and squat exercises. These quadriceps resistance exercises do not need more than basic lower limb gym equipment, can simply progress from double to single leg, and can be completed in a limited or increased range of movement (Figure 6). A resistance exercise progression guide is also outlined in Figure 6, recommending that if

a participant can do 1-2 more repetitions than the prescribed amount, then it is appropriate to progressively overload (Schoenfeld, Ogborn, et al., 2016).

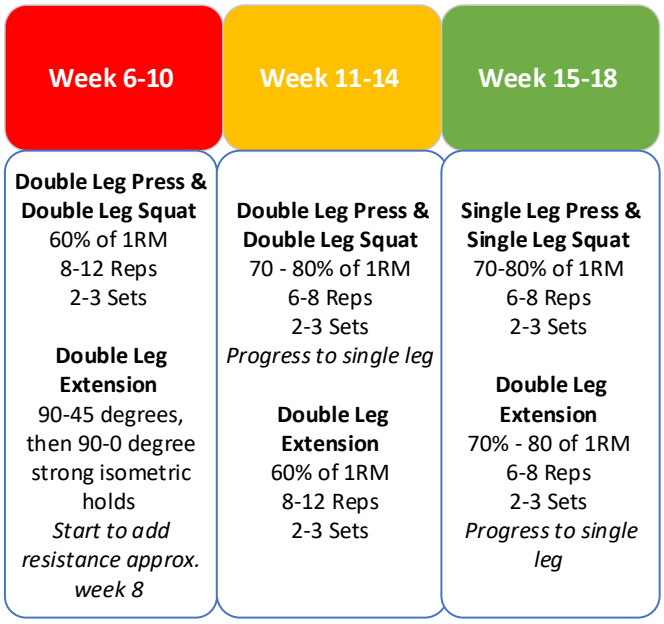

Figure 6. Quadriceps resistance exercise progression guide

Quadriceps resistance training programme for weeks 6-18 of ACLR rehabilitation. These exercises are to be completed each follicular phase session. Other resistance exercises i.e. hamstring, gluteal, and calf exercises can also be added by the physiotherapist in the follicular phase as individually required. If the participant can do 1-2 more repetitions than the required amount, progress load by 2-10% i.e. increase weight, increase set number, reduce rest time, move to single leg. If the participant cannot do 1-2 more repetitions than the required amount, maintain status quo.

Females need support to attend and engage

Previous ACLR patients noted that they need support from their physiotherapist to attend ACLR rehabilitation. This strong reported need for support is despite no consensus currently in the literature on the efficacy of supervised versus unsupervised rehabilitation (Walker et al., 2020). The literature recommends that more high-quality research is needed to provide more specific evidence. In the interim, health professionals and patients should decide whether they should attend supervised rehabilitation based on this evidence, along with patient preferences and values. However, the females in this study described a clear, strong preference for continuous, supervised rehabilitation. Rehabilitation from an ACL injury is a significant commitment which requires dedication to a long-term training programme. Women may engage with

more familial & domestic labour and, therefore, require extra support throughout the rehabilitation process to attend the sessions with a professional and receive guidance (Moreno-Colom, 2015). This support and allocated time may provide participants a structured time for rehabilitation that they might not have in the home environment. In addition, while athletes and patients asked for gym sessions, they did not specifically note that they were comfortable with RT and rehabilitation exercises. Females may be less familiar with RT as women engage in it at lower rates than men throughout their lifetime. Previous research suggested that women may need more supervision to learn about resistance and neuromuscular training as part of a programme (Vasudevan & Ford, 2022). This suggestion for supervision is in line with the females' requests in this study. Therefore the MC phase-based programme includes fully supervised sessions with physiotherapists.

Moreover, health professionals described the cost of rehabilitation as a potential barrier for patients to engage in a rehabilitation programme. However, it is interesting to note that no athlete or patient described this as a barrier. In a scoping review of facilitators and barriers, the cost of treatment was noted as a barrier to rehabilitation by ACLR patients. It is essential to note that this study was conducted in New Zealand, where ACL rehabilitation is subsidised by a national, no-fault accident insurance scheme. Patients and athletes may not have described cost as a barrier as physiotherapy is often assumed by many in the public as free. In addition, the athlete and patient focus groups may not have captured different socioeconomic backgrounds with different financial considerations. For some, financial considerations are a significant barrier to attending rehabilitation; therefore, the MC phase-based programme considers, in the first instance, a funding model to provide funding to participants with whom it may not be able to engage otherwise.

In contrast, athletes and patients did not foresee any barriers to tracking their cycle, using a basal body thermometer daily, and testing for ovulation monthly using a urinary ovulation kit. Recent research from New Zealand showed that over half of female athletes track their cycles on mobile applications (Heather et al., 2021). However, women saw the value of having one datasheet where their MC information and their physiotherapy information could be combined and easily accessed throughout the proposed MCPBR research study. This was recommended to be on an online platform which can be accessed easily via smartphone or desktop. A datasheet template has been developed for the MCPBR programme, which can be copied to each patient's individual datasheet. Each individual patient's password protected datasheet includes demographic details, surgery details, physiotherapy attendance, exercise outside of physiotherapy, and MC information. The sheet is available to participants as part of the MCPBR programme research study.

Lastly, athletes and patients advised that they may need their physiotherapists to provide some basic education regarding the MC but that these women do not need detailed education to partake in the programme. Therefore, a concise education pack is available for all participants in the MCPBR programme. This pack will educate participants regarding how to track their cycle using calendar tracking, basal body temperature recording, and urinary ovulation kits. Additional education is available via online links to educational articles and videos for women who express interest in further information.

Strength is important but difficult to measure

Athletes and patients noted that they expected and enjoyed receiving objective, quantifiable data to understand their injury-related deficits. These results are in line with previous research, where regular assessments were previously described as the second most crucial facilitator of rehabilitation, second only to a good relationship with the rehabilitation provider (Walker et al., 2020). In addition, physiotherapists and surgeons reported that it is challenging to measure knee strength six weeks post-ACLR. These health professionals reported that patients' pain inhibits their ability to extend after an ACLR. Therefore, the programme will test one RM isometric knee extension strength of injured versus uninjured legs at eighteen weeks post ACLR to assess quadriceps limb symmetry. In addition, a one RM knee extension of the uninjured leg is assessed at six weeks to identify any contralateral strength changes post-surgery, as seen previously in those with ACLR (Lepley, 2015).

Physiotherapists also advised prescribing a clear strength testing protocol as part of the programme. Therefore, a testing protocol is available to guide physiotherapists as part of the trial (Table 6). This protocol guides the assessment of maximum knee extension strength using a handheld dynamometer or a knee extension machine in line with guidance from previous literature (Sinacore et al., 2017). These strength measures are taken post the twelve-week intervention programme. In addition, these testing results are included in the patient's data sheet for participants to read. Likewise, surgeons and physiotherapists have outlined their unease with testing hopping before six months post-ACLR. Therefore, a validated patient-reported functional outcome measure is used to assess function in the MC phase-based RT programme (Knee Injury and Osteoarthritis Outcome Score).

Table 6. Strength testing protocol

Warm Up & Testing Protocol

All participants should complete a warm up before 1RM testing as follows:

1. A low intensity (<4 rate of perceived exertion scale) 10 minute warm up on a bicycle.
2. 1 set x 10 reps of the minimum weight on the knee extension machine OR with minimum weight applied by examiner for those with no knee extension machine.
3. 1 set × 10 reps (load increased by 10–20%)
4. Commence protocol as below.

Knee Extension Machine

1. Requires a knee extension machine.
2. All 1-RM testing should begin with the uninvolved limb and alternated between limbs.
3. The tester will instruct the patient to extend the knee against the resistance of the machine in a slow and controlled fashion.
4. Trials are deemed successful when the patient has achieved the targeted angle of knee extension and maintained it for 2 seconds.
5. Resistance is increased after a successful trial on each limb by 2.00 to 14.00 kg, at the tester's discretion, depending on the difficulty of the previous repetition.
6. Failure is defined as 3 unsuccessful attempts to lift the weight to the targeted angle, with a rest interval of up to 60 seconds given between attempts.

Handheld Dynamometer

1. A digital HHD can be used to test the uninvolved limb, followed by the involved limb.
2. Patients will be seated on a standard treatment table, with the dynamometer fixed to the table leg using an inelastic strap.
3. The strap should be secured to allow no more than 85° of knee flexion during the quadriceps muscle contraction.
4. To aid trunk and pelvis stabilisation, participants should grasp the edge of the treatment table. Patients will complete 3 practice trials (50%, 75%, and 100% perceived effort), followed by 3 maximal effort contractions lasting 5 seconds, with 60-second rest intervals.
5. The force sensor will be placed just proximal to the ankle joint, with an inelastic strap countering all resistance to knee extension.
6. The tester should stabilise the position of the HHD in relation to the shank but do not provide any counterforce.

7. The final 1-RM values for the involved and uninvolved legs are to be recorded.
8. Testing must be done at 90-0 knee extension. As time progresses clearly the resistance of the test needs to increase.

7. The peak force is to be recorded for each trial in kgs.

Overall, a focus group approach was considered necessary when designing a programme for two reasons. Firstly, this co-design approach was deemed necessary to ensure the design and adaptation of a MC phase-based programme meets the needs of patients, surgeons, and physiotherapists. Secondly, this study recruited athletes and patients to draw upon women's perspectives on what they would prefer in their rehabilitation programmes. Therefore, the programme would not only be designed in line with their MC phases but also consider women's preferences and their specific requests for an ACLR rehabilitation programme. In summary, the findings from the focus groups indicate several key findings thought to be important when adapting a MC phase-based RT programme to meet the requirements for women after ACLR. These recommendations are summarised in Table 7.

Table 7. Considerations for developing a menstrual cycle phase-based rehabilitation programme for females after ACLR.

Considerations
1. Have a consistent baseline between groups – exclude postoperative non-weight bearing status
2. Commence at a specific time point (approx. 4 -6 weeks) post operation
3. Preference for multiple gym-based sessions per week
4. Preference for an equal number of sessions per week
5. Session content depends on MC phase
6. Prescribe specific exercises and progressions
7. Preference for supervised physiotherapy sessions
8. Programme to be adaptable
9. Remove any cost barrier
10. Provide a centralised online system to input data
11. Provide basic MC education
12. Prescribe a clear strength testing protocol (do not test strength at the start of the programme)
13. Measure function by self-report status
14. Include objective measures for patients to track

Based on these results, the research team developed a novel MC phase-based rehabilitation programme (Figure 7).

Figure 7. Proposed menstrual cycle phase-based rehabilitation programme

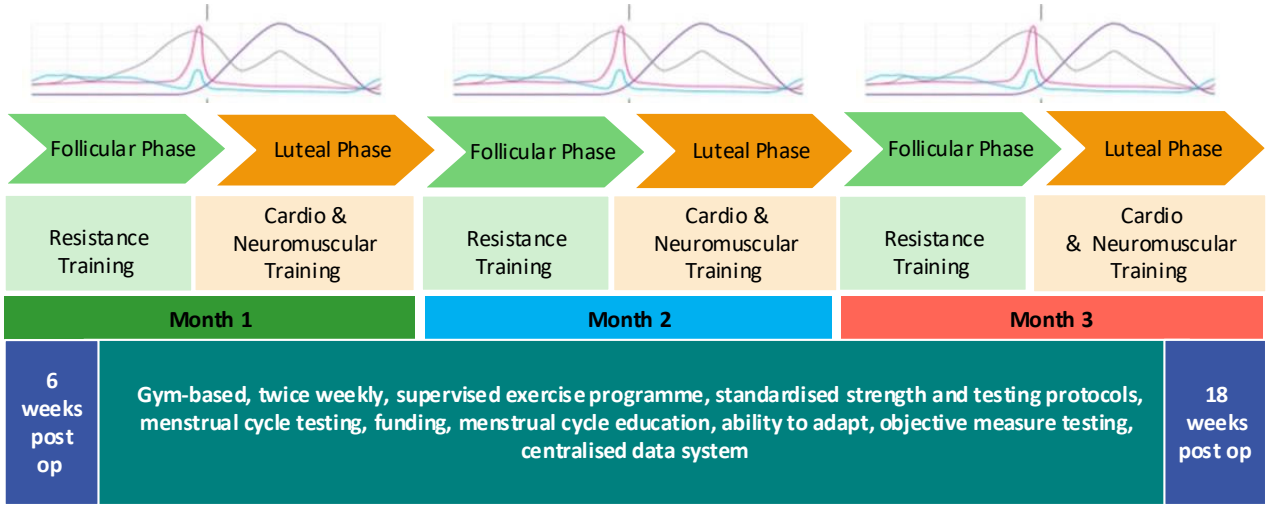

Figure 7. Proposed Menstrual Cycle Phase-Based Rehabilitation Programme. Visual representation of the menstrual cycle phase-based quadriceps resistance training programme. Training commences at 6 weeks post-surgery until 18 weeks post-surgery. Participants attend twice weekly to a gym-based setting for supervised rehabilitation. These sessions can be adapted if needed, i.e. telehealth. All data will be entered into an online data sheet visible to the researcher, physiotherapist, and patient. Females will receive menstrual cycle education and input menstrual cycle information to their datasheet to establish their menstrual cycle phase. Resistance training is completed in the follicular phase sessions and cardiovascular and neuromuscular exercise is completed in the luteal phase sessions. Physiotherapists will use standardised strength testing to measure outcomes and use standardised progression protocols to prescribe strength exercise. Funding will be available for women to attend sessions.

Methodological considerations and limitations

To our knowledge, this is the first study to investigate the perspectives of athletes, ACLR patients, physiotherapists, and orthopaedic surgeons to inform the development of a MC phase-based ACLR rehabilitation programme. This is also the first study to specifically ask females what has worked well in their previous rehabilitation programmes. The interpretive descriptive methodology enabled the design of a rehabilitation programme, aimed to improve health outcomes. However, some limitations should be considered when analyzing the results. The number of participants was small and partially purposively selected. The athletes, patients, physiotherapists, and orthopaedic surgeons who attended the focus groups may be more likely to be engaged and positive towards ACLR rehabilitation. Therefore, there is a risk of bias

here regarding the enthusiasm for and engagement with rehabilitation from the focus group participants. Similarly, there may be an underestimation of participants who are uncomfortable discussing the MC, as only those who were comfortable would have self-selected into the study. In addition, no women who identify as Māori or Pasifika took part in the study. Females who identify as Māori and Pasifika may have specific preferences for ACLR rehabilitation, which this focus group report would not have captured. Furthermore, there was no follow-up with these participants to discuss the programme after it was developed. Future studies could include more women to provide further data regarding specific aspects of rehabilitation that work well or would be desirable for this population group.

Conclusions

Focus groups made three leading suggestions when designing a MC phase-based ACLR rehab programme. Firstly, the programme should be consistent in its approach, with the date of commencement of the programme and the weekly number of sessions not dependent on MC phases. Secondly, researchers should provide physiotherapy supervision and financial and technological support to athletes carrying out the programme. Thirdly, participants acknowledged that measuring strength is essential, but collecting an accurate strength measure is difficult when most RT loading programmes commence. Therefore, an initial proxy measure (e.g., patient-reported function) and an accurate final strength measure will be collected. This input from key stakeholders enabled the development of a new MCPBR programme. Future research should investigate the programme's effectiveness in improving RT responses following ACLR.

CHAPTER 5: The effect of menstrual cycle phase-based rehabilitation for females following anterior cruciate ligament reconstruction: a randomised controlled trial.

This chapter consists of the following paper prepared for submission to British Journal of Sports Medicine.

Prelude

This chapter involves a formal evaluation of the effectiveness of a female-specific, MCPBR versus UC on LSI, quadriceps maximum strength and self-reported lower limb function for females following ACLR. Forty one females participated in a 12-week intervention from six to 18 weeks post ACLR. Participants were randomly assigned to one of two groups: MCPBR (n=20) or UC (n=21). Knee extensor strength of the non-injured leg was measured at baseline. Knee extensor strength of both legs and the LSI of participants' maximum isometric knee extensor strength were calculated at the end of the trial. Self-reported symptoms and function were also taken at baseline and at the end of the trial using the International Knee Documentation Committee Questionnaire (IKDC), The Knee Injury and Osteoarthritis Outcome Score (KOOS) and The Knee Self-Efficacy Scale (K-SES). Thirty-eight females completed the study. Data which did not comply with MC verification criteria were excluded (n = 4), thus data of n = 34 were included in the analysis. Therefore, the study was underpowered to detect a difference in the primary outcome, which limits the study's ability to draw definitive conclusions. However, LSI following MCPBT was 84% (74-93) and 81% (62-88) following UC (p= 0.24). The injured leg strength at eighteen weeks post ACLR was 39.3kg (14.1) following MCPBR, compared to 30.8kg (11.9) following UC, (p=.07). Both groups

achieved excellent outcomes and therefore, this study supports twice-weekly, supervised, gym-based rehabilitation, with targeted quadriceps strengthening and regular strength testing. Furthermore, this study demonstrated that a full scale RCT to investigate MCBPR in females post ACLR is feasible. Future research should investigate a larger cohort of females, including interim bilateral strength measures of both legs over a longer period. Similarly, it would be pertinent to understand females' experience of MCPBR post-ACLR.

Introduction

In recent years, the incidence of anterior cruciate ligament (ACL) injuries in females has surged, with females being three to six times more susceptible to such injuries than males (Zbrojkiewicz et al., 2018, Sutherland et al., 2019). These increased rates of injury can be attributed to a combination of anatomical, biomechanical, physiological, and gender-related environmental factors (Parsons et al., 2021, Hewett et al., 2006). Following ACL reconstruction (ACLR), females tend to have a diminished quadriceps strength recovery, report poorer knee-related function, and are less likely to return to sports compared to their male counterparts (Kuenze, Pietrosimone, et al., 2019, Devana et al., 2022). This reduced quadriceps strength is associated with increased rates of subsequent ACL injuries and early onset post-traumatic osteoarthritis (Grindem et al., 2016, Tourville et al., 2014). There is a notable underrepresentation of females in ACLR research, resulting in a lack of tailored guidelines for their rehabilitation (Mok et al., 2022, Culvenor et al., 2022).

Initial rehabilitation following ACLR includes an emphasis on restoring lower limb strength, particularly in the quadriceps (Kuenze et al 2014). The effectiveness of

resistance training (RT) is influenced by various factors (Hawley et al., 2011, Douglas et al., 2017). Specifically, oestrogen, a hormone present in females, is recognized for its anabolic impact on skeletal muscle (Lowe et al., 2010). Conversely, progesterone exerts anti-oestrogenic effects and is considered catabolic (Kriengsinyos et al., 2004). Recent reviews, despite methodological limitations and small sample sizes, suggest that non-injured, naturally cycling women should focus their RT during the FP of their menstrual cycle (MC) to benefit from rising oestrogen levels and reduced progesterone levels (Oostuyse et al., 2022, Thompson et al., 2020).

However, MC phase-based RT has not been investigated in women post-ACLR. Therefore, the primary objective of this study is to investigate if MC phase-based rehabilitation (MCPBR), where women post ACLR periodise RT to the FP of the MC (MC), results in improved quadriceps strength symmetry following ACLR, compared to usual physiotherapy rehabilitation. The secondary objective was to investigate if MCPBR resulted in improved self-reported functional outcomes and self-efficacy in women following ACLR compared to usual physiotherapy care (UC).

Methods

Study Design

This RCT adheres to the Consolidated Standards of Reporting Trials (CONSORT) and the Consensus of Exercise Reporting Template (CERT) guidelines (Appendix 39) and the TIDER guidelines (Appendix 40). The study protocol was registered with the Australian and New Zealand Clinical Trials Registry (Trial registration number: ACTRN12621000517875 https://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=381720&isReview=true). The study was a randomised, single-blind, two-arm, parallel, active-controlled, study

which evaluated the effectiveness of MCPBR versus usual physiotherapy rehabilitation care (UC).

Participants

Females aged 16 years or older, residing in New Zealand, who had undergone anterior cruciate ligament surgery and had a regular MC were eligible for the trial. Females filled in a screening form to evaluate their MC status and injury history (Appendix 12). Females using a copper intrauterine device (IUD) were eligible for inclusion as Copper IUDs do not affect ovulation (Ortiz & Croxatto, 2007). Females using the progestin-dosed IUD for over one year were also eligible for inclusion. The progestin-dosed IUD cause anovulatory cycles within the first year, but after that, most cycles are ovulatory (Apter et al., 2014). Considering most women would be ovulating, it was deemed appropriate to include these females to increase the sample size of the study, and furthermore, understand if this type of rehabilitation would be feasible for this group. Exclusion criteria included using the oral contraceptive pill (OCP) as no ovulation occurs in females taking OCP, and they are not appropriate to group together with menstruating females for research purposes (Janse de Jonge et al., 2019). In addition, the study excluded females under 16 years old, those whose surgery included the use of an allograft/synthetic graft, and those undergoing revision surgery, as these were identified as possible confounding variables. These participants may have different post-operative protocols, affecting their ability to participate in the trial protocol.

Surgeons and physiotherapists identified potential participants in their clinics between August 2021 – November 2022 and gave these patients a study advert. The research team advertised the study on general media (newspaper articles, television news

stories) and social media, which linked to an online site for potential participants (https://sites.google.com/tcd.ie/femaleaclrehab/home). All interested participants then contacted the primary researcher. The participants then completed screening questions and received standardised written and oral information about the trial. All participants provided written consent. Trial recruitment was stopped in November 2022 as planned, after winter injury season concluded.

Changes to trial protocol

Firstly, in the trial protocol excluded females with meniscal repairs and cartilage injuries greater than grade II as these were considered potential confounding factors which may limit engagement with the rehabilitation programme. However, it was identified by physiotherapists that these patients would be able to engage with rehabilitation without limitation. Therefore, they were removed from the exclusion list. Secondly, in the trial protocol it was noted that physiotherapists would measure participants 1RM leg extension strength of both legs at the start and end of the trial. However, physiotherapists noted that pain would limit participant's ability to carry out a true 1RM strength test six weeks post ACLR. Therefore, only non-injured leg strength is measured at the start of the trial, and both legs were measured at the end. Thirdly, SPSS (SPSS, version 29, IMB Corp, NY, USA) and Graphpad Prism (GraphPad Prism version 8.0.0 for Mac, GraphPad Software, San Diego, CA, USA) were used as statistical software, not R (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria) as noted in the protocol, as the research team were more familiar with these programmes at the time of data analysis.

Location

Twenty-eight private physiotherapy clinics throughout New Zealand participated in the trial, and two of these clinics had intervention and control participants. There are approximately 3,000 ACLRs per year in New Zealand (*Annual Report* 2022). However, as this study targeted a sub-section of this population, it was designed as a multicentre trial to increase the feasibility of recruiting the required subjects. All clinics had access to a leg extension machine or handheld dynamometer to measure 1RM knee extension strength. All clinics who had intervention had access to gym equipment including leg press and leg extension machines, or appropriate alternatives.

Randomisation and blinding

The primary researcher generated a randomisation list online. After the participants consented to the research study, the primary researcher randomly allocated them to one of two groups. The study used block randomisation to obtain equal groups of 10 control and intervention participants throughout the study. After randomisation, the primary researcher informed the treating physiotherapist of the participant's group assignment. The participants were blind to their group assignment. The participants were aware from the study information sheet that the study would examine different training typed based on phases of the MC phase, but did not know what was involved in either the control or intervention group specifically. They were only aware that they would track their cycle, and the physiotherapist would prescribe their exercises.

Interventions

The participants were randomised into two groups: (1) MCPBR or (2) UC. Once enrolled in the programme, clients could attend their current physiotherapy clinic. If they

needed to enrol in a clinic, the primary researcher would organise their attendance at a physiotherapy clinic in their local area. All clinics had to have access to gym facilities on-site or in the local area, to carry out the testing and strength protocol. The research team sent each participant the educational and MC testing education material and testing kits (Appendix 14). These testing kits included basal body thermometers, a urinary cup, and 20 ovulation strip tests. Each participant had a password-protected Google Sheet for the trial, which the primary researcher and physiotherapist could also access (Appendix 13). The participants entered their menstrual information to their data sheet. This included entering in their menstruation dates monthly, their basal body temperature every morning, and uploading the results of their urinary ovulation tests (approximately five per month) during the days leading towards ovulation. Participants commenced tracking their MC once they were recruited into the study, usually pre-operatively, which allowed a minimum of six weeks MC tracking before the study began. The primary researcher monitored and assisted with queries regarding MC tracking throughout the trial. The research team educated the physiotherapists regarding the study protocols and the MC via a training session in person, via video call, or by phone call. Additionally, the primary researcher sent a written booklet with instructions following the verbal conversation (Appendix 11). The research team also created a website for the physiotherapists seeing patients as part of the trial which had links to the instruction book, demonstration videos which included exercises and outcome measurement taking, and frequently answered questions (https://sites.google.com/tcd.ie/mcphasedaclrehab/home).

Commencing six weeks post-operation, no matter their MC phase, both groups attended physiotherapy appointments for a thirty-minute individual session twice weekly for twelve weeks (Figure 8). Both groups engaged in supervised rehabilitation exercises during this time. Short-term studies examining resistance programmes have shown that

most strength increases occur within the first four to eight weeks (Hickson et al., 1994). Therefore, this study continued for approximately 12 weeks to ensure participants engaged in approximately three rounds of four-week-long MC phase-based training. Physiotherapists offered telehealth sessions or a home exercise routine if a participant was occasionally unable to attend the clinic. Physiotherapists recorded each participant's attendance and exercises in their individual Google Sheet. No motivation strategies were used. The research team and physiotherapist advised participants that they could not perform lower limb RT outside the physiotherapy programme. However, the research team advised participants that they may complete cardiovascular exercises, including walking, cycling, and swimming, along with neuromuscular, core strength and upper limb RT outside of their scheduled physiotherapy sessions. Participants noted the volume of exercise completed outside of physiotherapy on their Google Sheet. All participants were instructed to attend physiotherapy twice weekly. However, the detail of their twice-weekly physiotherapy sessions was different depending on the group assignment.

Programme:

1. MCPBR: Participants completed RT as part of their individualised, supervised physiotherapy sessions during the FP of their MC. Squat, leg press and knee extension exercises were compulsory in each FP rehabilitation session. The protocol advised that knee extension should be incorporated per surgeons' instructions and in line with current recommendations for open-chain exercises following ACLR (Van Melick et al., 2016). For example, the research team advised physiotherapists to prescribe a restricted range of movement on the leg extension machine before progressing to a full range of movement (Van Melick et al., 2016). Physiotherapists added extra resistance exercises to the FP sessions as indicated,

such as hamstring curls. RT intensity was commenced initially with approximately three sets of 8-12 reps of each exercise at 60-80% of 1RM. Physiotherapists gave participants rest periods between sets in line with ACSM Position Stand Progression Models in RT for Healthy Adults (Kraemer et al., 2002). They used a principle of progressive overload, which recommended that if a participant can do one to two more repetitions than the prescribed amount, then increase resistance, increase repetitions, or reduce rest times (Schoenfeld, Wilson, et al., 2016). Overall, the aim was for the participant to undergo moderate to vigorous intensity training, as measured by Borg Rate of Perceived exertion scale and guided by the physiotherapist. The general aim was to reduce repetitions and increase load over the study period. The physiotherapists prescribed neuromuscular and cardiovascular exercises for the LP of their MC, at low to moderate intensity, as measured by Borg Rate of Perceived exertion scale and guided by their treating physiotherapist. The luteal phase-based training commenced once a positive ovulation test was recorded by the participant. The research protocol did not define these exercises; however, the research team provided an exercise guide for the physiotherapists (Appendix 11).

2. UC: Participants completed their individualised, supervised rehabilitation as guided by their physiotherapist most often in keeping with referring surgeons post operative protocols. The same or similar exercises that were prescribed to the intervention group were expected to be prescribed to participants in the control group without timing the regime to the participant's MCs. The research team provided a general guide for ACL rehabilitation to physiotherapists carrying out UC based on recent consensus statements (Van Melick et al., 2016) (Appendix 11: Part B).

Figure 8. Menstrual cycle phase-based rehabilitation programme.

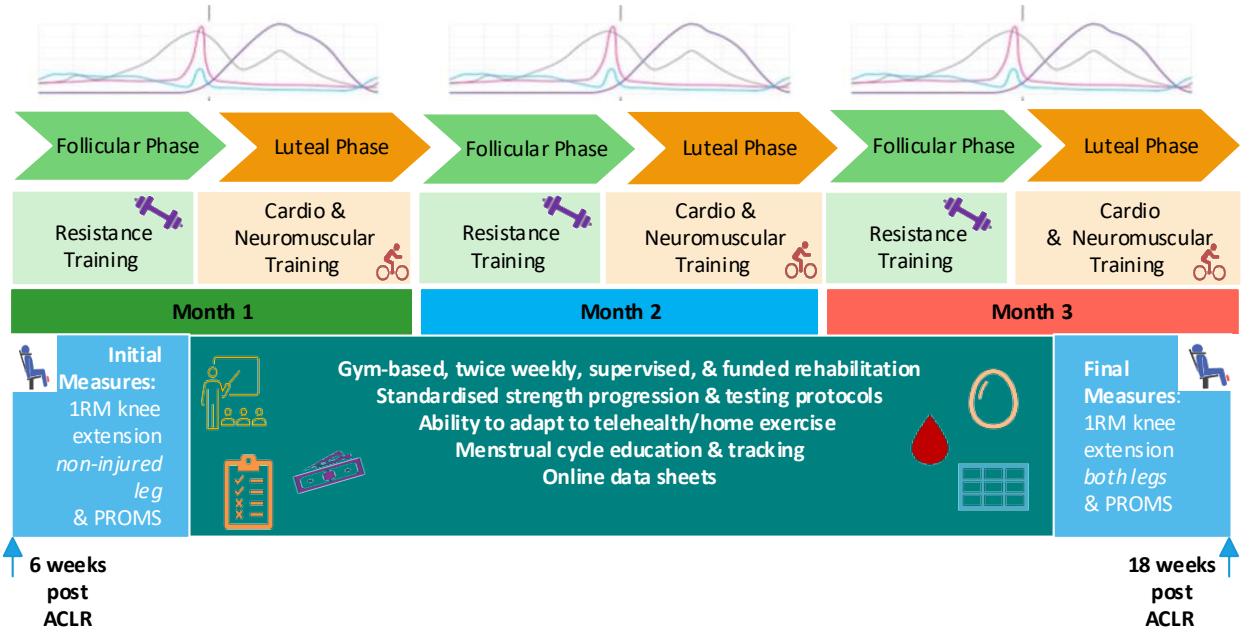

Figure 8. Visual representation of the MC phase-based quadriceps resistance training programme. Training commenced at six weeks post-surgery and until 18 weeks post-surgery. Participants attended twice weekly to a gym-based setting for supervised rehabilitation. These sessions were adapted if needed, i.e. telehealth. The researcher, physiotherapist, and participants entered all data into an online datasheet. Females received MC education and inputted information into their datasheet to establish their MC phase. Participants engaged in resistance training in the follicular phase sessions and cardiovascular and neuromuscular exercises in the luteal phase sessions. Physiotherapists used standardised strength testing to measure outcomes and standardised progression protocols to prescribe strength exercises. Funding was available for females to attend sessions.

MC Verification and Post Hoc Exclusions

Participants in both groups confirmed their regular MCs using a three-step method. Firstly, participants used calendar tracking to mark the days of menses. Secondly, participants recorded their basal body temperature in their Google Sheet every morning. Thirdly, participants confirmed their ovulation using a daily urinary prediction kit from 10 days post menses until a positive result every month. Participants were excluded from analysis if there was more than one month where temperature and urinalysis did not verify ovulation. In addition, if participants' cycles were extended or shortened by greater than seven days outside their norm for more than two cycles, they were excluded from post hoc analyses.

Outcomes

Trial outcomes are summarised in Table 8.

Table 8. Trial primary and secondary outcome measurement and interpretation

Construct & Measure	**Time point (s)**	**Assessment Method**	**Interpretation, Validity, Reliability**
Primary Outcome			
Limb symmetry index (LSI) (%) of maximum knee extension strength (1RM) injured versus non-injured leg.	1RM knee extension strength of the *non-injured leg* at *6 weeks & 18 weeks* post-ACLR. 1RM knee extension strength of *injured leg* at *18 weeks post-ACLR* only.	Physiotherapists carried out 1RM knee extension strength test with participants using a knee extension machine or handheld dynamometer. The physiotherapists carrying out the research programme carried out the data collection. These were physiotherapists experienced with collecting strength measurement data for patients post-ACL injury. The reliability of measures was ensured across different sites by the primary researcher carrying out training sessions (in person or online) for physiotherapists who completed the knee extension testing. In addition, the research time provided written	1RM strength of the affected limb is divided by the 1RM unaffected limb, multiplied by 100 to obtain a percentage difference between limbs. Recent research has defined 90% LSI as the standard target for maximum quadriceps strength of the injured versus non-injured leg following ACLR (Adams et al., 2012, Lynch et al., 2015). Recent research has recommended 1RM testing on a knee extension machine for testing strength following ACL due to sufficient construct and criterion validity (Urhausen et al., 2022). Future trials are needed to establish reliability of 1RM strength testing on knee extension machines following ACLR (Urhausen et al., 2022). In contrast, isometric extensor strength tests using handheld dynamometry offer sufficient intra-rater reliability (Urhausen et al., 2022).

		and video online instructions, as per Appendix 11.	
Secondary Outcomes			
Self-reported knee function (The Knee Injury and Osteoarthritis Outcome Score (KOOS)) (26).	6 & 18 weeks post-ACLR.	Self-reported questionnaire.	The KOOS addressed the participants' pain, symptoms, activities of daily living, sport and recreation function, and knee-related quality of life (26). The score is a percentage score from 0 to 100, 0 representing extreme problems and 100 representing no problems. Roos et al., 1998 concluded the KOOS is valid and reliable for patients undergoing ACLR.
Self-reported knee function (The International Knee Documentation Committee Questionnaire (IKDC)) (27).	6 & 18 weeks post-ACLR.	Self-reported questionnaire.	The IKDC includes seven questions on knee symptoms. It also includes questions on knee function and activity (Collins et al., 2011). Scores range from 0 points (lowest level of function or highest level of symptoms) to 100 points (highest level of function and lowest level of symptoms). The IKDC is considered valid and reliable for use in a broad patient population, including following ACLR (Higgins et al., 2007)
Self-efficacy regarding their knee injury (English Knee Self-Efficacy Scale (K-SES)) (28).	6 & 18 weeks post-ACLR.	Self-reported questionnaire.	The K-SES questionnaire (English version) consists of 22 items subdivided into 4 categories: daily activities (A), sports and leisure activities (B), physical activities (C), and future knee function (D) (28). Participants respond to each item on an 11-point scale, where 0 indicates poor self-efficacy and 10 indicates strong self-efficacy. The English K-SES is a valid and reliable measure for knee-specific self-efficacy in individuals following a sport-related intra-articular knee injury in the previous five years (Ezzat et al., 2020).

Power/Sample Size Estimation

Based on a previous studies by Harput et al. (2019) and Reis et al. (1995) the research team estimated that with an alpha level of 0.05 and 90% power, a sample size of 27 in each group would enable an 80% probability of detecting a 20% limb symmetry difference between the two groups. Reis et al. (1995) noted a 20% superior improvement in strength following FP-based training as compared to regular RT. Furthermore, Harput et al. (2019) noted a 28% change in strength following cross training as compared to UC following ACLR. Harput et al. (2019) was a fully powered study, with 30 participants, as based off their previous pilot study. Noting that this study would use handheld dynamometers and knee extension machines, and not isokinetic dynamometry to measure strength, numbers were boosted by 10% to 30 per group. Assuming a dropout rate of 20%, the recruitment target was 36 per group.

Statistical Methods

Continuous variables distribution was assessed using the Spiro-Wilk test. Variables that were normally distributed are expressed as mean (standard deviation). Variables that were not normally distributed are expressed as median (inter-quartile range). Categorical variables are expressed as count (%). Categorial variables were compared between groups using Chi-squared test, and continuous variables using either unpaired t-test (normally distributed) or Mann Whitney U test (not normally distributed). The primary endpoint (LSI) was compared between groups using Mann Whitney U test. The secondary endpoints of KOOS, IKDC and K-SES scores were examined over time and between groups using repeated measures ANOVA. Demographic and clinical characteristics of the two groups were compared using unpaired t-test (normally distributed data). In all cases, P values <0.05 indicated statistical significance. Considering this was a real-life, in-clinic protocol, the research team expected to lose

some participants to follow up during the trial. Therefore, per protocol analysis was completed after the trial, excluding those who did not complete the protocol, adhere to the protocol, or meet post hoc MC verification.

Patient and Public Involvement

ACL patients & female athletes were involved in focus group sessions which informed the development of the trial protocol (O'Loughlin et al., 2023). The public was also aware of study recruitment as the evening news and an online newspaper article advertised the study. The research team has continued to engage with the athletes & groups involved with the focus groups and their communities (Netball New Zealand and Hockey New Zealand) regarding study recruitment and operations. The research team sent all focus group participants a one-page results sheet and published journal articles. In addition, the research team sent a one-page results sheet to participants involved with this study. A follow-up news story is planned to disseminate the results to the broader public.

Ethics, Diversity, and Inclusion Statement

The researchers discussed the project with Auckland University of Technology's Mātauranga Māori Committee, who provided comments and recommendations for the design and project to include Māori participants (Appendix 21). Firstly, considering the potential sensitivity of conversations with Māori around menstruation, the research team sought advice from Māori regarding the wording of the information sheet, consent form and forms used in the project. In addition, the research team translated the trial name, the advert and the participant information sheet into Te Reo Māori (Māori language). Thirdly, the research team designed the datasheet to identify the participant's daily MC

phase so the physiotherapist could check on the datasheet without the participant having to talk about MCs repeatedly.

Furthermore, the research team was gender balanced and included junior and senior researchers. There were two physiotherapists, a female athlete physiologist, and a researcher experienced in statistics and general surgery outcomes. The research protocol included the use of a handheld dynamometer and knee extension machine to ensure clinics in rural and urban New Zealand would be able to participate. The study provided fully funded physiotherapy sessions to ensure participants of different socioeconomic statuses could participate. Additionally, the study provided extra funding for physios for the extra time needed for rural physiotherapists to travel to the gym if facilities were not available on-site.

Results

Participants

Between July 2021 and November 2022, the study recruited 41 females from 73 potential participants (Figure 9). One participant was excluded before the study commenced, and two did not complete the trial. Four participants were excluded post priori as ovulation could not be consistently confirmed. Demographic data is described in Table 9.

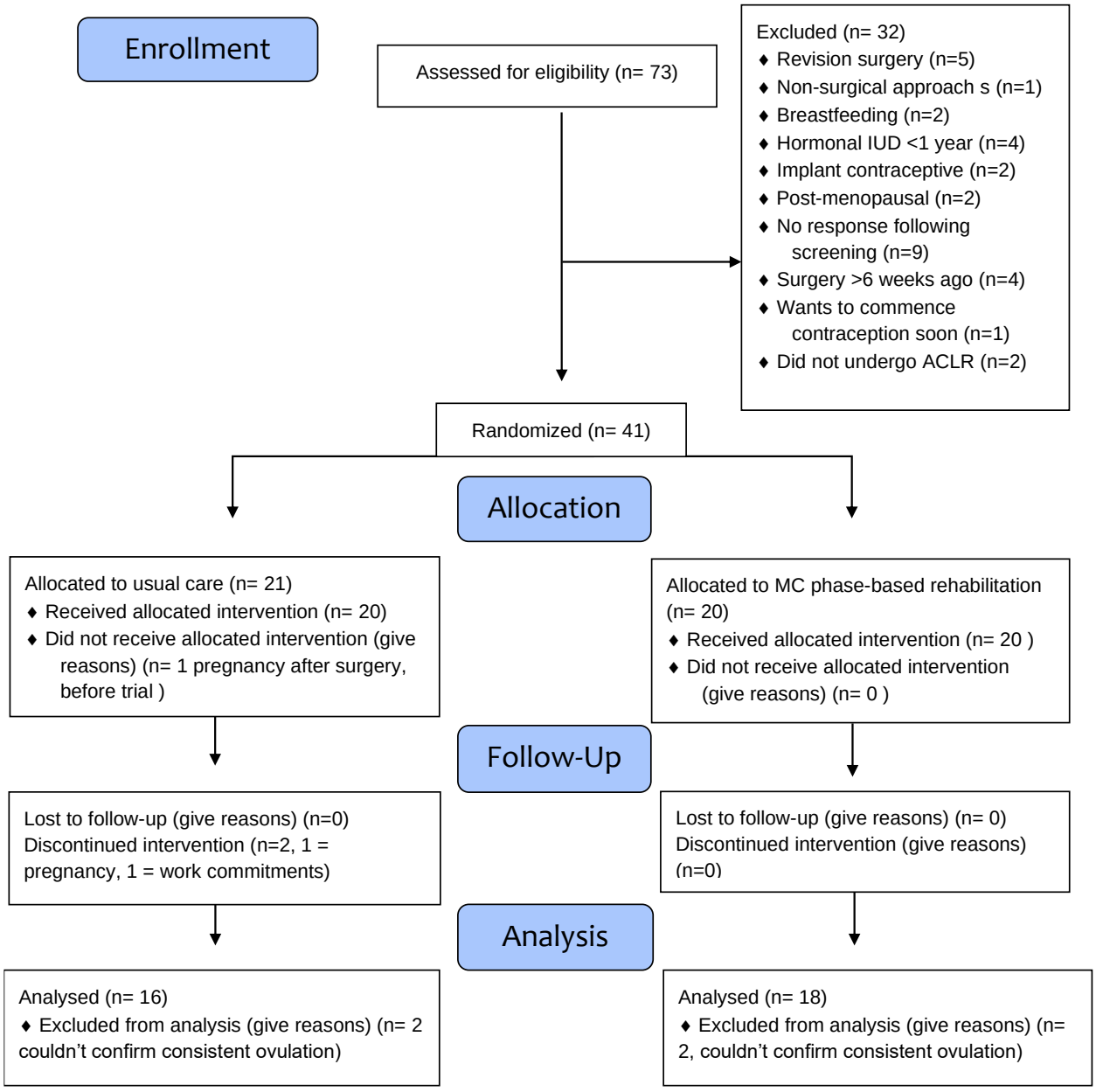

Figure 9. Flow of participants through study

Primary Outcome

With respect to the primary outcome (LSI), there were no statistically significant between-group differences at eighteen weeks post-ACLR (p=0.31) (Table 11). The MCPBR group's median and interquartile range was 84 (74-93) versus 81 (62-88) for the UC group (Figure 10). In addition, 33% of participants in the MCPBR group reached the standard 90% target of LSI post-ACLR versus 25% of the UC group (p=0.44). MCPBR's 1RM injured leg knee extension strength was 39.3kg (14.1) at the end of the trial period, whilst the UC group's 1RM knee extension of the injured leg was 30.8kg (11.9) (p=0.07) (Table 11, Figure 11). There was no between group difference for improvement in 1RM knee extension strength of the non-injured leg over the trial, (p=.26) (Table 12). However, the changes in 1RM knee extension strength in the non-injured leg over the course of the trial changed from 41.0kg (10.8) to 47.3kg (12.4) for those following MCPBR, as compared to UC, which changed from 38.1kg (7.9) to 40.7kg (9.5) (Table 12, Figure 12).

Secondary Outcomes

Total KOOS scores improved significantly for both groups throughout the trial from baseline to endpoint (p<.0001) (Table 12). All subscales improved for both groups (p<.0001) (Table 12, Figure 13). However, there was no between group effect (p=0.26), (Table 12). There were also no significant group differences for any initial or final subscale measures (Table 12).

IKDC scores improved significantly for both groups throughout the trial from baseline to endpoint) (p<.0001) (Table 12). However, there was no between group effect, (p=0.60) (Table 12).

Similarly, total K-SES scores improved significantly for both groups from baseline to endpoint, ($p<.0001$) (Table 12). All present subscales improved for both groups ($p<.0001$) (Table 12). There was no between group effect for the different present subscales (Table 12). In addition, in contrast, the future self-efficacy subscale did not significantly change from baseline to endpoint ($p=0.06$) and there was no between group effect for this subscale ($p=0.95$) (Table 12).

Table 9. Baseline demographic & treatment data comparing UC and MCPBR, measured by chi squared analysis

	UC (n=16)	MCPBR (n=18)	P-value
Age	30.2 (8.6)	32.9 (9.0)	0.37
Ethnicity			
NZ European	8 (50%)	12 (67%)	
Māori	2 (13%)	2 (11%)	
Samoan	1 (6%)	1 (6%)	
Chinese	1 (6%)	1 (6%)	0.35
Indian	0	2 (11%)	
Other European	3 (19%)	0	
Other Asian	1 (6%)	0	
MC Status			
Natural	13 (81%)	17 (94%)	
Copper IUD	1 (6%)	0	0.42
Hormonal IUD	2 (13%)	1 (6%)	
Contralateral Injury			
No	13 (81%)	15 (83%)	0.87
Yes	3 (19%)	3 (17%)	
RT Status			
Untrained	4 (25%)	9 (50%)	
Moderate	7 (44%)	3 (17%)	0.17
Well trained	5 (31%)	6 (33%)	
Injured leg dominant			
Yes	9 (56%)	9 (50%)	0.71
No	7 (44%)	9 (50%)	
Cause of Injury			
Team Sports	12(75%)	12(66%)	.59

Other (Snowsports, dancing, falls)	4 (25%)	6 (33%)	
Graft Type			
Hamstring	11 (69%)	15 (83%)	0.32
Bone Patella Bone	5 (31%)	3 (17%)	
Cartilage Damage			
None	11 (69%)	14 (78%)	
Grade 1	1 (6%)	2 (11%)	
Grade 2	3 (19%)	2 (11%)	0.62
Grade > 2	1 (6%)	0	
Meniscal Treatment			
No	9 (56%)	10 (56%)	
Meniscectomy	4 (25%)	4 (22%)	0.96
Meniscal Repair	3 (19%)	4 (22%)	
Ligament Injury			
No	12 (75%)	15 (83%)	
MCL	2 (13%)	3 (17%)	0.49
ACL	1 (6%)	0	
Multiple	1 (7%)	0	
Delay to surgery (days)	167 (56-343)	100 (68-316)	0.83

Table 10. Programme engagement & adherence, comparing UC and MCPBR, measured by unpaired t tests and Mann-Whitney U tests.

	UC (n=16)	MCPBR (n=18)	P-value
Physiotherapy sessions	18.0 (5.5)	19.7 (3.7)	0.27
Physiotherapy sessions in FP	8.5 (3.5)	9.3 (1.9)	0.35
Physiotherapy sessions in luteal phase	11 (6-12)	11 (7-12)	0.44
Home exercise physio sessions	0 (0-4)	0 (0-2)	0.70
Telehealth physio sessions	0 (0-0)	0 (0-0)	0.28
Days physiotherapy sessions included quadriceps strengthening exercises	17.4 (6.1)	9.6 (2.2)	<0.0001
Days physiotherapy included knee extension exercises	9.3 (7.3)	8.9 (3.2)	0.85
Total days active outside physio	45.3 (18.5)	40.2 (23.2)	0.45
Days no exercise outside physio	22.0 (13.9)	21.3 (18.2)	0.89
Measurement Equipment			
Knee extension machine	10 (63%)	14 (78%)	0.33
Handheld dynamometer	6 (37%)	4 (22%)	

Table 11. Final primary outcome scores comparing UC and MCPBR, measured by unpaired t tests.

	UC (n=16)	MCPBR (n=18)	P-value
1RM injured (kgs)	30.8 (11.9)	39.3 (14.1)	0.07
Limb symmetry index	81 (62-88)	84 (74-93)	0.31

Table 12. Change of outcomes from baseline to endpoint, comparing UC and MCPBR, measured by repeated measures ANOVA.

	UC (n=16)		MCPBR (n=18)		Time Effect	Treatment Effect
	Baseline	**Final**	**Baseline**	**Final**		
1RM non-injured	38.1 (7.9)	40.7 (9.5)	41.0 (10.8)	47.3 (12.4)	0.01	.26
KOOS total	62.3 (11.8)	75.3 (12.7)	65.9 (12.7)	73.2 (12.2)	<0.001	0.26
KOOS – Pain	58.8 (16.7)	81.9 (10.8)	52.6 (13.4)	82.7 (9.9)	<0.001	0.12
KOOS - Symptoms	50.8 (13.6)	80 (66-92)	48.5 (14.2)	79 (61-89)	<0.001	0.62
KOOS - ADL	75 (64-87)	96 (78-99)	73 (59-83)	95 (87-99)	<0.001	0.34
KOOS – Sports	22 (11-40)	66.3 (16.7)	22 (12-51)	65.5 (18.8)	<0.001	0.38
KOOS – QoL	31.0 (16.7)	58.6 (19.6)	22.3 (15.2)	52.3 (15.2)	<0.001	0.74
IKDC	41.4 (9.3)	70.6 (11.1)	37.5 (14.1)	64.3 (12.1)	<0.001	0.60
K-SES Total	63.7 (32.6)	132.2 (25.7)	52.6 (35.0)	129.6 (40.8)	<0.001	0.48
K-SES Movements	22 (9-32)	58.6 (14.9)	13 (7-23)	60.0 (22.0)	<0.001	0.59
K-SES Leisure	30.9 (17.2)	59.5 (12.1)	22.9 (16.3)	57.7 (14.4)	<0.001	0.29
K-SES Future self-efficacy	12.1 (6.0)	15 (10-17)	10.8 (5.2)	14 (8-17)	0.06	0.95

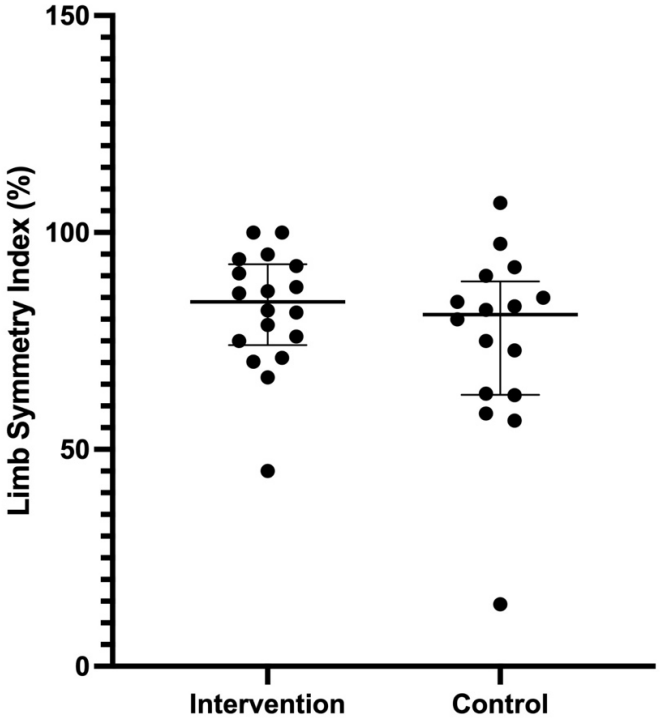

Figure 10. Graphical representation of LSI result at 18 weeks post ACLR.

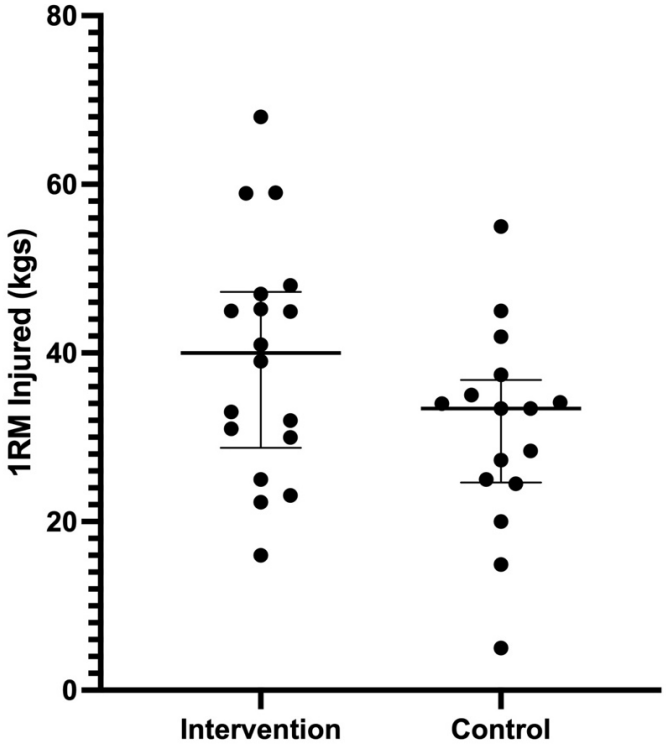

Figure 11. Graphical representation of 1RM injured leg at 18 weeks post ACLR.

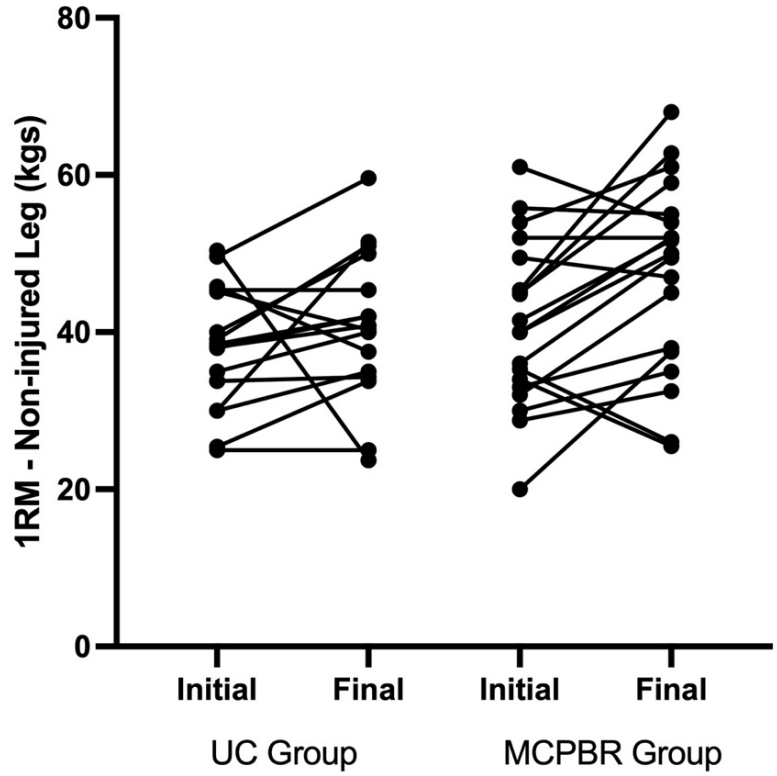

Figure 12. Change in 1RM non-injured leg.

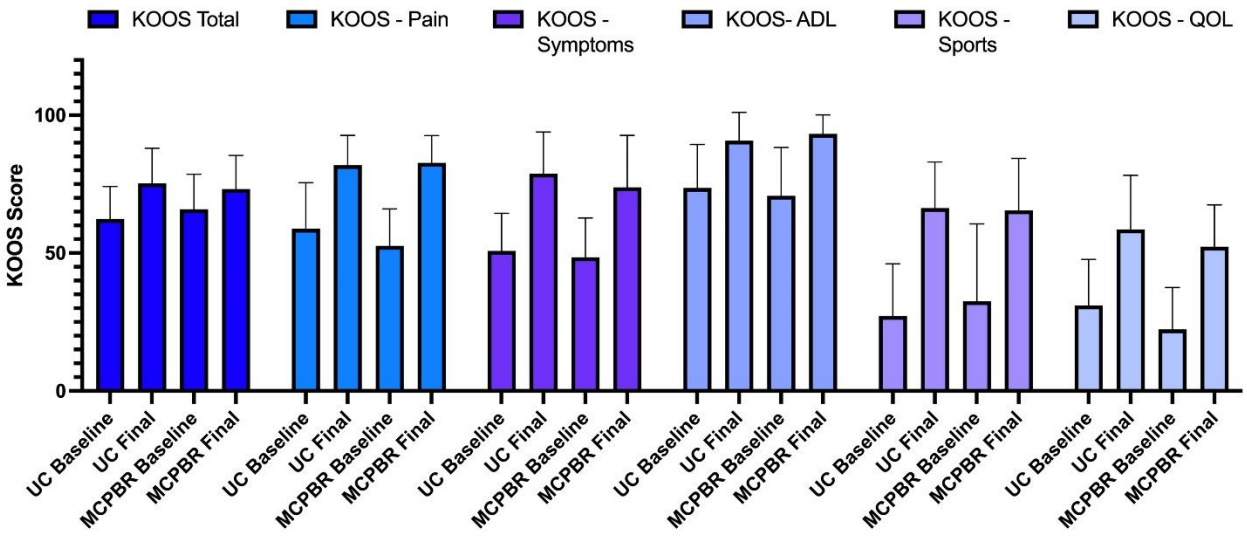

Figure 13. KOOS changes over trial.

Feasibility Outcomes:

As it was not possible to achieve the required statistical power within the study recruitment timeframe, the analysis also takes into account feasibility results to evaluate the practicality and acceptability of the intervention. These implementation and practicality outcomes are summarised in Table 13. The study had a 56% recruitment rate, with 41 participants enrolled, whilst the target was 72. Out of a possible 24 rehabilitation appointments, participants in the MCPBR group attended 19.7 (82% of the available appointments), and participants in the UC group attended 18 (75% of the available appointments) (p=0.27) (Table 10). One participant was excluded due to non-compliance with the MC tracking criteria.

There were no adverse events reported. Regarding resource utilisation, participants in both groups did not utilise telehealth or alternative home exercises, instead attending their appointments in a gym setting, as planned. However, to support these gym based sessions, the study provided funding to 82% of participants to pay for their physiotherapy appointment co-payment (portion of physiotherapy appointments that were not funded by The Accident Compensation Corporation). One intervention clinic's leg press machine was out of order for a portion of the trial period. Therefore, lunge exercises were substituted during this time. Another intervention clinic did not have a knee extension machine and used ankle weights to add resistance to the knee extension exercises. Three participants contracted Covid 19 during their trial, and the research team offered them an extra two weeks in the trial to allow for recovery. Regarding the practicality of synchronising the rehabilitation sessions, this was feasible for most participants, with only three participants excluded as researchers could not identify their MC phases clearly. Two of these three had an IUD, meaning 50% (2/4) of those with an IUD were excluded from the trial.

The research team retrospectively reviewed the participants' datasheets to establish the effects of MC synchronisation on training patterns, and to establish an estimation of days the groups engaged in quadriceps strengthening exercises (i.e. squats, lunges) and specific knee extension exercises. MCPBR and UC participants attended 9.3 (1.9) and 8.5 (3.5) appointments in the FP of their MCs, respectively. Those in the MCPBR group engaged in quadriceps strengthening exercises on 9.6 (2.2) days, and participants in the UC participated in quadriceps strengthening exercises on 17.4 (6.1) days (p=<.0001) (Table 10). However, participants in the MCPBR and UC groups engaged in a similar amount of knee extension exercises; 8.9 (3.2) and 9.3 (7.3) sessions respectfully (p=0.85) (Table 10). Females in the MCPBR group reported exercising outside of physiotherapy on 40.2 ± 23.2 days whilst females in the UC groups reported exercising on 46.1 ± 18.9 days (p=0.45).

Table 13: Feasibility Outcomes

Category	Outcome	Result
Implementation	Recruitment rate	56% (41/72) enrolled versus planned recruitment target.
	Attrition	7% (3/42) enrolled lost to follow up.
	Adherence with rehabilitation programme	MCPBR: 82% attendance (19.7/24) of the available appointments. UC: 75% attendance (18/24) of the available appointments.
	Adherence to MC tracking criteria	3% (1/34 finishers) excluded due to non-compliance with MC tracking.
Practicality	Adverse effects	Zero adverse effects.
	Use of resource	0% use of telehealth sessions. 0% use of sessions changed to home exercise programmes. 82% of participants required funding. 7% (2/28) of locations had issues with equipment during trial.
	Feasibility of synchronization with MC	8% (3/37 finishers) excluded for being unable to identify consistent ovulation. 50% (2/4) of those with IUD excluded for not being able to establish consistent ovulation.
	MC synchronisation effects on training	MCPBR: 9.3 sessions in FP. 8.5 sessions in LP. UC: 8.5 sessions in FP. 11 sessions in LP. MCPBR: 9.6 sessions with quadricep exercises. UC: 17.4 sessions with quadricep exercises.

Discussion

This randomised controlled trial is the first study to investigate a female specific, MCPBR on outcomes for females following ACLR. The objective of the study was to establish if MCPBR affects quadriceps strength recovery or self-reported function in females following ACLR. However, this novel study, designed as a superiority trial, did not meet statistical power requirements. Therefore, preliminary efficacy and initial feasibility outcomes will be discussed.

Outcomes

Primary Outcome

The main finding of this study was that the MCPBR and UC groups had similar knee extension LSI at the end of the study. Females had a median LSI of 84% in the MCPBR group and 81% following UC. Whilst these were not statistically different numbers, even small differences in LSI can be important for females after ACLR, as there is a 3% reduced reinjury rate for every one percentage point increase in strength symmetry post ACLR (Grindem et al., 2016). Recent studies recommend 90% LSI as the standard target for extension strength symmetry following ACLR (Adams et al., 2012; Lynch et al., 2015). Thirty three percent of females in the MCPBR group and 25% in the UC group met the stricter LSI goal of 90%. These LSI cut-offs are pertinent as criterion-based rehabilitation has surpassed time-based rehabilitation (Whittaker et al., 2022). Furthermore, a previous retrospective study by Cristiani et al. (2019) reported that only 35.7% of ACLR patients (45.7% female participation) achieve an average 1RM knee extension strength of 90% of their uninjured leg at six months post-ACLR and being of female sex reduces those odds. At only eighteen weeks post-ACLR, 33% of the

females in the MCPBR group had achieved 90% LSI, and 25% in the UC group had achieved 90% LSI,. Together, these results indicate comparatively high levels of LSI at this time compared to previously reported figures.

Similarly, the average strength of the injured leg was not significantly different at 18 weeks post-ACLR following MCPBR or UC. Additionally, the change in strength of participants' non-injured leg over the course of the trial did not show a significant difference following MCPBR and UC. However, the limited statistical power limited the studies internal validity and ability to draw firm conclusions. These results are not in line with previous research (Wikstrom et al., 2017; Reis et al., 1995; Sung et al., 2014) which described superior strength gains following MC phase-based RT in non-injured populations. However, these previous studies investigated high frequency FP based RT, where participants engaged in a higher volume of RT sessions during the FP. In contrast, in the current study, participants in the MCPBR group did not engage in a higher frequency of RT sessions in the FP. Instead, they attended biweekly rehabilitation during all MC phases and the session content was dictated by the MC phase (i.e., during the FP, participants completed RT). Furthermore, no limitations were given to the UC group regarding the content of their rehabilitation sessions. Interestingly, the physiotherapists prescribed quadriceps exercises more frequently to the UC group as compared to the MCPBR group who were restricted to twice weekly quadricep strengthening during their FP. Therefore, overall, UC likely engaged with higher amounts of quadriceps strengthening as compared to MCPBR. Thus, it is possible that the volume of quadriceps training may have affected RT responses in this study.

It is also worth noting that, whilst the MCPBR group underwent rehabilitation timed to the phases of their MC, the UC group also underwent twice-weekly, supervised, fully funded, and gym-based rehabilitation. Therefore, the rehabilitation the participants engaged in as part of UC was also in line with recommendations from Chapter 2 and what females requested as their choice of ACL rehabilitation (O'Loughlin et al., 2023). This programme was comprehensive, based on best practice in New Zealand, and had twelve weeks of targeted quadriceps strengthening. Furthermore, education regarding strength testing and prescription was provided to physiotherapists prescribing both UC and MCPBR to measure pre and post study quadriceps strength which may have improved their confidence in prescribing and testing strength in this population. Physiotherapists have previously acknowledged needing help with strength training and testing protocols (O'Loughlin et al., 2023). The UC group responded very well to the UC programme, resulting in a high median LSI (81%), which may have affected the ability for MCPBR to show a substantive improvement over the UC group. Importantly, considering the lack of female specific research in this area, both groups' results provide support, specifically for females, that twice-weekly, supervised, gym-based rehabilitation, with targeted quadriceps strengthening and regular strength testing provide excellent clinical early outcomes post-ACLR.

Secondary Outcomes

All the KOOS subscales improved throughout the study for both groups. There was no significant difference between groups for KOOS change or absolute values at start or finish. The minimal important change (MIC), defined as the smallest change in the outcome that a patient perceives as important, has been established for two subscales: 1) MIC for KOOS Sport/Recreation is 12.1, and 2) MIC for KOOS Quality of Life (QoL) is 18.3 (Ingelsrud et al., 2018). The average change for KOOS Sports/Recreation in this

study was 43.5 and 44.3 for the MCPBR and UC groups, respectively. The average change for KOOS QoL was 30 and 27.6 for the MCPBR and UC groups, respectively. Both mean change scores were considerably higher than the MIC score, indicating an excellent self-reported sport and quality of life improvement for both groups participating in the study. However, it is worth noting that, in this study the mean change was based off a slightly different timeframe, at four and half months post ACLR, whilst the MIC was established based on a sample of 744 registry patients who were at six, twelve, and twenty four months post ACLR. However, the registry patients were of a similar age to this study, 29.9 (11.6) years old, and 52.6% were female.

Furthermore, previous literature has identified a patient acceptable symptom score (PASS score) for KOOS (Ingelsrud et al., 2015). A PASS score is the number on a scale at which the patient considers their symptoms acceptable for that point in time. In this study, 61% of participants in the MCPBR group and 56% in the UC group met the six-month PASS criteria for the KOOS ADL subscale. This compares favourably to this previous research where 55% of 598 patients from the Norwegian Knee Registry considered their symptoms acceptable at their six-month follow-up (Ingelsrud et al., 2015). Similarly, IKDC scores improved throughout the study for both groups. Patients after ACL injury prefer the IKDC measure to the KOOS measure (Hambly & Griva, 2010). These findings further underscore the positive response observed in both MCPBR and UC rehabilitation approaches within this study.

Likewise, the total and present knee self-efficacy improved for all participants. There were also no between-group differences. Only future self-efficacy remained the same throughout the study for both groups. The impact of treatment on future self-efficacy requires further investigation (Flosadottir et al., 2018). However, it would be expected

that to improve an individual's long-term outlook on a knee injury, they may need to meet rehabilitation and complete their goals before such changes occur. This study was a short-term one with insufficient time for long-term increases in future self-efficacy.

Feasibility Outcomes

The recruitment rate, 56% of the enrolled participants originally targeted, may reflect the timing of the trial. This trial recruited participants from 2021 to 2022, during ongoing Covid 19 lockdowns and social distancing protocols in New Zealand. However, in addition, this study recruited only a small proportion of ACL injuries in New Zealand; women with the eumenorrheic MC. Future studies will need to account for this restricted population when planning timelines for future trials. However, there was a low rate of attrition in the trial with only three participants not completing the trial. Two of these were due to pregnancy and one was due to work commitments. This attrition rate was lower than the expected 20% rate used in the study's sample size estimation. This low rate of attrition supports that this programme is feasible to research as part of a larger trial and can be used to estimate sample sizes for future research trials.

The MCPBR intervention used in this study was the first to utilise MCPBR to periodise exercise following ACLR. Adherence to MCPBR was positive, with participants attending most scheduled physiotherapy appointments. This high attendance rate provides support that MCPBR is feasible to implement as part of research in physiotherapy clinics. Females have previously outlined their need for support, engagement, frequent physiotherapy sessions, and desire to see their objective outcome measures change over time (O'Loughlin et al., 2023). In addition, this study provided funding to participants to support participants to attend their sessions. Combined, these factors together may have contributed to the positive adherence to the

trial programme. Furthermore, participants in this trial undertook a three-step verification method to verify their MC. Only one participant was excluded due to non-compliance with this three-step method. The individual reported her non-compliance was due to work commitment and an inability to commit to the extra requirements. Therefore, these results also support that most participants were adherent with the MC verification requirements needed to implement this trial. Still, it is noted that this MC tracking requirement was stated clearly on the trial participant information sheet, and so it may be that those who were not able to comply with this requirement did not enrol in the study. These results will help plan MC phase-based RT programme and MC tracking protocols in future studies.

Regarding practicality, there were no adverse events noted in this study. Furthermore, they were low levels of utilisation of telehealth appointments and home exercise sessions. These low utilisation rates are not surprising, as mentioned above, females were clear in the planning stage of this trial, that they wanted in person support in gym-based rehab sessions (O'Loughlin et al., 2023). Therefore, frequent, in-person gym sessions are recommended for future trials. Also, as mentioned above, funding was provided to 82% of trial participants, which paid for their physiotherapy session costs. Financial barriers have not been noted as significant barriers to physiotherapy treatment by previous research (O'Loughlin et al., 2022; Walker et al., 2020). Still, physiotherapists did specify that funding must be provided to patients for them to engage in frequent physiotherapy appointments (O'Loughlin et al., 2022). This funding requirement would have to be considered by future research.

Only two clinics had equipment faults during the trial. This low number supports the practicality of using both handheld dynamometry and knee extension as equipment options in a multicentre trial. However, several physiotherapy clinics were unable to see patients in their own physical premises but saw participants at a local gym to use their equipment. These local arrangements enabled this study to recruit females in both urban and rural settings. Arrangements such as this could be considered by future studies, especially if future studies have a focus on equitable inclusion from females from urban and rural areas.

The synchronisation of the rehabilitation sessions with MC phase was feasible for most participants, with only three participants being excluded as researchers could not identify their MC phases clearly. Two of these three had an IUD, meaning 50% (two out of four) were excluded from the trial. One year after the insertion of a hormonal IUD, most cycles are ovulatory (Apter et al., 2014). However, in this trial, considering the high number excluded, and the considerable research time used to attempt to track these participants' MC, supports that it may not be practicable for those with an IUD to synchronise RT to their MC, or include in future studies. The synchronisation of the rehabilitation sessions with MC phase did not affect the amount of sessions females attended in the different MC phases. However, the restriction of RT to the FP for the MCPBR group meant that overall, the MCPBR group have engaged in less overall quadriceps loading as compared to UC. This lower amount of loading may have been a negative aspect of engaging with the MCPBR. Subsequently, this lower amount of loading for the MCPBR group supports that, in future studies, a higher frequency of RT should be prescribed in the FP to ensure an overall similar amount of engagement in RT between groups. Overall, these implementation and practicality feasibility findings

support a full scale RCT study investigating MCBPR in physiotherapy clinics is feasible. Acceptability of patients and physiotherapists will be further discussed in future studies.

Strengths

Firstly, this study investigated a specific rehabilitation approach for naturally cycling females post-ACLR. This study was a novel design, explicitly aimed to improve outcomes for females by benefitting from female hormone fluctuations and females-specific preferences for ACLR rehabilitation. This is in line with previous research that has recommended research questions for ACL rehabilitation should focus on developing new questions about what works for which context, for whom, and when some criteria are relevant (Gokeler et al., 2014). Also, this study was the first to adapt previous menstrual phased trial designs that demonstrated improved strength outcomes for non-injured females and applied them to a rehabilitation context.

Secondly, the adherence to this specific programme was high, with females in the MCPBR group attending 19.7 appointments and the UC group attending 17.6 appointments out of a possible 24 within the 12 weeks. This high adherence of groups is in line with previous studies which have investigated MC phase-based RT in non-injured females and noted no difference in adherence between phase-based or regular training (Wikström-Frisén et al., 2017). Adherence and participation rates are pertinent in an ACLR rehabilitation environment, as they may alter interventions' apparent effects (Walker et al., 2020). However, the high adherence in this study indicates that it is practicable to carry out MCPBR in the physiotherapy clinic with good adherence.

Thirdly, this study was designed utilising recommendations given by females for in-clinic, gym-based, supervised sessions. This design was most likely why adherence was high and utilisation of telehealth and home exercise sessions were low. Fourthly, this trial provided detailed protocols to physiotherapists including guidance regarding training frequency, intensity, volume, progression, and duration of the training period as recommended by Augusston et al. (2013). The research team provided these training, strength training and testing protocols to physiotherapists in easy-to-use multi-media formats on an online website, enabling the physiotherapists to watch video content as reminders of how to carry out strength training and testing.

Finally, this study used temperature, urinalysis, and calendar tracking to verify the participants' MC status. The research team also excluded four females post priori due to being unable to verify regular ovulation which ensure that the results reflect the truth in the population studied rather than methodological error and ensure a high level of internal validity (Elliott-Sale et al., 2021; Patino & Ferreira, 2018). It is worth noting that this trial did not use the three-step gold standard (calendar mapping, urinalysis, and blood serum analysis) to verify ovarian hormone status (Schaumberg et al., 2017). However, the combination of methods used in this study ensures that participants who are not regularly menstruating were excluded.

Limitations

There are several limitations to consider in this study. This study did not meet the numbers required for statistical power; with only 34 participants who completed the study, whilst the target was 72. This relatively low participant numbers would have affected our findings and may mean that the true value of MCPBR is not reflected in the

study results, as a small sample size may result in a Type II error. Overall, this small sample size has led the study's limited statistical power, which limited this study's ability to detect a true effect if it existed. Therefore, this study may not have identified real differences between MCPBR and UC, when there may have been some. This small sample size may also have meant that there was a risk of sampling bias, and an increased variability of outcomes, of which both may increase the chance of Type I and Type II errors. In addition, Type I or Type II errors could have occurred due the study's inability to control confounding variables, such as the different proportions of those included in each group with a different graft types, participants' age, contralateral injury, and delay to surgery for example. Additionally, the small sample size meant that the study was unable carry out subgroup analysis, which may have provided extra insight into how results may have varied across different subpopulations, such as those who carried out more or less quadriceps strengthening. Not accounting for the UC group undergoing a higher amount of the intervention within a trial could also have further led to a Type II error.

It is acknowledged however that this study recruited a small subset of patients undergoing ACLR; females with a naturally cycling MC. Previous studies which have recruited for MC phase-based training have also had low participant numbers, which may reflect the difficulty recruiting this subset of the female population (Thompson et al., 2020). Additionally, this study recruited participants from August 2021 – November 2022. Auckland, New Zealand, had Covid 19 restrictions until December 2022, which had implications for sports, elective surgery, physiotherapy, and study recruitment.

Participants did not have an initial strength test of their injured leg, as physiotherapists noted that pain may limit patients' ability to carry out a 1RM knee extension test at this

time. This lack of an initial strength test could have meant that baseline differences were erroneously interpreted as treatment effects, or concurrently, a Type II errors may have occurred if true baseline differences were not accounted for and masked**.**

In this study, the absence of a reliability assessment conducted across different sites is acknowledged as a limitation. While researchers undertook several measures to ensure the reliability of data collected within each site, the consistency of measurements across the various sites was not measured. This limitation introduces the possibility of site-specific inconsistencies that could potentially affect the generalisability of the study findings to broader populations or settings. Future research could benefit from implementing reliability assessments across sites to further strengthen the validity of the study results. Furthermore, the study may have been at risk of testing bias, as physiotherapists were not blinded to treatment group allocation, which may have led to a Type I error.

No hamstring muscle strength was measured, as it was considered that, whilst strength deficits in the hamstring groups are common, quadriceps recovery is the focus for patients post ACLR. In addition, no measures of muscle diameter, atrophy or the effect of MCPBR on lower limb muscle mass were recorded by the physiotherapists in the study. Increased satellite cell recruitment can lead to several benefits, including reduced muscle atrophy (Oostuyse & Bosch, 2010). Wikstrom Frisen et al. (2017) and Sung et al. (2014) both reported increased lean body mass for FP-based training as compared to regular training, and luteal phase-based training, respectively. Disuse atrophy of the quadriceps is common for patients post-ACLR, and recent research has recommended further research into postoperative atrophy. Future studies should

investigate the role of MCPBR on muscle atrophy following ACLR (Thomas et al., 2016).

This study did not use blood hormonal verification to verify MC status, i.e. progesterone to confirm ovulation, which may mean that some participants may not have ovulated and are involved in the trial. However, the research team tracked the patients' cycles by calendar mapping, ovulation testing and basal body temperature verification.

The results following MCPBR would only apply to non-pregnant, pre-menopausal, regularly cycling girls and females not taking the OCP. Subsequently, the results for this arm of the trial would not be generalisable to all females. Additionally, no long-term data was collected, including the return to function such as hopping, return to sports, or reinjury rates. Over three quarters of the females in this programme injured their ACL during either team sports or snow sports, which underlines the need for future long terms trials to research return to sport outcomes in the future. Finally, this study did not discuss the experience of engaging with MCPBR. Considering this is the new rehabilitation style, it would be pertinent to understand female's experiences with rehabilitating in this way. This study is underway, but is outside the scope of the current thesis. Wikström-Frisén et al. (2016) reported that more participants who underwent a 16-week RT programme experienced FP-based RT as positive, compared to regular or luteal phase-based training. It is unknown whether this noted preference for FP based training may relate to MC phase differences in mood or motivation. Mood or motivation for training was not reported or monitored in this study. However, motivation for training is essential for athletes post ACLR, as higher motivation during rehabilitation is associated with returning to pre-injury sport (Sonesson et al., 2017).

Conclusion

Results from this study demonstrate that, at eighteen weeks following ACLR, MCPBR and UC produced similar knee extension strength LSI outcomes. It's important to note that this trial was originally designed as a superiority trial. However, the study was underpowered to detect a difference in the primary outcome, which limits the study's ability to draw definitive conclusions. This study also reports that participants who engaged in MCPBR and UC had similar LSI, self-reported function and self-efficacy at eighteen weeks post ACLR. Both groups achieved excellent outcomes early in the ACLR rehabilitation pathway and therefore, overall, this study supports twice-weekly, supervised, gym-based rehabilitation, with targeted quadriceps strengthening and regular strength testing for females post-ACLR. Furthermore, this study demonstrated that a full scale RCT to investigate MCBPR in females post ACLR is feasible. MCPBR was considered implementable and practicable for a future large scale RCT based in physiotherapy clinics. Future research should investigate a larger cohort of females, including interim bilateral strength measures of both legs, and long-term functional outcomes over a longer period. Similarly, it would be pertinent to understand females' experience regarding engaging with MCPBR post-ACLR.

SECTION 3: DISCUSSIONS AND CONCLUSIONS

CHAPTER 6: Discussion

Aims and findings

The primary hypothesis of the thesis was that the intervention group would achieve a greater quadriceps strength recovery following follicular phase (FP)-based resistance training (RT) programme, as part of rehabilitation, compared to the usual care (UC). The secondary hypothesis of the thesis was that the intervention group would have greater self-reported functional outcome changes compared to UC .

The overall aims of the thesis were as follows:

- Review the available evidence regarding menstrual cycle (MC) phase-based RT programmes and establish if there is a role for MC phased RT for females post anterior cruciate ligament reconstruction (ACLR).
- Explore key stakeholders' knowledge of the MC, establish whether they discuss it, and explore how comfortable they are discussing it in the sports medicine environment.
- Establish what aspects of current ACLR rehabilitation work well for females and their preferences for adapting a MC phase-based RT approach for the rehabilitation environment; to inform the design of a MC phase-based rehabilitation (MCPBR) programme for females after ACLR.
- Develop, plan and deliver a randomised controlled trial to evaluate the effect of a MCPBR programme on maximum isometric knee strength and self-reported knee function for females post ACLR.

A summary of findings is outlined in Table 14:

Table 14. Chapter aims and results

Chapter	Aims	What was known	What this research adds
Chapter 2 – The role of MC phase-based RT for females post ACLR: a scoping review protocol & scoping review.			
2	Review the available evidence regarding MC phase-based RT programmes and establish if there is a role for MC phased RT for females post ACLR. Specifically, establish: i) If studies have investigated MC phase-based RT programmes in females post ACLR. ii) The different methodologies of MC phase-based RT programmes. iii) The known effects of MC phase-based resistance training. iv) If these findings provide a gap for future experimental studies in an ACLR rehabilitation context.	Females perform RT following ACLR. Females have reduced quadriceps and hamstring strength recovery of their injured leg post-ACLR compared to men, despite similar timeframes post-surgery, pre-injury activity levels, and graft source. The limited research to date (which has noted issues with methodological limitations, small sample sizes and lack of clarity regarding co-intervention) suggests that follicular-phase-based RT may be beneficial to improve strength training responses in eumenorrheic females.	There were a small number of studies which were limited by methodological issues. No studies were found that investigated MC phase-based RT in females following anterior ligament reconstruction. No studies found that investigated MC phase-based RT in females following ACLR. Review results suggest that MC phase-based training may be pertinent to investigate in females post-ACLR. Six primary studies, despite methodological limitations, small sample sizes, and hypothesis generating designs, suggest that FP-based RT may enhance chronic strength training responses, including superior strength, power, lean mass gain, and reduced dysmenorrhea symptoms.

			There is scope to investigate FP-based RT in females following ACLR.

Chapter 3 - Discussing the MC in the sports medicine clinic: perspectives of orthopaedic surgeons, physiotherapists, athletes, and patients

3	Explore key stakeholders' knowledge of the MC, establish whether they discuss it, and explore how comfortable they are discussing it in the sports medicine environment. Specifically, establish: i) What orthopaedic surgeons, physiotherapists, female athletes, and patients know and think about the MC ii) If orthopaedic surgeons, physiotherapists, female athletes, and patients discuss the MC in the clinic, and iii) How comfortable are orthopaedic surgeons, physiotherapists, female athletes, and patients are discussing the MC in the sports medicine clinic	Recently, there has been a global increase in female-based sports performance and medical research related to the MC. Much of this research focuses on the MC's quantitative physiological and biological aspects. However, females experience the MC within a broader sociocultural context and through their lived experiences. The MC is considered a social stigma and is a taboo subject. Evidence from New Zealand indicates that many females are embarrassed about discussing their MC.	Participants described the MC as a pertinent and evolving topic in the sports medicine clinic. Participants also described how a dearth of education and discussion had given rise to a lack of MC knowledge. Health professionals were interested in injury risk and performance associated with MC fluctuations, while females were interested in MC regularity, symptoms, and impact on their sports. The sports medicine community does not routinely discuss the MC in the clinic. However, when they do, there can be challenges, such as the sex/gender of the health professional and the age of the patient. However, sports medicine health professionals have strategies for when this occurs, i.e., developing trust with the patient.

		Recent research has identified barriers to athletes communicating with support staff regarding their MC in New Zealand.	
Chapter 4 – The development of a MCPBR programme for females after ACLR			
4	Establish what aspects of current ACLR rehabilitation work well for females and their preferences for adapting a MC phase-based RT approach for the rehabilitation environment; to inform the design of a MCPBR programme for females after ACLR. Specifically, establish: i) The aspects of ACLR post-operative rehabilitation that currently work well for females athletes, ACLR patients, physiotherapists, and surgeons. ii) How researchers can adapt previously designed MC phase-based RT programmes to suit females after ACLR injury. iii) Aspects of the newly designed MCPBR programme to consider to increase compliance.	Females engage in rehabilitation with the assumption that they are receiving evidence-based treatment. However, the most recent, up-to-date consensus statements on rehabilitation post ACLR do not have any specific recommendations regarding a female-specific approach to rehabilitation. Meanwhile, non-injured, naturally cycling females have been advised, where possible, to concentrate their RT in the FP of their MC to benefit from rising levels of oestrogen and low levels of progesterone. These studies did not investigate this training approach in females following ACLR injury.	Females preferred frequent (twice weekly) supervised rehabilitation sessions in a gym. Females need funding support, MC education, an easy-to-use online spreadsheet to record their information, and an ability to adapt to telehealth or home exercises, if needed, to engage with a MC phase-based rehab programme. Physiotherapists need support such as written protocols for strengthening exercise progressions and strength testing using knee extension machines and handheld dynamometers. Physiotherapists also noted difficulty recording strength measures of the injured leg in patients for some time due to pain after ACLR.

5	Evaluate the effect of MC phase-based strengthening rehabilitation programme on maximum isometric knee strength and self-reported knee function for females post ACLR. Specifically: i) investigate if a MC phase-based rehabilitation, where females post ACLR periodise RT to the FP of the MC, results in improved quadriceps strength symmetry following ACLR, compared to usual physiotherapy rehabilitation. ii) investigate if MCPBR improves self-reported functional outcomes and self-efficacy in females following ACLR compared to usual physiotherapy rehabilitation.	Following ACLR, patients commence rehabilitation which includes restoring knee range of movement and lower limb strength. Females are under-represented in ACLR research (56-95% male participation throughout ACL trials). Subsequently, there are no female-specific ACLR rehab guidelines. However, females may have specific needs and preferences for ACL rehabilitation. Recent reviews have recommended that non-injured, naturally cycling females, where possible, concentrate RT to the FP of their MC to benefit from rising oestrogen levels and low progesterone levels.	MCBPR resulted in similar limb symmetry indices and self-reported functional outcomes as UC for females 18 weeks post ACLR. However, the study was underpowered to detect a difference in the primary outcome, which limits the study's ability to draw definitive conclusions. A full scale RCT to investigate MCBPR in females post ACLR is feasible. Both groups achieved excellent outcomes early in the ACLR rehabilitation pathway and therefore, overall, this study supports twice-weekly, supervised, gym-based rehabilitation, with targeted quadriceps strengthening and regular strength testing for females post-ACLR.

MCPBR: Menstrual Cycle Phase Based Rehabilitation; UC: Usual Care; MC: Menstrual Cycle; ACL: Anterior Cruciate Ligament; ACLR: Anterior Cruciate Ligament Reconstruction.

The Perspective and Content of This Discussion

During the analysis of this thesis, the following themes emerged:

(i) MCPBR is achievable, and results in similar outcomes as UC for females post ACLR.

(ii) Females have specific needs following ACLR and whilst undergoing MCPBR.

(iii) Female-specific needs require extra resources and planning to achieve improved knee outcomes following ACLR.

The first theme discusses how MC phase-based training is pragmatic and practical in a clinical setting and produces similar changes in strength and patient reported functions for women post ACLR, as compared to UC. Factors that impact the rehabilitation design's feasibility and impact on outcomes are discussed with reference to chapters 2 to 5.

The second theme discusses the support females need following ACLR and when undergoing MCBPR. This theme describes the different supports females outlined they would need during ACL rehabilitation, specifically MCPBR, with references to chapters two to five.

Furthermore, the third theme discusses the additional requirements for females/female-specific research to achieve the best outcomes. Examples of these needs and different requirements are discussed with reference to chapters two through five.

Theme 1. MCPBR is achievable, and results in similar outcomes as UC for females post ACLR.

This thesis has demonstrated that MCPBR is feasible in a clinical setting, and results in similar strength outcomes and self-reported function as excellent quality UC for female patients after ACLR. In Chapter 2, the review outlined several outcomes that were specifically improved by MC phase-based RT in previous studies and were appropriate for females post-ACLR. These outcomes included improved strength (Reis et al., 1995), muscle mass (Sung et al., 2014), reduction in pain symptoms (Zainab et al., 2021), and improved training experience (Wikström-Frisén et al., 2016). Also, in Chapter 2, the scoping review outlined MC phase-based RT methodologies, including the duration, content, and intensity of exercises used in the previous literature. Therefore, this thesis deemed that these MC phase-based RT programmes were suitable to adapt for females following ACLR.

In Chapter 3, the focus groups indicated that whilst there was a lack of knowledge regarding the MC, the physiotherapists and patients were open to learning more and perceived the topic as relevant for the sports medicine environment. Surgeons, physiotherapists, athletes, and patients described barriers to discussing the topic openly, including the patient's age and sex/gender of the health professional and patient. Surgeons and physiotherapists noted that discussing the MC is pertinent for the sports medicine clinic, and they already had strategies for comfortable discussions regarding the MC clinic. These included creating trust with the patient, explaining why they needed to discuss the MC, and using questionnaires to screen females for MC issues before coming to the clinic. Thus, discussing the MC in the sports medicine clinic in the context of a MC phase-based training programme was considered achievable.

These previous studies in the scoping review, in Chapter 2, had eight to sixteen-week programme durations, carried out multiple times weekly in gyms (Reis et al., 1995; Sakamaki-Sunaga et al., 2016; Sung et al., 2014; Wikström-Frisén et al., 2017). However, in contrast, females in Chapter 4 noted their preference for in-clinic rehabilitation of the same frequency every week, so appointment scheduling would not differ depending on the menstrual phase. Therefore, in Chapter 5, the study's physiotherapy sessions were scheduled twice weekly, and the quadriceps exercises were prescribed in the cycle's FP only. Within these FP RT sessions, best practice RT protocols were used. RT intensity was commenced initially with approximately three sets of eight to twelve repetitions of each exercise at 60-80% of one RM (1RM). Physiotherapists gave participants rest periods between sets in line with American College of Sports Medicine Position Stand Progression Models in RT for Healthy Adults (Kraemer et al., 2002). Physiotherapists used a principle of progressive overload, which recommended that if a participant can do one to two more repetitions than the prescribed amount, they increased resistance, increased repetitions, or reduced rest times (Schoenfeld, Wilson, et al., 2016). Overall, the aim was for the participant to undergo moderate to vigorous intensity training, as measured by Borg Rate of Perceived exertion scale and guided by the physiotherapist.

This detailed guide for physiotherapists contrasted with the findings of a previous systematic review of RT protocols following ACLR by Augustsson et al. (2013). This review noted that only a handful of previous ACLR rehabilitation studies contained basic information regarding their RT protocol, and only two out of six previous studies included a sufficient level of strength training documentation. None the included studies were tailored towards females. Overall, the structured guide

provided by this study (Appendix 11 and Figure 6) for physiotherapists enabled females to engage with high quality RT sessions during their MCPBR programme.

Also, in Chapter 4, females outlined their preferences for how physiotherapy programmes could adopt a MC phase-based training approach. Their recommendations included commencing the programme at a specific time point postoperatively and having the same number of physiotherapy sessions no matter the MC phase. Females starting at the same time postoperatively ensured that recording the patients' initial outcomes at the same time post-ACLR was feasible. In addition, having two appointments per week meant that, consistently, physiotherapists could book their appointments far in advance to ensure they could provide the required twice-weekly sessions without having to schedule dependent on the MC phase. This scheduling was different to previous MC phase-based training programmes (Reis et al., 1995; Wikström-Frisén et al., 2017), but enabled MC phase-based training to be scheduled in advance in busy physiotherapy clinics. However, this frequency of appointments meant that overall, MCPBR had lesser overall quadriceps loading as compared to UC. Because no limitations were given to the UC group by the study regarding what was included in their rehabilitation sessions. physiotherapists prescribed quadriceps exercises on 17.4 (6.1) days to the UC group compared to 9.6 (2.2) days for the MCPBR group. Therefore, overall, UC engaged with higher amounts of quadriceps strengthening as compared to MCPBR, which may have been a negative impact of engaging with the MCPBR approach. Subsequently, this would suggest that, in line with previous studies, a higher frequency of RT should be prescribed in the FP, perhaps using a mix of in clinic and home/gym-based sessions, to ensure a similar amount of engagement in RT between groups.

Females in Chapter 3 recommended receiving basic MC education prior to engaging with MCBPR. In addition, physiotherapists in Chapter 3 noted they would also need education before prescribing MC phase-based training to patients. The research team provided basic MC education to both physiotherapists and patients as part of the trial in Chapter 5, enabling both groups to have increased understanding and awareness of the MC phases and hormonal changes. This education addressed the findings in Chapter 3 and previous qualitative research where health professionals outlined their insufficient knowledge of and eagerness to learn more about the MC (Findlay et al., 2020; O'Loughlin et al., 2023). This MC education and increased knowledge for physiotherapists and patients is important in empowering females to understand and become aware of their monthly MC and associated hormonal changes, and how they may be relevant to the rehabilitation environment. Furthermore, females also outlined extra support they would need to engage with a MCPBR programme. These are discussed in the next section, as part of theme two, "Females have specific needs following ACLR and whilst undergoing MCPBR".

Similarly, in Chapter 4, physiotherapists noted that they would need straightforward strength testing and progression protocols to aid their clinical reasoning whilst prescribing MCPBR. Strength testing protocols are not only needed for MC phase-based training. Only a few physiotherapists have access to isokinetic dynamometry, considered the gold standard for assessing knee musculature strength following ACLR (Nagai et al., 2020). Whilst most physiotherapists in the focus group reported having access to either a handheld dynamometer or knee extension machine in their clinics, recent research in New Zealand noted that less than half of New Zealand physiotherapists carry out strength testing using recommended measures such as a handheld dynamometer or knee extension machine (Fausett et al., 2022). Therefore, the research team educated the physiotherapists regarding the study protocols and the MC via a training session in person, via video, or by phone.

Additionally, the primary researcher sent written and video form instructions, enabling physiotherapists to watch video content as reminders of strength testing protocols and training progressions.

In Chapter 5, the adherence to MCPBR was slightly higher than UC. Females attended 80% of their appointments in the MCPBR group. This number of appointments was high, averaging 19.7 over the twelve weeks. A recent retrospective study in New Zealand has reported that patients attend an average of 12 rehabilitation sessions in the first year following ACLR (Fausett et al., 2019). However, Chapter 5 demonstrates that it is achievable for females to attend more frequent sessions following ACLR. Furthermore, the research team excluded only one of 41 females due to not inputting her MC data, further supporting that tracking their cycle whilst attending physiotherapy is also achievable for females interested in this type of training. MC tracking applications have recently become prominent, allowing females to track their cycles and predict their menstruation dates (Worsfold et al., 2021). A recent study carried out in New Zealand reported that over half of elite sport females track their MCs (Heather et al., 2021). Therefore, this thesis supports that females tracking their cycle to enable participation in MCPBR is achievable for females post-ACLR.

The primary hypothesis was that the intervention group would achieve a greater quadriceps strength recovery following FP-based RT programme, as part of rehabilitation, compared to the control group. In pre-trial planning, physiotherapists outlined that participants would not be able to engage in a true knee extension 1RM strength test of their injured leg at the start of the trial, due to knee pain at six weeks post ACLR. Therefore, in contrast to other similar studies (Sung et al., 2014; Wikström-Frisén et al., 2017), this study did not use a pre and post measure for the primary outcome. Instead, the research team considered the limb symmetry index

(LSI) the most appropriate measure to detect differences in strength outcomes in females 18 weeks post-ACLR. 90% LSI is the standard target for 1RM extension strength symmetry following ACLR (Lynch et al., 2015). Contrary to the initial hypothesis, in Chapter 5, females' LSI of knee extension strength were not significantly different between MCPBR and UC groups. Additionally, the change in strength of participants' non-injured leg over the course of the trial did not show a significant difference between MCPBR and UC. In this trial, the non-injured leg was the only leg the physiotherapist measured pre- and post-trial. Similarly, the average strength of the injured leg was not significantly different at 18 weeks post ACLR following MCPBR or UC. Furthermore, the secondary hypothesis was that the intervention group would have greater self-reported functional outcome changes compared to the UC group. The study results demonstrated improvement for all participants in all patient reported outcome measures (PROMs) used but there were no between-group differences. However, the limited statistical power limited the studies internal validity and ability to draw firm conclusions regarding the primary outcome measure. The study recruited participants from August 2021 to November 2022. During this time Covid 19 lockdown periods affected sporting participation, elective surgery, and rehabilitation environments. Overall, 34 participants completed the study, whilst the target was 72.

The lack of difference between MCPBR and UC did not align with most previous studies in this area which carried out good quality MC verification (Reis et al., 1995; Sung et al., 2014; Wikström-Frisén et al., 2017). However, as mentioned previously, participants in the UC and MCPBR groups did not attend a similar number of quadriceps RT sessions, which is different to previous studies (Reis et al., 1995; Wikström-Frisén et al., 2017). In addition, the primary outcome measure in this study was LSI, at 18 weeks post-ACLR. The UC group achieved a median LSI of 81% at 18 weeks post-ACLR, which exceeded the studies initial expectations and

indicate comparatively high levels of LSI at this time compared to previously reported figures.

This lack of between group differences may be because the UC group in this study also underwent high quality twice-weekly, supervised, fully funded, and gym-based rehabilitation, in line with females' requested choice of ACL rehabilitation (O'Loughlin et al., 2023), and evidence based guidelines for ACL rehabilitation (Culvenor et al., 2022). These outcomes following UC and MCPBR suggest that females especially respond well to this regular, fully funded, in person rehabilitation. This is important to note as most ACLR research and recommendations are based on male research (Bruder et al., 2023). Furthermore, the RCT in Chapter 5 was powered to detect a 20% difference in strength between groups, based on prior assumptions. Nonetheless, the LSI in the UC group, at 81%, was beyond what was anticipated at 18 weeks post-ACLR. Therefore, the study's power calculation was based on the best available information at the time but may not have accounted for the positive response to good quality UC. Overall, it is also worth noting, that whilst the 20% difference was not observed, as previously mentioned, even small differences in LSI can be important for females after ACLR. LSI is a significant predictor of a knee reinjury, and there is a 3% reduced reinjury rate for every one percentage point increase in strength symmetry post ACLR (Grindem et al., 2016).

In addition, this study finished at 18 weeks post ACLR, and many return to sport outcomes, which the PROMs measured would not be applicable for a period after this. Hence, it is unknown whether MCPBR has any impact on longer term self-reported functional outcomes as compared to UC. Therefore, collectively, the results demonstrate that females responded extremely well to both MCPBR and well-designed UC. Further investigation is needed to understand if, with appropriate sample sizes, MCPBR results in improved outcomes following ACLR. In addition, it

would be also pertinent to establish if the excellent early outcomes can be replicated in larger or different populations of females following high quality twice-weekly, supervised, fully funded, and gym-based UC.

Theme 2. Females have specific needs following ACLR and whilst undergoing MCPBR.

This thesis also outlined, over several chapters, how females needed support following ACLR and whilst undergoing MCPBR. In Chapter 3, patients and athletes discussed how they track the MC, the symptoms they experience over the cycle, the impact of these symptoms on their sporting endeavours, and the regularity of their cycles. On the other hand, physiotherapists and surgeons were interested in the risk of injury, what stage of the MC their patient was injured, and whether their patient was at risk of a diagnosis such as Relative Energy Deficiency in Sport (RED-S) syndrome. Females reported tracking their cycles often. However, physiotherapists reported only utilising this information in high-performance sports environments. Females have reported that MC-related symptoms can impact them from participating in sports (Bruinvels et al., 2021; Heather et al., 2021). Therefore, MC symptoms could affect a woman's ability to attend rehabilitation post-ACLR.

Furthermore, the MC may impact their mood and motivation for training, which can also affect ACL rehabilitation and return to sports outcomes (Prado et al., 2021). Physiotherapists should ask females if they track their cycle, if they have symptoms, and understand when to refer to a general practitioner or specialist doctor if these symptoms are outside normal limits. Additionally, a recent systematic review by McNulty et al. (2020) reports that it is unclear if there is a particular time of the cycle when athletes have improved performance and recommend more high-quality research in this area. However, physiotherapists could also discuss this with

patients in the clinic, as MC symptoms and their effects on performance, or their perceived effects on performance, might be highly individual (Findlay et al., 2020). Overall, Chapter 3 provides a starting point for physiotherapists and medical professionals to be aware that their patients are tracking their cycle and are interested in their symptoms and their impact on their sport.

In Chapter 4, a range of females outlined their preferences for ACL rehabilitation. Many of these were general preferences that may inform general ACL rehabilitation, and others informed specifically the MC phase-based rehab programme. For example, females in this study clearly wanted to attend multiple sessions of supervised, gym-based physiotherapy per week post-ACLR. Previous research has not indicated an optimal amount of sessions for physiotherapy following ACLR (Walker et al., 2020). Frequently physiotherapists provide exercises for patients to do in their own time and instil motivation and the patients to complete these at home (Coppola & Collins, 2009). However, evidence in many physiotherapy fields shows that non-adherence is often very high with home exercises (Lonsdale et al., 2012). Specifically, with ACLR patients, prospective studies found associations between knee function (Lim et al., 2019), higher return to sports and superior quality of life (Przybylak et al., 2019) in highly supervised groups than in low supervision home-based groups.

There could also be a gender difference here, considering that females may be more unfamiliar with RT as gyms can be heavily gendered, which may disadvantage females' participation (Fisher et al., 2017). This lack of previous engagement with RT may lead to unfamiliarity for females when physiotherapists prescribe them a resistance exercise programme. In addition, recent longitudinal research by Doan et al. (2022) describes that that as women's paid or family work hours increase, physical activity reduces. Women tend to have family work such as cooking meals

and taking care of children which cannot be easily moved or fitted around other demands, such as health demands, because they are routine, daily and rigid (Moreno-Colom, 2015). In contrast, men's physical activity is unaffected by paid work hours, and family time appears protective as male's family work, such as mowing lawns, appears to be flexible and able to incorporate or accommodate physical activity (Doan et al., 2022; Moreno-Colom, 2015). Therefore, females may have less time available to prioritise home rehabilitation exercises and there may be an extra onus for females to complete their rehabilitation at structured times. Subsequently, females may require more scheduled, supervised physiotherapy sessions than males. This potential need for supervision aligns with results from Chapter 4, where females reported their preference for multiple supervised sessions per week.

Furthermore, females' preference for specifically gym-based rehabilitation is unsurprising, considering some participants' positive responses in Chapter 4 about their previous experience with ACL rehabilitation in a gym setting. Gym settings enable patients to carry out resistance exercises in the clinic so females can complete their rehabilitation exercises before they go home.

Regarding MCPBR, athletes and patients did not foresee any barriers to tracking their cycle, using a basal body thermometer daily, and testing for ovulation monthly using a urinary ovulation kit. However, they advised having one datasheet where their MC and physiotherapy information could be combined and easily accessed throughout the proposed MCPBR research study. Females recommended that this datasheet is on an online platform accessed easily via smartphone or desktop. These recommendations were included in the design of the MCPBR programme, as described in Chapter 5.

These recommendations resulted in a twice weekly, gym-based, supervised programme in Chapter 5. Both MCPBR and UC groups saw significant improvement throughout the trial, with 33% of females in the MCPBR group and 25% in the UC group meeting 90% maximum limb symmetry of knee extension strength. Recent studies recommend 90% LSI as the standard target for one RM extension strength symmetry following ACLR (Adams et al., 2012; Lynch et al., 2015). A recent study by Cristiani et al. (2019) reported that only 35.7% of ACLR patients (45.7% females) achieve an average of 90% knee extension limb symmetry at six months post-ACLR. They also noted that being of the female sex reduces those odds. At only eighteen weeks post-ACLR, 33% of the females in the MCPBR group had achieved 90% LSI, and a further 17% were within 5% of this cut-off. These results indicate comparatively high levels of LSI at this time compared to previously reported figures. Whilst the MCPBR group underwent rehabilitation timed to the phases of their MC, it is worth noting that UC was twice weekly, supervised, and gym-based rehabilitation. Therefore, UC was also in line with recommendations from Chapter 2 and what females requested as their choice of ACL rehabilitation. It is clear, whilst slightly improved outcomes were noted for the MCPBR group, that UC also underwent quality rehabilitation, to which females responded well. Therefore, overall, there is scope to continue to carry out quantitative and qualitative research with diverse groups of females to establish what they need, want, and respond well to following different ACL rehabilitation.

In contrast, in Chapter 5, they were many females for whom this trial did not meet their needs. These include adolescent girls, females who take the oral contraceptive pill (OCP), and pregnant, postpartum, and post-menopausal females. These females may also need specific considerations for their rehabilitation. For example, adolescent girls are more likely to sustain ACL injuries (Bloom et al., 2020), and

younger patients are more likely to reinjure (Webster & Feller, 2016). There has been previous research on the effect of the OCP on muscle repair and gain (Riechman & Lee, 2022). However, whether researchers have considered the effects of regaining strength post-ACLR is unknown.

Furthermore, pregnant females may have different challenges when undergoing ACLR rehabilitation; for example, they may deal with fatigue and nausea, gain body weight, and have a different centre of gravity. Current guidelines recommend that females who have not engaged in RT before can consider engaging in RT throughout pregnancy (White et al., 2014). However, it is warranted to consider and investigate whether physiotherapists are comfortable prescribing RT post-ACLR in this population. This thesis clearly articulates how females need specific support following ACLR, specifically MCPBR.

Theme 3. Female-specific needs require extra resources and planning.

Throughout the thesis, it is clear that tailoring to female-specific needs requires extra resources and planning. In the case of MC phase-based resistance training, Chapter 2 identified many methodological issues in previous studies investigating MC phase-based resistance training. These methodological issues included low participant numbers, lack of MC verification, and the need for posteriori exclusions for irregular MCs. These are all important, and mostly, female-specific needs when researching the effect of female hormones on RT responses. High participant numbers are essential to meet statistical power requirements (Dorey, 2011).

Regarding low participant numbers, considering that MC phase-based RT only applies to a specific cohort of females, researchers can only research this sub-section of the population. Therefore, there may be implications on timeframes for

recruiting studies, leading to low participant numbers or more extended data collection periods for this type of study. In Chapter 5, 73 females were assessed for eligibility for the trial. However, 11 were excluded before the trial due to breastfeeding and contraceptive use, while two females were excluded later for becoming pregnant, and a further four were excluded to due inconsistent ovulation, leading to 17 excluded due to female specific factors. In addition, females were ineligible to enrol if they were taking the OCP (approximately 26% of the NZ female population (Ministry of Health, 2016). These additional constraints affected the trial's ability to meet statistical power. These are female-specific exclusions, in addition to general surgical-related exclusions in ACL research, i.e., revision surgery. Researchers have previously noted that researchers need more time for their research, funding, and collaboration on a multi-site design to encourage participation in female-specific trials (Emmonds et al., 2019). This thesis also acknowledges that this is also the case for physiotherapy research focusing on the MC's effect on rehabilitation.

In Chapter 3, physiotherapists, surgeons, athletes, and patients reported needing more MC knowledge. They noted they lacked structured education at school, which aligns with New Zealand (Heather et al., 2021) and international research (Chrisler, 2013). This reported lack of education outlines the importance of health professionals not assuming athletes have a high level of knowledge or understanding when discussing the MC in the clinic. Physiotherapists and patients requested further education regarding the MC to be informed enough to discuss the MC in the clinic. These results underline the need for increased MC education for sports medicine support staff (Findlay et al., 2020). These results also add that professional training programmes or postgraduate continuing professional development programmes within sports medicine should be not only targeted towards females in these medical teams but open for all, with males encouraged to

attend. Sporting organisations should ensure that funding is provided for support staff to attend such courses to enable good advice to be given to their athletes regarding the MC.

In Chapter 3, females noted that they would only be comfortable discussing the MC in the clinic if they were comfortable with and trusted their physiotherapist. The importance of developing trust is in line with the previous literature (Findlay et al., 2020). However, Chapter 3 extends this knowledge by noting that females stressed that trust was crucial when discussing the MC with men. A lack of trust was the only noted barrier to mixed-gendered conversations, and similarly, gaining trust was the only noted enabler to these mixed-gendered conversations. Furthermore, patients outlined that they would not usually understand why a sports medicine health professional would want to discuss their MC. This lack of understanding aligns with athletes' previously noted lack of awareness regarding MC-related medical and performance research. In line with this, health professionals should explain to the athlete why this MC discussion is appropriate in the sports medicine environment. It takes extra time for physiotherapists to build rapport with patients and explain why the MC topic is appropriate for discussion in the sports medicine clinic. This explanation is an extra commitment for health professionals working with menstruation-age females.

In Chapter 4, females were clear regarding their preference for multiple gym-based physiotherapy sessions per week. In New Zealand, this is significantly more than the previously noted average of 12 sessions in the first year post ACLR (Fausett et al., 2019). The research team provided financial support to the participants in Chapter 5. However, physiotherapy funding is subsidised or wholly funded in New Zealand by the Accident Compensation Corporation (ACC). ACC is a no-fault insurance scheme which funds rehabilitation and treatment costs for personal injuries caused by an

accident (Todd, 2011), including anterior cruciate ligament injuries. ACC is the primary funder of physiotherapy services in New Zealand (Reid & Larmer, 2007). However, ACC funding does not usually cover the total treatment cost, so patients usually pay a co-payment to see the physiotherapist (Fitzjohn, 2007). After a certain number of physiotherapy treatments, physiotherapists can request further funding. If females need more sessions to reach an outcome, physiotherapists will have to engage in a process to request more funding from ACC. Regarding the request for gym-based sessions after ACL injury, clinic managers may need extra timetabling consideration in remote rural locations where clinics may not have access to gym facilities. Other options may need consideration, such as gym-sharing agreements in local areas.

In Chapter 5, the MCPBR approach required MC verification and posteriori exclusion of females with irregular MCs. Verifying the MC means that researchers must factor equipment such as thermometers, urinary ovulation tests, and potentially blood laboratory tests into their research plan and budget. These are additional resources needed to investigate MCPBR. A recent methodological paper by Elliot-Sale et al. (2021) notes that researchers should not use financial restrictions to eliminate females from research. When translated to clinical practice, calendar tracking may be sufficient to establish that females are in a specific MC phase.

Furthermore, as noted in Chapter 5, there is inter and intra- individual variation in MCs. When prescribing exercises based on the MC phase, physiotherapists must know each participant and check their data sheet before the appointment, which requires time and consideration on behalf of the physiotherapist. However, individual women do follow personalised MC timing and hormone profiles, which show less variation than the variation that is seen across the population as a whole

(Häggström, 2014). Therefore, once a physiotherapist has established the female's usual cycle rhythm, it is feasible to track an individual female's cycle over a long period. Despite this feasibility, it is still clear that tailoring to female-specific needs such as MC tracking, requires extra resources and planning. It is worth considering therefore, that in the past, females have had inferior outcomes following ACLR (Bruder et al., 2023). Thus, the status quo is likely to improve the trajectory of outcomes for females after ACLR. Consequently these extra resources and processes provide an opportunity to improve outcomes for females after ACLR significantly.

Strengths and Limitations of the thesis

Strengths:

Overall, there are many strengths identified within this thesis. Chapter 2 is the first review to consider the methodologies of current MC phase-based RT programmes and identify opportunities for research in females post ACLR. Females post-ACL need efficient and effective RT protocols to improve strength outcomes following surgery (Bruder et al., 2023). The qualitative study in Chapter 3 was the first to explore health professionals' and non-health professionals' knowledge and perceptions of the MC and establish their comfort in discussing it in sports medicine clinics. This study provides several practical suggestions for physiotherapists when discussing the MC in the sports medicine clinic. Chapter 4 was the first study to investigate the perspectives of athletes, patients, physios, and orthopaedic surgeons to inform the development of a novel MCPBR programme following ACLR. It is the first study to specifically ask females what worked well in their previous rehabilitation programmes and what they would prefer in a newly designed, females/female-specific rehabilitation programme. The results from this study can also aid in future designs of females-specific ACL rehabilitation programmes. In Chapter 5, the research team investigated a novel rehabilitation approach for naturally cycling

females post-ACLR. This study tailored exercises to specific female hormone fluctuations, and the research team designed the study in line with females' recommendations for ACL rehabilitation programmes. Researchers provided easy-to-use multimedia formats on online websites, which enabled physiotherapists to watch video content as reminders of strength testing protocols and training progressions. Finally, the trial also had stringent inclusion and exclusion criteria, and postpriori exclusions occurred when participants did not meet the stipulated requirements for MC verification.

Limitations:

Several limitations within the thesis are identified. In Chapter 2, the scoping review identified a small number of studies with small sample sizes and methodological issues. In addition, the review did not undertake any formal quality assessment. The aim was to provide a general overview of existing literature; thus, there is no synthesised result to any question. Furthermore, this study occurred in New Zealand, and specific New Zealand culture may have affected our findings. It is also worth noting that no Māori participants participated in the focus group studies. Therefore, these reports would not have captured their perceptions, cultural knowledge, and comfort in discussing the MC. In Chapter 4, the participants who attended the focus groups also may be more likely to be engaged and positive towards ACL rehabilitation.

In Chapter 5, participant numbers did not meet the required sample size to detect a difference in primary outcome. This study did not meet the numbers required for statistical power; with only 34 participants completed the study, whilst the target was 60 This limited number of participants could have influenced the study results, potentially leading to Type II errors and an inability to detect genuine differences between MCPBR and UC. This small sample size may also have introduced

sampling bias and increased outcome variability, raising the risk of Type I and Type II errors. Furthermore, the study couldn't effectively control for confounding variables. Additionally, the limited sample size prevented subgroup analysis, which could have provided valuable insights into different subpopulations. It is acknowledged however that this study recruited a small subset of patients undergoing ACLR; females with a naturally cycling MC. Additionally, this study recruited participants from August 2021 – November 2022. New Zealand had intermittent lockdown and varying Covid restrictions during 2021 and 2022 which had implications for sports, elective surgery, physiotherapy, and study recruitment.

Furthermore, in Chapter 5, participants did not have an initial strength test of their injured leg. Therefore, there was no pre-study measure for the study's primary outcome. In addition, the study did not collect long-term data, including functional measures such as hop tests, return to sport or re-injury rates. Regarding MC verification, there was no blood hormone verification for ovulation status. Finally, this thesis did not collect experience data regarding females' experiences with MCPBR.

Implications for Health Professionals Including Physiotherapists.

Based on the outcomes of this thesis, there are several practical implications beneficial for physiotherapists, ACL patients, and researchers:

- Health professionals should ask patients if they regularly have MC symptoms, whether they track their cycle, and if they have noticed any patterns or insights with their MC-related symptoms.
- Health professionals should be aware that some females may have more or less MC knowledge than others.
- If physiotherapists discuss the MC with young females, consider their parent's/guardian/caregivers presence.

- Health professionals should develop trust with females and give context to females as to why the MC is appropriate to discuss in the sports medicine clinic before discussing their MC.
- Health professionals should engage in ongoing education regarding the MC symptoms, different injury rates around the MC, and MC effects on performance and recovery.
- If health professionals and a patient agree to share MC data, find a pragmatic way to share MC information, for example, using an online datasheet or wellness tracking application with a coach function.
- Health professionals should consider referring female patients for supervised, frequent, and efficient gym-based resistance-training based rehabilitation sessions for women post-ACLR.
- There is a need for health professionals, especially physiotherapists, to engage in ongoing practical education regarding strength testing and progression protocols following ACLR.
- There is a need for senior health professionals such as physiotherapy managers/clinical leads to train staff about strength testing and progression protocols and provide straightforward strength testing and progression protocols and equipment in clinics.
- Health professionals should consider sharing aspects of ACLR rehabilitation programme delivery like PROMS and strength measures with patients to improve the outcome and transparency of the intervention.
- Health professionals should offer rehabilitation to be adaptable to females' needs, i.e., the ability to change the scheduled session to telehealth, reschedule, have children present, or change to a home exercise programme.
- If females engage in MC phase-based resistance exercise and wish to do so after ACLR, physiotherapists can prescribe resistance exercise in the FP and neuromuscular/cardiovascular exercise in the LP of the MC.

Future Research Opportunities

The abovementioned limitations can help identify future directions for injury research in New Zealand and internationally. In addition, this thesis identifies many areas for future research which are listed below:

- Firstly, there is a need to determine, with sufficient sample size and statistical power, whether MCPBR improves strength (and other) outcomes following ACLR, compared to UC or other variations of rehabilitation.
- Future research should continue to periodically review MC phase-based RT research as more is published, to understand it's effect on strength outcomes for females.
- Future research should also investigate a wider pool of diverse females regarding their knowledge and perceptions of, and comfort in discussing, the MC in the sports medicine environment.
- Future researchers may wish to conduct further qualitative research which asks a more diverse number of females what their preference is for general ACL rehabilitation and MCPBR in an ACL rehabilitation environment.
- Specifically, in Aotearoa in New Zealand, there is a gap for further consultation with Māori and Pasifika females to understand their culturally specific needs for ACL rehabilitation.
- There is an opportunity for future research to examine the long-term effects of MCPBR, including functional tests such as hopping, landing, returning to sport and re-injury rates.
- Furthermore, future research should investigate the experience of MCPBR for females post ACLR to establish what specific aspects of the MCPBR do or do not work well for patients.

- Similarly, there is a role for follow-up with physiotherapists who carried out MCPBR to determine what specific aspects of the MCPBR do or do not work well for physiotherapists.
- Many factors mediate muscular adaptations including recovery, diet, and sleep. Whilst this study did not capture these metrics, future trials which may be able to link to recovery data, perhaps from smartphone application data sharing, may provide more valuable insights.
- There is also a role for future research to examine MCPBR in females who do not undergo an ACLR but opt for a non-operative pathway.
- There was no opportunity for females who take the OCP to become involved with this research. Previous research has investigated the OCP's effect on strength training responses in non-injured females. There may be a role for future research to investigate the effect of the OCP on strength recovery following ACLR.
- In the same vein, pregnant or postpartum women were also not eligible for participation in this study as they would not have had regular hormonal fluctuations. There is a role for future research to investigate female-specific approaches for all stages of a female athlete's life span, including but not limited to female adolescence, pregnancy, the postpartum period, perimenopause and postmenopause. These are especially relevant for females post ACLR in New Zealand as many women injure their ACL in adolescence at age 30 and above.
- Finally, there is a role for future research to investigate MC phase-based RT in other patient population groups, i.e., following a rotator cuff injury or after Achilles tendon repair.

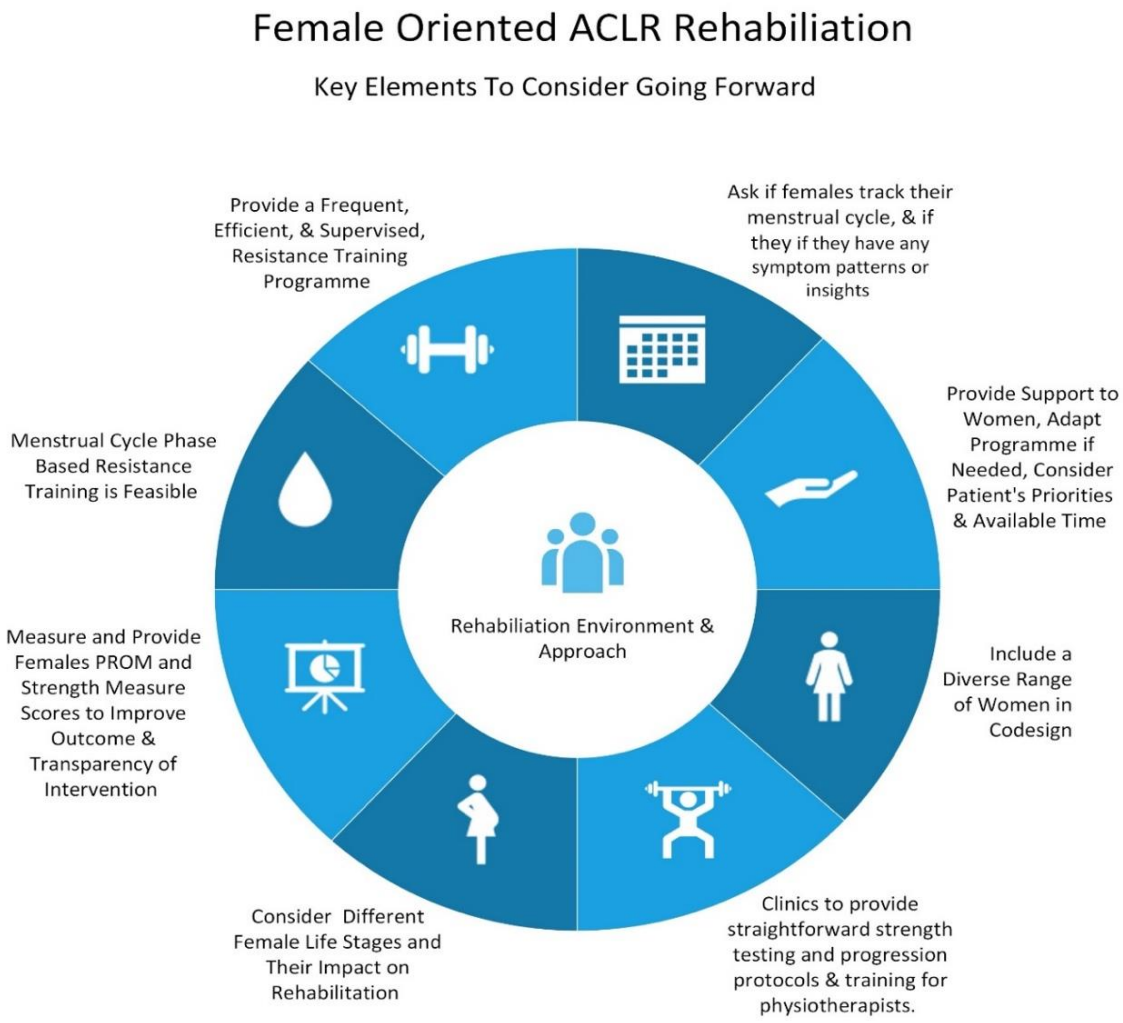

Figure 14. Key elements to consider for female oriented ACLR rehabilitation.

Summary and Conclusions

Summary

The primary purpose of this thesis was to establish the effect of a female-specific, MC phase-based ACLR rehabilitation programme on strength recovery and self-reported functional outcomes for females after ACLR. It was unknown if there was a role in investigating MCPBR in anterior cruciate ligament populations. Secondly, health professionals' and females' knowledge about the MC and how comfortable they are talking about the cycle in the sports medicine clinic was unknown. Thirdly, females' preferences for ACL rehabilitation programmes were also unknown. Fourthly, it was unknown how to design a novel MC phase-based programme to utilise female sex hormone fluctuations and women's reported preferences. Finally,

the effectiveness of MC phase-based RT programmes to improve maximum quadriceps strength and self-reported functional outcomes for females was unknown.

The overall findings for this thesis were that i) previous RT programmes tailored to phases of the MC had methodologies and results which were applicable to women post ACLR, ii) that health professionals and non-health professionals consider the MC to be a pertinent and evolving topic in the sports medicine clinic, iii) but females have specific preferences for a MC phase based rehab programme ACL rehab including a gym-based, supervised, funded physiotherapy programme, which includes MC education and a centralised database for patients to record their MC and physiotherapy information, and iv) MCPBR is feasible, and results in similar strength outcomes and self-reported function as compared to UC.

Conclusion

This thesis provides a novel insight into the relevance of previous MC phase-based RT protocols and their effects on females following ACLR. It also provides a novel insight into health professionals' and non-health professionals' knowledge, perceptions and comfort discussing the MC, in addition to female-specific preferences for ACL rehabilitation. This study was the first to consider and test a female-specific ACLR rehabilitation programme that researchers tailored to the MC but also considered female-specific needs. Overall, these findings should assist health professionals and researchers in considering female-specific approaches that could improve outcomes for females post-ACLR. Future research should address the thesis limitations and build on the ideas presented in this thesis for a better understanding of the role of the MC hormonal fluctuations, sex, and gender-specific preferences, and female outcomes following ACLR.

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APPENDICES

Appendices Section A: Ethics Approval

Appendix 1. AUT Ethics Approval Study I

Auckland University of Technology Ethics Committee (AUTEC)

Auckland University of Technology
D-88, Private Bag 92006, Auckland 1142, NZ
T: +64 9 921 9999 ext. 8316
E: ethics@aut.ac.nz
www.aut.ac.nz/researchethics

26 August 2020

Duncan Reid
Faculty of Health and Environmental Sciences
Dear Duncan

Ethics Application: **20/224 The effect of a menstrual cycle phased rehabilitation programme on strength recovery and self-reported functional outcomes after anterior cruciate ligament reconstruction.**

Thank you for submitting your responses to AUTEC's conditions. We are pleased to advise that your ethics application is approved , subject to the following conditions:

1. Provision of the PGR9 and reviewer comments. If these do not include a thorough review of the method, AUTEC would like to see an independent peer review of this aspect of the research.

Please provide us with a response to the points raised in these conditions, indicating either how you have satisfied these points or proposing an alternative approach. AUTEC also requires copies of any altered documents, such as Information Sheets, surveys etc. You are not required to resubmit the application form again. Any changes to responses in the form required by the committee in their conditions may be included in a supporting memorandum.

Please note that the Committee is always willing to discuss with applicants the points that have been made. There may be information that has not been made available to the Committee, or aspects of the research may not have been fully understood.

Once your response is received and confirmed as satisfying the Committee's points, you will be notified of the full approval of your ethics application. Full approval is not effective until all the conditions have been met. Data collection may not commence until full approval has been confirmed. If these conditions are not met within six months, your application may be closed and a new application will be required if you wish to continue with this research.

To enable us to provide you with efficient service, we ask that you use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

We look forward to hearing from you,

(This is a computer-generated letter for which no signature is required)

The AUTEC Secretariat
Auckland University of Technology Ethics Committee

Cc: emolough@tcd.ie

Appendix 2. HDEC Ethics Approval Study II

Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@health.govt.nz

28 May 2021

Ms Emma O'Loughlin
8 Orchy Crescent,
Southgate
Wellington 6023

Dear Ms O'Loughlin

Re:	**Ethics ref:**	**21/CEN/92**
	Study title:	A randomised controlled trial to evaluate the effect of a menstrual cycle phased rehabilitation programme on quadriceps extensionstrength for females post Anterior Cruciate Ligament Reconstruction

I am pleased to advise that this application has been ***approved*** by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows.

1. The Committee noted that for future responses to Provisional Approval (if any), tracked changes version of documents is required to aid in assessment.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Central Health and Disability Ethics Committee is required.

Standard conditions:

2. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

3. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or https://clinicaltrials.gov/.

4. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Appendix 3. AUT Ethics Approval Study II

Auckland University of Technology Ethics Committee (AUTEC)

Auckland University of Technology
D-88, Private Bag 92006, Auckland 1142, NZ
T: +64 9 921 9999 ext. 8316
E: ethics@aut.ac.nz
www.aut.ac.nz/researchethics

25 June 2021

Duncan Reid
Faculty of Health and Environmental Sciences

Dear Duncan

Re Ethics Application: **21/203 A randomised controlled trial to evaluate the effect of a menstrual cycle phased rehabilitation programme on quadriceps extension strength for females post Anterior Cruciate Ligament Reconstruction.**

Thank you for providing evidence as requested, which satisfies the points raised by the Auckland University of Technology Ethics Committee (AUTEC).

Your ethics application has been approved for three years until 25 June 2024.

Standard Conditions of Approval

1. The research is to be undertaken in accordance with the Auckland University of Technology Code of Conduct for Research and as approved by AUTEC in this application.
2. A progress report is due annually on the anniversary of the approval date, using the EA2 form.
3. A final report is due at the expiration of the approval period, or, upon completion of project, using the EA3 form.
4. Any amendments to the project must be approved by AUTEC prior to being implemented. Amendments can be requested using the EA2 form.
5. Any serious or unexpected adverse events must be reported to AUTEC Secretariat as a matter of priority.
6. Any unforeseen events that might affect continued ethical acceptability of the project should also be reported to the AUTEC Secretariat as a matter of priority.
7. It is your responsibility to ensure that the spelling and grammar of documents being provided to participants or external organisations is of a high standard and that all the dates on the documents are updated.

AUTEC grants ethical approval only. You are responsible for obtaining management approval for access for your research from any institution or organisation at which your research is being conducted and you need to meet all ethical, legal, public health, and locality obligations or requirements for the jurisdictions in which the research is being undertaken.

Please quote the application number and title on all future correspondence related to this project.

For any enquiries please contact ethics@aut.ac.nz. The forms mentioned above are available online through http://www.aut.ac.nz/research/researchethics

(This is a computer-generated letter for which no signature is required)

The AUTEC Secretariat
Auckland University of Technology Ethics Committee

Cc: emolough@tcd.ie

Appendix 4. HDEC Ethics Approval Change of Advert Study II

Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011
hdecs@health.govt.nz

Ethics reference: 2021 AM 10394

23 September 2021

Tēnā koe

APPROVAL OF AMENDMENT

Study title: A randomised controlled trial to evaluate the effect of a menstrual cycle phased rehabilitation programme on quadriceps extension strength for females post Anterior Cruciate Ligament Reconstruction

I am pleased to advise that this amendment was **approved** by the Central Health and Disability Ethics Committee (the Committee). This decision was made through the post-approval pathway./CF):

Further information and assistance

Please contact the HDECs Secretariat at hdecs@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information.

Nāku noa, nā

Mrs Helen Walker

Chair

Central Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix 5. AUT Ethics Approval Change of Advert Study II

Auckland University of Technology Ethics Committee (AUTEC)

Auckland University of Technology
D-88, Private Bag 92006, Auckland 1142, NZ
T: +64 9 921 9999 ext. 8316
E: ethics@aut.ac.nz
www.aut.ac.nz/researchethics

29 September 2021

Duncan Reid
Faculty of Health and Environmental Sciences

Dear Duncan

Re: Ethics Application: **21/203 A randomised controlled trial to evaluate the effect of a menstrual cycle phased rehabilitation programme on quadriceps extension strength for females post Anterior Cruciate Ligament Reconstruction.**

Thank you for your request for approval of amendments to your ethics application.

The amendments to the recruitment protocol have been approved.

Standard Conditions of Approval.

1. The research is to be undertaken in accordance with the Auckland University of Technology Code of Conduct for Research and as approved by AUTEC in this application.
2. A progress report is due annually on the anniversary of the approval date, using the EA2 form.
3. A final report is due at the expiration of the approval period, or, upon completion of project, using the EA3 form.
4. Any amendments to the project must be approved by AUTEC prior to being implemented. Amendments can be requested using the EA2 form.
5. Any serious or unexpected adverse events must be reported to AUTEC Secretariat as a matter of priority.
6. Any unforeseen events that might affect continued ethical acceptability of the project should also be reported to the AUTEC Secretariat as a matter of priority.
7. It is your responsibility to ensure that the spelling and grammar of documents being provided to participants or external organisations is of a high standard.
8. AUTEC grants ethical approval only. You are responsible for obtaining management approval for access for your research from any institution or organisation at which your research is being conducted. When the research is undertaken outside New Zealand, you need to meet all ethical, legal, and locality obligations or requirements for those jurisdictions.

Please quote the application number and title on all future correspondence related to this project.

For any enquiries please contact ethics@aut.ac.nz. The forms mentioned above are available online through http://www.aut.ac.nz/research/researchethics

(This is a computer-generated letter for which no signature is required)

The AUTEC Secretariat
Auckland University of Technology Ethics Committee

Cc: emolough@tcd.ie; Stacy Sims

Appendices Section B: Research Tools

Appendix 6. Focus Group Protocol

Focus Group Protocol

1. The primary researcher introduced herself and the research team.
2. The primary researcher explained the method of focus groups.
3. The primary researcher outlined the flow of the meeting.
4. The primary researcher outlined the purpose of the group and the goals of the meeting
5. The primary researcher discussed the ground rules, and open participation was encouraged.
6. The primary researcher reemphasized that the findings would be ananonymized
7. The primary researcher gave each participant some time to introduce themselves and ask any questions.
8. The first question of the focus group protocol followed.
9. The primary researcher gave the participants enough time to discuss each question thoroughly until there were no more opinions.
10. The primary researcher relayed the main findings of each question and ask if anyone had anything further to add.
11. Once there were no other questions to ask, and the participants expressed all opinions, the primary researcher thanked the participants and closed the session.

Appendix 7. Focus Groups Qs Med Professionals

Focus Group Study – Potential Questions for Medical Professionals;

1. What knowledge do you have of the menstrual cycle and associated hormonal fluctuations?
2. Do you have any experience or knowledge of tracking the menstrual cycle?
3. How comfortable do/would you feel talking about the menstrual cycle in clinic to your patients?
4. Are you aware of any cultural beliefs of practices surrounding the menstrual cycle in NZ?
5. In your opinion, would this programme be feasible to run/participate with in clinic?
6. Are there any barriers or difficulties identified with this programme?
7. Is this programme similar or different to usual care provided to your ACLR patients? Please elaborate on similarities and differences between the programme and usual care.
8. What works well or doesn't work well in your rehabilitation programmes at the moment?
9. Are there any barriers to changing appointment scheduling to align with the menstrual cycle? What would be the maximum number of sessions you would book participants per week into your clinic?
10. How easy or difficult would it be to fill in the data collection sheet? Are there any barriers identified with filling out this sheet?

Appendix 8. Focus Groups Qs ACLR Patients

Focus Group Study – Potential Questions for Current ACLR Patients

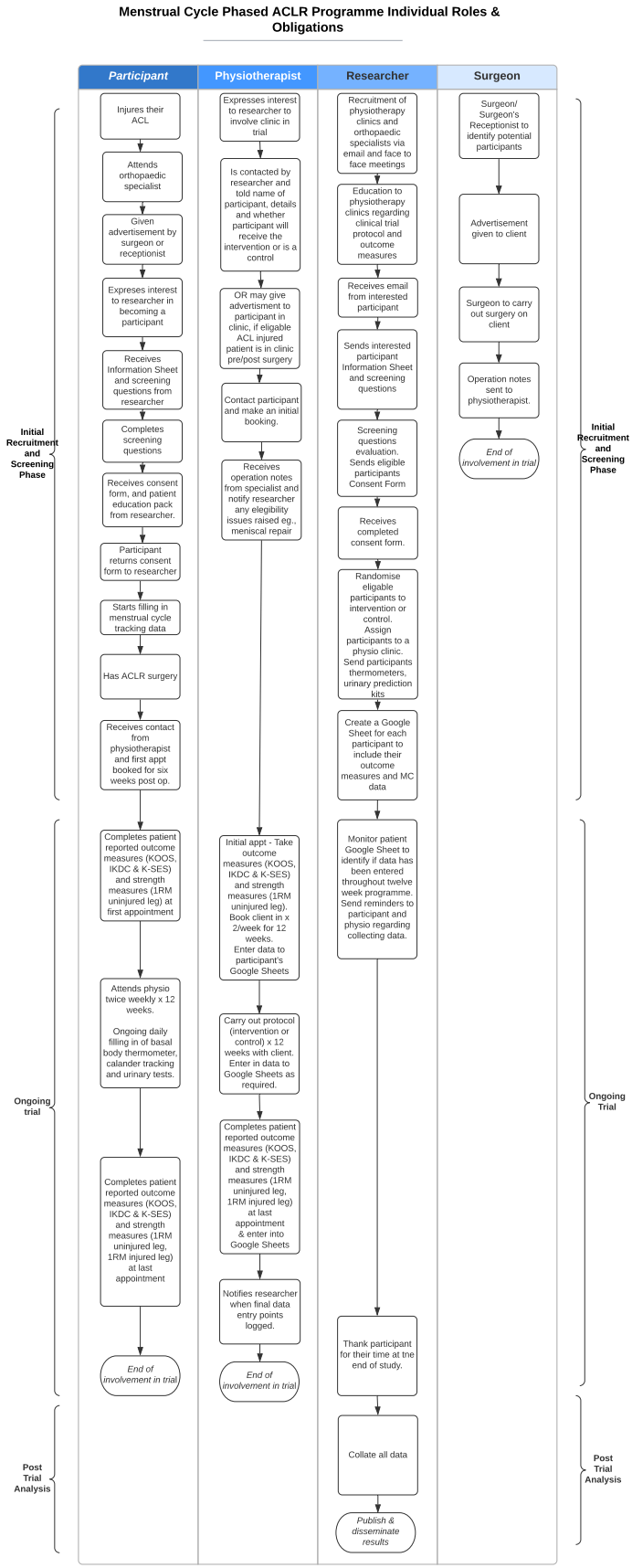
1. What knowledge do you have of your monthly menstrual cycle?
2. Have you ever tracked your menstrual cycle before?
3. How comfortable would you feel talking about your menstrual cycle in clinic with your physiotherapist?
4. Do you have any cultural beliefs of practices surrounding your menstrual cycle?
4. Have you ever discussed your menstrual cycle with a health professional before?
3. Does this programme that I have described sound similar or different to your current rehabilitation programme? What is similar, and what is different?
4. What would make it easier for you to stick to this rehabilitation programme?
5. What works well in your rehab programme at the moment?
6. What doesn't work well in your rehabilitation programme at the moment?
7. What would be the maximum number of sessions you would be able to attend per week?
7. Would you like some days to be a home based programme instead of in clinic?
8. How would you feel about tracking your menstrual cycle for a few months?
9. The rehabilitation programme would include participants completing approximately three fully funded urinary tests at home to confirm what part of their cycle they are in. How would you feel about doing some urinary tests with a home urinary testing kit as part of your rehabilitation programme?

Appendix 9. Focus Groups Qs Athletes

Focus Group Study – Potential Questions for Female Athletes

1. What knowledge do you have of your monthly menstrual cycle?
2. Have you ever tracked your menstrual cycle before?
3. How comfortable would you feel talking about your menstrual cycle/ period in clinic with a physiotherapist?
4. Have you ever discussed your menstrual cycle with a health professional before?
5. Do you have any cultural beliefs of practices surrounding your menstrual cycle?
3. What are some things you would expect from a rehabilitation programme?
4. What would make it easier for you to stick to this rehabilitation programme?
7. What would be the maximum number of physiotherapy sessions you would be able to attend per week?
7. Would you like some days to be a home based programme instead of in clinic?
8. Would you be happy to track your cycle and tell the physiotherapist when you are at certain points of your cycle?
9. The rehabilitation programme would include participants completing approximately three fully funded urinary tests at home to confirm what part of their cycle they are in. How would you feel about doing some urinary tests with a home urinary testing kit as part of your rehabilitation programme?

Appendix 10. RCT Roles & Responsibilities – Swimlane Diagram



Appendix 1: Menstrual Cycle Phased ACLR Rehabilitation Guide for Physiotherapists

Part A: Guide for Intervention Group

This includes

- Instructions for first and last appointments.
- Instructions for how to measure quadriceps strength.
- Instructions for verifying menstrual cycle phase with participant.
- Instructions for periodization of rehab.
- Instructions regarding which strengthening exercises to complete with participant, and a guideline for the progression of these.
- Examples of exercises appropriate for the luteal phase rehabilitation sessions.

Initial Appointment - Six weeks Post Operation

1. Screen operation notes and notify researcher if client does not meet inclusion criteria.
2. Check Google Sheets to ensure calendar tracking, basal body temperature and ovulation prediction results have been entered by participant.
3. Establish participant's MC phase and enter result into Google Sheet.
4. Client to complete KOOS 12 form and enter result into Google Sheet.
5. Client to complete IKDC Subjective Knee Evaluation Form and enter result into Google Sheet.
6. Client to complete K-SES form and enter result into Google Sheet.
7. Ensure appointments booked x 2/week for 12 weeks and enter dates into Google Sheet.
8. Obtain 1RM knee extension strength of the uninjured leg and enter into Google Sheet.

How to assess 1RM

Knee Extension 1 RM

- Requires a knee extension machine.
- All 1-RM testing should begin with the uninvolved limb and alternated between limbs.
- The tester will instruct the patient to extend the knee against the resistance of the machine in a slow and controlled fashion.
- Trials are deemed successful when the patient has achieved the targeted angle of knee extension and maintained it for 2 seconds.
- Resistance is increased after a successful trial on each limb by 2.00 to 14.00 kg, at the tester's discretion, depending on the difficulty of the previous repetition.
- Failure is defined as 3 unsuccessful attempts to lift the weight to the targeted angle, with a rest interval of up to 60 seconds given between attempts.
- The final 1-RM values for the involved and uninvolved legs are to be recorded.
- Testing can be done at 90-0 knee extension or 90- 45 knee extension. As time progresses clearly the resistance of the test needs to increase.

Reference

Sinacore et al. Diagnostic Accuracy of Handheld Dynamometry and 1-Repetition- Maximum Tests for Identifying Meaningful Quadriceps Strength Asymmetries JOSPT 2017 47 (2) 97-107.

Periodization of Rehab Programme

How to establish if the participant is in Follicular Phase:

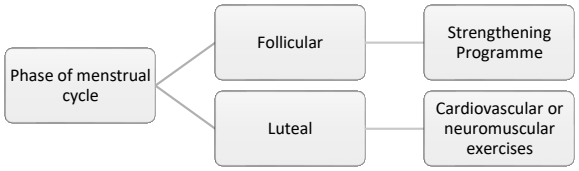
1. They have logged their recent menses into their calendar
2. They have not yet logged a positive urinary ovulation predictor kit result.

How to establish if the participant is in Luteal Phase:

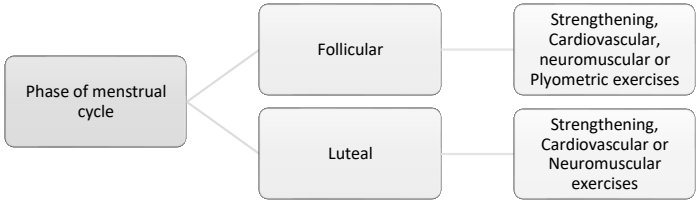
1. Their calendar indicates that ovulation should have occurred.
2. They have entered several raised basal body thermometer reading.
3. They have entered in a positive urinary kit result.

Periodization:

Intervention Group



Control Group



Follicular Phase Guide

Please complete these three exercises per session in the follicular phase.

Olympic Leg Press – Closed Kinetic Chain

Squat – Closed Kinetic Chain

Seated Knee Extension – Open Kinetic Chain

*Open chain exercises should be incorporated as per surgeons' instructions.
chain should start at 90-45 degrees, then full arc 90-0 but without resistance. Strong isometric quads holds are to be encouraged at the end of the full arc.
* From 8-12 weeks (week 4 of research study) on you can introduce resistance and graduate this over the next 4-6 weeks.

Progression Guide:

Week 6-10

Double Leg Leg Press & Double Leg Squat
60% of 1RM
8-12reps
2-3 sets

Leg extension
90-45 degrees, then 90-0. Strong isometric holds
Start to add resistance approx week 8.

Week 11-14

Double Leg Press & Double Leg Squat
70-80% of 1RM
6-8 reps
2-3 sets
Progress to Single Leg

Double Leg Knee Extension
60% of 1RM
8-12reps
2-3 sets

Week 15 - 18

Single Leg Press & Single Leg Squat
70-80% of 1RM
4-6 reps
2-3 sets

Single Leg Knee extension
70-80% of 1RM
6-8 reps
2-3 sets

Remember! Any increase in pain and swelling following exercise sessions indicates the exercises were too hard - drop back to previous week until the knee settles.
**Strength exercises should be done at the start of each session (before neuromuscular control or mobility exercises).*
** Multi-joint exercises (leg press and squat) should be done before single joint (leg extension) exercises.*

Do I progress the client?

Luteal Phase Guide	Final Appt – 18 weeks Post Operation

All exercises stated below are examples of exercises that are suitable (depending on the participant's ability) to complete within the luteal phase sessions.

Cardiovascular Exercises:
Walking
Ergo machine
Rowing
Cycling

Neuromuscular Exercises:
Toe Stand
Toe/Heel Walk
Bosu/ Wobble Board Stand/Single Leg Stand/Mini squat/Step Ups.
Step up/downs
Lateral step up/downs
Single leg Stand/Balance – Star exercise, balance & reach
Grapevine
Medicine Ball Core exercise
Graduated Agility exercises with good movement form
Consider controlled vertical Hopping (on the spot) when movement patterns are appropriate.

1. Check Google Sheets to ensure calendar tracking, basal body temperature, ovulation prediction, outcome measures and exercise records are entered.
2. Client to complete KOOS 12 form enter result into Google Sheet.
3. Client to complete IKDC Subjective Knee Evaluation Form enter result into Google Sheet.
4. Client to complete K-SES form enter result into Google Sheet.
5. Obtain isometric quadriceps strength measures with handheld dynamometer on bilateral lower limbs enter result into Google Sheet.
6. Obtain 1RM knee extension strength of bilateral lower limbs enter result into Google Sheet.
7. Email researcher to acknowledge end of protocol with patient.

Part B: Guide for Control Group

- It is expected the control group will also receive an evidence based, phased, and criterion based progressive ACLR rehabilitation programme.
- Below is an adapted postoperative rehabilitation guide from VanMelick et al., 2016 and Adams et al., 2012 which can be used as a guide for best practice post op ACLR rehabilitation for the control group.

Phase 2 - Range of motion/strength/muscle reactivation/balance (2-12 weeks)

Goals:
Build Knee Strength
Restore normal range of motion
Restore balance and walking confidence

Intermediate Postoperative Phase (Weeks 3-5) Milestones
Knee flexion ROM to within 10° of uninvolved side
Quadriceps strength greater than 60% of uninvolved side

Treatment
Tibiofemoral mobilizations with rotation for ROM if joint mobility is limited
Progress bike duration (10-minute minimum)
Begin graduated balance and proprioceptive activities

Late Postoperative Phase (Weeks 6-8) Milestones
Quadriceps strength greater than 80% of uninvolved side
Normal gait pattern
Full knee ROM (compared to uninvolved side)
Knee effusion of trace or less

Treatment

Progress exercises in intensity and duration
Continue exercise programme at fitness facility (if all milestones are met)

Maintaining or gaining quadriceps strength (greater than 80% of uninvolved side)

Treatment
Sports-specific activities- graduate from easy to more challenging over time

Phase 3 -Function: In a controlled Environment and with good movement patterns -running, jumping, hopping, landing (3-6 months)

Goals
Restore strength to 80% of uninvolved limb
Restore functional movements - running, jumping, landing, hopping, landing

Follow-up Functional Testing(4 Months, 5 Months, 6 Months, 1 Year Postoperative)

Milestones Functional Phase (3-6 months)
•Maintaining gains in strength (greater than or equal to 90% to 100%)
•Consider controlled vertical Hopping (on the spot) when movement patterns are appropriate
•Return-to-sport criteria (see below)
•Recommend changes in rehabilitation as needed. Progression may emphasize single-leg activities in gym, explosive types of activities (cutting, jumping, plyometrics, landing training)

Appendix 12. Screening Questions for Interested Participants – RCT

Female ACLR Rehab Programme Screening Questions

This is short survey to make sure you will be a good fit for our programme. If you have any queries about the questions, call or text Emma on 0221723949, or email her on ccq8275@autuni.ac.nz

* Indicates required question

1. What is your name? *

2. What age are you? *

3. What is your address? *

4. Do you have at least 9 menstrual cycles per calendar year? *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Unsure
- [ ] Other: _____

5. Over the past year, did your menstrual cycles usually last about 21 and 35 days? *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Unsure
- [ ] Option 4
- [ ] Other: _____

6. Are you taking the oral contraceptive pill? *

Mark only one oval.

- ◯ Yes
- ◯ No

7. Do you have an IUD or an implant? *

Mark only one oval.

- ◯ Yes
- ◯ No

8. If so, how long ago was it inserted?

Mark only one oval.

- ◯ <12 months
- ◯ > 12 months
- ◯ > 2 years ago
- ◯ > 3 years ago
- ◯ > 4 years ago

9. If so, what brand?

10. Are you taking any other medication? *

Check all that apply.

- [ ] Yes
- [ ] No

11. If so, what brand?

_____

12. Are you pregnant? *

Mark only one oval.

- ◯ Yes
- ◯ No

13. Have you given birth or breastfed within the last year? *

Mark only one oval.

- ◯ Yes
- ◯ No

14. Have you missed your period for three months or more? *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Unsure

15. Is this in the past 2 years?

_____

16. Have you ever been diagnosed with an eating disorder or with RED-S syndrome? *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Unsure
- [ ] Other: _____

17. In the past 3 months, how often have you exercised per week? *

Check all that apply.

- [ ] No involvement in regular physical activity for the last 3 months
- [ ] Up to three times per week
- [ ] More than three times per week

18. Do you complete resistance training as part of your exercise? *

Check all that apply.

- [ ] Yes
- [ ] No

19. If so, can you expand? What type of resistance training this is? eg. gym workout, crossfit training, combination exercises etc

_____

_____

_____

_____

_____

20. When did you injure your ACL? *

_____

21. When is your surgery booked for? *

22. How did you injure your ACL? *

23. Have you had a previous ACL reconstruction on this leg or your other leg?

Mark only one oval.

- Yes, this leg
- No
- Yes, opposite leg

24. Do you have a physio at the moment? *

Mark only one oval.

- Yes
- No

25. If so, what is your physios name & what clinic do they work in?

26. What ethnicity group do you belong to? *

Check all that apply.

- New Zealand European
- Maori
- Samoan,
- Cook Islands Maori
- Tongan
- Niuean
- Chinese
- Indian,
- Other (such as Dutch, Japanese, Tokelauan)

Appendix 13. Data Collection Sheet RCT

Researcher to Fill		Physio to Fill			
Participant Details		**Operation Details**	**Outcome Measures**	**Initial Appointment**	**Final Appointment**
Participant Name	Emma O'Loughlin	Date of Surgery	KOOS Score	35	49
Date of ACLR Injury	1/4/2021	Type of Graft	IKDC Score	35	12
Age	29	Cartilage Damage?	K-SES Score	7	16
Ethnicity	NZ European	Meniscal Surgical Treatment?	1Rep Maximum Knee Extension Strength		
Resistance Training Status	Trained	Associated Ligamentous injuries?	*- Uninjured Leg*	52kg	75kg
Menstrual Cycle Status	Natural Cycle - No Contraceptive		*- Injured Leg*	[redacted]	66kg
			As measured by	Knee Extension Machine	Knee Extension Machine

Participant to Fill						
Pre Programme Menstrual Cycle Recording Date		**Do you have your period today?**	**Temperature**	**Used your ovulation kit?**	**Positive/Negative**	**Calendar Phase**	**Have you exercised today?**
	05/23	No	36.66	Yes	Positive	Not Sure	
	05/24	No	36,4	No		Luteal	
	05/25	No	36.4	No		Luteal	
	05/26	No	36.4	No		Luteal	
	05/27	No	36.4	No		Luteal	
	05/28	No	36,4	No		Luteal	
	05/29	No	36.4	No		Luteal	
	05/30	No	36.4	No		Luteal	
	05/31	No	36,4	No		Luteal	

Participant to Fill							Physio to Fill			
Day of Programme	**Date**	**Do you have your period today?**	**Temperature**	**Used your ovulation kit?**	**Positive/Negative**	**Calendar Phase**	**Physio Dates Booked**	**Attended Physio?**	**Strength Exercises (Reps, Sets, Weight)**	**Other exercises completed**
Day 1 - Week 1	06/01	No	36,4	No		Luteal	Booked	Yes		Initial Appt - 1RM Testing
	06/02	No	36.4	No		Luteal				
	06/03	No	36.2	No		Luteal	Booked	No - Rescheduled		
	06/04	No	36.5	No		Luteal	RESCHEDULED	Yes		Bike, SL Stand, Core, plank, bridge, clams
	06/05	No	36.3	Yes		Luteal				
	06/06	Yes	36.22	No		Follicular				
	06/07	Yes	36.22	No		Follicular				
Day 8 - Week 2	06/08	Yes	36.4	No		Follicular	Booked	Yes	Squat double leg 10 x 3 x 40kg, Leg press 15 x 3 x 55kg, Knee ext 15 x 3 x 15kg double leg	
	06/09	Yes	36,4	No		Follicular				
	06/10	Yes	36.4	No		Follicular	Booked	Yes	Squat double leg 10 x 3 x 40kg, Leg press 15 x 3 x 55kg, Knee ext 15 x 3 x 15kg double leg	
	06/11	No	36,4	No		Follicular				
	06/12	No	36.4	No		Follicular				
	06/13	No	36.2	No		Follicular				
	06/14	No	36.35	No		Follicular				
Day 15 - Week 3	06/15	No	36.55	Yes	Negative	Follicular	Booked	Yes	Squat double leg 10 x 3 x 40kg, Leg press 15 x 3 x 55kg, Knee ext 15 x 3 x 15kg double leg	
	06/16	No	36,7	Yes	Positive	Luteal				Wobble Board Stand, Step up/downs Lateral step up/downs Single leg Stand/Balance – Star exercise, balance & reach
	06/17	No	36.4	No		Luteal	Booked	Yes		
	06/18	No	36.4	No		Luteal				
	06/19	No	36,4	No		Luteal				
	06/20	No	36.4	No		Luteal				
	06/21	No	36.36	No		Luteal				
Day 22 - Week 4	06/22	No	36.36	No		Luteal	Booked	Yes		Ergo, side steps, bike, toe walks
	06/23	No	36,22	No		Luteal				
	06/24	No	36.22	No		Luteal	Booked	No - Rescheduled		
	06/25	No	36.22	No		Luteal				Wobble Board Stand, Step up/downs Lateral step up/downs Single leg Stand/Balance – Star exercise, balance & reach
	06/26	No	36	No		Luteal	Rescheduled	Yes		
	06/27	No	36	No		Luteal				
	06/28	No	36.22	No		Luteal				
Day 29 - Week 5	06/29	No	36,22	No		Luteal				Wobble Board Stand, Step up/downs Lateral step up/downs Single leg Stand/Balance – Star exercise, balance & reach
	06/30	No	36.22	No		Luteal	Booked	Yes		
	07/01	Yes	36,22	No		Follicular				
	07/02	Yes	36.4	No		Follicular	Booked	Yes	Squat double leg 10 x 3 x 40kg, Leg press 15 x 3 x 55kg, Knee ext 15 x 3 x 15kg double leg	
	07/03	Yes	36,1	No		Follicular				
	07/04	Yes	36.1	No		Follicular				
	07/05	Yes	36.1	No		Follicular				
Day 36 - Week 6	07/06	No	36,1	No		Follicular				
	07/07	No	36.1	No		Follicular	Booked	Yes	Squat double leg 10 x 3 x 40kg, Leg press 15 x 3 x 55kg, Knee ext 15 x 3 x 15kg double leg	
	07/08	No	36,1	No		Follicular				
	07/09	No	36.1	No		Follicular	Booked	Yes	Squat double leg 10 x 3 x 40kg, Leg press 15 x 3 x 55kg, Knee ext 15 x 3 x 15kg double leg	
	07/10	No	36.1	No		Follicular				
	07/11	No	36.1	No		Follicular				

	07/12	No	36.1	No		Follicular				
Day 43 - Week 7	07/13	No	36.1	No		Follicular				
	07/14	No	36.35	No		Follicular				
	07/15	No	36.4	Yes		Luteal	Booked	Yes		Wobble Board Stand, Step up/downs Lateral step up/downs Single leg Stand/Balance – Star exercise, balance & reach
	07/16	No	36.45	Yes	Positive	Luteal				
	07/17	No	36.45	No		Luteal	Booked	Yes		Wobble Board Stand, Step up/downs Lateral step up/downs Single leg Stand/Balance – Star exercise, balance & reach
	07/18	No	36.45	No		Luteal				
	07/19	No	36.45	No		Luteal				
Day 50 - Week 8	07/20	No	36.6	No		Luteal				
	07/21	No	36,6	No		Luteal				
	07/22	No	36.6	No		Luteal				
	07/23	No	36,6	No		Luteal	Booked	Yes		Wobble Board Stand, Step up/downs Lateral step up/downs Single leg Stand/Balance – Star exercise, balance & reach
	07/24	No	36.6	No		Luteal				
	07/25	No	36.6	No		Luteal	Booked	Yes		Wobble Board Stand, Step up/downs Lateral step up/downs Single leg Stand/Balance – Star exercise, balance & reach
	07/26	No	36.6	No		Luteal				
Day 57 - Week 9	07/27	No	36.6	No		Luteal				
	07/28	No	36.4	No		Follicular				
	07/29	No	36.1	No		Follicular				
	07/30	No	36.1	No		Follicular				
	07/31	Yes	36.1	No		Follicular	Booked	Yes	Squat double leg 10 x 3 x 40kg, Leg press 15 x 3 x 55kg, Knee ext 15 x 3 x 15kg single leg	
	08/01	Yes	36.1	No		Follicular				
	08/02	Yes	36.1	No		Follicular	Booked	Yes	Squat double leg 10 x 3 x 40kg, Leg press 15 x 3 x 55kg, Knee ext 15 x 3 x 15kg single leg	
Day 64 - Week 10	08/03	Yes	36.1	No		Follicular				
	08/04	Yes	36,1	No		Follicular				
	08/05	Yes	36.1	No		Follicular				
	08/06	No	36,1	No		Follicular	Booked	Yes	Squat double leg 10 x 3 x 40kg, Leg press 15 x 3 x 55kg, Knee ext 15 x 3 x 15kg single leg	
	08/07	No	36.1	No		Follicular				
	08/08	No	36.1	No		Follicular				
	08/09	No	36.35	No		Follicular	Booked	Yes	Squat double leg 10 x 3 x 40kg, Leg press 15 x 3 x 55kg, Knee ext 15 x 3 x 15kg single leg	
Day 71 - Week 11	08/10	No	36.4	Yes	Positive	Luteal				
	08/11	No	36.45	No		Luteal				
	08/12	No	36.45	No		Luteal				
	08/13	No	36.45	No		Luteal	Booked	Yes		Wobble Board Stand, Step up/downs Lateral step up/downs Single leg Stand/Balance – Star exercise, balance & reach
	08/14	No	36.45	No		Luteal				
	08/15	No	36,6	No		Luteal	Booked	Yes		Wobble Board Stand, Step up/downs Lateral step up/downs Single leg Stand/Balance – Star exercise, balance & reach
	08/16	No	36.6	No		Luteal				
Day 78 - Week 12	08/17	No	36.6	No		Luteal				
	08/18	No	36.6	No		Luteal		Yes		Wobble Board Stand, Step up/downs Lateral step up/downs Single leg Stand/Balance – Star exercise, balance & reach
	08/19	No	36,6	No		Luteal				
	08/20	No	36.6	No		Luteal				
	08/21	No	36,6	No		Luteal		Yes		Final Appt: Outcome Measures - 1RM Testing
	08/22	No	36.6	No		Luteal				
Day 84 - Finish Trial	08/23	No	36.3	No		Luteal				

[redacted] Data Entry Sheet

1	
2	96.66
3	97.62
4	96.98
5	96.04
6	96.58
7	96.53
8	96.45
9	96.58
10	96.8
11	97.16
12	96.56
13	96.53
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15	96.9
16	97.19
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18	97.79
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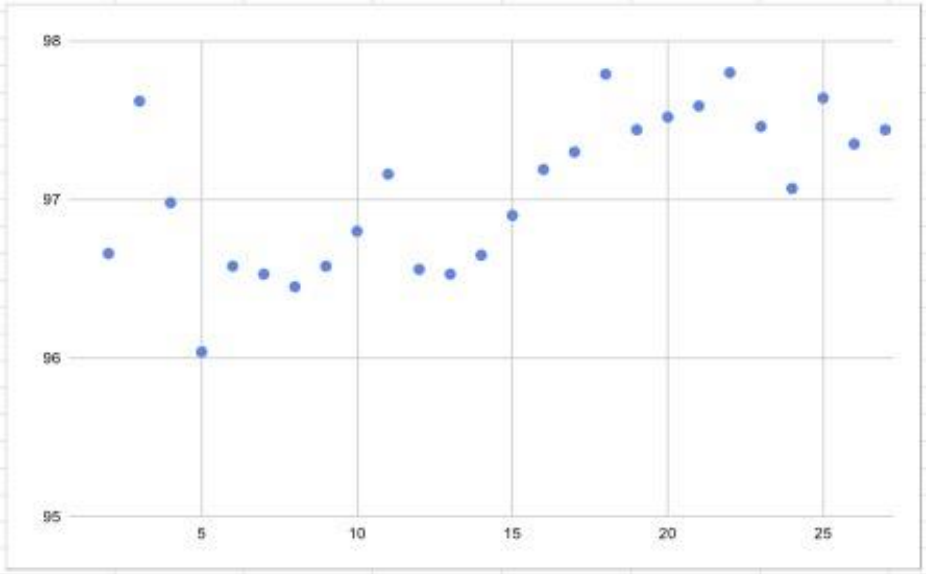
27	97.44



[redacted] Data Entry Sheet

1	
2	96.66
3	97.62
4	96.98
5	96.04
6	96.58
7	96.53
8	96.45
9	96.58
10	96.8
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13	96.53
14	96.65
15	96.9
16	97.19
17	97.3
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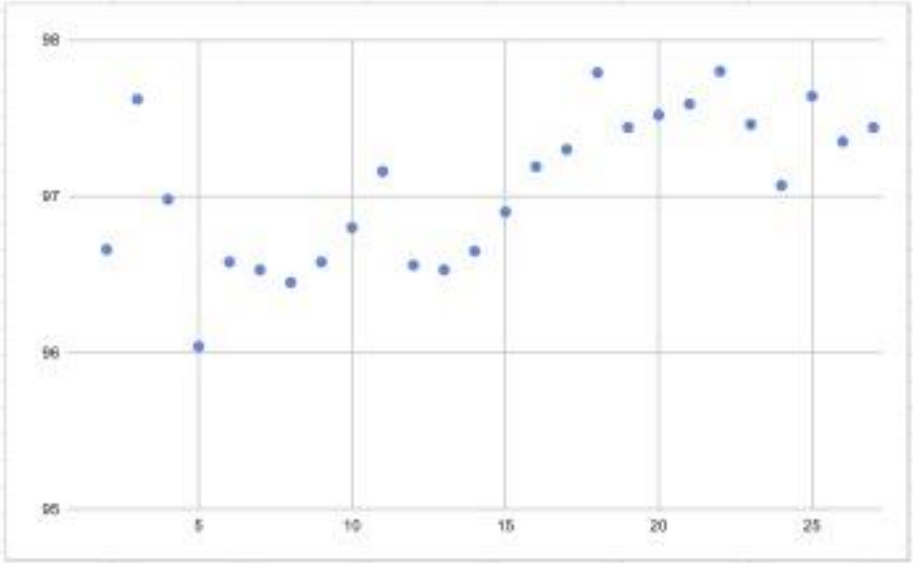
25	97.84
26	97.35
27	97.44



[redacted]Data Entry Sheet

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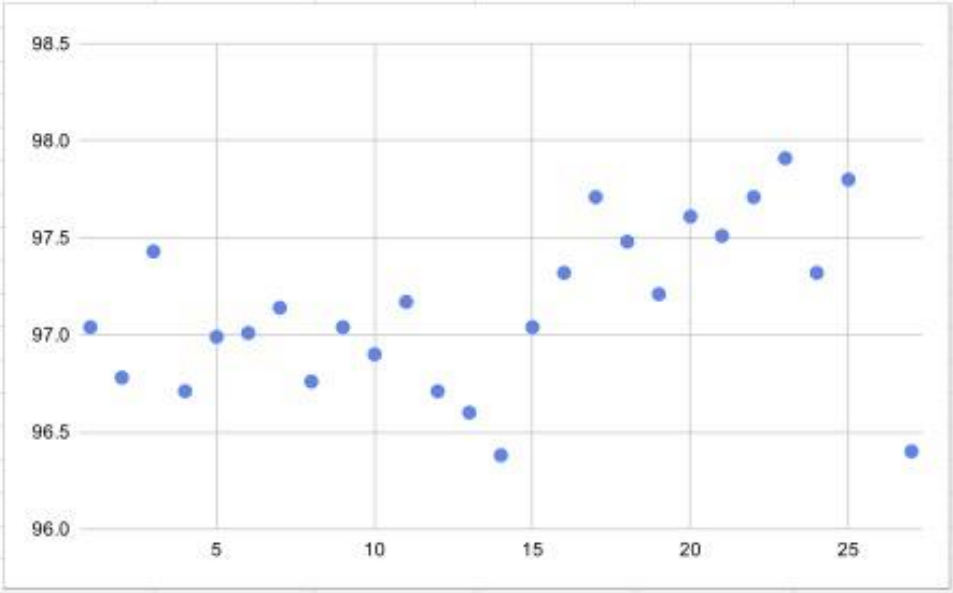
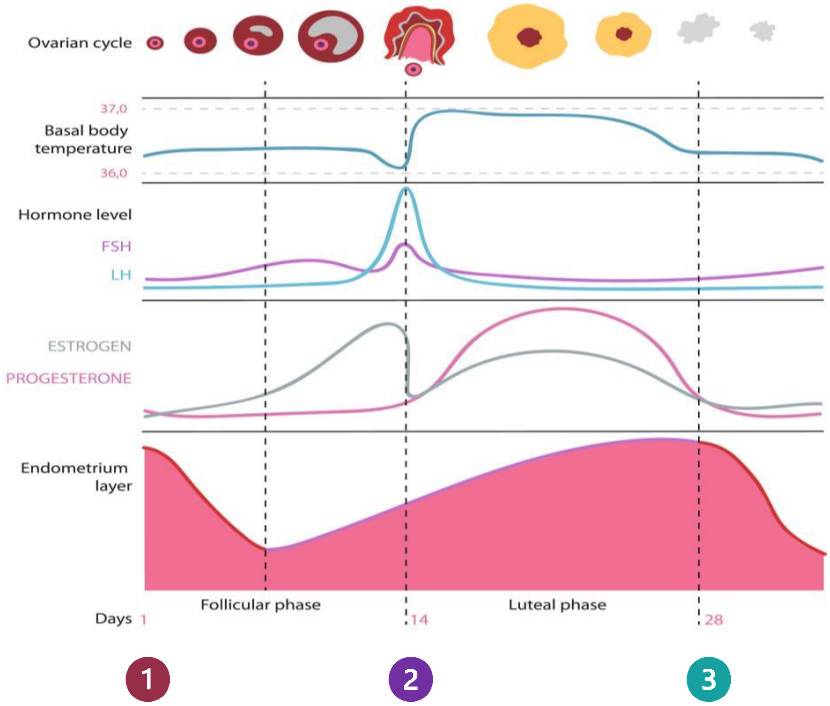
3	97.43
4	96.71
5	96.99
6	97.01
7	97.14
8	96.76
9	97.04
10	96.9
11	97.17
12	96.71
13	96.6
14	96.38
15	97.04
16	97.32
17	97.71
18	97.48
19	97.21
20	97.61
21	97.51
22	97.71
23	97.91
24	97.32
25	97.8
26	
27	96.4



Participant Education Pack

Thank you for your interest in taking part in 'A Female Specific Menstrual Cycle Phased Anterior Cruciate Ligament Rehab Programme'.
The research team will track your menstrual cycle as part of the programme. This education pack aims to educate you about your menstrual cycle, and the processes involved to track your menstrual cycle.

The Menstrual Cycle



1. When you get your period, this is the first day of the follicular phase.

2. Ovulation occurs on approximately day 14. This is when your ovary releases an egg.
Once ovulation occurs, you are in the luteal phase.
Your basal body temperature and luteinising hormone (LH) levels rise around ovulation.

3. The luteal phase lasts about two weeks.
When you get your period again, you have finished the luteal phase.
You will now start a new menstrual cycle.

Tracking Your Menstrual Cycle

The research team will send you a link to your own online logbook (a Google Sheet), and will post you a basal body thermometer and an ovulation predictor kit to help track your menstrual cycle.
Tracking your menstrual cycle is a **3 step process.**

1 Record your period in your online logbook.
When? Daily when you have your period.

- The length of the menstrual cycle is the duration from your first menstrual bleeding day to the day before the next bleeding begins.

2 Measure your basal body temperature.
When? Daily.

- The process for basal body temperature tracking is simple, but it does require a small commitment.
- Every morning before getting out of bed, take your temperature and note it in your logbook.
- The thermometer needs to be placed under the tongue and left there until it beeps.
- Take your temperature as close to the same time every day as you can.
- You should have a minimum of five hours of sleep before measuring.

3 Use an ovulation prediction kit
When? Daily, starting 10 days from the start of your period, until a positive result is recorded.

If you have a short cycle, you should start using an ovulation test kit 4 day prior to your cycle's midpoint. *(The research team can help you with this).*

- Your ovulation kit instructions can be found here: https://www.pregmate.com/pages/ovulation-test-strips-instructions-for-use
- In short:
  1. Dip the strip into the urine for 3-5 seconds.
  2. Lay the strip flat.
  3. Read results in 5 minutes.

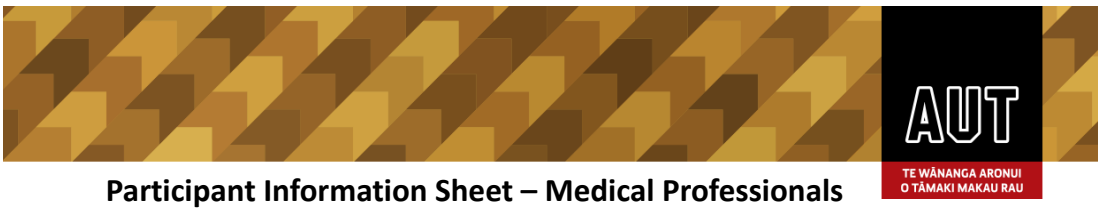
  Positive: If two colour lines are visible and the test line is equal to or darker than the control line.

  Negative: Only one line appears in the control area or the test line is lighter than the control line.
- Record the results in your logbook.
- **How long should I continue to perform the test?** At least 5 days or until the LH surge has been detected.

Any questions? Contact the research team at ccq8275@autuni.co.nz or 0221723949
The research team is here to help you understand this information and is available via email or phone at any time, to answer any questions you may have.

Appendices Section C: Participant Information Sheets

Appendix 15. Study I PIS Med Professionals



Participant Information Sheet – Medical Professionals

Date Information Sheet Produced:

20th August 2020

Project Title

The effect of a menstrual cycle phased rehabilitation programme on strength recovery and self-reported functional outcomes after anterior cruciate ligament reconstruction.

An Invitation

The project is being undertaken my myself, Emma O'Loughlin, physiotherapist and AUT PhD student. I would like to invite you to participate in a focus group study focusing on the development of a menstrual cycle phased rehabilitation programme. This research will contribute to my PhD qualification.

What is the purpose of this research?

The purpose of this research is to develop a menstrual cycle phased rehabilitation programme.

Rates of female anterior cruciate ligament (ACL) injuries have increased in recent years. ACL reconstruction (ACLR) outcomes are poorer for females and they are more likely to suffer a subsequent injury. Quadriceps strength has shown to be a predictor of outcomes and subsequent injuries for those with ACLR. This has been shown to be inferior in females. Menstrual cycle phased resistance training programmes have been shown to significantly increase quadriceps strength and volume in females. However, historically, this has only been examined in non-injured populations.

Focus groups will be used here to gather information from you regarding your knowledge of the/your menstrual cycle, your attitude towards discussing the menstrual cycle, and your opinions of a menstrual cycle phased rehabilitation programme. Three independent and separate focus groups will be used to develop and provide feedback on the menstrual cycle phased rehabilitation programme.

The study will use the themes that emerge from the focus groups to develop a menstrual cycle phased rehabilitation programme. Investigating a menstrual cycle phased rehabilitation programme creates an opportunity to merge the areas of sports and exercise medicine and sports and exercise performance research. This will aim to improve female ACLR patient outcomes.

This research study is an initial study for my PhD qualification. The findings of this research may be used for my academic publications and presentations. I am employed as a Clinical Advisor for The Accident Compensation Corporation, and this PhD is currently funded as part of my continuing professional education.

How was I identified and why am I being invited to participate in this research?

You have been invited to participate in the study due to your involvement with anterior cruciate ligament reconstruction rehabilitation.

Three independent and separated focus groups will be used in the research, consisting of different participants.

The criteria to be chosen and invited into this particular focus group for medical professionals includes a) doctors must be registered with the New Zealand Medical Council and b) physiotherapists must be registered with the Physiotherapy Board of New Zealand. Further to this, you will be chosen based on your focus and experience in sports medicine, specifically ACL surgeries or rehabilitation.

All those that will agree to participate will be invited/selected to join the focus groups. In case that the number of potential participants exceeds the maximum number of 6-8 members per a focus group, the principle of "first come, first served" will be employed.

How do I agree to participate in this research?

You are encouraged to read this information sheet thoroughly and email the primary researcher if you have any questions. A consent form is also attached to this e mail. Please also read this thoroughly and email the primary researcher at emolough@tcd.ie if you have any questions. I will provide answers or more explanation in case of any questions.

If you would like to participate in the research, please e mail me at ccq8275@autuni.co.nz to accept or refuse the invitation.

All the information will be stated during the presentation at the beginning of the focus group meetings again. In case of any questions, the adequate amount of time will be given to provide answers. The consent form will be then signed and approved by each participant at the beginning of the meeting of the focus groups.

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

What will happen in this research?

Involvement in this research group will involve attending one focus group session in your local area (locations to be confirmed) or over Zoom technology. The length of each focus group meeting will depend on the discussion; however, the length of each meeting should not exceed 2-3 hours. These meetings also include signing and approving the consent forms.

Initially, I will introduce myself and the project to you. Then, the protocol and data collection sheet will be shown and described to you and an explanation will be given regarding how the meeting will proceed. The first set of questions will investigate your knowledge of the menstrual cycle, your experience or knowledge of tracking the menstrual cycle, your overall comfort in talking about the menstrual cycle to your patients and your knowledge of any cultural considerations regarding the menstrual cycle. Following this, a second set of questions will be asked regarding your overall opinion of the outlined programme, any barriers identified, similarities and differences from this proposed rehabilitation programme with 'usual care' ACLR rehabilitation. The final set of questions will be regarding the practicality of the data collection sheet that would be used in clinic. For data collection purposes, I will be using audio-recording equipment and will take notes during these focus groups.

What are the discomforts and risks?

No risk is anticipated. You will be simply asked to answer the questions regarding your knowledge of the menstrual cycle, your attitudes to the menstrual cycle, your opinion of the proposed menstrual cycle phased rehabilitation programme and possible ideas, opinions, suggestions and/or recommendations for this.

You are not expected to experience risk or discomfort because of cultural, employment, financial or similar pressures.

How will these discomforts and risks be alleviated?

You will not be pushed to answer if you don't want to. You will be allowed to join the conversation/discussion, but you will not be forced to answer to all of the questions if you don't want to. The focus groups will be based on the friendly environment to make you feel comfortable, useful, important and encouraged to help develop a new rehabilitation programme. You will join the research only if you want to participate and everything will be organized in the way that will be the most convenient for you.

What are the benefits?

The benefits to you, as a participant include;

- Your active involvement in the development of a new menstrual cycle phased ACLR rehabilitation programme will provide you with deeper knowledge and insight into the menstrual cycle.

- The results of focus groups will provide you with opinions, suggestions, recommendations, and feedback regarding the menstrual cycle and current and proposed rehabilitation programmes. That should help you better understand the needs and demands of current ACLR patients and female athletes.

- The newly designed menstrual cycle phased ACLR rehabilitation programme will be available for you at the end of the whole study, to implement with your patients.

- Results from the focus groups may indicate that menstrual cycle education is needed for medical professionals, and if so, specific education objectives or recommendations can be recommended.

The benefits to me, as the researcher include;

- Firstly, this research is one of the several parts of my PhD study. The outcomes of the focus groups should provide me with themes to aid the specific menstrual cycle phased rehabilitation programme that will be used in Study II, the multicentre randomised controlled trial. The menstrual cycle phased rehabilitation program will be implemented in intervention clinics that are participating in the study. These intervention groups will be compared to the control group, regarding outcomes after rehabilitation.

- Secondly, I will gain an understanding of medical and non-medical professionals' knowledge of, and attitudes towards, the menstrual cycle.

- Thirdly, I will get an opportunity to participate in the development of a menstrual cycle phased ACLR rehabilitation programme that that could be later be used by physiotherapy clinics in not just New Zealand but also internationally. Menstrual cycle phased rehabilitation programmes could be further assessed, analysed and researched in different populations. The researcher could, therefore, contribute to outcomes post ACLR rehabilitation, improve ACLR patient's health and performance, and/or extend their sporting careers.

The benefits to the wider community include;

- At the end of this focus group study there will be many who are more aware of the menstrual cycle, and your own knowledge or lack of knowledge regarding same.

- The outcomes of the research will lead to the development of a new menstrual cycle phased ACLR rehabilitation programme. At the end of the study, this menstrual cycle phased ACLR rehabilitation programme will be available for the whole ACLR medical community to use.

- A newly designed menstrual cycle phased ACLR rehabilitation programme could later work as a basis of similar menstrual cycle phased rehabilitation programmes for other injuries and it could be therefore later spread not only in the ACLR community but also in other similar sports and rehabilitation generally.

How will my privacy be protected?

You will not be identified in the final summary of the findings of the research. You might be only referred to depending on the focus group they belong to (physiotherapists, orthopaedic surgeons, current ACLR patients, female athletes). No names or personal data will be mentioned in the final report.

What are the costs of participating in this research?

Each participant will have to provide your own travel to the focus group study. In terms of time commitment, the length of each focus group meeting will depend on the discussion; however, the length of each meeting should not exceed 2-3 hours. You will only have to attend for one session.

What opportunity do I have to consider this invitation?

You will have one month to consider and respond (accept or refuse) this invitation.

Will I receive feedback on the results of this research?

A brief summary of the findings will be made available by e mail to you. The dissemination of the summary, findings, and results of the whole research will be also provided via peer review journal papers and conference presentations.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Dr Duncan Reid, duncan.reid@aut.ac.nz, (+649) 921 9999 ext 7806.
Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, *ethics@aut.ac.nz* , (+649) 921 9999 ext 6038.

Whom do I contact for further information about this research?

Please keep this Information Sheet and a copy of the Consent Form for your future reference. You are also able to contact the research team as follows:

Researcher Contact Details:

Emma O'Loughlin, ccq8275@autuni.co.nz

Project Supervisor Contact Details:

Dr Duncan Reid, duncan.reid@aut.ac.nz

Approved by the Auckland University of Technology Ethics Committee on *type the date final ethics approval was granted*, AUTEC Reference number *type the reference number*

Appendix 16. Study I PIS ACLR Patients

Participant Information Sheet – Current ACLR Patients

Date Information Sheet Produced:

20th August 2020

Project Title

The effect of a menstrual cycle phased rehabilitation programme on strength recovery and self-reported functional outcomes after anterior cruciate ligament reconstruction.

An Invitation

The project is being undertaken my myself, Emma O'Loughlin, physiotherapist and AUT PhD student. I would like to invite you to participate in a focus group study focusing on the development of a menstrual cycle phased rehabilitation programme. This research will contribute to my PhD qualification.

What is the purpose of this research?

The purpose of this research is to develop a menstrual cycle phased rehabilitation programme.

Rates of female anterior cruciate ligament (ACL) injuries have increased in recent years. ACL reconstruction (ACLR) outcomes are poorer for females and they are more likely to suffer a subsequent injury. Quadriceps strength has shown to be a predictor of outcomes and subsequent injuries for those with ACLR. This has been shown to be inferior in females. Menstrual cycle phased resistance training programmes have been shown to significantly increase quadriceps strength and volume in females. However, historically, this has only been examined in non-injured populations.

Focus groups will be used here to gather information from you regarding your knowledge of the/your menstrual cycle, your attitude towards discussing the menstrual cycle, and your opinions of a menstrual cycle phased rehabilitation programme. Three independent and separate focus groups will be used to develop and provide feedback on the menstrual cycle phased rehabilitation programme.

The study will use the themes that emerge from the focus groups to develop a menstrual cycle phased rehabilitation programme. Investigating a menstrual cycle phased rehabilitation programme creates an opportunity to merge the areas of sports and exercise medicine and sports and exercise performance research. This will aim to improve female ACLR patient outcomes.

This research study is an initial study for my PhD qualification. The findings of this research may be used for my academic publications and presentations. I am employed as a Clinical Advisor for The Accident Compensation Corporation, and this PhD is currently funded as part of my continuing professional education.

How was I identified and why am I being invited to participate in this research?

You have been invited to participate in the study due to your involvement with anterior cruciate ligament reconstruction rehabilitation.

Three independent and separated focus groups will be used in the research, consisting of different participants.

The two criterions to be chosen and invited into this particular focus group are a) that you are currently participating currently in an ACLR rehabilitation programme in any independent physiotherapy clinic within New Zealand and b) you are female. You will be excluded if you have been/are currently a patient or client of myself, the researcher.

All those that will agree to participate will be invited to join the focus groups. In case that the number of potential participants exceeds the maximum number of 6-8 members per a focus group, the principle of "first come, first served" will be employed.

How do I agree to participate in this research?

You are encouraged to read this information sheet thoroughly and email the primary researcher if you have any questions. A consent form is also attached to this e mail. Please also read this thoroughly and email the primary researcher at emolough@tcd.ie if you have any questions. I will provide answers or more explanation in case of any questions.

If you would like to participate in the research, please e mail me at ccq8275@autuni.co.nz to accept or refuse the invitation.

All the information will be stated during the presentation at the beginning of the focus group meetings again. In case of any questions, the adequate amount of time will be given to provide answers. The consent form will be then signed and approved by each participant at the beginning of the meeting of the focus groups.

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

What will happen in this research?

Involvement in this research group will involve attending one focus group session in your local area (locations to be confirmed) or over Zoom technology. The length of each focus group meeting will depend on the discussion; however, the length of each meeting should not exceed 2-3 hours. These meetings also include signing and approving the consent forms.

Initially, I will introduce myself and the project to you. Then, the menstrual cycle phased rehabilitation protocol and will be shown and described to you and an explanation will be given regarding how the meeting will proceed. The first set of questions will investigate your knowledge of the menstrual cycle, your experience tracking your menstrual cycle, your overall comfort in talking about the menstrual cycle to health practitioners and any cultural considerations you have regarding the menstrual cycle. Following this, a second set of questions will be asked regarding your opinion of participating in the outlined programme, any barriers identified, similarities and differences to the rehabilitation programme you are currently involved with. The final set of questions will be regarding your feelings about completing urinary tests with a home urinary testing kit as part of your rehabilitation programme, as the menstrual cycle phased rehabilitation programme would include participants completing approximately three fully funded urinary tests at home to confirm what part of their cycle they are in. For data collection purposes, I will be using audio-recording equipment and will take notes during these focus groups.

What are the discomforts and risks?

No risk is anticipated. You will be simply asked to answer the questions regarding your knowledge of the menstrual cycle, your attitudes to the menstrual cycle, your opinion of the proposed menstrual cycle phased rehabilitation programme and possible ideas, opinions, suggestions and/or recommendations for this.

You are not expected to experience risk or discomfort because of cultural, employment, financial or similar pressures.

How will these discomforts and risks be alleviated?

You will not be pushed to answer if you don't want to. You will be allowed to join the conversation/discussion, but you will not be forced to answer to all of the questions if you don't want to. The focus groups will be based on the friendly environment to make you feel comfortable, useful, important and encouraged to help develop a new rehabilitation programme. You will join the research only if you want to participate and everything will be organized in the way that will be the most convenient for you.

What are the benefits?

The benefits to you, as a participant include;

- You will get an opportunity to participate in the development of a new menstrual cycle phased ACLR rehabilitation program specific to their needs and demands.

- You will get an opportunity to participate in discussion regarding their knowledge of the menstrual cycle, and your peers' attitudes towards the menstrual cycle which will provide you with deeper knowledge and insight into the menstrual cycle.

The benefits to me, as the researcher include;

- Firstly, this research is one of the several parts of my PhD study. The outcomes of the focus groups should provide me with themes to aid the specific menstrual cycle phased rehabilitation programme that will be used in Study II, the multicentre randomised controlled trial. The menstrual cycle phased rehabilitation program will be implemented in intervention clinics that are participating in the study. These intervention groups will be compared to the control group, regarding outcomes after rehabilitation.

- Secondly, I will gain an understanding of medical and non-medical professionals' knowledge of, and attitudes towards, the menstrual cycle.

- Thirdly, I will get an opportunity to participate in the development of a menstrual cycle phased ACLR rehabilitation programme that that could be later be used by physiotherapy clinics in not just New Zealand but also internationally. Menstrual cycle phased rehabilitation programmes could be further assessed, analysed and researched in different populations. The researcher could, therefore, contribute to outcomes post ACLR rehabilitation, improve ACLR patient's health and performance, and/or extend their sporting careers.

The benefits to the wider community include;

- At the end of this focus group study there will be many who are more aware of the menstrual cycle, and your own knowledge or lack of knowledge regarding same.

- The outcomes of the research will lead to the development of a new menstrual cycle phased ACLR rehabilitation programme. At the end of the study, this menstrual cycle phased ACLR rehabilitation programme will be available for the whole ACLR medical community to use.

- A newly designed menstrual cycle phased ACLR rehabilitation programme could later work as a basis of similar menstrual cycle phased rehabilitation programmes for other injuries and it could be therefore later spread not only in the ACLR community but also in other similar sports and rehabilitation generally.

How will my privacy be protected?

You will not be identified in the final summary of the findings of the research. You might be only referred to depending on the focus group they belong to (physiotherapists, orthopaedic surgeons, current ACLR patients, female athletes). No names or personal data will be mentioned in the final report.

What are the costs of participating in this research?

Each participant will have to provide your own travel to the focus group study. In terms of time commitment, the length of each focus group meeting will depend on the discussion; however, the length of each meeting should not exceed 2-3 hours. You will only have to attend for one session.

What opportunity do I have to consider this invitation?

You will have one month to consider and respond (accept or refuse) this invitation.

Will I receive feedback on the results of this research?

A brief summary of the findings will be made available by e mail to you. The dissemination of the summary, findings, and results of the whole research will be also provided via peer review journal papers and conference presentations.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Dr Duncan Reid, duncan.reid@aut.ac.nz, (+649) 921 9999 ext 7806.
Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, *ethics@aut.ac.nz* , (+649) 921 9999 ext 6038.

Whom do I contact for further information about this research?

Please keep this Information Sheet and a copy of the Consent Form for your future reference. You are also able to contact the research team as follows:

Researcher Contact Details:

Emma O'Loughlin, ccq8275@autuni.co.nz

Project Supervisor Contact Details:

Dr Duncan Reid, duncan.reid@aut.ac.nz

Approved by the Auckland University of Technology Ethics Committee on *type the date final ethics approval was granted*, AUTEC Reference number *type the reference number*

Participant Information Sheet – Female Athletes

Date Information Sheet Produced:

20th August 2020

Project Title

The effect of a menstrual cycle phased rehabilitation programme on strength recovery and self-reported functional outcomes after anterior cruciate ligament reconstruction.

An Invitation

The project is being undertaken my myself, Emma O'Loughlin, physiotherapist and AUT PhD student. I would like to invite you to participate in a focus group study focusing on the development of a menstrual cycle phased rehabilitation programme. This research will contribute to my PhD qualification.

What is the purpose of this research?

The purpose of this research is to develop a menstrual cycle phased rehabilitation programme.

Rates of female anterior cruciate ligament (ACL) injuries have increased in recent years. ACL reconstruction (ACLR) outcomes are poorer for females and they are more likely to suffer a subsequent injury. Quadriceps strength has shown to be a predictor of outcomes and subsequent injuries for those with ACLR. This has been shown to be inferior in females. Menstrual cycle phased resistance training programmes have been shown to significantly increase quadriceps strength and volume in females. However, historically, this has only been examined in non-injured populations.

Focus groups will be used here to gather information from you regarding your knowledge of the/your menstrual cycle, your attitude towards discussing the menstrual cycle, and your opinions of a menstrual cycle phased rehabilitation programme. Three independent and separate focus groups will be used to develop and provide feedback on the menstrual cycle phased rehabilitation programme.

The study will use the themes that emerge from the focus groups to develop a menstrual cycle phased rehabilitation programme. Investigating a menstrual cycle phased rehabilitation programme creates an opportunity to merge the areas of sports and exercise medicine and sports and exercise performance research. This will aim to improve female ACLR patient outcomes.

This research study is an initial study for my PhD qualification. The findings of this research may be used for my academic publications and presentations. I am employed as a Clinical Advisor for The Accident Compensation Corporation, and this PhD is currently funded as part of my continuing professional education.

How was I identified and why am I being invited to participate in this research?

You have been invited to participate in the study due to your involvement with anterior cruciate ligament reconstruction rehabilitation.

Three independent and separated focus groups will be used in the research, consisting of different participants. The criteria who to invite as participants will, therefore, depend on the focus group. In the case of this specific focus group the only criterion to be chosen and invited into this focus group will be your participation currently in a sport with high ACLR injury rates (Netball, Soccer, Rugby). You will be excluded if you have been/are currently a patient or client of myself, the researcher.

All those that will agree to participate will be invited/selected to join the focus groups. In case that the number of potential participants exceeds the maximum number of 6-8 members per a focus group, the principle of "first come, first served" will be employed.

How do I agree to participate in this research?

You are encouraged to read this information sheet thoroughly and email the primary researcher if you have any questions. A consent form is also attached to this e mail. Please also read this thoroughly and email the primary researcher at emolough@tcd.ie if you have any questions. I will provide answers or more explanation in case of any questions. If you would like to participate in the research, please e mail me at ccq8275@autuni.c.nz to accept or refuse the invitation.

All the information will be stated during the presentation at the beginning of the focus group meetings again. In case of any questions, the adequate amount of time will be given to provide answers. The consent form will be then signed and approved by each participant at the beginning of the meeting of the focus groups.

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

What will happen in this research?

Involvement in this research group will involve attending one focus group session in your local area (locations to be confirmed) or over Zoom technology. The length of each focus group meeting will depend on the discussion; however, the length of each meeting should not exceed 2-3 hours. These meetings also include signing and approving the consent forms.

Initially, I will introduce myself and the project to you. Then, the menstrual cycle phased rehabilitation protocol will be shown and described to you and an explanation will be given regarding how the meeting will proceed. The first set of questions will investigate your knowledge of the menstrual cycle, your experience tracking your menstrual cycle, your overall comfort in talking about the menstrual cycle to health practitioners and any cultural considerations you have regarding the menstrual cycle. Following this, a second set of questions will be asked regarding your expectations of a rehabilitation programme, any things that would help you attend a rehabilitation programme, and your opinion of participating in the outlined rehabilitation programme. The final set of questions will be regarding your feelings about completing urinary tests with a home urinary testing kit as part of your rehabilitation programme. For data collection purposes, I will be using audio-recording equipment and will take notes during these focus groups.

What are the discomforts and risks?

No risk is anticipated. You will be simply asked to answer the questions regarding your knowledge of the menstrual cycle, your attitudes to the menstrual cycle, your opinion of the proposed menstrual cycle phased rehabilitation programme and possible ideas, opinions, suggestions and/or recommendations for this.

You are not expected to experience risk or discomfort because of cultural, employment, financial or similar pressures.

How will these discomforts and risks be alleviated?

You will not be pushed to answer if you don't want to. You will be allowed to join the conversation/discussion, but you will not be forced to answer to all of the questions if you don't want to. The focus groups will be based on the friendly environment to make you feel comfortable, useful, important and encouraged to help develop a new rehabilitation programme. You will join the research only if you want to participate and everything will be organized in the way that will be the most convenient for you.

What are the benefits?

The benefits to you, as a participant include;

- You will get an opportunity to participate in the development of a new menstrual cycle phased ACLR rehabilitation program specific to their needs and demands.

- You will get an opportunity to participate in discussion regarding their knowledge of the menstrual cycle, and your peers' attitudes towards the menstrual cycle which will provide you with deeper knowledge and insight into the menstrual cycle.

The benefits to me, as the researcher include;

- Firstly, this research is one of the several parts of my PhD study. The outcomes of the focus groups should provide me with themes to aid the specific menstrual cycle phased rehabilitation programme that will be used in Study II, the multicentre randomised controlled trial. The menstrual cycle phased rehabilitation program will be implemented in intervention clinics that are participating in the study. These intervention groups will be compared to the control group, regarding outcomes after rehabilitation.

- Secondly, I will gain an understanding of medical and non-medical professionals' knowledge of, and attitudes towards, the menstrual cycle.

- Thirdly, I will get an opportunity to participate in the development of a menstrual cycle phased ACLR rehabilitation programme that that could be later be used by physiotherapy clinics in not just New Zealand but also internationally. Menstrual cycle phased rehabilitation programmes could be further assessed, analysed and researched in different populations. The researcher could, therefore, contribute to outcomes post ACLR rehabilitation, improve ACLR patient's health and performance, and/or extend their sporting careers.

The benefits to the wider community include;

- At the end of this focus group study there will be many who are more aware of the menstrual cycle, and your own knowledge or lack of knowledge regarding same.

- The outcomes of the research will lead to the development of a new menstrual cycle phased ACLR rehabilitation programme. At the end of the study, this menstrual cycle phased ACLR rehabilitation programme will be available for the whole ACLR medical community to use.

- A newly designed menstrual cycle phased ACLR rehabilitation programme could later work as a basis of similar menstrual cycle phased rehabilitation programmes for other injuries and it could be therefore later spread not only in the ACLR community but also in other similar sports and rehabilitation generally.

How will my privacy be protected?

You will not be identified in the final summary of the findings of the research. You might be only referred to depending on the focus group they belong to (physiotherapists, orthopaedic surgeons, current ACLR patients, female athletes). No names or personal data will be mentioned in the final report.

What are the costs of participating in this research?

Each participant will have to provide your own travel to the focus group study. In terms of time commitment, the length of each focus group meeting will depend on the discussion; however, the length of each meeting should not exceed 2-3 hours. You will only have to attend for one session.

What opportunity do I have to consider this invitation?

You will have one month to consider and respond (accept or refuse) this invitation.

Will I receive feedback on the results of this research?

A brief summary of the findings will be made available by email to you. The dissemination of the summary, findings, and results of the whole research will be also provided via peer review journal papers and conference presentations.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Dr Duncan Reid, duncan.reid@aut.ac.nz, (+649) 921 9999 ext 7806.
Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, *ethics@aut.ac.nz* , (+649) 921 9999 ext 6038.

Whom do I contact for further information about this research?

Please keep this Information Sheet and a copy of the Consent Form for your future reference. You are also able to contact the research team as follows:

Researcher Contact Details:

Emma O'Loughlin, ccq8275@autuni.co.nz

Project Supervisor Contact Details:

Dr Duncan Reid, duncan.reid@aut.ac.nz

Approved by the Auckland University of Technology Ethics Committee on *type the date final ethics approval was granted*, AUTEC Reference number *type the reference number*

Participant Information Sheet

"A Female Specific Menstrual Cycle Phased Anterior Cruciate Ligament Rehab Programme"

"He hōtaka whakamātūtū e aro ana ki te wahine, te mate marama me te tīhae o te turi"

"A randomised controlled trial to evaluate the effect of a menstrual cycle phased rehabilitation programme on quadriceps extension strength for females post Anterior Cruciate Ligament Reconstruction"

- Emma O'Loughlin
- Auckland University of Technology
- Phone Number: 0221723949
- Ethics committee ref: 21/CEN/92

You are invited to take part in a study on the effects of the menstrual cycle on outcomes for females after anterior cruciate ligament reconstruction surgery. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

Nei te tono ki a koe kia whai wāhi ki te kaupapa nei e rangahau ana i ngā hononga o te mate marama ki te hauora o te wahine whai muri i tōna poka i te tīhae o te turi. Kei a koe te whiringa mēnā rānei, kāore rānei koe e whai wāhi mai. Mēnā kāore koe i te pīrangi, kāore he here, ā, kāore te taumata o te manaakitanga e rerekē. Mēnā e hiahia ana koe ki te whai wāhi mai, heoi, katahi ka tini ōu whakaaro, ka taea e koe te wehe atu i te kaupapa.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time, without experiencing any disadvantage.

Kei a koe te whiringa mēnā rānei ka whai wāhi mai koe ki tēnei rangahau, ā, ahakoa tō whiringa, kāore he taumahatanga e taka ki a koe. Ka taea e koe te wehe atu i te kaupapa, ā, kāore he taumahatanga e taka ki a koe.

WHAT IS THE PURPOSE OF THE STUDY?

- Rates of female ACL injuries have increased in recent years. Results after surgery are worse for females and females are more likely to suffer another injury. Quadriceps strength has shown to be able to predict outcomes and further injuries for those who have had anterior cruciate ligament (ACL) surgery. Females usually have less quadriceps (knee muscle) strength compared to males. Menstrual cycle phased strength training programmes have been shown to increase quadriceps strength and size in females. However, before, this has only been researched in people who don't have injuries.
- The purpose of this research is to understand what effect completing certain exercises at certain parts of the menstrual cycle has on the strength of knee muscles and ability for females to use their knee following rehabilitation after ACL reconstruction surgery.

HOW IS THE STUDY DESIGNED?

- 54 females are expected to take part
- All participants must be willing to participate in rehabilitation with a physiotherapist twice a week for thirty minutes for twelve weeks, where you will participate in strengthening and other exercises.
- All participants must also be willing to track their menstrual cycle daily for twelve weeks, using a calendar and a thermometer daily and once a month use a urinary ovulation testing kit to confirm when you ovulate.
- There are two groups in this trial, a control group, and an intervention group. You have a 50% chance of being in either group.
- In both groups, physiotherapists will measure the strength of your knee muscles at the start and end of the twelve weeks. Also, you will have to fill in three questionnaires at the start and end of the twelve weeks.

WHO CAN TAKE PART IN THE STUDY?

- You have been chosen to participate as you are 16 years old or older who have undergone anterior cruciate ligament surgery and have a regular menstrual cycle.
- You can be involved if you have the copper IUD or hormonal IUD (Mirena) but cannot be included if you are using the oral contraceptive pill.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?:

- You will be expected to enter your menstrual cycle diary, basal body temperature and the results of your ovulation test (via the kit that will be given to you) on an online sheet.

- The researcher will discuss which physiotherapy clinic you will attend based on your geographical location and preference.
- Physiotherapists will measure the strength of your knee muscles at the start and end of the twelve weeks. Also, you will have to fill in three questionnaires at the start and end of the twelve weeks.
- You will attend twice weekly physiotherapy visits, which will include different exercises, and are expected to take 30 minutes.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

- Whilst there is minimal risk anticipated from participating in this study, it is acknowledged you may feel uncomfortable or experience embarrassment/ whakamā talking about your menstrual cycle. In the event that this occurs, you are welcome to tell the treating physiotherapist, who will cease the conversation without prejudice. The physiotherapist can contact the support services indicated below on your behalf if you wish.
- You are not expected to experience risk or discomfort because of employment, financial or similar pressures.
- It is acknowledged you may be asked to exercise throughout your whole menstrual cycle, which may be different to what you usually do. You will not be pushed to attend your rehabilitation if you don't want to. The rehabilitation programme is designed to help you recover from your surgery. If you do not feel like you can participate in rehabilitation some days, there can be flexibility regarding the content of the session. You will join the research only if you want to participate and everything will be organized in the way that will be the most convenient for you.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

The benefits to you, as a participant may possibly include:

- improved quadriceps strength of your injured knee
- improved function of your injured knee

WHAT ARE THE ALTERNATIVES TO TAKING PART?

- If you don't want to take part, you can attend any physiotherapist for rehabilitation after your ACL reconstruction surgery.

WILL ANY COSTS BE REIMBURSED?

- We will endeavor to contribute as much as possible towards your treatment costs, however you may have to pay for some physiotherapy treatment sessions.
- Please contact the researcher if you have any difficulty with paying for your physiotherapy treatment as part of the trial.
- *Tēnā, whakapā mai ki te kairangahau mēnā he raru te pūtea mō te maimoatanga kōmiri ki te hono mai ki tēnei rangahau.*

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home or at the physiotherapist. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the study researchers, and physiotherapists will record information about you and your study participation. This includes your details such as your age, when you had your injury, the results of any study assessments such as your knee strength and your questionnaire results. Information will also be collected about your menstrual cycle, the amount of exercise you do usually and your knee surgery records. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only researchers, your physiotherapist and The Health and Disability Ethics Committee (for legal and regulatory purposes) will have access to your identifiable information.

Ko ngā kairangahau me tō kaikōmiri anake ngā mea e āhei ana ki ngā mōhiohio mōu.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher.

Kia noho muna ai ngā mōhiohio mōu, kāore e whakaurua ngā mōhiohio e tohu ai i a koe ki ngā rīpoata o te ***kairangahau****.*

Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed. This de-identified data may be accessed and used by the following groups:

- **The Investigator and suitably trained and experienced research team, to conduct the study.**
- **An approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative for the sole purpose of checking the accuracy of the information recorded for the study.**

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

No future research will be completed using your information.

Security and Storage of Your Information.

Your identifiable information is held online on a password protected Google Sheet during the study. After the study it is transferred to a secure password protected Excel spreadsheet and stored for at least 10 years, then destroyed.

The following forms of data will be retained by your treating physiotherapist and will form part of your clinical record. These documents will not be archived or destroyed as described above:

- **Knee muscle strength measures**
- **Questionnaire forms you have filled out, about your knee function.**

All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

This research includes basic information such as your age range, and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and tests during the study.

If you have any questions about the collection and use of information about you, you should ask Emma O'Loughlin.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing your physiotherapist or Study Researcher Emma O'Loughlin.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

- If you change your mind you can inform your physiotherapist or the researcher Emma O'Loughlin
- Your collected data until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study
- After the study, you can attend your treating physiotherapist or any other physiotherapist, to continue on your rehabilitation if you so wish. This will be charged at regular physiotherapy session costs.
- When the trial has finished, and the final participant has finished their intervention, you are able to be told which treatment you received.

CAN I FIND OUT THE RESULTS OF THE STUDY?

- A brief lay person summary of the results will be made available by email to you when the trial has finished.
- *Ki te hiahia koe, ka tukuna ā-īmera he whakarāpopototanga o ngā hua te rangahau i tōnā mutunga.*
- Then the results of the whole research will be also provided as a journal paper and as conference presentations.
- The study will be registered as a clinical trial and here is the trial name, A Female Specific Anterior Cruciate Ligament Menstrual Cycle Phased Rehab Programme, and link - https://www.anzctr.org.au/ACTRN12621000517875p.aspx.

WHO IS FUNDING THE STUDY?

- The researcher is a physiotherapist and has received funding from The New Zealand Manipulative Physiotherapists Association (NZMPA).

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Central Health and Disability Ethics Committee (HDEC) has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Emma O'Loughlin, PhD Candidate/Co-Ordinating Investigator
0221723949
ccq8275@autuni.ac.nz

Dr Duncan Reid, Project Supervisor
021473545
duncan.reid@aut.ac.nz

For Māori health support please contact:
Whānau Care Services
Phone: (04) 806 0948
Email: wcs@ccdhb.org.nz

Kia whai i ngā kaiāwhina hauora Māori, whakapā atu ki:
Whānau Care Services
nama: (04) 806 0948
īmera: wcs@ccdhb.org.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@advocacy.org.nz
Website:	https://www.advocacy.org.nz/

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone:	0800 4 ETHIC
Email:	hdecs@health.govt.nz

Appendix 19. Consent form Study I

Consent Form

Project title: ***The effect of a menstrual cycle phased rehabilitation programme on strength recovery and self-reported functional outcomes after anterior cruciate ligament reconstruction.***

Project Supervisor: ***Dr Duncan Reid, Dr Stacy Sims, Dr Mark Fulcher***

Researcher: ***Emma O'Loughlin***

- ☐ I have read and understood the information provided about this research project in the Information Sheet dated 19th July 2020.
- ☐ I have had an opportunity to ask questions and to have them answered.
- ☐ I understand that identity of my fellow participants and our discussions in the focus group is confidential to the group and I agree to keep this information confidential.
- ☐ I understand that notes will be taken during the focus group and that it will also be audio-taped and transcribed.
- ☐ I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without being disadvantaged in any way.
- ☐ I understand that if I withdraw from the study then, while it may not be possible to destroy all records of the focus group discussion of which I was part, I will be offered the choice between having any data that is identifiable as belonging to me removed or allowing it to continue to be used. However, once the findings have been produced, removal of my data may not be possible.
- ☐ I agree to take part in this research.
- ☐ I wish to receive a summary of the research findings (please tick one): Yes ☐ No ☐

Participant's signature: .....

Participant's name: .....

Participant's Contact Details (if appropriate):

……..

……..

……..

……..

Date:

Approved by the Auckland University of Technology Ethics Committee on ***type the date on which the final approval was granted*** ***AUTEC Reference number*** ***type the AUTEC reference number***

Note: The Participant should retain a copy of this form.

Consent Form

A Female Specific Anterior Cruciate Ligament Rehab Programme

Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information including my age, when I had my injury, my knee strength, my questionnaire results, my menstrual cycle, the amount of exercise I usually do, and my knee surgery records.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	
I understand the compensation provisions in case of injury during the study.	
I know who to contact if I have any questions about the study in general.	
I understand my responsibilities as a study participant.	
I wish to receive a summary of the results from the study.	**Yes ☐ No ☐**

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ **Date:** _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ **Date:** _____

Appendices Section D: Letters of support

Appendix 21. Matauranga Māori Committee Support Letter

School of Clinical Sciences

Mātauranga Māori Committee

Verification of Māori Consultation

This document provides verification that the research project named below was discussed with the School of Clinical Sciences Mātauranga Māori Committee, Auckland University of Technology. Specific comments and recommendations are indicated following the table.

Title of project: A Female Specific Anterior Cruciate Ligament (ACL) Rehab Programme.		
Research Team members and affiliations: Emma O'Loughlin PhD Candidate, Professor Duncan Reid, Dr Stacy Sims Research Associate, all associated with Sports Performance Research Institute New Zealand (SPRINZ), AUT.		**Meeting Date:** **5/5/2021**
Discussion Areas		**Discussed**
Whakapapa: Relationships		
Researcher experience in field		X
Consultation with local stakeholders		
Consenting process		
Clarity of data usage		
Dissemination of findings		
Benefits to participants		x
Protecting the rights & interest of Māori		
Clear purpose of project		X
Relevance to Māori		x
Likely outcome for participants, communities, other stakeholders		
Participant recruitment methods		
Māori involvement in project (participants, researchers, etc.)		x
Cultural & Social Responsibility		
Participants' access to appropriate advice		
Participants treated with dignity and respect		x
Privacy and confidentiality		
Whānau support		
Transparency of research process		
Mana tangata – Power & Authority		
Reciprocity (acknowledgements, compensation, gifts)		x
Risks of participation identified		
Ownership of outcomes		
Informed consent process		

Comments

1.	This project is a multicentre study investigating if timing exercises with the menstrual cycle results in improved knee strength in females following anterior cruciate ligament (ACL) surgery compared to standard rehabilitation.
2.	Participants will be 72 females who are 16 years or older, have a regular menstrual cycle, are not on the oral contraceptive pill, and have undergone ACL reconstruction surgery. The researchers are not specifically targeting Māori at this point.
3.	Prior consultation in relation to Māori participation has influenced the design of the data collection forms – using Google sheets rather than having to repeatedly talk about menstrual cycles with a researcher. However, the person providing this cultural advice is unlikely to be able to continue their support with the research process going forward.
4.	The nature of the injury will mean that more sports people will be involved, but it is open to the general population.
5.	

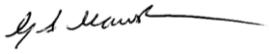
Recommendations made by Committee

1.	The committe noted that Māori are over-represented ACL injury in some age groups, and would encourage the researchers to deliberately target Māori. The general difficulty in recruiting women meeting the eligibility criteria was acknowledged, but the high representation of Māori women in elite sports needs to be recognised.
2.	The committee noted that multiple physiotherapy sessions were likely to be expensive, and may be a barrier to some Māori. The team's efforts to ensure that there is no cost to participants taking part was acknowledge. This included working with lead physiotherapists to reduce cost, using research funding to offset costs and targeting physiotherapists already working on a pilot project (escalated care pilot project) where there are no surcharges.
4.	The sensitivity of conversations with Māori around menstruation, despite respect that the team are trying to show, is also a potential barrier to engaging Māori in the project. The committee would strongly recommend connecting with Māori for support in this area.
5.	The committee acknowledge the understanding that exercising at specific stages of the menstrual cycle may be counter to general cultural practices of both Māori and non-Māori participants. There is likely to be a need for education regarding the rationale for this.. They intent to respect participants who may not want to exercise at specific times without excluding them from the project in appreciated.
6.	The committee noted that a good knowledge of language and context will be important when talking to and writing for Māori. Further advice from Māori around wording of the information sheet, consent form and forms used in the project is recommended.

7.	Tammi Wilson-Uluinayau will speak with a Māori physiotherapist based in Tauranga who is starting to work women's health and the menstrual cycle, as she may be interested in supporting the project.

Please contact the Committee's Administrator Greta Smith at socs-mmc@aut.ac.nz if you have any questions about this feedback.

You may be contacted in 12 months' time for feedback about the process and the usefulness of these comments and recommendations to your project.

Signature:  2020

Grant Mawston
Mātauranga Māori Consultation Committee

Appendix 22. Locality Letter for Private Practice trial engagement

Locality Authorisation Letter

Multicentre Randomised Controlled Trial - "A Female Specific Menstrual Cycle Phased Anterior Cruciate Ligament Rehab Programme"

Expected start date: 1 June 2021
Expected end date: 1 June 2022

Ethics Committee application and approval number: 21/CEN/92
Clinical trial registry number: ACTRN12621000517875p
Co-ordinating Investigator: Emma O'Loughlin
Additional Investigators: Professor Duncan Reid, Dr Stacy Sims

Locality authorisation involves checking the issues below:	Checked by locality	Checked by applicant
The lead/principal investigator(s) at the locality is/are suitably qualified, experienced, registered and indemnified to take professional responsibility (under the direction of the CI) for the conduct of the study at this locality		
This locality's physical facilities are adequate for the conduct of the study		
Conducting the study at this locality would have no adverse effect on the provision of publicly funded health care at that locality		
Appropriate arrangements are in place for notifying other relevant local health or social care staff about the study, and for making available any extra support that might be required by participants		
Appropriate arrangements are in place for providing information to potential participants in the study who may not adequately understand information in English		
Applicants have included relevant locality-specific information and contact details in the local version of the participant information sheet and consent form		
Applicants have taken reasonable steps (particularly consultation with Māori, where appropriate) to ensure that they have identified and adequately addressed local cultural issues that may arise from the study		

I acknowledge this physiotherapy clinic named _____ declares we have checked the above.

Signed:

OR

_____ _____

Clinic's Chief Executive Officer An individual to whom the CEO has delegated responsibility.

Date:

Signed:

OR

_____

Applicant/Co-ordinating Investigator Date:

Appendices Section E: Research Outputs from Thesis or Publication from Thesis

Appendix 23**.** Female Athlete Conference abstract 2020

Session Title

Menstrual cycle phased rehabilitation for females post Anterior Cruciate Ligament Reconstruction (ACLR): Is it time to play to female strengths?

Presenter's Name(s) and Credentials

Emma O'Loughlin BSc (Hons) Physiotherapy, PhD Candidate, The Sports Performance Research Institute New Zealand (SPRINZ), Auckland University of Technology, Auckland, New Zealand.

A brief abstract

ACLR rates are exponentially increasing in females, & their ACLR outcomes are poorer compared to males (Tan et al., 2016). They are also more likely to suffer a subsequent injury compared to males (Nawasreh et al., 2018). Quadriceps strength has shown to be a predictor of outcomes and subsequent injuries for those with ACLR (Grindem et al., 2016), and this has been shown to be inferior in females (Kuenze et al., 2019). Despite females having specific physiological, hormonal and biomechanical considerations, there is a dearth of female-specific rehabilitation programme protocols, advice, or research in general. Menstrual cycle (specifically mid follicular) phased resistance training programmes have been shown to significantly increase quadriceps strength and volume in females (Reis et al., 1995; Sung et al., 2014; Wikstrom-Frisen et al., 2017). However, historically, this has only been examined in a non-injured population. Specifically, there are currently no published studies examining the effects of a female-specific post-operative ACLR rehabilitation programme, targeting strength exercises periodised with their menstrual phases. Therefore, this presentation will describe the gap here, and opportunity for future research examining menstrual cycle phased rehabilitation strengthening programmes for females post ACLR. Such research would aim to contribute to improving quadriceps strength and outcomes for females post ACLR.

Three learning objectives

- Explain current ACLR outcomes for females, and the factors that predict these outcomes.
- Discuss the effects of current menstrual cycle phased resistance programmes, including critical analysis and methodological considerations of these studies.
- Demonstrate the gap in female-specific ACLR rehabilitation programme research, and justify the need for investigation of a menstrual cycle phased ACLR rehabilitation programme.

Appendix 24. SMNZ Conference Abstract 2021

Knowledge and attitudes to the menstrual cycle in the sports medicine environment: A qualitative study exploring the perceptions of orthopaedic surgeons, physiotherapists, female athletes, and ACL patients in Aotearoa.

Emma O'Loughlin [a, b], Dr Duncan Reid [a], Dr Stacy Sims [a, c]

[a] The Sports Performance Research Institute New Zealand (SPRINZ) Auckland University of Technology, Level 2, AUT Millennium, 17 Antares Place, Rosedale, Auckland 0632, New Zealand; [b]Department of Surgery and Anaesthesia, University of Otago, Wellington 6242, New Zealand; [c]WHISPA Group, High Performance Sport New Zealand, Auckland, New Zealand

Abstract

Objective: To explore key members of the sports medicine community's knowledge of the menstrual cycle, comfort discussing the menstrual cycle, and cultural beliefs or practices in female elite athletes.

Methods: Qualitative study. Semi-structured focus group sessions with orthopaedic surgeons, sports physiotherapists, ACL patients, and athletes (n=18). Focus groups were transcribed verbatim and analysed using six- phase reflexive thematic analysis.

Results: The menstrual cycle was noted to be previously perceived as a taboo subject. Health professionals, patients, and athletes report a lack of structured education regarding the menstrual cycle. Menstrual cycle tracking is commonplace at an individual level by patients, athletes, and female physiotherapists. However, utilisation of this information is seen as "the icing on the cake" or for areas with more resources, such as a high-performance sport environment. Most health professionals, patients, and athletes reported feeling generally comfortable discussing the menstrual cycle. However, many individual factors such as age, gender, and culture of the clinician and the patient were identified as barriers to discussing the menstrual cycle in the sports medicine clinic. Surgeons and physiotherapists reported using pre-screening tools and questionnaires to commence the conversation. Furthermore, developing trust before initiating the conversation was identified as a facilitator to an open conversation regarding the menstrual cycle. Patients' culture was perceived as an additional consideration to consider by surgeons and physiotherapists when discussing the menstrual cycle.

Conclusion: Participants revealed they sometimes feel uncomfortable discussing the menstrual cycle in a clinical setting. Participants identified a need and want for further education regarding the menstrual cycle. Screening tools and questions were identified as facilitators to open and frank discussions regarding the menstrual cycle. Athletes and patients do not usually see the menstrual cycle as a topic associated with sports medicine and musculoskeletal injuries. Researchers and clinicians should be cognisant of a person's cultural perspective and background when discussing the menstrual cycle.

Appendix 25**.** BASEM Conference Abstract 2022

Title Discussing the menstrual cycle in the sports medicine clinic: perspectives of orthopaedic surgeons, physiotherapists, athletes, and patients.

Authors Emma O'Loughlin [a,b,] Duncan Reid [a] and Stacy Sims [a,c]

Affiliations

[a] The Sports Performance Research Institute New Zealand (SPRINZ) Auckland University of Technology, Level 2, AUT Millennium, 17 Antares Place, Rosedale, Auckland 0632, New Zealand; [b]Department of Surgery and Anaesthesia, University of Otago, Wellington 6242, New Zealand; [c]WHISPA Group, High Performance Sport New Zealand, Auckland, New Zealand

Corresponding author address and email

Emma O'Loughlin

Email: ccq8275@aut.ac.nz

Address: The Sports Performance Research Institute New Zealand (SPRINZ), Level 2, AUT Millennium, Auckland University of Technology, 17 Antares Place, Rosedale, 0632, Auckland, New Zealand

Contact details for author who will present if selected:

Emma O'Loughlin: ccq8275@aut.ac.nz, The Sports Performance Research Institute New Zealand (SPRINZ), Level 2, AUT Millennium, Auckland University of Technology, 17 Antares Place, Rosedale, 0632, Auckland, New Zealand

Introduction and Purpose

Recently, there has been an increase in female oriented sports medicine research related to physiological aspects of the menstrual cycle. However, it is unclear if this topic is routinely and openly discussed in the sports medicine clinic. In addition, sports medicine health professionals' knowledge, perceptions, and comfort in discussing the menstrual cycle in the sports medicine clinic are unknown.

Material and Methods

This study explored members of the sports medicine community's knowledge, perceptions of, and comfort discussing the endogenous menstrual cycle. Five semi-structured focus group sessions were conducted with 18 participants (2 orthopaedic surgeons, 9 sports physiotherapists, 3 patients, and 4 athletes) in Wellington, New Zealand.

Results

An inductive and semantic approach of reflexive thematic analysis revealed a number of theme that described the menstrual cycle as a pertinent and evolving topic in the sports medicine clinic. The first theme ‘A dearth of education and discussion has given rise to a perceived lack of menstrual cycle knowledge’ reflects the participants’ consensus regarding a lack of knowledge of the menstrual cycle. In contrast, ‘Different (mismatched) concerns of health professionals and non-health professionals’ describes contrasting menstrual cycle-related concerns reported by health professionals and non-health professionals. The third theme ‘Health professionals have specific strategies to enable comfortable menstrual cycle conversations’ describes the common barriers to in-clinic menstrual cycle discussions, and pragmatic approaches health professionals take to tackle these barriers. Finally, ‘The menstrual cycle is a gendered topic’ reflects participants’ descriptions of the menstrual cycle as a gendered topic within the sports medicine environment.

Conclusion

While many participants described general comfort discussing the menstrual cycle, participants identified several factors affecting this, including health professional and non-health professional age, culture, sex, and/or gender. This study highlights the importance of developing trust, giving context, and being aware of each patient's concerns and sociocultural status when discussing the menstrual cycle in the sports medicine clinic.

Appendix 26. SMNZ Conference Abstract 2022

Using Focus Groups to Design and Evaluate a Rehabilitation Programme for Women post-Anterior Cruciate Ligament Reconstruction.

Background: In recent years, women's rates of anterior cruciate ligament (ACL) injuries and anterior cruciate ligament reconstruction (ACLR) have increased. In New Zealand, young women are the fastest growing subgroup for incidence of ACLR in the previous ten years (Ref). Research has recommended FP-based resistance training for non-injured, naturally cycling women to enhance resistance training responses. FP-based resistance training has not been adapted for women following anterior cruciate ligament reconstruction (ACLR). A menstrual cycle phased rehabilitation programme would have to consider the pragmatics of rehabilitation environments, including postoperative rehabilitation protocols and scheduling considerations. Additionally, the particular settings and circumstances of women's lives may create different enablers and barriers to completing effective ACLR rehabilitation.

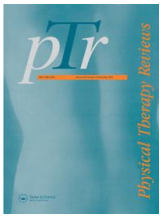
Objective: First, draw upon perspectives of women athletes and women post ACLR to establish critical enablers and barriers for women engaging with rehabilitation. Secondly, establish women-specific needs and preferences for a newly designed ACLR rehabilitation programme. Thirdly, engage with physiotherapists and orthopaedic surgeons to ensure the design and adaptation of the newly designed ACLR programme meets the needs of these health professional groups.

Method: Semi-structured focus group sessions with orthopaedic surgeons, sports physiotherapists, ACL patients, and athletes (n=18). Focus groups were transcribed verbatim and analysed using a six-phase reflexive thematic analysis. Focus groups discussed what works well in current ACLR rehabilitation and provided advice regarding designing a proposed menstrual cycle phase-based resistance training programme. Data was analysed using a six-phase reflexive thematic analysis. Thematic analysis informed the development of a new menstrual cycle phased ACLR rehabilitation programme for women.

Results: Three themes were constructed from the data. The first theme, "Preference for a consistent gym-based programme", refers to women’s preference to attend gym-based rehabilitation multiple times per week. On a similar note, the second theme, “Women need support to attend and engage", describes the different support structures women advised they would need to take part in general ACLR rehabilitation, including consistent supervision and support from their physiotherapist. In addition, it outlines specific supports women need to partake in a menstrual cycle phased rehabilitation programme, such as specific technology and education. The third theme, "Strength is important but difficult to measure", outlines that objective measures are essential to women understanding their progress throughout their rehabilitation. In contrast, it also describes the difficulties health professionals report in measuring strength and function post ACLR rehabilitation.

Conclusion: Input from women athletes, women post ACLR, physiotherapists, and surgeons enabled the development of a new menstrual cycle phased rehabilitation programme for women. Future focus groups will examine women's experiences of the programme and improvement opportunities.

Appendix 27. Published Manuscript: Chapter 2 Scoping review protocol



Physical Therapy Reviews

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/yptr20

Is there a role for menstrual cycle phased resistance training programmes for women post anterior cruciate ligament reconstruction? A scoping review protocol

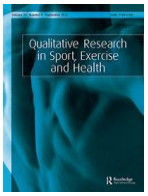
Emma O'Loughlin, Duncan Reid & Stacy Sims

To cite this article: Emma O'Loughlin, Duncan Reid & Stacy Sims (2021): Is there a role for menstrual cycle phased resistance training programmes for women post anterior cruciate ligament reconstruction? A scoping review protocol, Physical Therapy Reviews, DOI: 10.1080/10833196.2021.2017613

To link to this article: https://doi.org/10.1080/10833196.2021.2017613

Published online: 22 Dec 2021.

Appendix 28. Published Manuscript: Chapter 3



Qualitative Research in Sport, Exercise and Health

Routledge
Taylor & Francis Group

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/rqrs21

Discussing the menstrual cycle in the sports medicine clinic: perspectives of orthopaedic surgeons, physiotherapists, athletes and patients

Emma O'Loughlin, Duncan Reid & Stacy Sims

To cite this article: Emma O'Loughlin, Duncan Reid & Stacy Sims (2022): Discussing the menstrual cycle in the sports medicine clinic: perspectives of orthopaedic surgeons, physiotherapists, athletes and patients, Qualitative Research in Sport, Exercise and Health, DOI: 10.1080/2159676X.2022.2111459

To link to this article: https://doi.org/10.1080/2159676X.2022.2111459

ORIGINAL ARTICLE

The development of a menstrual cycle phase-based rehabilitation programme for women post-anterior cruciate ligament reconstruction: A focus group study

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ABSTRACT

Aim: Research has recommended follicular phase-based resistance training for women to enhance resistance training responses. Follicular phase-based resistance training has not been adapted for women following anterior cruciate ligament reconstruction (ACLR). This study aimed to develop a novel menstrual cycle phase-based ACLR rehabilitation programme appropriate for testing on women following ACLR.

Study Design: Two phases: i) Focus groups with orthopaedic surgeons, physiotherapists, patients and athletes, ii) the development of a menstrual cycle phase-based ACLR rehabilitation programme.

Setting: New Zealand sports and sports medicine environment.

Participants: Athletes, patients post ACLR, physiotherapists, orthopaedic surgeons.

Interventions: Focus groups discussed what works well in current ACLR rehabilitation and provided advice regarding designing a proposed menstrual cycle phase-based resistance training programme.

Outcome Measures: Data was analyzed using reflexive thematic analysis. A menstrual cycle phase-based ACLR rehabilitation programme was developed.

Results: Three themes were constructed from the data: (1) Preference for a consistent gym-based programme – referring to women's reported desire for frequent rehabilitation sessions in a gym; (2) Women need support to attend and engage –highlighting the different support structures women need to take part in a rehabilitation programme; (3) Strength is important but challenging to measure – outlining the difficulties health professionals have measuring strength in this population.

Conclusions: Input from key stakeholders enabled the development of a new menstrual cycle phase-based rehabilitation programme that will undergo further testing. Including women with previous ACLR injuries, current athletes, and health professionals should enhance the delivery and engagement with the programme. Whether this programme impacts strength gain following surgery has yet to be assessed.

Keywords: thematic analysis; menstrual cycle; physiotherapy; female athlete; sports medicine.

Appendices Section F: Supplementary Files from Publications

Appendix 30**.** Scoping Review Protocol Pilot Search Strategy

Preliminary Database Search 1

Databases searched: EBSCO Health Database (CINAHL, Medline, SportDiscus), Web of Science, Scopus.

Keywords used: (menstruation OR menstrual cycle) AND (anterior cruciate ligament OR acl) AND (resistance training OR physiotherapy OR physical therapy OR rehab).

Results: Sixty-six studies were found (EBSCO 54, Web of Science 12, Scopus 0). Zero studies met the criteria after abstract review.

Preliminary Database Search 2

Databases searched: EBSCO Health Database (CINAHL, Medline, SportDiscus), Web of Science, Scopus.

Keywords used: (physiotherapy OR physical therapy OR rehab) AND (menstruation OR menstrual cycle)

Results: Six hundred and seven studies were found (EBSCO Healthline 252 results, Web of Science 337, Scopus 18). Zero studies met the criteria after abstract review.

Both searches were restricted to peer-reviewed articles in the English language, and there was no date restriction for years of published articles. The "Apply related words" function was disabled in the EBSCO searches because the word "period" was misconstrued for a time period rather than menstruation.

Appendix 31**.** Scoping Review Protocol Data Extraction **I**nstrument

Scoping review details	
Scoping Review title	Is there a role for menstrual cycle phased resistance training programmes for women post ACLR? A scoping review protocol.
Review objective	Describe what is known about menstrual cycle phased resistance training programmes in injured and non-injured women and identify any existing gaps in knowledge.
Review question	Is there a role for menstrual cycle phased resistance training programmes for women post ACLR? Have MC phased resistance training programmes been investigated in women post ACLR? What is known about the methodologies of MC phased resistance training programmes? What is known about MC phased resistance training effects on strength outcomes and motivation for training? Do these findings provide a gap for future experimental studies in an ACLR rehabilitation context?
Inclusion/exclusion criteria	
Population	Include injured or non-injured pre-menopausal women of any age.
Concept	MC phased strengthening programmes (at least one MC length of 28-40 days duration) – how are these carried out? What are their effects? Should these be investigated in different populations or environments?
Context	Rehabilitation gym, non-clinical gym, laboratory, or home-based environments.
Evidence source details and characteristics	
Citation details	
Author/s, country, date, title, journal, volume, issue, pages, study ID	
Study Design	
Study Aim/Purpose	
Participants (age, number, resistance training status, injury status)	
Details extracted from the source of evidence (programme design, programme duration, menstrual cycle verification method)	
Results/outcome of the study (outcome measures used, results)	

Appendix 32**.** Scoping Review Protocol Result Template

Below is an example of a results template to present key characteristics and results of the articles reviewed. The information in the first column is fictitious.

Author, Year & Location	**Jones, 2021, USA**
Study Type	Randomised Controlled trial
Population	N = 8 non injured eumenorrheic females aged 17-35
Participant Training Status	All participants resistance trained
Resistance Training Programme Design	8 lower limb unilateral resistance training sessions in FP & 2 in LP per cycle.
Comparison	Opposite lower limb completed 8 lower limb unilateral resistance training sessions in LP & 2 in FP per cycle
Programme Duration	12 weeks
MC Verification Method	Calendar tracking. Ovulation tests. Blood serum analysis
Outcome Measure	Maximum knee extension strength on an isokinetic leg press
Results	Increased maximum strength in FP resistance training group

Appendix 33**.** Scoping Review – PRISMA Checklist

PRISMA Checklist Item

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	Line 1-2
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	Line 5-26
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	Line 83– 87
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualise the review questions and/or objectives.	Line 86-91
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	Line 96-98
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	Line 106-121
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	Line 133 – 137, & Line 146-147
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	Line 139 – 151

Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	Line 154- 156 & Appendix 35
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	Appendix 31
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	Line 158-159
Synthesis of results	13	Describe the methods of handling and summarising the data that were charted.	Line 155
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	Line 161 – 171, Appendix 36 & 37 & Figure 5.
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	Table 2.
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	N/A
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	Table 2
Synthesis of results	18	Summarise and/or present the charting results as they relate to the review questions and objectives.	Line 161-281, & Table 2
DISCUSSION			
Summary of evidence	19	Summarise the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	Line 283-409
Limitations	20	Discuss the limitations of the scoping review process.	Line 411-421
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	Line 423-437

FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	Title Page

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

** Where sources of evidence (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.*

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with information sources (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

Appendix 34**.** Scoping Review Search Strategies

Preliminary Database Search

Preliminary Search 1

Databases: EBSCO Health Database (CINAHL, Medline, SportDiscus), Web of Science, Scopus.

Keywords: (menstruation OR menstrual cycle) AND (anterior cruciate ligament OR acl) AND (resistance training OR physiotherapy OR physical therapy OR rehab).

Limits: English Language

Results: 66 studies were found (EBSCO 54, Web of Science 12, Scopus 0). Zero studies met the criteria after abstract review.

Preliminary Search 2

Databases: EBSCO Health Database (CINAHL, Medline, SportDiscus), Web of Science, Scopus.

Keywords: (physiotherapy OR physical therapy OR rehab) AND (menstruation OR menstrual cycle)

Limits: English Language

Results: 607 studies were found (EBSCO Healthline 252 results, Web of Science 337, Scopus 18). Zero studies met the criteria after abstract review.

Note: "Apply related words" function was disabled in the EBSCO searches because the word "period" was misconstrued for a time period rather than menstruation.

Final Search Strategy:

EBSCO Medline search strategy

250 results when English Language limit applied

1	*menstrual cycle/ or follicular phase/ or luteal phase/*
2	*((menstrua* adj3 (cycle* or phase* or timing or track* or regular or progesterone or oestrogen or estrogen)) or (follicul* adj3 (ovar* or phase* or matur* or releas*)) or luteal or eumenorrh*).tw,kf.*
3	*1 or 2*
4	*rehabilitation/ or exercise therapy/ or resistance training/*
5	*Physical Therapy Modalities/*
6	*Weight Lifting/ or Muscle Strength/*

7	*(Rehabilitation or physiotherap* or "physical therap*" or ((resistance or weight or weights or strength) adj3 (training or exercis*)) or (muscle* adj3 (resistance or strengthen* or training or exercis* or build* or enhanc*)) or "weight lifting" or "lifting weight*").tw,kf.*
8	*or/4-7*
9	*3 and 8*
10	*limit 9 to english language*

Ovid EBM Reviews – Cochrane Central Register of Controlled Trials search strategy:

81 results when English Language limit applied

1	*menstrual cycle/ or follicular phase/ or luteal phase/*
2	*((menstrua* adj3 (cycle* or phase* or timing or track* or regular or progesterone or oestrogen or estrogen)) or (follicul* adj3 (ovar* or phase* or matur* or releas*)) or luteal or eumenorrh*).mp.*
3	*1 or 2*
4	*rehabilitation/ or exercise therapy/ or resistance training/*
5	*Physical Therapy Modalities/*
6	*Weight Lifting/ or Muscle Strength/*
7	*(Rehabilitation or physiotherap* or "physical therap*" or ((resistance or weight or weights or strength) adj3 (training or exercis*)) or (muscle* adj3 (resistance or strengthen* or training or exercis* or build* or enhanc*)) or "weight lifting" or "lifting weight*").mp.*
8	*or/4-7*
9	*3 and 8*
10	*limit 9 to english language*

CINAHL search strategy

151 results when English Language limit applied

S 1	*(MH "Menstrual Cycle") OR (MH "Follicular Phase") OR (MH "Luteal Phase")*
S 2	*TI ((menstrua* N3 (cycle* or phase* or timing or track* or regular or progesterone or oestrogen or estrogen)) or (follicul* N3 (ovar* or phase* or matur* or releas*)) or luteal or eumenorrh*) OR AB ((menstrua* N3 (cycle* or phase* or timing or track* or regular or progesterone or oestrogen or estrogen)) or (follicul* N3 (ovar* or phase* or matur* or releas*)) or luteal or eumenorrh*)*

S3	*S1 OR S2*
S4	*(MH "Rehabilitation") OR (MH "Physical Therapy") OR (MH "Therapeutic Exercise") OR (MH "Abdominal Exercises") OR (MH "Back Exercises") OR (MH "Core Exercises") OR (MH "Lower Extremity Exercises") OR (MH "Muscle Strengthening") OR (MH "Isokinetic Exercises") OR (MH "Isometric Exercises") OR (MH "Isotonic Exercises") OR (MH "Kegel Exercises") OR (MH "Resistance Training") OR (MH "Upper Extremity Exercises") OR (MH "Arm Exercises") OR (MH "Rehabilitation, Athletic")*
S5	*(MH "Weight Lifting")*
S6	*(MH "Muscle Strength")*
S7	*TI (Rehabilitation or physiotherap* or "physical therap*" or ((resistance or weight or weights or strength) N3 (training or exercis*)) or (muscle* N3 (resistance or strengthen* or training or exercis* or build* or enhanc*)) or "weight lifting" or "lifting weight*") OR AB (Rehabilitation or physiotherap* or "physical therap*" or ((resistance or weight or weights or strength) N3 (training or exercis*)) or (muscle* N3 (resistance or strengthen* or training or exercis* or build* or enhanc*)) or "weight lifting" or "lifting weight*")*
S8	*S4 OR S5 OR S6 OR S7*
S9	*S3 AND S8*

SPORTDiscus search strategy

122 results when English Language limit applied

S1	*TI ((menstrua* N3 (cycle* or phase* or timing or track* or regular or progesterone or oestrogen or estrogen)) or (follicul* N3 (ovar* or phase* or matur* or releas*)) or luteal or eumenorrh*) OR AB ((menstrua* N3 (cycle* or phase* or timing or track* or regular or progesterone or oestrogen or estrogen)) or (follicul* N3 (ovar* or phase* or matur* or releas*)) or luteal or eumenorrh*) OR SU ((menstrua* N3 (cycle* or phase* or timing or track* or regular or progesterone or oestrogen or estrogen)) or (follicul* N3 (ovar* or phase* or matur* or releas*)) or luteal or eumenorrh*) OR KW ((menstrua* N3 (cycle* or phase* or timing or track* or regular or progesterone or oestrogen or estrogen)) or (follicul* N3 (ovar* or phase* or matur* or releas*)) or luteal or eumenorrh*)*
S2	*TI (Rehabilitation or physiotherap* or "physical therap*" or ((resistance or weight or weights or strength) N3 (training or exercis*)) or (muscle* N3 (resistance or strengthen* or training or exercis* or build* or enhanc*)) or "weight lifting" or "lifting weight*") OR AB (Rehabilitation or physiotherap* or "physical therap*" or ((resistance or weight or weights or strength) N3 (training or exercis*)) or (muscle* N3 (resistance or strengthen* or training or exercis* or build* or enhanc*)) or "weight lifting" or "lifting weight*") OR SU (Rehabilitation or physiotherap* or "physical therap*" or ((resistance or weight or weights or strength) N3 (training or exercis*)) or (muscle* N3 (resistance or strengthen* or training or exercis* or build* or enhanc*)) or "weight lifting" or "lifting weight*") OR KW (Rehabilitation or physiotherap* or "physical therap*" or ((resistance or weight or weights or strength)*

	N3 (training or exercis)) or (muscle* N3 (resistance or strengthen* or training or exercis* or build* or enhanc*)) or "weight lifting" or "lifting weight*")*
S3	*S1 AND S2*

Scopus search strategy

432 Results

(TITLE-ABS-KEY ((menstrua W/3 (cycle* OR phase* OR timing OR track* OR regular OR progesterone OR oestrogen OR estrogen)) OR (follicul* W/3 (ovar* OR phase* OR matur* OR releas*)) OR luteal OR eumenorrh*) AND TITLE-ABS-KEY (rehabilitation OR physiotherap* OR "physical therap*" OR ((resistance OR weight OR weights OR strength) W/3 (training OR exercis*)) OR (muscle* W/3 (resistance OR strengthen* OR training OR exercis* OR build* OR enhanc*)) OR "weight lifting" OR "lifting weight*")) AND (LIMIT-TO (LANGUAGE , "English"))*

Web of Science search strategy

367 Results with English Language limit applied

TS= ((menstrua NEAR/3 (cycle* OR phase* OR timing OR track* OR regular OR progesterone OR oestrogen OR estrogen)) OR (follicul* NEAR/3 (ovar* OR phase* OR matur* OR releas*)) OR luteal OR eumenorrh*) AND TS=(rehabilitation OR physiotherap* OR "physical therap*" OR ((resistance OR weight OR weights OR strength) NEAR/3 (training OR exercis*)) OR (muscle* NEAR/3 (resistance OR strengthen* OR training OR exercis* OR build* OR enhanc*)) OR "weight lifting" OR "lifting weight*")*

Google Scholar Search Strategy

3,160 results

(intitle:menstrual OR intitle:menstruation OR intitle:follicular OR intitle:luteal OR intitle:eumenorrheic) (phase OR cycle) (resistance OR strength) (training OR exercise)

Appendix 35**.** Scoping Review Data Charting Form

Scoping review details	
Scoping Review title	Is there a role for menstrual cycle phased resistance training for women post ACLR? A scoping review protocol.
Review objective	Describe what is known about menstrual cycle phased resistance training in injured and non-injured women and identify any existing gaps in knowledge.
Review question	Is there a role for menstrual cycle phased resistance training for women post ACLR? (1) Has menstrual cycle phased resistance training been investigated in women post ACLR? (2) What is known about the methodologies of menstrual cycle phased resistance training programmes? (3) What is known about menstrual cycle phased resistance training effects? (4) Do these findings provide a gap for future experimental studies in an ACLR rehabilitation context?
Inclusion/exclusion criteria	
Population	Pre-menopausal women, regardless of injury status
Concept	Menstrual cycle phased resistance training
Context	Rehabilitation gym, non-clinical gym, laboratory, or home-based environments.
Type of evidence source	Primary research studies. Review articles.
Evidence source details and characteristics	
Citation details: - Author/s - Country - Date - Title - Journal - Volume - Issue	

- Pages
- Study ID

Study Design:

Study Aim/Purpose:

Participants:

- Age
- Number
- Resistance training status
- Injury status

Details extracted from the source of evidence

Programme

- Design
- Duration

Review Aim

Menstrual cycle verification method

Exclusion of non-confirming data

Results of the study

Conclusions

Appendix 36**.** Scoping Review Studies Excluded at Full-Text Screening

Studies excluded at full-text screening (database searching)

	Excluded Study	**Exclusion Reason**
1.	Oosthuyse T, Bosch AN. The effect of the menstrual cycle on exercise metabolism: implications for exercise performance in eumenorrhoeic women. Sports Med. 2010;40(3):207-227. doi:10.2165/11317090-000000000-00000	Does not report responses/methods of menstrual cycle phased resistance training
2.	Kraemer WJ, Ratamess NA. Hormonal responses and adaptations to resistance exercise and training. Sports Med. 2005;35(4):339-361. doi:10.2165/00007256-200535040-00004	Does not report responses/methods of menstrual cycle phased resistance training
3.	Nakamura Y., Aizawa K. (2017) Sex Hormones, Menstrual Cycle and Resistance Exercise. In: Hackney A. (eds) Sex Hormones, Exercise and Women. Springer, Cham. https://doi.org/10.1007/978-3-319-44558-8_14	Book
4.	Sakamaki M, Yasuda T, Abe T. Comparison of low-intensity blood flow-restricted training-induced muscular hypertrophy in eumenorrheic women in the follicular phase and luteal phase and age-matched men. Clinical Physiology and Functional Imaging. 2012;32(3):185-191. doi:10.1111/j.1475-097x.2011.01075.x.	Reports acute effects of menstrual cycle phased resistance exercise
5.	Ian Shrier (Best of the Literature Editor), Peter D. Brukner & Constance M. Lebrun (2004) Best of the Literature, The Physician and Sportsmedicine, 32:3, 7-8, DOI: 10.1080/00913847.2004.11440658	Editorial
6.	Tiidus PM. Can estrogens diminish exercise induced muscle damage?. Can J Appl Physiol. 1995;20(1):26-38. doi:10.1139/h95-002	Does not report responses/methods of menstrual cycle phased resistance training
7.	Sakamaki, Mikako; Yasuda, Tomohiro; Sato, Yoshiaki; Abe, Takashi Comparison Of Muscle Hypertrophy During Follicular And Luteal Phases Following 6-days Blood-Flow Restricted Resistance Training, Medicine & Science in Sports & Exercise: May 2010 - Volume 42 - Issue 5 - p 741 doi: 10.1249/01.MSS.0000386150.31603.5c	Conference presentation

8.	Markofski MM, Braun WA. Influence of menstrual cycle on indices of contraction-induced muscle damage. J Strength Cond Res. 2014;28(9):2649-2656. doi:10.1519/JSC.0000000000000429	Reports acute effects of menstrual cycle phased resistance exercise
9.	T. Serebryaka, L.M. Smirnova. Biomechanical features of restoration of the lower limb function after reconstruction of the anterior cruciate ligament by various tendon grafts. Gait & posture v.73 suppl.1 , 2019, pp.281 – 281.	Does not report responses/methods of menstrual cycle phased resistance training
10.	Kendall, BK & Eston, Roger. The effect of menstrual cycle status and oral contraceptive use on exercise-induced muscle damage. Journal of Sports Sciences (2002). January, 53-54.	Conference presentation
11.	Williams NI, Bullen BA, Arthur JW, Skrinar GS, Turnbull BA. Effects of short-term strenuous endurance exercise upon corpus luteum function. Med Sci Sports Exerc. 1999;31(7):949-958. doi:10.1097/00005768-199907000-00006	Examined aerobic exercise periodization
12.	Consitt LA, Copeland JL, Tremblay MS. Endogenous anabolic hormone responses to endurance versus resistance exercise and training in women. Sports Med. 2002;32(1):1-22. doi:10.2165/00007256-200232010-00001	Does not report responses/methods of menstrual cycle phased resistance training
13.	Romero-Parra N, Cupeiro R, Alfaro-Magallanes VM, et al. Exercise-Induced Muscle Damage During the Menstrual Cycle: A Systematic Review and Meta-Analysis. J Strength Cond Res. 2021;35(2):549-561. doi:10.1519/JSC.0000000000003878	Reports acute effects of menstrual cycle phased resistance exercise
14.	Friedmann-Bette, B. Gender differences in muscular adaptation to strength training. Isokinetics and Exercise Science, vol. 16, no. 3, pp. 163-180, 2008. doi**:** 10.3233/IES-2008-0322	Conference Abstract
15.	Hansen M, Kjaer M. Influence of sex and estrogen on musculotendinous protein turnover at rest and after exercise. Exerc Sport Sci Rev. 2014;42(4):183-192. doi:10.1249/JES.0000000000000026	Does not report responses/methods of menstrual cycle phased resistance training
16.	Romero-Parra, Nuria & Cupeiro, Rocío & Alfaro-Magallanes, Víctor & Rael Delgado, Beatriz & Barba Moreno, Laura & Maestre-Cascales, Cristina & Castro, Eliane & Peinado, Ana. (2020). Menstrual Cycle And Menopause Influence On Creatine Kinase Response After Exercise-induced Muscle Damage: 786 Board #1 May 27 3:15 PM - 5:15 PM. Medicine & Science in Sports &	Conference Presentation

	Exercise. 52. 187-187. 10.1249/01.mss.0000675528.38414.83.	
17.	McCormick, K. M., et al. "Menstrual cycle effects on exercise induced changes in muscle soreness, serum creatine kinase and myoglobin." Medicine & Science in Sports & Exercise 17.2 (1985): 278.	Reports acute effects of menstrual cycle phased resistance exercise
18.	Athletics Weekly Women: Time Your Training Cycles	Non peer reviewed magazine
19.	Kang S, Kim E, Ju SB, Lim ST. Variation in myokine and adipokine levels according to menstrual cycle following regular resistance exercise [published online ahead of print, 2021 Sep 9]. J Sports Med Phys Fitness. 2021;10.23736/S0022-4707.21.12785-9. doi:10.23736/S0022-4707.21.12785-9	Does not report responses/methods of menstrual cycle phased resistance training
20.	Serebryak T & Smirnovaa LM. Biomechanical features of restoration of the lower limb function after reconstruction of the anterior cruciate ligament by various tendon grafts	Conference abstract
21.	Julian R, Sargent D. Periodisation: tailoring training based on the menstrual cycle may work in theory but can they be used in practice?. Science and Medicine in Football. 2020;4(4):253-254. doi:10.1080/24733938.2020.1828615.	Editorial
22.	Sousa M, Dellagrana R, Lunardi M, Rossato M, Hoinaski L, Bento C, Freitas C. Menstrual cycle and use of different doses of oral contraceptive do not affect torque parameters in strength training programs. Motricidade. 2020;16(2)176-183.	Does not report methods/ effects of menstrual cycle phased training.
23.	Shephard RJ. Exercise and training in women, Part II: Influence of menstrual cycle and pregnancy. Can J Appl Physiol. 2000;25(1):35-54. doi:10.1139/h00-003	Does not report methods/ effects of menstrual cycle phased training.
24.	Arazi, Hamid & Nasiri, Sabikeh & Eghbali, Ehsan. (2018). Is there a difference toward strength, muscular endurance, anaerobic power and hormonal changes between the three phase of the menstrual cycle of active girls?. Apunts. Medicina de l'Esport. 54. 10.1016/j.apunts.2018.11.001.	Does not report effects of menstrual cycle phased training.
25.	Augustine JA, Nunemacher KN, Heffernan KS. Menstrual phase and the vascular response to acute resistance exercise. Eur J Appl Physiol. 2018;118(5):937-946. doi:10.1007/s00421-018-3815-1	Does not report effects of menstrual cycle phased training.
26.	Brown N, Knight CJ, Forrest (Née Whyte) LJ. Elite female athletes' experiences and perceptions of the menstrual cycle on training and sport	Does not report effects of

	performance. Scandinavian Journal of Medicine & Science in Sports. 2021;31(1):52-69. doi:10.1111/sms.13818.	menstrual cycle phased training.
27.	Janse de Jonge XA. Effects of the menstrual cycle on exercise performance. Sports Med. 2003;33(11):833-851. doi:10.2165/00007256-200333110-00004	does not report effects of menstrual cycle phased training.
28.	Gil A, Neto GR, Sousa MSC, et al.. Effect of strength training with blood flow restriction on muscle power and submaximal strength in eumenorrheic women. Clinical Physiology and Functional Imaging. 2017;37(2):221-228. doi:10.1111/cpf.12291.	Does not report effects of menstrual cycle phased training.
29.	Kraemer RR, Heleniak RJ, Tryniecki JL, Kraemer GR, Okazaki NJ, Castracane VD. Follicular and luteal phase hormonal responses to low-volume resistive exercise. Med Sci Sports Exerc. 1995;27(6):809-817.	Acute effects of menstrual cycle phased resistance training.
30.	Lamont LS, Lemon PW, Bruot BC. Menstrual cycle and exercise effects on protein catabolism. Med Sci Sports Exerc. 1987;19(2):106-110.	Acute effects of menstrual cycle phased resistance training
31.	Okamoto T, Kobayashi R, Sakamaki-Sunaga M. Effect of Resistance Exercise on Arterial Stiffness during the Follicular and Luteal Phases of the Menstrual Cycle. Int J Sports Med. 2017;38(5):347-352. doi:10.1055/s-0043-101377	Acute effects of menstrual cycle phased resistance training
32.	Oleka CT. Use of the Menstrual Cycle to Enhance Female Sports Performance and Decrease Sports-Related Injury. J Pediatr Adolesc Gynecol. 2020;33(2):110-111. doi:10.1016/j.jpag.2019.10.002	Editorial
33.	Prado RCR, Silveira R, Kilpatrick MW, Pires FO, Asano RY. The effect of menstrual cycle and exercise intensity on psychological and physiological responses in healthy eumenorrheic women. Physiology & Behavior. 2021;232:113290. doi:10.1016/j.physbeh.2020.113290.	Acute effects menstrual cycle phased exercise.
34.	Rocha-Rodrigues S, Sousa M, Lourenço Reis P, et al.. Bidirectional Interactions between the Menstrual Cycle, Exercise Training, and Macronutrient Intake in Women: A Review. Nutrients. 2021;13(2):438. doi:10.3390/nu13020438.	Does not report effects of menstrual cycle phased training.
35.	Romero-Moraleda B, Coso JD, Gutiérrez-Hellín J, Ruiz-Moreno C, Grgic J, Lara B. The Influence of the Menstrual Cycle on Muscle Strength and	Does not report effects of menstrual

	Power Performance. J Hum Kinet. 2019;68:123-133. Published 2019 Aug 21. doi:10.2478/hukin-2019-0061	cycle phased training.
36.	Timon R, Corvillo M, Brazo J, Robles MC, Maynar M. Strength training effects on urinary steroid profile across the menstrual cycle in healthy women. European Journal of Applied Physiology. 2013;113(6):1469-1475. doi:10.1007/s00421-012-2575-6.	Does not report effects of menstrual cycle phased training.
37.	Brown M. (2013) Estrogen Effects on Skeletal Muscle. In: Spangenburg E. (eds) Integrative Biology of Women's Health. Springer, New York, NY. https://doi.org/10.1007/978-1-4614-8630-5_3	Book chapter
38.	Kissow J, Jacobsen KJ, Gunnarsson TP, Jessen S, Hostrup M. Effects of Follicular and Luteal Phase-Based Menstrual Cycle Resistance Training on Muscle Strength and Mass. Sports Med. 2022;52(12):2813-2819. doi:10.1007/s40279-022-01679-y	Current opinion paper.
39.	O'Bryan, SM, Connor, KR, Drummer, DJ, Lavin, KM, & Bamman, MM. (2022). Considerations for Sex-Cognizant Research in Exercise Biology and Medicine. Frontiers in Sports and Active Living, 4, 903992. https://doi.org/10.3389/fspor.2022.903992	Does not report responses/methods of menstrual cycle phased resistance training.
40.	Masjedi H, Rajabi H, Motamedi P. Changes in Insulin-Like Growth Factor 1 and Quadriceps Muscle Size in Follicular Stage Compared to Luteal Stage in Adaptation to Resistance Training in Young Women. Jundishapur Journal of Medical Sciences. 2022; 20(6):556-565. doi: 10.32598/JSMJ.20.6.2447	Not in English.
41.	Nolan D, Elliott-Sale KJ, Egan B. Prevalence of hormonal contraceptive use and reported side effects of the menstrual cycle and hormonal contraceptive use in powerlifting and rugby [published online ahead of print, 2022 Jan 6]. Phys Sportsmed. 2022;1-6. doi:10.1080/00913847.2021.2024774	Does not report methods/ effects of menstrual cycle phased training.

Studies excluded at full-text screening (other sources citations, reference lists)

	Excluded Study	**Exclusion Reason**
	Deschenes MR, Kraemer WJ. Performance and physiologic adaptations to resistance training. Am J	Does not report methods/ effects of menstrual

	Phys Med Rehabil. 2002;81(11 Suppl):S3-S16. doi:10.1097/00002060-200211001-00003	cycle phased training.
	Statham G. Understanding the effects of the menstrual cycle on training and performance in elite athletes: A preliminary study. Prog Brain Res. 2020;253:25-58. doi:10.1016/bs.pbr.2020.05.028	Does not report methods/ effects of menstrual cycle phased training.
	Ramos PR, Rodrigo S, Marcus K, Flávio Oliveira P, Yukio K. Menstrual Cycle, Psychological Responses, and Adherence to Physical Exercise: Viewpoint of a Possible Barrier. Frontiers in Psychology. 2021(12) doi:10.3389/fpsyg.2021.525943	Does not report methods/ effects of menstrual cycle phased training.
	Alexander SE, Pollock AC, Lamon S. The effect of sex hormones on skeletal muscle adaptation in females [published online ahead of print, 2021 May 18]. Eur J Sport Sci. 2021;1-11. doi:10.1080/17461391.2021.1921854	Does not report methods/ effects of menstrual cycle phased training.
5.	Hackney, A.C 2016. Sex hormones, exercise and women: Scientific and clinical aspects. Springer International Publishing Switzerland 2017. doi:10.1007/978-3-319-44558-8.	Book chapter
6.	Kell RT. The influence of periodized resistance training on strength changes in men and women. J Strength Cond Res. 2011;25(3):735-744. doi:10.1519/JSC.0b013e3181c69f22	Does not report methods/ effects of menstrual cycle phased training.
7.	Kraemer WJ, Gordon SE, Fleck SJ, et al. Endogenous anabolic hormonal and growth factor responses to heavy resistance exercise in males and females. Int J Sports Med. 1991;12(2):228-235. doi:10.1055/s-2007-1024673	Does not report methods/ effects of menstrual cycle phased training.
8.	Kraemer WJ, Mazzetti SA, Nindl BC, et al. Effect of resistance training on women's strength/power and occupational performances. Med Sci Sports Exerc. 2001;33(6):1011-1025. doi:10.1097/00005768-200106000-00022	Does not report methods/ effects of menstrual cycle phased training.
9.	Kraemer WJ, Nindl BC, Ratamess NA, et al. Changes in muscle hypertrophy in women with periodized resistance training. Med Sci Sports Exerc. 2004;36(4):697-708. doi:10.1249/01.mss.0000122734.25411.cf	Does not report methods/ effects of menstrual cycle phased training.
10.	Kraemer WJ, Ratamess NA. Hormonal responses and adaptations to resistance exercise and training. Sports Med. 2005;35(4):339-361. doi:10.2165/00007256-200535040-00004	Acute menstrual cycle effects/responses to resistance exercise

11.	McClung JM, Davis JM, Wilson MA, Goldsmith EC, Carson JA. Estrogen status and skeletal muscle recovery from disuse atrophy. J Appl Physiol (1985). 2006;100(6):2012-2023. doi:10.1152/japplphysiol.01583.2005	Does not report effects of MENSTRUAL CYCLE phased training
12.	Reilly T. The Menstrual Cycle and Human Performance: An Overview. Biological Rhythm Research. 2000;31(1):29-40. doi:10.1076/0929-1016(200002)31:1;1-0;ft029.	Does not report effects of MENSTRUAL CYCLE phased training
13.	Rhea MR, Alderman BL. A meta-analysis of periodized versus nonperiodized strength and power training programs. Res Q Exerc Sport. 2004;75(4):413-422. doi:10.1080/02701367.2004.10609174	Does not report effects of MENSTRUAL CYCLE phased training
14.	Walts CT, Hanson ED, Delmonico MJ, Yao L, Wang MQ, Hurley BF. Do sex or race differences influence strength training effects on muscle or fat?. Med Sci Sports Exerc. 2008;40(4):669-676. doi:10.1249/MSS.0b013e318161aa82	Does not report effects of MENSTRUAL CYCLE phased training
15.	Geiker NR, Ritz C, Pedersen SD, Larsen TM, Hill JO, Astrup A. A weight-loss program adapted to the menstrual cycle increases weight loss in healthy, overweight, premenopausal women: a 6-mo randomized controlled trial. Am J Clin Nutr. 2016;104(1):15-20.	Does not report effects of menstrual cycle phased training.

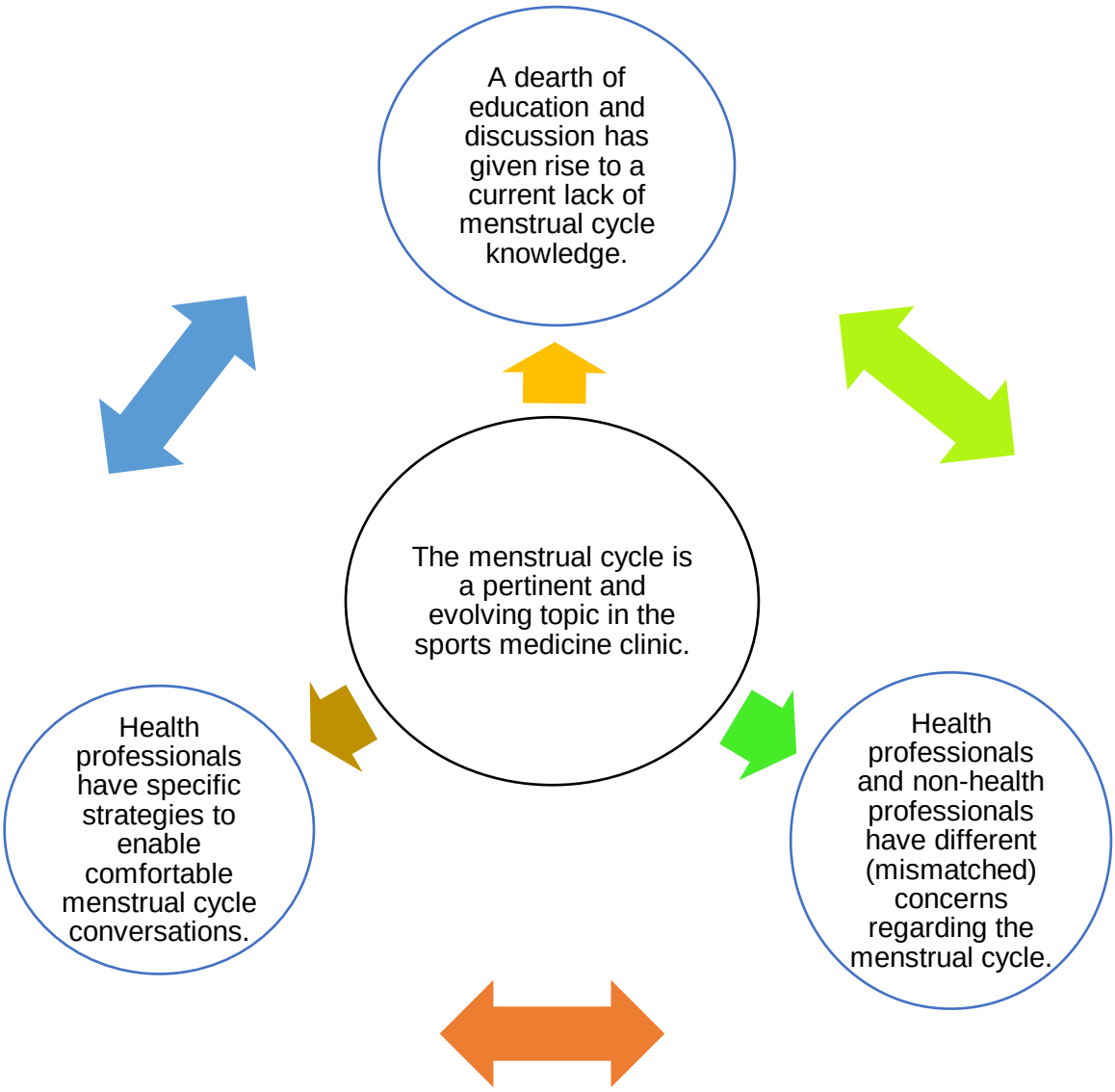
Appendix 37**.** Scoping Review: Included Studies

Full Texts Included in Review

	Included Study	**Relevance to Review Question**
1.	Reis E, Frick U, Schmidtbleicher D. Frequency Variations of Strength Training Sessions Triggered by the Phases of the Menstrual Cycle. Int. J. Sports MEd. 1995; 16:545-550.	Reports methods & effects of menstrual cycle phased resistance training.
2.	Wikström-Frisen L, Boraxbekk CJ, Henriksson-Larsen K. Effects on power, strength and lean body mass of menstrual/oral contraceptive cycle based resistance training. J Sports Med Phys Fitness. 2017; 57(1-2):43-52.	Reports methods & effects of menstrual cycle phased resistance training.
3.	Zainab S, Nithyashree P, Jumanah R, Kamalakannan M, Prathap S, Kumaresan A. A study to compare the effectiveness of core strengthening exercises for phase I and phase II of menstrual cycle in primary dysmenorrhea subjects. Biomedicine. 2021; 41(2):315-317.	Reports methods & effects of menstrual cycle phased resistance training.
4.	Sung E, Han A, Hinrichs T, Vorgerd M, Manchado C, Platen P. Effects of follicular versus luteal phase-based strength training in young women. SpringerPlus. 2014(3):668.	Reports methods & effects of menstrual cycle phased resistance training.
5.	Wikström-Frisén L, Boraxbekk C-J, Larsén K. Increasing training load without risking the female athlete triad: Menstrual cycle based periodized training may be an answer? The Journal of sports medicine and physical fitness. 2016; 57.	Reports methods & effects of menstrual cycle phased resistance training.
6.	Sakamaki-Sunaga M, Min S, Kamemoto K, Okamoto T. Effects of Menstrual Phase-Dependent Resistance Training Frequency on Muscular Hypertrophy and Strength. J Strength Cond Res. 2016; 30(6):1727-1734.	Reports methods & effects of menstrual cycle phased resistance training.
7.	Sung ES, Kim JH. The difference effect of estrogen on muscle tone of medial and lateral thigh muscle during ovulation. J. Exerc. Rehabil. 2018; 14(3):419-423.	Reports methods & effects of menstrual cycle phased resistance training.
8.	Gharahdaghi N, Phillips BE, Szewczyk NJ, Smith K, Wilkinson DJ, Atherton PJ. Links Between Testosterone, Oestrogen, and the Growth Hormone/Insulin-Like Growth Factor Axis and Resistance Exercise Muscle Adaptations. Frontiers in physiology. 2021; 11:621226.	Discusses methods & effects of menstrual cycle phased resistance training.
9.	Knowles OE, Aisbett B, Main LC, Drinkwater EJ, Orellana L, Lamon S. Resistance Training and Skeletal Muscle Protein Metabolism in	Discusses methods & effects of menstrual

	Eumenorrheic Females: Implications for Researchers and Practitioners. Sports Med. 2019; 49(11):1637-1650.	cycle phased resistance training.
10.	Randell RK, Clifford T, Drust B, et al. Physiological Characteristics of Female Soccer Players and Health and Performance Considerations: A Narrative Review. Sports Med. 2021; 51(7):1377-1399.	Discusses methods & effects of menstrual cycle phased resistance training.
11.	Thompson B, Almarjawi A, Sculley D, Janse de Jonge X. The Effect of the Menstrual Cycle and Oral Contraceptives on Acute Responses and Chronic Adaptations to Resistance Training: A Systematic Review of the Literature. Sports Med. 2020; 50(1):171-185.	Discusses methods & effects of menstrual cycle phased resistance training.
12.	Hansen M, Langberg H, Holm L, et al. Effect of administration of oral contraceptives on the synthesis and breakdown of myofibrillar proteins in young women. Scand J Med Sci Sports. 2011; 21(1):62-72.	Discusses methods & effects of menstrual cycle phased resistance training.
13.	Vargas-Molina S, Petro JL, Romance J et al. Menstrual cycle-based undulating periodized program effects on body composition and strength in trained women: a pilot study. Science & Sports doi:10.1016/j.scispo.2021.11.003	Reports methods & effects of menstrual cycle phased resistance training.
14.	Oosthuyse T, Strauss JA, Hackney AC. Understanding the female athlete: molecular mechanisms underpinning menstrual phase differences in exercise metabolism [published online ahead of print, 2022 Nov 19]. Eur J Appl Physiol. 2022;10.1007/s00421-022-05090-3. doi:10.1007/s00421-022-05090-3	Discusses methods & effects of menstrual cycle phased resistance training.

Appendix 38**.** Thematic Map: Themes related to the knowledge of, perceptions of, and comfort discussing, the menstrual cycle in the sports medicine environment.



Appendix 39. RCT CERT Checklist

CERT ✓ *C*onsensus on *E*xercise *R*eporting *T*emplate

A Checklist for what to include when reporting exercise programs

Section/Topic	Item #	Checklist item	Location **	
			Primary paper (page, table, appendix)	† Other (paper or protocol, website (URL)
WHAT: materials	1	Detailed description of the type of exercise equipment (e.g. weights, exercise equipment such as machines, treadmill, bicycle ergometer etc)	**Intro: Location**	
WHO: provider	2	Detailed description of the qualifications, teaching/supervising expertise, and/or training undertaken by the exercise instructor	**Intro: Study Design**	
HOW: delivery	3	Describe whether exercises are performed individually or in a group	**Intro: Programme**	
	4	Describe whether exercises are supervised or unsupervised and how they are delivered	**Intro: Programme**	
	5	Detailed description of how adherence to exercise is measured and reported	**Intro: Interventions**	
	6	Detailed description of motivation strategies	**Intro: Interventions**	
	7a	Detailed description of the decision rule(s) for determining exercise progression	**Intro: Programme**	
	7b	Detailed description of how the exercise program was progressed	**Intro: Programme**	
	8	Detailed description of each exercise to enable replication (e.g. photographs, illustrations , video etc)	**Trial Website**	
	9	Detailed description of any home program component (e.g. other exercises, stretching etc)	**Methods: Interventions**	
	10	Describe whether there are any non-exercise components (e.g. education, cognitive behavioural therapy, massage etc)	**Methods: Interventions**	
	11	Describe the type and number of adverse events that occurred during exercise	**Results: Participants**	

WHERE: location	12	Describe the setting in which the exercises are performed	**Methods: Intervention**
WHEN, HOW MUCH: dosage	13	Detailed description of the exercise intervention including, but not limited to, number of exercise repetitions/sets/sessions, session duration, intervention/program duration etc	**Methods: Programme**
TAILORING: what, how	14a	Describe whether the exercises are generic (one size fits all) or tailored whether tailored to the individual	**Methods: Programme**
	14b	Detailed description of how exercises are tailored to the individual	**Methods: Programme**
	15	Describe the decision rule for determining the starting level at which people commence an exercise program (such as beginner, intermediate, advanced etc)	**Methods: Programme**
HOW WELL: planned, actual	16a	Describe how adherence or fidelity to the exercise intervention is assessed/measured	**Methods: Intervention**
	16b	Describe the extent to which the intervention was delivered as planned	**Results: Participants & Programme**

***It is recommended that this checklist is used in conjunction with the Explanation and Elaboration Statement which is a guide each item in the CERT Checklist**

The CERT Checklist is designed for reporting details of an exercise intervention. The CERT Checklist should be used in conjunction with a reporting checklist appropriate for the study type e.g. the CONSORT Statement (www.consort-statement.org) for randomised controlled trials, the SPIRIT Statement (www.spirit-statement.org) for a clinical trial protocol. For further guidance regarding reporting guidelines please consult the EQUATOR network (www.equator-network.org)

** Authors – please use N/A if an item is not applicable Reviewers – please use "?" if information is not provided or not/insufficiently reported

† If the information is not provided in the primary paper that is under consideration, please provide details of where this information is available e.g. in a published protocol, published papers (provide citation details) or on a website (provide the URL).

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
1.	**BRIEF NAME** Provide the name or a phrase that describes the intervention.	**Title**	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	**Intro**	
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	**Methods: Participants**	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	**Methods: Intervention**	
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	**Methods: Intervention & Programme**	
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	**Methods: Intervention & Programme**	
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	**Methods: Location**	

	WHEN and HOW MUCH	**Methods: Intervention & Programme & Figure 8**	
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.		
	TAILORING	**Methods: MC Verification**	
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.		
	MODIFICATIONS	**Results: Programme**	
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).		
	HOW WELL	**Results: Participants, & Table 8&9**	
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.		
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	**Results: Participants, & Table 8&9**	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Appendices Section E: Outcome Measure Forms

Appendix 41. KOOS Form

Knee Injury and Osteoarthritis Outcome Score (KOOS)

Pain

P1 How often is your knee painful?	☐ Never	☐ Monthly	☐ Weekly	☐ Daily	☐ Always

What degree of pain have you experienced the last week when…?

P2 Twisting/pivoting on your knee	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P3 Straightening knee fully	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P4 Bending knee fully	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P5 Walking on flat surface	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P6 Going up or down stairs	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P7 At night while in bed	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P8 Sitting or lying	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P9 Standing upright	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme

Symptoms

Sy1 How severe is your knee stiffness after first wakening in the morning?	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sy2 How severe is your knee stiffness after sitting, lying, or resting later in the day?	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sy3 Do you have swelling in your knee?	☐ Never	☐ Rarely	☐ Sometimes	☐ Often	☐ Always
Sy4 Do you feel grinding, hear clicking or any other type of noise when your knee moves?	☐ Never	☐ Rarely	☐ Sometimes	☐ Often	☐ Always
Sy5 Does your knee catch or hang up when moving?	☐ Never	☐ Rarely	☐ Sometimes	☐ Often	☐ Always
Sy6 Can you straighten your knee fully?	☐ Always	☐ Often	☐ Sometimes	☐ Rarely	☐ Never
Sy7 Can you bend your knee fully?	☐ Always	☐ Often	☐ Sometimes	☐ Rarely	☐ Never

Activities of daily living

What difficulty have you experienced the last week…?

A1 Descending	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A2 Ascending stairs	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A3 Rising from sitting	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A4 Standing	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A5 Bending to floor/picking up an object	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A6 Walking on flat surface	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A7 Getting in/out of car	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A8 Going shopping	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A9 Putting on socks/stockings	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A10 Rising from bed	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A11 Taking off socks/stockings	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A12 Lying in bed (turning over, maintaining knee position)	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A13 Getting in/out of bath	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A14 Sitting	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A15 Getting on/off toilet	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A16 Heavy domestic duties (shovelling, scrubbing floors, etc)	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A17 Light domestic duties (cooking, dusting, etc)	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme

Sport and recreation function

What difficulty have you experienced the last week…?

Sp1 Squatting	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sp2 Running	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sp3 Jumping	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sp4 Turning/twisting on your injured knee	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sp5 Kneeling	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme

Knee-related quality of life

Q1 How often are you aware of your knee problems?	☐ Never	☐ Monthly	☐ Weekly	☐ Daily	☐ Always
Q2 Have you modified your lifestyle to avoid potentially damaging activities to your knee?	☐ Not at all	☐ Mildly	☐ Moderately	☐ Severely	☐ Totally
Q3 How troubled are you with lack of confidence in your knee?	☐ Not at all	☐ Mildly	☐ Moderately	☐ Severely	☐ Totally
Q4 In general, how much difficulty do you have with your knee?	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme

Appendix 42. IKDC Form

2000 IKDC SUBJECTIVE KNEE EVALUATION FORM

Name: First Last **Date:**

Physician: **Date of Injury:**

SYMPTOMS*:

*Grade symptoms at the highest activity level at which you think you could function without significant symptoms, even if you are not actually performing activities at this level.

1.What is the highest level of activity that you can perform without significant knee pain?

- ○ Very strenuous activities like jumping or pivoting as in basketball or soccer
- ○ Strenuous activities like heavy physical work, skiing or tennis
- ○ Moderate activities like moderate physical work, running or jogging
- ○ Light activities like walking, housework or yard work
- ○ Unable to perform any of the above activities due to knee pain

2.During the past 4 weeks, or since your injury, how often have you had pain?

	0	1	2	3	4	5	6	7	8	9	10	
Never	○	○	○	○	○	○	○	○	○	○	○	Constant

3.If you have pain, how severe is it?

	0	1	2	3	4	5	6	7	8	9	10	
No pain	○	○	○	○	○	○	○	○	○	○	○	Worst pain imaginable

4.During the past 4 weeks, or since your injury, how stiff or swollen was your knee?

- ○ Not at all
- ○ Mildly
- ○ Moderately
- ○ Very
- ○ Extremely

5.What is the highest level of activity you can perform without significant swelling in your knee?

- ○ Very strenuous activities like jumping or pivoting as in basketball or soccer
- ○ Strenuous activities like heavy physical work, skiing or tennis
- ○ Moderate activities like moderate physical work, running or jogging
- ○ Light activities like walking, housework or yard work
- ○ Unable to perform any of the above activities due to knee swelling

6.During the past 4 weeks, or since your injury, did your knee lock or catch?

○ Yes ○ No

7.What is the highest level of activity you can perform without significant giving way in your knee?

- ○ Very strenuous activities like jumping or pivoting as in basketball or soccer
- ○ Strenuous activities like heavy physical work, skiing or tennis
- ○ Moderate activities like moderate physical work, running or jogging
- ○ Light activities like walking, housework or yard work
- ○ Unable to perform any of the above activities due to giving way of the knee

Page 2 – 2000 IKDC SUBJECTIVE KNEE EVALUATION FORM

SPORTS ACTIVITIES:

8.What is the highest level of activity you can participate in on a regular basis?

- ○ Very strenuous activities like jumping or pivoting as in basketball or soccer
- ○ Strenuous activities like heavy physical work, skiing or tennis
- ○ Moderate activities like moderate physical work, running or jogging
- ○ Light activities like walking, housework or yard work
- ○ Unable to perform any of the above activities due to knee

9.How does your knee affect your ability to:

		Not difficult at all	Minimally difficult	Moderately Difficult	Extremely difficult	Unable to do
a.	Go up stairs	○	○	○	○	○
b.	Go down stairs	○	○	○	○	○
c.	Kneel on the front of your knee	○	○	○	○	○
d.	Squat	○	○	○	○	○
e.	Sit with your knee bent	○	○	○	○	○
f.	Rise from a chair	○	○	○	○	○
g.	Run straight ahead	○	○	○	○	○
h.	Jump and land on your involved leg	○	○	○	○	○
i.	Stop and start quickly	○	○	○	○	○

FUNCTION:

10. How would you rate the function of your knee on a scale of 0 to 10 with 10 being normal, excellent function and 0 being the inability to perform any of your usual daily activities which may include sports?

FUNCTION PRIOR TO YOUR KNEE INJURY:

	0	1	2	3	4	5	6	7	8	9	10	
Couldn't perform daily activities	○	○	○	○	○	○	○	○	○	○	○	No limitation in daily activities

CURRENT FUNCTION OF YOUR KNEE:

	0	1	2	3	4	5	6	7	8	9	10	
Cannot perform daily activities	○	○	○	○	○	○	○	○	○	○	○	No limitation in daily activities

0 IKDC Score

Print Form

Submit

APPENDIX D: Knee Self-Efficacy Scale

The **Knee Self-Efficacy scale** is a questionnaire regarding how confident you feel in your ability to perform different activities **right now** and how confident you feel about your knee function **in the future.**

You should base your answers on **your perception of how confident you are in your ability** to perform the different activities and not about how well you actually perform them. If you have never tried the activity, please base your answer on how confident **you think you are.**

Present knee self-efficacy: movements and actions

Check the box for the number that best describes ***how confident you are in your ability*** to perform the activity ***right now*** regardless of pain/discomfort.

0 = Not confident at all **10 = Very confident**

How confident are you in:	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Walking down stairs/down hill	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Jumping ashore from a boat	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Running after small children	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Running after a streetcar/bus	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Jumping sideways from one leg to another	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Doing a single leg hop on the injured leg	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Standing and moving around in a small, rocking boat	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Making quick changes in directions while running	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Squatting	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Present knee self-efficacy: leisure activities and sports

Check the box for the number that best describes ***how confident you are in your ability*** to perform the activity ***right now*** regardless of pain/discomfort.

0 = Not confident at all **10 = Very confident**

How confident are you in:	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Walking in the woods	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Going out dancing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Working in the garden	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cycling longer distances	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cross-country skiing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Horseback riding	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Swimming	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Hiking in the mountains	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Future knee self-efficacy

Check the box for the number that best describes ***how confident you are about*** your knee in the future.

0 = Not confident at all **10 = Very confident**

How confident are you:	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Of not having another injury to your knee	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
That you will not completely destroy your knee	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐