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The development and initial validation of the Health and Reproductive Survey (HeRS)

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Abstract

Background: Due to the diversity in profiles associated with the female reproductive cycle and their potential physiological and psychological effects, monitoring the reproductive status of exercising females is important from a practical and research perspective. Moreover, as physical activity can influence menstrual function, the effects of physical activity energy expenditure on reproductive function should also be considered.

Aim: The aim of this study was to develop and establish initial face and content validity of the Health and Reproductive Survey (HeRS) for physically active females, which is a retrospective assessment of menstrual function from menarche (first menstruation) to menopause (cessation of menstruation).

Methods: Face validity was evaluated qualitatively, and the initial content validity was established through a principal component analysis. The face validity process was completed by 26 females aged 19–67 years and the content validity was established through a survey sent to a convenience sample of 392 females, of which 230 females (57.9% and aged 18–49 years) completed the survey.

Results: The revisions made following the face validation improved the understanding, flow, and coherence of the survey. The principal component analysis indicated that, at a minimum, the survey measures these constructs: menstrual cessation and associated moderators, athletic participation and performance levels (as associated with menstruation change and the menstrual cycle), age and menstrual cessation, hormonal contraception ("birth control"), and menarche and associated moderators.

Conclusion: The Health and Reproductive Survey (HeRS) is a partially validated tool that can be used by researchers to characterize the menstrual status of physically active females relative to their physical activity status.

Keywords

amenorrhea, female, female athlete, menstrual function, performance, physical activity, survey development, sport participation

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Introduction

The female reproductive cycle starts with menarche (first menstruation) and ends with menopause (last menstruation) and pertains to the cyclical changes that occur in the ovaries and uterus. The menstrual cycle is a circamensal rhythm that lasts 29 days on average, although there is large inter- and intra-individual variation in cycle length. Cycles can last between 24 and 35 days and still be described as normal.[1,2] The average age of menarche is 12 years, and it can take months, and often years, before the menstrual cycle becomes consistent, since lifestyle (e.g. physical activity and nutritional practices), genetic (e.g. *KISS1* gene), socioeconomical (e.g. low socioeconomic status is associated with earlier menarche), geographical (e.g. country of birth), and biological (e.g. race and body mass index) factors regulate the menstrual cycle.[3] The menstrual cycle is also subject to numerous irregularities, such as amenorrhea (no menstruation), oligomenorrhea (cycles longer than 35 days), anovulation (a cycle without ovulation), dysmenorrhea, heavy menstrual bleeding, and luteal phase deficiency (shortened time between ovulation and period).[4] Additional perturbations occur regularly, such as pregnancy (increased estrogen and progesterone levels and amenorrhea), lactational amenorrhea (no periods while breastfeeding, increased prolactin levels, and decreased reproductive hormones), and hormonal contraceptive use (decreased endogenous ovarian hormone levels). Finally, other hormonal or physical changes can also affect menstrual cycles, such as polycystic ovary syndrome (increased androgen levels), endometriosis, hyperprolactinemia, Asherman's syndrome, and various medications.[4] The median age of menopause is 49 years and is characterized by 12 consecutive months of spontaneous amenorrhea, when no other pathologic or physiologic cause can be identified.[5]

Physical activity, fitness, exercise, and athletic performance are often used interchangeably in the literature, especially lay publications, to describe purposeful movement to improve functional status. These words, however, represent discrete differences in the world of sport and exercise science and several definitions have been proposed for each of these terms. For this article, we will use the following definitions: physical activity is any bodily movement that requires energy expenditure.[6] Exercise is a subcategory of physical activity that is planned, structured, repetitive, and purposeful and is intended to improve or maintain fitness.[6] Fitness characterizes the ability to perform aspects of sports, occupations, or daily activities, while athletic performance describes the efforts made by an athlete to attain specific objectives over a period of time.[6] Since the aim of this study was to develop a survey that assessed menstrual function across the life course, we focused on the entire spectrum of physical activity participation and not simply athletic or sport participation.

The association between estrogen and progesterone and physical activity is bidirectional. First, the female sex hormones have numerous physiologic functions, including growth and development in adolescence, fertility in adulthood, and the maintenance and regulation of bone health, body temperature, and cholesterol production.[7–10] In addition, ovarian hormones affect the cardiovascular, immune, skeletal, and central nervous systems, and act on cells in the kidneys, hypothalamus, bone marrow, skin, and liver.[11–20] Potential changes in physiological functioning were first noted in 1877[21] and since this seminal article, researchers have investigated the effects of ovarian hormones on athletic and other physical performance metrics, although a consensus on the magnitude and direction of these changes has yet to be established.[22]

Second, physical activity energy expenditure has been shown to affect menstrual function.[23] When compared to non physically active females with appropriate energy availability (EA), physically active females with low EA are more likely to have irregular menstrual cycles and suffer from certain types of menstrual dysfunction.[24,25] Low EA is the cornerstone of Relative Energy Deficiency in Sport (RED-S) and occurs when an athlete's caloric intake is inadequate for baseline functioning and physical activity energy expenditure.[26] Numerous endocrine changes have been noted in association with low EA, including reduced ovarian hormone concentrations.[27] Loucks and Thuma[28] suggested that that an EA of 30 kcal/kg fat-free mass/day was sufficient to avoid disturbances in luteinizing hormone pulsatility,[28] but more recently, De Souza et al.[29] suggested that EA above this threshold does not always protect against menstrual disturbances. Low EA-related menstrual cycle disturbances range from subtle to severe[30,31] and, although rare, might result in subsequent infertility.[32] Severe menstrual disturbances, such as amenorrhea and oligomenorrhea, have been reported in around 30% of exercising females,[33] while subtle menstrual disturbances, such as luteal phase defects and anovulation, may also occur in much higher numbers of exercising females,[30,34,35] despite the presence of seemingly "normal" menstrual cycles (i.e. menstruation occurring at regular intervals). The prevalence of oligomenorrhea and amenorrhea has also been shown to be higher in athletes, particularly in those competing in certain sports with either an aesthetic component or in those where there is a desire for leanness such as in ballet, gymnastics, or endurance running.[24,25]

Contrary to the situation observed in competitive or highly active females, most females in developed nations are in positive energy balance and rarely do excessive amounts of physical activity.[36] In fact, physical activity has been shown to decline by as much as 7% a year in adolescent girls,[37] which can continue into adulthood, resulting in few females meeting the recommended guidelines for physical activity participation during their reproductive years.[38] Physical inactivity correlates with larger body size, which can affect reproductive functioning, resulting in various reproductive sequelae including anovulation, subfertility, and infertility.[38] As such, physical activity energy expenditure is a major determinant of menstrual function.

Due to the diversity in endocrine profiles associated with the reproductive cycle, and the bidirectional relationship between physical activity and menstrual function, it is important to monitor the reproductive status of exercising females from a health, physiological and performance perspective. Therefore, the aim of this study was to develop and initially validate a retrospective survey that assesses physical activity and menstrual function across the lifespan.

Methods

Survey development

Institutional Review Board approval was sought and granted by the University of North Carolina, Greensboro (IRB #19-0378). The Health and Reproductive Survey (HeRS) (version 1) was developed by a working group with expertise in female health, sports endocrinology, sport and exercise science, and survey measurement methods. Using both literature and clinical experience, questions were drafted to focus on two main areas: physical activity and sport history participation, and reproductive health from menarche to current status. In order to assess reproductive health across the lifespan, the survey was divided into five sections: (1) menarche/first period, (2) 13–18 years, (3) 19–24 years, (4) 25–40 years, and (5) 40+ years of age.

The survey has 571 questions, although some questions or sections can be skipped depending on the respondent's age and personal history. The first section, "Your First Period," has 29 questions pertaining to the onset of the menstrual cycle. This section asks questions about specific events, circumstances, and lifestyle choices at the time of menarche and about familial (specifically maternal and female siblings) reproductive health. The next four sections of the survey assess reproductive health between different age ranges, with each section containing 138 identical questions corresponding to a set timeframe. The second section (13–18 years) is the longest section, having four additional questions: what age high school was started and completed, the number of periods per year, and if menstruation ever stopped for 2 or more months. Each section of the survey requires participants to confirm their age to ensure that they are not completing a section of the survey that is not relevant to them. The survey is designed to be completed within 12–15 min for native English speakers with at least a third-grade literacy rate.

Survey validation

A two-phase approach was used to assess the preliminary validity of this survey. The first phase used a qualitative approach for face validity followed by the second phase that used a principal component analysis (PCA) to establish content validity. The next phase in the validity process for HeRS is to test the recall reliability of the survey over a 4- and 6-month period.

Part I: face validity. Establishing face validity, the extent to which a measure assesses what it is intended to measure,[39] is a common first step in survey validation. Face validity is a subjective judgment made by participants about whether an instrument appears to be an appropriate measure of the targeted variables and assessment objectives.[40,41] Without face validity, a measure cannot achieve construct validity,[41] and is needed for data to be considered credible.[42] Face validity was evaluated by assessing the clarity and substance of the questions and response options, and the flow of the survey.

Version 1 of HeRS was revised based on feedback from the authors on this article and was sent to a second team of subject experts, who evaluated the initial set of questions (version 1) for accuracy, relevance, length, and clarity, resulting in version 2 of the survey. Following this, 26 females aged 19–67 years were recruited from a convenience sample to establish face validity by taking the survey, having provided informed consent to take part in the study. Each participant completed the revised (version 2) survey online on one occasion between 1 September 2018 and 26 September 2018. Following completion of version two of the survey, the participants received an email thanking them for their time and participation, as well as seeking feedback about the survey. Three open-ended questions were applied: (1) clarity (i.e. was anything confusing?), (2) relevance (i.e. was anything missing from the survey?), and (3) responses (i.e. were the response options adequate?). Participants were asked to return their feedback via email. Twelve of the participants provided feedback. Based on the feedback provided for version 2, the survey was further modified and/or reorganized, resulting in version three of HeRS, which was the version used to establish face and content validity. Table 1 provides examples of revisions from version two of HeRS to version three of HeRS.

Part II: content validity. To establish content validity, the revised survey (version 3) was sent to a convenience sample of 392 females, of which 230 females (57.9% and aged 18–49 years) completed and submitted the survey. All participants provided informed consent prior to completing the survey. A PCA was conducted using the "princomp" procedure in SAS® analytic software (version 9.4, SAS Institute, Inc. NC, USA). The analysis is based on the correlation matrix so there is no need to standardize the variables.[43] The 13 to 18-year section was used for validation, as it reflects the furthest timepoint from the present day, thus requiring the greatest recall effort. In addition, the

Table 1. Examples of feedback received for the face validity assessment and the resultant changes.

Was anything confusing?	Change made	Was anything missing?	Change made	Were the response options adequate?	Change made
When I answered, "I don't know about performance at a higher level in high school when I got my first period," the skip logic needs to lead me to the next question in the next section, and currently, it does not so I wasn't sure how to proceed	The skip logic was corrected.	Identify what is considered as taking birth control, like do IUD's count as taking birth control?	IUD's as an option was added.	I felt that all answer choices made sense and were relevant—even if they didn't apply to me.	None.
It might be helpful for an introductory question about birth control—asking folks if they ever used birth control before asking questions about it.	A question was added to the 13 to 18-year section asking if the participant had ever used birth control. Based on the response, a skip pattern was added to advance to the next section if "no" was answered.	Side effects from birth control—need a "Not Applicable" choice.	A "not applicable" choice was added.	You need to include "I don't know" to the "How old was each sister when she had her first period?"	"I don't know" was added as an option.

IUD: intrauterine device.

questions in this section are identical to the questions in all subsequent sections. The questions in the 13 to 18-year section yielded 154 variables, of which 35 were included in the PCA. Excluded variables corresponded to questions that garnered fewer than 10 responses or were constant (i.e. there was no variability in responses).

The PCA was used to validate the constructs (i.e. the underlying concepts or themes) measured by the survey. The internal consistency of questions loading on the same component was assessed using Cronbach's α.[44] A factor loading of at least 0.3 was applied to estimate the correlation among responses to questions in each component. As we did not observe factor loadings that were ± 0.6 or greater,[45] we adopted a data-driven approach using the absolute value of 0.3, to allow for the identification of a greater number of themes. Items were considered to represent an acceptable level of internal consistency if the Cronbach's α value was >0.70 (benchmark reported in Collingridge[45]). We created a scree plot and charted the variance explained by the components to illustrate the PCA results.

Results

Phase I: face validation

The feedback received from the participants (Table 1) was used to fine-tune the survey and resulted in version three of the survey. Of the 12 included participants, 2 were aged 13–18 years, 2 were aged 18–24 years, 5 were aged 25–39 years, and 3 were aged 40 years or older.

Phase II: content validity

From the 230 participants who completed the content validity phase, 23 were aged 18–24 years, 129 were aged 25–40 years, and 78 were aged 40 years or older. Participants resided in either the United Kingdom or the United States. Table 2 shows the components, the labels we assigned, and the Cronbach's α values. Components 1, 2, 3, and 6, measuring moderators of menstruation and menstrual cessation, and athletic participation and performance levels, had good internal consistency (0.73–0.94). Component 4, which was labeled "age and menstrual cessation," had moderate internal consistency (0.53). Component 5, reflecting contraception usage, had no other variables loading with it. The seventh component, reflecting moderators of menstruation, was the first component showing poor internal consistency (−0.25).

Figure 1 shows the rationale for identifying the first six components as the main analytic themes represented in the survey. This scree plot shows the chosen cut-off point (component 6), where the slope changes from a steep line to a flatter line.[46] Figure 1 also shows the proportion of variance explained by the components, indicating that the first six components explain approximately 50% of the variance.

Discussion

The purpose of this study is two-fold: (1) to develop a questionnaire for use in research settings to better understand how physical activity influences the menstrual cycle throughout the life span, and vice versa, and (2) to initially establish face and content validity. Discussion around the menstrual cycle among physically active females and stakeholders (i.e. medical staff) is still in its relative infancy. While there has been increased media attention to this area in the last few years, few teams are conducting any form of extensive evaluation or monitoring of how physical activity impacts and influences the menstrual cycle and vice versa. Often, if these data are being collected, it may just be that the first day of a new menstrual

Table 2. Components, measures of consistency, variables, and construct labels from the principal component analysis.

Component	Cronbach's α	Variables	Construct label
1	0.75	Amenorrhea between 13 and 18 years Anorexia between 13 and 18 years No diagnosed conditions between 13 and 18 years Age diagnosed with amenorrhea Age diagnosed with anorexia Period cessation without contraception Longest length of time without period	Menstrual cessation and associated moderators
2	0.73	Menstruation change with increased physical activity Menstruation change with decreased physical activity Lower physical performance at certain point in menstrual cycle	Athletic participation and performance levels
3	0.94	Menstruation change with increased physical activity Menstruation change with decreased physical activity	Athletic participation levels
4	0.53	Age when high school began Age when high school completed Number of periods per year Period cessation without contraception	Age and menstrual cessation
5	Not applicable	First period without hormones or lifestyle changes	Birth control
6	0.92	Higher physical performance at certain point in menstrual cycle Lower physical performance at certain point in menstrual cycle	Athletic performance
7	−0.25	Age of first period First period without hormones or lifestyle changes Between 13 and 18 years, used any form of birth control	Menarche and associated moderators

cycle is logged, failing to capture any information about menstrual history and a large number of other factors known to be relevant for long-term health and performance.

The revisions made following the face validation phase improved the understanding, flow, and coherence of the survey. PCA and Cronbach's α test showed adequate internal consistency within the first six components identified. The HeRS was initially validated using a large variety of age groups in different contexts; therefore, external validity was also established. The PCA indicates that, at a minimum, the survey measures these constructs: menstrual cessation and associated moderators, athletic participation and performance levels (as associated with menstruation change and the menstrual cycle), age and menstrual cessation, hormonal contraception ("birth control"), and menarche and associated moderators. Internal consistency breaks down at the seventh component, where the plots also indicate a logical rationale for identifying the first six components as the main analytic themes measured by the survey. As such, we believe HeRS to be a partially valid instrument for collecting data on physically active females and reproductive health in adolescence. Although we established the initial validity of the survey for the 13 to 18-year timeframe, we believe the instrument would also be valid for collecting the same information at other times of life, as the same questions were posed for other ages. However, we recognize that this manuscript is the first step in the validation process and that further investigation is needed, including validating questions for the other sections in the survey. The HeRS is an easy to administer, comprehensive tool, and the validation of the survey supports its future use in research and practice.

Mena et al.[36] suggested that the ability to properly assess the influence of physical activity on reproductive outcomes is limited by the range of physical activity interventions employed with minimal information on physical activity volume, overall energy expenditure, attendance, or adherence information. They further stated that only a few studies have supplied adequate information on physical activity intensity, frequency, mode, duration of session, or duration of the intervention, and few have included true control groups. This highlights the need for a detailed reproductive survey that can provide extensive data and insight related to the influence of physical activity and its associations with reproductive health. The HeRS can fill this gap by providing a valid means for assessing reproductive function over time and in association with physical activity.

The HeRS was designed by reproductive health experts to gather information from biologically born females regarding their current and historical reproductive history. As the survey developers, we intentionally designed this survey to be administered online, so that it could be completed by anyone with access to the Internet. There is a need for a non-invasive, low-cost, valid, and reproducible method for defining menstrual status that can be used to track and monitor reproductive functioning over time. Otherwise practitioners are reliant on either (1) expensive blood samples for the determination of estrogen and progesterone, which only provide a snapshot of the current hormonal profile, or (2) non-structured interviews, which can be time-consuming

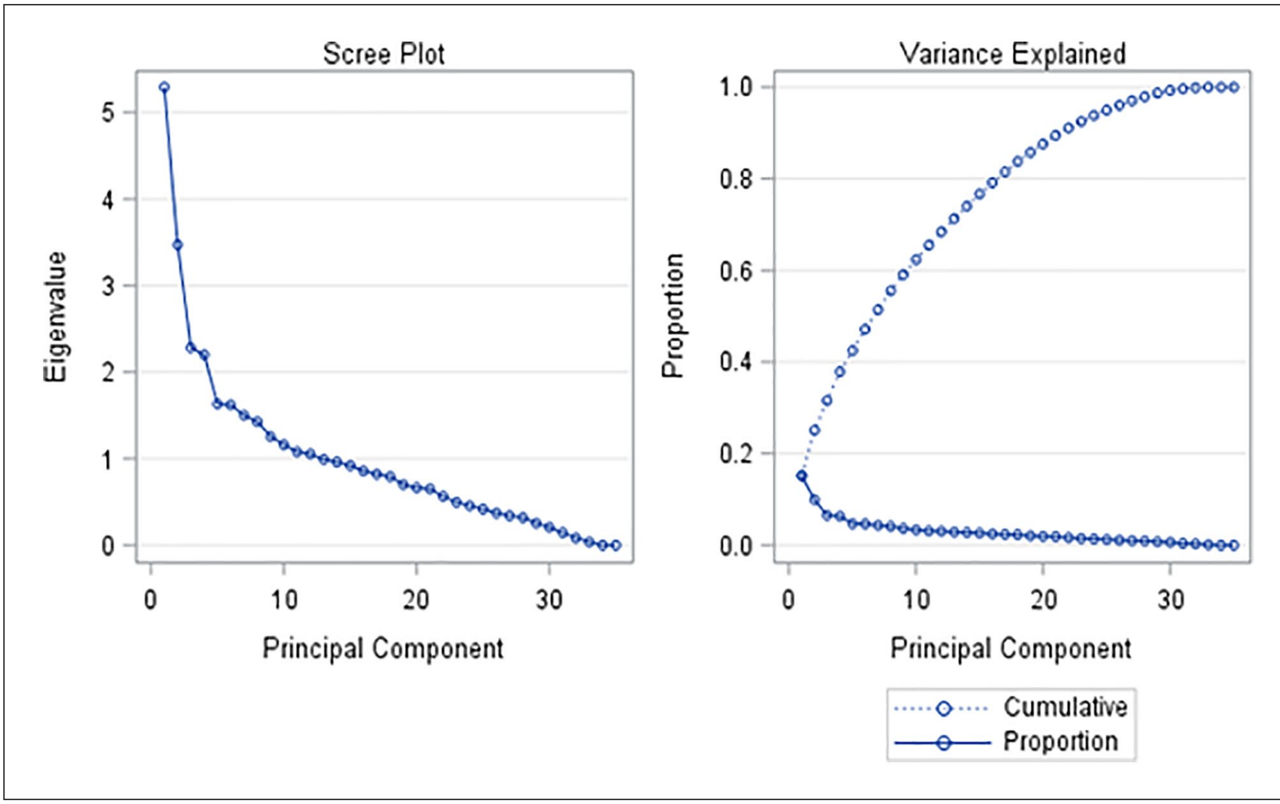

Figure 1. Scree plot and chart of variance.

and highly variable. Both techniques, blood samples and interviewing, also rely on specialist facilities and resources, such as a phlebotomist, a biochemist and wet laboratory, and a qualitative methodologist. The HeRS can help overcome these barriers, can be easily administered, and provides both current and historical data.

From a practical perspective, the menstrual cycle and its irregularities have been reported by physically active females to affect their ability to train and perform due to changes in physical (e.g. cramps, fatigue, and pain) and psychological (e.g. irritability, mood changes, and depression) functioning.[47] As such, a survey tool that allows for longitudinal menstrual cycle tracking (including symptoms and side effects) and participant characterization (such as amenorrhea and oligomenorrhea) alongside sports participation could have a big impact on the applied community, as it could provide sports practitioners and researchers with data on the effects of physical activity on menstrual status and vice versa. This information could be used to tailor training and recovery programs, which could optimize health and performance.

Subtle menstrual disturbances occur in approximately 50% of exercising females,[30] thus, seemingly "normal" menstrual cycles (e.g. having a cycle duration of 24–35 days) are not necessarily indicative of proper reproductive function, nor are they synonymous with the "textbook" cyclic hormonal fluctuations. Additional tools, such as a comprehensive reproductive survey that goes beyond simply determining the length of the menstrual cycle, can provide vital information about the status of reproductive health in females. The HeRS has a wide range of exploratory questions regarding the menstrual cycle and hormonal contraceptive use to provide detailed information regarding reproductive functioning, thus helping to detect menstrual disturbance which may direct future treatment for optimal reproductive health.

In addition, the prevalence of menstrual irregularities in active populations is not routinely monitored, meaning that the impact of such conditions on health and performance is poorly understood. Previous research has shown the prevalence of primary amenorrhea in adolescent athletes to be between 1% and 6%,[48] with rates of secondary amenorrhea ranging from 3% to 65%.[25,49] Investigation into other types of menstrual dysfunction in physically active females is less common, although females participating in intense physical activity during pre-puberty have been shown to be more likely to commence menarche at a later age, increasing injury risk,[50,51] which can partly be attributed to difficulties in identification, diagnosis, and a lack of awareness of what is normal. The HeRS will raise awareness of these issues, as it contains a comprehensive list of menstrual disturbances and their definitions, which may help the respondents to identify a potential issue and encourage them to present for further investigation. It may also capture existing menstrual conditions, thus allowing for quantification of the frequency of these issues in physically active populations.

The HeRS is a retrospective tool, spanning the reproductive years, meaning that a limitation of this survey could be an individual's ability to recall enough accurate detail to make each section meaningful. In addition, like all surveys, the HeRS is a self-report measure that relies on truthfulness and candor. Nevertheless, the HeRS fills a gap in the literature by providing an initially validated tool to assess the relationship between menstrual function, age, and physical activity. Moreover, the established external validity increases its generalizability. As such, the HeRS is a legitimate survey, which at a minimum allows for the determination of constructs such as menstrual cessation and associated moderators, athletic participation and performance levels, age, and birth control. Future research could further examine the variables loading onto the fourth principal component (age and menstrual cessation): age when high school began; age when high school completed; number of periods per year; and, period cessation without contraception since the Cronbach's a value was just 0.53 (near chance).

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