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Developing a school-based ovulatory-menstrual health literacy program for adolescent females: protocol for a quasi-experimental mixed method study.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-023582
Article Type:	Protocol
Date Submitted by the Author:	13-Apr-2018
Complete List of Authors:	Roux, Felicity; Curtin University - Perth City Campus, School of Public Health Burns, Sharyn; Curtin University, Western Australian Centre for Health Promotion Research, School of Public Health Chih, Hui; Curtin University - Perth City Campus, School of Public Health Hendriks, Jacqui; Curtin University - Perth City Campus
Keywords:	school-based intervention, health literacy, menstruation, dysmenorrhoea, abnormal uterine bleeding, premenstrual syndrome

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TITLE

Developing a school-based ovulatory-menstrual health literacy program for adolescent females: protocol for a quasi-experimental mixed method study.

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Keywords: school-based intervention; health literacy; menstruation; dysmenorrhoea; abnormal uterine bleeding; premenstrual syndrome

Total Word Count: 3496 words

ABSTRACT**Introduction**

A review of international and Australian school-based resources suggests that teaching of the ovulatory-menstrual (OM) cycle is predominantly couched in biology. A whole person framework that integrates the spiritual, intellectual, social and emotional dimensions with the biological changes of the OM cycle is needed to facilitate adolescent OM health literacy. This study aims to develop and trial an intervention for 13-16-year old adolescent females. Enhancing positive attitudes towards OM health will be coupled with developing skills to monitor and self-report OM health. These skills aim to foster acceptance of the OM cycle as a “vital sign” and facilitate confident communication of common OM disturbances (namely, dysmenorrhoea, abnormal uterine bleeding and premenstrual molimina), which are noted to impact on school and social activities.

Methods and Analysis

Phase One will comprise a Delphi panel of women’s health specialists, public health professionals and curriculum consultants, and focus groups with adolescent females, teachers and school healthcare professionals. This will

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3 inform the development of an intervention to facilitate OM health literacy. The
4 Delphi panel will also inform the development of a valid questionnaire to
5 evaluate OM health literacy, which will be assessed for test-retest reliability.
6 Phase Two will trial the intervention with a convenience sample of 175
7 adolescent females from one single-sex school. The mixed methods evaluation
8 of the intervention will include a pre- and post-intervention questionnaire.
9 One-on-one interviews with teachers and school healthcare professionals will
10 expand understanding of the barriers, enablers and suitability of
11 implementation of the intervention in a school-based setting. Finally, focus
12 groups with purposively selected trial participants will further refine the
13 intervention.
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19 **Ethics and dissemination**

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21 This study's findings will be disseminated through local community seminars,
22 conferences, peer-reviewed articles and media channels where appropriate.
23 The Curtin University Human Research Ethics Committee has approved this
24 study (approval HRE2018-0101).
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28 **ARTICLE SUMMARY**

29 **Strengths and Limitations of this study**

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- 32 ➤ To our knowledge, this will be the first study aimed at the whole person
33 OM health literacy of adolescent females, which aims to raise OM health
34 awareness and confidence to address OM health disturbances.
 - 35 ➤ A consumer-empowered study that engages multiple stakeholders.
 - 36 ➤ The selection of a single-sex school may reduce the intervention's
37 generalisability.
 - 38 ➤ The risk of bias is present as participant recruitment will be restricted to
39 private schools.
 - 40 ➤ Limited funds restrict implementing and evaluating trials in a larger
41 sample of other schools.
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Developing a school-based ovulatory-menstrual health literacy program for adolescent females: protocol for a quasi-experimental mixed method study.

Felicity Roux, Sharyn Burns, Hui Jun Chih, Jacqui Hendriks

INTRODUCTION

The American College of Obstetricians & Gynecologists' Committee for Adolescent Health Care and the American Academy of Pediatrics' Committee on Adolescence have jointly and repeatedly recommended that the ovulatory-menstrual (OM) cycle is to be considered a "vital sign" in assessing overall health.^{1,2} For all young girls, menarche is the culmination of a sustained intricate hormonal interplay which is governed by the hypothalamic-pituitary-ovarian axis.³ As this ongoing cyclical process matures slowly,^{4,5} disturbances can present such as dysmenorrhoea, abnormal uterine bleeding (AUB) and premenstrual syndrome (PMS).⁶

Studies in Australia suggest the prevalence of dysmenorrhoea in adolescent females ranges from 80% to 93%.⁷⁻¹⁰ International studies suggest similar rates of prevalence: 68% in Italy,¹¹ 69% in Nigeria,¹² 73% in Brazil¹³ and 83% in Singapore.¹⁴ Globally, the rates for girls missing school because of dysmenorrhoea range from 12% to 37%.^{7,9,11,13} For women subsequently diagnosed with endometriosis, a recent literature review suggests considerable direct financial costs associated with this chronic disease, ranging from USD 1109 (£682) to USD 12 118 (£6170) per patient per year in Canada and the USA respectively.¹⁵ In Australia, the Government has indicated its intention to create a National Action Plan for Endometriosis to provide support for women facing this medical condition.¹⁶

AUB menstrual disturbance can occur at both ends of reproductive life. Studies suggest prevalence ranges for adolescent females from 21% in Egypt¹⁷ and Brazil,¹³ and 40% in Australia.⁹ The costs of investigating and managing this condition are estimated around AUD 6 million (£2.65 million) per annum.¹⁸

Another common OM disturbance is PMS. A report of global studies posits its prevalence at 51-86%, and comments that severe cases are disabling and can interfere with schooling and relationships.¹⁹ An early study found that a PMS diagnosis was associated with an average annual increase of USD 59 (GBP 30) in direct costs and USD 4333 (GBP 2271) in indirect costs per patient compared with patients without PMS.²⁰

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3 In Australian studies, the prevalence of adolescent females consulting a
4 healthcare professional about their menstrual disturbance ranged from 18% to
5 34%.^{7, 9, 10} Without diagnosis and treatment, cycle disorders worsen over time,
6 as does any underlying pathology.²¹
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9 Adolescent health literacy is an emerging field, and knowledge about it is not
10 as extensive as that of adult health literacy.²² Nutbeam's Health Outcome
11 Model²³ offers a framework to explore adolescent health literacy. It begins by
12 situating health literacy as a key outcome of health education. In this Model,
13 health literacy is realised after sequentially acquiring three core skills:
14 functional skills (such as information searching and comprehension),
15 interactive skills (including personal application of health knowledge,
16 engagement with health caregivers, decision making and self-confidence) and
17 critical skills to appraise information.²³ Coincidentally, the progression from
18 functional to critical health literacy skills aligns with the trajectory of
19 adolescent cognitive and social development.²⁴ Qualitative research in Britain
20 applied the functional and interactive skills of Nutbeam's Model²³ to
21 understand how children make meaning of health information through their
22 own embodied experience.²⁵ One Canadian exploratory study extended the
23 first two core skills of Nutbeam's Model²³ to the final core skill of critical health
24 literacy by using task-oriented measurements of evaluation.²⁶ The three core
25 skills of Nutbeam's Model²³ will be used as a framework in this study to
26 develop and evaluate OM health literacy in adolescents.
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36 As girls grow, develop and begin assuming responsibility for their health, they
37 are still minors: firstly, under the close care of parents and family, and secondly
38 under the wider care of healthcare professionals and teachers. Schools play an
39 important role in developing health literacy because of curriculum
40 requirements around personal development^{27, 28} and the time children spend
41 in education.
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45 However, in Australia, many teachers lack training and confidence to facilitate
46 contemporary relationships and sexuality education (RSE). In primary schools,
47 qualitative studies have observed a tendency of teachers to outsource puberty
48 education^{29, 30} and that less than half of female teachers felt very confident in
49 teaching menstruation.³¹ In primary and secondary schools, a lack of
50 confidence has been noted in teachers to deliver RSE programs.^{32, 33} A
51 synthesis of international qualitative reviews of school-based RSE programs
52 suggests that teachers are best placed to fulfil the needs for continuity and
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meeting key curriculum outcomes. It was noted that some teachers were embarrassed to teaching RSE, which may be linked to their poor training.³⁴ In Australia, RSE training is not mandatory for pre-service teachers, and so not all teachers may have received this training.³⁵ This raises questions about girls developing their OM health literacy.

Furthermore, available educational resources in Australia about OM cycles focus predominantly on ovulation and menstruation as a biological events.³⁶⁻³⁹ The resources contain limited information about ovulation as the governing event of the OM cycle. In some regions of New Zealand, a school-based menstrual health education program on endometriosis (the *me* program) has been delivered annually since 1997.⁴⁰ The *me* program is delivered in one 60-minute session, which is akin to the vaccination model.²⁹ This short time frame is problematic in equipping adolescents with the skills to recognise their own OM cycle patterns because the OM cycle is complex, highly individualised and fluctuates over weeks. Additionally, the *me* program focuses on only one common OM disturbance, and it is predicated on a negative OM experience rather than framing OM health positively. The Australian Rite Journey program⁴¹ was adapted for girls and it could be considered to overcome these drawbacks through its fertility awareness challenge of charting one cycle to identify the individual's unique OM pattern.⁴² No data exist to measure if teachers are equipped to teach OM health, or if this aspect of the program is offered. These programs do not promote the OM cycle as a "vital sign" and its use as a personal health monitor to identify common OM disturbances,^{1,2} or its place within the core skill set of critical health literacy.²³ In addition, there is no evidence of their effect on girls' attitudes to the OM cycle, or measures of their confidence in explaining their OM experiences to healthcare professionals.

METHODS AND ANALYSIS

Research objectives

This study aims to develop and trial an OM health literacy intervention for delivery to female students aged 13-16 years. The study's objectives will be completed in two phases:

Phase One: Development

1. To develop a school-based adolescent OM health literacy intervention after consultation with experts in health and education, and with the

primary (adolescent females) and secondary (teachers and school healthcare professionals) target groups.

2. To develop a valid and reliable questionnaire to measure adolescent OM health literacy.

Phase Two: Intervention Trial

1. To trial the intervention in one single-sex secondary school.
2. To refine the intervention after consultation with the primary and secondary target groups.
3. To provide recommendations regarding the future utility of the intervention.

Research setting

The study will be based in Perth, Western Australia. In Phase One, five schools will be approached to offer female students, teachers and healthcare professionals the opportunity to participate in focus groups. Representation across various sociodemographic backgrounds will be sought based on schools' Index of Community Socio-Educational Advantage values.⁴³ The setting for Phase Two will be one purposively selected school in the Perth metropolitan area. The school will be single-sex to eliminate study burden that a co-educational school may experience. To avoid possible testing effects, schools in Phase One will not be approached for Phase Two.

Phase One: Development

The development phase of the OM health literacy intervention and questionnaire is illustrated in Figure 1:

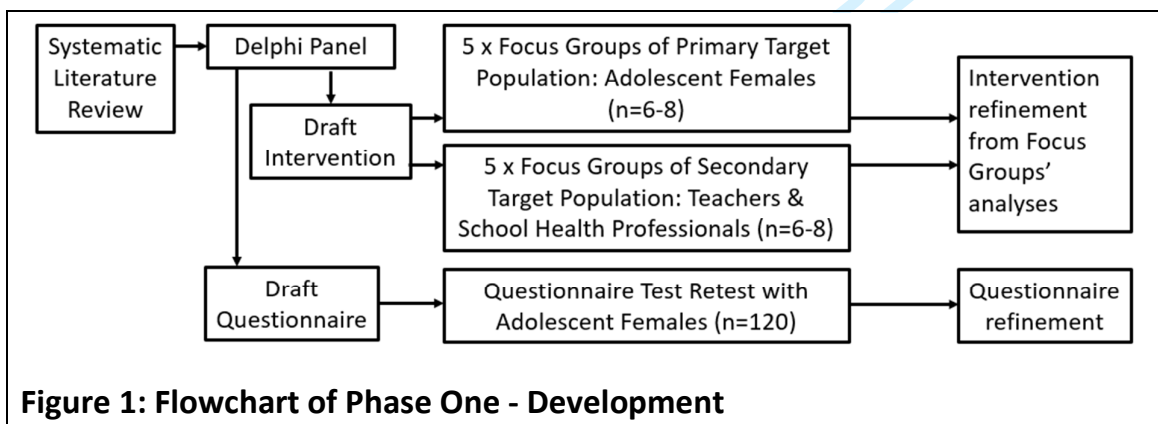


Figure 1: Flowchart of Phase One - Development

A Systematic Literature Review (SLR) of OM health programs for adolescent females

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3 The SLR will include an assessment of previous reviews of OM health programs
4 and primary studies published in English using the PRISMA flow diagram and
5 check list.⁴⁴ The inclusion dates extend from the present back to 1980, which is
6 when a mainstream book that used the Odeblad's findings⁴⁵ to describe OM
7 cycle phases was published.⁴⁶ The key search words will include: [adolescen*
8 OR teen?age*] AND [menstrua* OR menarch*, ovulat* OR fertil* OR
9 reproduc*] AND [educat* OR teach* OR school*] AND [chart* OR record* OR
10 track* OR diary] AND [knowledge OR aware* OR "health literacy"] AND
11 [attitude OR opinion OR "body image" OR confidence]. Initial databases to be
12 used are CINAHL, Informit, Ovid, Proquest, Science Direct, Medline and Web of
13 Science. The SLR aims to identify components that would enhance the
14 opportunity for changes in knowledge, attitude and help-seeking behaviours in
15 adolescent females. Studies which do not demonstrate review from a
16 healthcare professional or are not school-based will be excluded. Each study
17 will be assessed on how it addresses:
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- 25 1. The primary target population (adolescent females age 13-16 years), and
26 consideration of:
 - 27 a. Comprehensiveness (such as coverage of common complaints,
28 evidence of program development by fertility specialists and the
29 guidance for participants to identify personal OM cycle phases);
 - 30 b. Fostering a positive attitude towards the OM cycle (e.g. the
31 Australian Medical Association has suggested a relationship
32 between education and body image);⁴⁷ and
 - 33 c. Fostering an improvement in confidence to communicate with
34 healthcare professionals.
- 35 2. The secondary target population (teachers and school healthcare
36 professionals), and consideration of content and integration within the
37 curricula, ease and comfort of the program delivery, training, efficacy of
38 delivery in school-based settings, dissemination and program evaluation.
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46 **Delphi study**

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48 A Delphi study offers a consensus building method through group
49 communication and feedback from a panel of experts in the field.⁴⁸ For this
50 study's purposes, the classes of experts have been identified⁴⁹ as women's
51 health specialists, public health professionals and curriculum consultants.
52 Delphi studies do not rely upon statistical power, but rather group dynamics
53 for achieving consensus, with the literature suggesting 10-18 experts.⁴⁹ The
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3 panel's first task will be to inform the development of the intervention by
4 collecting their feedback on how the intervention can:
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- 6 1. be mapped to the mandated Health & Physical Education curriculum for
7 Grades 9 and 10 (ages 13-16 years) in Western Australia;²⁷ and
- 8 2. incorporate the whole person framework for the following dimensions
9 of human being: spiritual, physical, intellectual, social and emotional;
10 and
11 and
12
- 13 3. address the needs of:
 - 14 a. the Primary target group (such as materials, and the format,
15 number and length of class sessions, which the literature for
16 school-based menstrual health and well-being promotional
17 interventions has preliminarily indicated);⁵⁰⁻⁵² and
 - 18 b. the Secondary target group (such as material guides and a
19 professional support and development plan).
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24 The Delphi panel's feedback on the intervention's development will be collated
25 as a preliminary draft. In its review, members will be able to suggest items that
26 might not have been initially considered.⁴⁹ Subsequent iterations will identify
27 and rank the most important factors until members achieve 70% consensus on
28 the draft intervention.^{49, 53}
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32 The Delphi panel's second task will be to refine the questionnaire to measure
33 OM health literacy using existing valid and reliable items and scales to test:
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- 35 1. adolescent health literacy^{22, 26, 54-58} and
- 36 2. knowledge, attitudes and experiences of menstruation.⁵⁹⁻⁶³
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39 The Delphi panel will be asked to evaluate how the items and scales meet the
40 study's aims and objectives, and to make alternative contributions. Their
41 feedback will be collated as a preliminary draft questionnaire, which will be
42 reviewed and ranked in an iterative process to identify and rank the items,⁴⁹
43 with consensus achieved at 70%,⁵³ which will provide content validation.⁴⁸
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47 **Focus groups of the Primary Target Population**

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49 Focus groups with adolescent females will be conducted to gain insight on⁶⁴
50 and to elicit priorities for issues⁶⁵ to be included in the intervention. To reduce
51 the possibility of distress, 16-year-old girls will be approached because most
52 will have already attained up to three years of gynaecological age and are
53 more likely to be familiar with the responsibilities and experience of their OM
54 cycles. Personal information will not be solicited, but rather what the
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3 participants believe to be important for adolescent OM health in general. Each
4 of the five socio-demographically diverse schools will be asked to purposively
5 select six to eight 16 year old female students to form one focus group.⁶⁶ A
6 total of 30-40 participants will thus be allocated into five focus groups (n= 6 to
7 8 per group).
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9

10 **Focus groups of the Secondary Target Population**

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12 Teachers from health, physical education, science and religious studies and
13 school healthcare professionals (such as nurses, psychologists and counsellors)
14 are the most likely group to implement the intervention in Phase Two and
15 beyond.⁶⁷ They may provide insight⁶⁵ into mapping the intervention to the
16 curriculum and its practical facilitation in class. The purpose is to gain an
17 understanding of the issues surrounding the program's content, delivery,
18 training and future continuation. Each of the five socio-demographically
19 diverse schools will be asked to purposively select 6 to 8 of their teachers and
20 healthcare professionals to form one focus group. In total, 30-40 participants
21 will be allocated into five focus groups (n= 6 to 8 per group).
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28 Additional focus groups in either population may be recruited to saturation,
29 which is consistent with qualitative research.⁶⁸ The focus groups will be
30 facilitated by the research team using a semi-structured interview guide, and
31 conducted at a suitably quiet location at each school.
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34 **Qualitative data analysis**

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36 Focus groups' data will be digitally recorded and transcribed verbatim. To
37 maintain dependability and determine credibility, the data will be reviewed by
38 three researchers, two of whom have extensive experience in this field.^{69, 70}
39 Data will be coded using NVivo V.10 software. A constant comparison analysis
40 will allow for the thematic discovery⁷¹ that is necessary to finalise the
41 intervention's development. The 32-item Consolidated criteria for reporting
42 qualitative studies (COREQ-32)⁷² will be used to report on the conduct,
43 method, context, findings, analysis and interpretations of the qualitative
44 studies. The key findings based on the SLR, Delphi Panel and COREQ-32 will
45 inform the refinement of the intervention in preparation for its trial.
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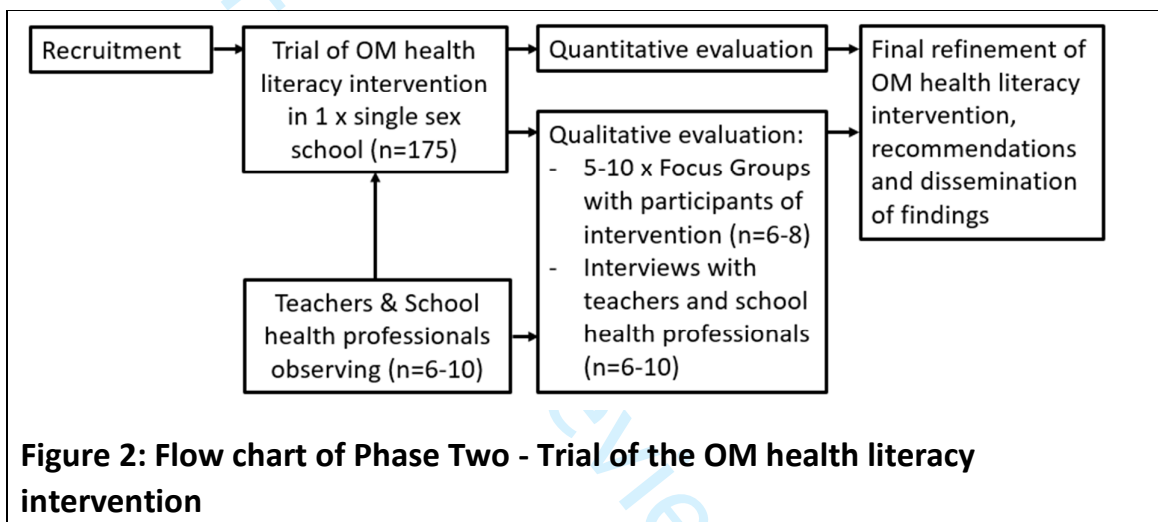
51 **Questionnaire Test-retest**

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53 A group of at least 120 adolescent females^{50, 73, 74} will be recruited from one
54 school to assess test-retest reliability of the questionnaire over a fortnight.⁷⁵ To
55 thank them for their time, the participants will be invited to enter a draw for a
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AUD 30 gift voucher at each sitting. Questionnaires will be administered online through Qualtrics™. Participants will enter their responses in real time from either personal or school supplied devices. The test-retest reliability will be deemed acceptable at Cronbach's alpha value of >0.7 .⁷⁶ The research team will use the findings of the test-retest process to refine the questionnaire for use in Phase Two.

Phase Two: Trial

The trial and evaluation of the OM health literacy intervention is shown in Figure 2:



One single sex school in Perth WA will be purposively selected. The trial will run within a complete school year to reduce the risk of participant loss. Both primary and secondary target populations will be recruited from the same school:

1. The primary target population will be adolescent females aged 13-16 years. This age range falls in Grade 9, at which the intervention is targeted and which also provides the likeliest opportunity to recruit given curriculum time restrictions in more senior years. All Grade 9 girls will be invited. The intervention will be provided at the school's convenience and delivered by the student researcher.
2. The secondary target population will be teachers in health, physical education, science and religious studies, as well as the school's healthcare professionals which may include the school nurses, psychologists and counsellors. These staff will be invited through convenience sampling to observe the delivery of the intervention.

Quantitative evaluation by adolescent participants

Using the questionnaire developed in Phase One, the OM health literacy scores of the 13-16-year-old adolescent females will be recorded at baseline and immediate post intervention. To detect a medium-sized difference of 4 points between the baseline score and the immediate post intervention score at 5% significance and 80% power, a sample size of at least $n=105$ is required. With a 60% retention at post measurement,⁵¹ a total of at least 175 adolescent females will be recruited.

It is expected that the OM health literacy scores will comprise of four key aspects:

1. OM health knowledge;
2. OM health attitudes;
3. self-perceived confidence to communicate OM cycle health; and
4. ability to recognise OM cycle phases.

The scores will be assessed for normality. If normally distributed, the descriptive statistics of the OM health literacy scores will be reported in mean and standard deviation. Paired t tests will be used to compare the difference between baseline and immediate post intervention. If the data are not normally distributed, descriptive statistics will be reported in median and interquartile range and transformed or analysed using Wilcoxon signed-rank test. Statistical significance will be achieved at 0.05. Data will be analysed using STATA version 14 (StataCorp LP).

Qualitative evaluation with intervention participants

All Grade 9 intervention participants age 13-16 years will be invited to qualitatively evaluate the study. A semi-structured interview guide will be used to:

1. explore understanding of OM health;
2. explore common attitudes towards OM health;
3. identify generic experiences of OM cycle charting; and
4. generate feedback on the course content and its structure.

Approximately three focus groups ($n=6-8$ per group) will be conducted in a quiet location at the school's convenience. Additional focus groups may be recruited to saturation. This operates concurrently with sampling, data collection, coding, data comparison and analysis to allow theory to emerge.⁷⁷

Qualitative evaluation with teachers and school healthcare professionals

The teachers and school healthcare professionals who observed the intervention's trial will be invited to participate in a one-on-one semi-structured interview. The interview guide will discuss opinions on:

1. the appropriateness of the program for the primary target group;
2. elements of the trial that were successful and those which need modification; and
3. items required to address the efficacy of implementation in schools (such as resources to implement the program, how to equip teachers and healthcare professionals to deliver the program, and how well it maps to the curriculum).

Qualitative data analysis

Whilst conducting the student focus groups and school staff interviews, new threads of interest may arise. The discussion guides may be modified for subsequent focus groups and interviews.⁷⁸ This allows for questions to be modified as part of the understanding process.⁷⁹ The focus groups and interviews will be conducted to saturation, which will be determined when no new concepts surface from repeated data review.⁷⁷

The qualitative data generated from the focus groups and interviews will be recorded and transcribed verbatim. Data will be coded with NVivo, then discussed and reviewed by the research team. Using a grounded theory approach,⁸⁰ the data will be analysed by constant comparison, whereby data is continually sorted and the information is coded into commonly occurring key themes.⁷⁹ After final coding, the data will be thematically analysed to include the perspectives that emerged and allow for an inductive development of theory.⁷¹ This process is consistent with other qualitative based studies.^{78, 81} COREQ-32 will be used to report the conduct, method, context, findings, analysis and interpretations of the qualitative studies.⁷²

Using a mixed-method approach gives depth and breadth to findings using the above qualitative and quantitative instruments. A triangulation of data sources cross-check to inform the refinement of the intervention. Cost analysis will feature in the final stage of refining the intervention.

ETHICS & DISSEMINATION

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3 Ethics approval has been obtained from Curtin University (HRE2018-0101).
4 Additional ethics approval will be sought at key milestones as stipulated by
5 HREC. Prior to participation in the study, informed written consent will be
6 obtained from parents or guardians and student participants. Each participant
7 will be informed of the voluntary nature of the study, their right to withdraw at
8 any time without prejudice and maintenance of anonymity. Confidentiality
9 procedures will include delinked data collection, direct computer entry of de-
10 identified data, and encrypted data storage on secure computers. Focus groups
11 and interviews will be held in familiar environments whilst mindful of the
12 participants' privacy and safety.
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18 The questionnaire will be administered according to a standard protocol that
19 includes eligibility checks, confidentiality, ethical consent and administering
20 incentives. Communication with participants will be age-appropriate.
21 Information about suitable support services will be given to all participants and
22 referral to a school healthcare professional will be made available for the
23 participants if they become distressed by the focus groups, questionnaire test-
24 retest or participation in the intervention.
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28 The dissemination of results will include:
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- 30 1. a de-identified report of the study findings will be given to participating
31 schools for dissemination to their staff and families for having
32 generously participated;
33
- 34 2. dissemination of the study's findings to healthcare professionals,
35 educationalists and academics through local community, health and
36 education conferences and international peer-reviewed journals;
37
- 38 3. presentations at school-based professional development workshops and
39 community-based seminars including web-based setting, where
40 appropriate, to encourage the integration of the study's findings into
41 public health and education policies; and
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- 43 4. dissemination of the study's questionnaire for use by researchers
44 developing interventions for adolescent reproductive health literacy,
45 and by teachers delivering puberty programs as part of sexuality and
46 relationship education in accordance with curricula requirements.
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51 REFERENCES

52

- 53 1. American Academy of Pediatrics Committee on Adolescence and American College of
54 Obstetricians and Gynecologists Committee on Adolescent Health Care. Menstruation in girls and
55 adolescents: Using the menstrual cycle as a vital sign. *Pediatrics*. 2006; 118(5):2245-2250.
56 DOI:10.1542/peds.2006-2481.
57

2. American College of Obstetricians and Gynecologists Committee Opinion No. 651: Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign. *Obstetrics & Gynecology*. 2015; 126(6):e143-e146. DOI:10.1097/AOG.0000000000001215.
3. Marshall WA, Tanner JM. Variations in pattern of pubertal changes in girls. *Archives of Disease in Childhood*. 1969; 44(235):291. DOI:10.1136/adc.44.235.291.
4. Quint EH, Smith YR. Abnormal uterine bleeding in adolescents. *Journal of Midwifery & Women's Health*. 2003; 48(3):186-191. DOI:10.1016/S1526-9523(03)00061-8.
5. Hillard PA. Menstruation in Adolescents. *Annals of the New York Academy of Sciences*. 2008; 1135(1):29-35. DOI:10.1196/annals.1429.022.
6. Jamieson MA. Disorders of Menstruation in Adolescent Girls. *Pediatric Clinics of North America*. 2015; 62(4) DOI:10.1016/j.pcl.2015.04.007.
7. Hillen T, Grbavac S, Johnston P, Straton J, Keogh J. Primary dysmenorrhea in young Western Australian women: prevalence, impact and knowledge of treatment. *Journal of Adolescent Health*. 1999; 25(1):40-45. DOI:10.1016/S1054-139X(98)00147-5.
8. Pitts MK, Ferris JA, Smith AMA, Shelley JM, Richters J. Prevalence and correlates of three types of pelvic pain in a nationally representative sample of Australian women. *Medical Journal of Australia*. 2008; 189(3):138.
9. Parker M, Sneddon A, Arbon P. The menstrual disorder of teenagers (MDOT) study: determining typical menstrual patterns and menstrual disturbance in a large population-based study of Australian teenagers. *BJOG*. 2010; 117(2):185-192. DOI:10.1111/j.1471-0528.2009.02407.x.
10. Subasinghe AK, Happo L, Jayasinghe YL, Garland SM, Wark JD. Prevalence and severity of dysmenorrhoea, and management options reported by young Australian women. *Australian Family Physician*. 2016; 45(11):829-834.
11. Zannoni L, Giorgi M, Spagnolo E, Montanari G, Villa G, Seracchioli R. Dysmenorrhea, Absenteeism from School, and Symptoms Suspicious for Endometriosis in Adolescents. *Journal of Pediatric and Adolescent Gynecology*. 2014; 27(5):258-265. DOI:10.1016/j.jpag.2013.11.008.
12. Nwankwo TO, Aniebue UU, Aniebue PN. Menstrual Disorders in Adolescent School Girls in Enugu, Nigeria. *Journal of Pediatric and Adolescent Gynecology*. 2010; 23(6):358-363. DOI:10.1016/j.jpag.2010.04.001.
13. Pitangui AC, Gomes M, Lima A, Schwingel P, Albuquerque A, Cappato de Araujo R. Menstruation Disturbances: Prevalence, Characteristics, and Effects on the Activities of Daily Living among Adolescent Girls from Brazil. *Journal of Pediatric and Adolescent Gynecology*. 2013; 26:148-152. DOI:10.1016/j.jpag.2010.04.001.
14. Agarwal A, Venkat A. Questionnaire Study on Menstrual Disorders in Adolescent Girls in Singapore. *Journal of Pediatric and Adolescent Gynecology*. 2009; 22:365-371. DOI:10.1016/j.jpag.2009.02.005.
15. Soliman AM, Yang H, Du EX, Kelley C, Winkel C. The direct and indirect costs associated with endometriosis: a systematic literature review. *Human Reproduction*. 2016; 31(4):712-722. DOI:10.1093/humrep/dev335.
16. Commonwealth of Australia. National Action Plan on Endometriosis, 2017. Canberra Australia: Minister for Health; <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt130.htm> Accessed 2018 04 12
17. Nooh AM, Abdul-Hady A, El-Attar N. Nature and prevalence of menstrual disorders among teenage female students at Zagazig University, Zagazig, Egypt. *Journal of Pediatric and Adolescent Gynecology*. 2015; DOI:10.1016/j.jpag.2015.08.008.
18. Hickey M, Karthigasu K, Agarwal S. Abnormal Uterine Bleeding: a Focus on Polycystic Ovary Syndrome. *Women's Health*. 2009; 5(3):313-324. DOI:10.2217/WHE.09.20.
19. Rapkin A, Mikacich J. Premenstrual Dysphoric Disorder and Severe Premenstrual Syndrome in Adolescents. *Pediatric Drugs*. 2013; 15(3):191-202. DOI:10.1007/s40272-013-0018-4.

- 1
2
3 20. Borenstein EJ, Dean BB, Yonkers AK, Endicott AJ. Using the Daily Record of Severity of Problems
4 as a Screening Instrument for Premenstrual Syndrome. *Obstetrics & Gynecology*. 2007; 109(5):1068-
5 1075. DOI:10.1097/01.AOG.0000259920.73000.3b.
- 6 21. Vigil P, Ceric F, Cortés ME, Klaus H. Usefulness of Monitoring Fertility from Menarche. *Journal of*
7 *Pediatric and Adolescent Gynecology*. 2006; 19(3):173-179. DOI:10.1016/j.jpog.2006.02.003.
- 8 22. Manganello JA, Devellis RF, Davis TC, Schottler-Thal C. Development of the Health Literacy
9 Assessment Scale for Adolescents (HAS-A). *Journal of Communication in Healthcare*. 2015; 8(3):172-
10 184. DOI:10.1179/1753807615Y.0000000016.
- 11 23. Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health
12 education and communication strategies into the 21st century. *Health Promotion International*.
13 2000; 15(3):259-267.
- 14 24. Sansom-Daly U, Lin M, Robertson E, Wakefield CE, McGill B, Girgis A, et al. *Journal of Adolescent*
15 *Young Adult Oncology*. Health Literacy in Adolescents and Young Adults: An Updated Review, 2016;
16 5:106-118. DOI:10.1089/jayao.2015.0059.
- 17 25. Fairbrother H, Curtis P, Goyder E. Making health information meaningful: Children's health
18 literacy practices. *SSM - Population Health*. 2016; 2:476-484. DOI:10.1016/j.ssmph.2016.06.005.
- 19 26. Wu AD, Begoray DL, Macdonald M, Wharf Higgins J, Frankish J, Kwan B, et al. Developing and
20 evaluating a relevant and feasible instrument for measuring health literacy of Canadian high school
21 students. *Health Promotion International*. 2010; 25(4):444. DOI:10.1093/heapro/daq032.
- 22 27. School Curriculum and Standards Authority. Health and Physical Education Curriculum Pre-
23 Primary to Year 10 2017. Government of Western Australia;
24 [https://k10outline.scsa.wa.edu.au/home/p-10-curriculum/curriculum-browser/health-and-physical-](https://k10outline.scsa.wa.edu.au/home/p-10-curriculum/curriculum-browser/health-and-physical-education)
25 [education](https://k10outline.scsa.wa.edu.au/home/p-10-curriculum/curriculum-browser/health-and-physical-education) Accessed 2018 04 12
- 26 28. Family Planning Alliance Australia. Position Statement: Relationship and Sexuality Education in
27 Schools, 2016. http://familyplanningallianceaustralia.org.au/wp-content/uploads/2017/04/FPAASchools-Education_Position-Statement_001_v2c.pdf Accessed 2018 04 12
- 28 29. Goldman JDG. External Providers' Sexuality Education Teaching and Pedagogies for Primary
29 School Students in Grade 1 to Grade 7. *Sex Education*. 2011; 11(2):155-174.
30 DOI:10.1080/14681811.2011.558423.
- 31 30. Johnson RL, Sendall MC, McCuaig LA. Primary schools and the delivery of relationships and
32 sexuality education: the experience of Queensland teachers. *Sex Education*. 2014; 14(4):359-374.
33 DOI:10.1080/14681811.2014.909351.
- 34 31. Duffy B, Fotinatos N, Smith A, Burke J. Puberty, health and sexual education in Australian
35 regional primary schools: Year 5 and 6 teacher perceptions. *Sexuality, Society and Learning*. 2012:1-
36 18. DOI:10.1080/14681811.2012.678324.
- 37 32. Smith A, Schlichthorst M, Mitchell A, Walsh J, Lyons A, Blackman P, et al. Sexuality Education in
38 Australian Secondary Schools 2010: Results of the 1st National Survey of Australian Secondary
39 Teachers of Sexuality Education. Australian Research Centre in Sex Health and Society (La Trobe
40 University). 2011. DOI:10.4225/50/557E5B09832EB.
- 41 33. Burns S, Hendriks J. Sexuality and relationship education training to primary and secondary
42 school teachers: an evaluation of provision in Western Australia. *Sex Education*. 2018; Accepted
- 43 34. Pound P, Langford R, Campbell R. What do young people think about their school-based sex and
44 relationship education? A qualitative synthesis of young people's views and experiences. *BMJ Open*.
45 2016; 6(9) DOI:10.1136/bmjopen-2016-011329.
- 46 35. Carman M, Mitchell A, Schlichthorst M, Smith A. Teacher training in sexuality education in
47 Australia: how well are teachers prepared for the job? *Sexual Health*. 2011; 8(3):269-271.
48 DOI:10.1071/SH10126.
- 49 36. New South Wales Education. The Menstrual Cycle. Sydney, NSW Australia: Intel Corporation;
50 2013.
- 51 37. Walsh J. Talk soon. Talk often: A guide for parents talking to their kids about sex. Victoria:
52 Australian Research Centre in Sex Health & Society, La Trobe University; 2011.
- 53
54
55
56
57
58
59
60

- 1
2
3 38. Department of Health. Puberty: Menstrual Cycle. 2016. Government of Western Australia.
4 39. Department of Health. Puberty – things that change for girls. Government of Western Australia.
5 http://www.healthywa.wa.gov.au/Articles/N_R/Puberty-things-that-change-for-girls Accessed 2018
6 04 12
7 40. Bush D, Brick E, East MC, Johnson N. Endometriosis education in schools: A New Zealand model
8 examining the impact of an education program in schools on early recognition of symptoms
9 suggesting endometriosis. *Australian and New Zealand Journal of Obstetrics and Gynaecology*. 2017;
10 57(4):452-457. DOI:10.1111/ajo.12614.
11 41. Lines A, Gallasch G. *The Rite Journey: Rediscovering Rites of Passage for Boys*. Thymos. 2009;
12 3(1):74-89. DOI:10.3149/thy.0301.74.
13 42. Lines A, Gallasch G, Hobbs A, Bennett J. *The Rite Journey for girls: A Rite of Passage programme*
14 *for adolescents*. Adelaide, Australia: Authenticity; 2011.
15 43. Australian Curriculum Assessment and Reporting Authority. *Guide to understanding 2013 Index*
16 *of Community Socio-educational Advantage (ICSEA) values, 2013*. www.myschool.edu.au Accessed
17 2018 04 12
18 44. Moher D, Liberati A, Tetzlaff J, Altman DG. The PRISMA Group. Preferred Reporting Items for
19 Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Medicine*. 2009;
20 6(7):e1000097. DOI:10.1371/journal.pmed.1000097.
21 45. Odeblad E. The functional structure of human cervical mucus. *Acta obstetrica et gynecologica*
22 *Scandinavica*. 1968; 47:57.
23 46. Billings E, Westmore A. *The Billings method : controlling fertility without drugs or devices*.
24 Richmond, Vic.: Richmond, Vic. : Anne O'Donovan; 1980.
25 47. Australian Medical Association. *Position Statement: Health in the context of education, 2014*.
26 www.ama.com.au Accessed 2017 04 07
27 48. Keeney S, Hasson F, McKenna HP. *The Delphi technique in nursing and health research*.
28 Chichester, West Sussex: Chichester, West Sussex : Wiley-Blackwell; 2011.
29 49. Okoli C, Pawlowski SD. The Delphi method as a research tool: an example, design considerations
30 and applications. *Information & Management*. 2004; 42(1):15-29. DOI:10.1016/j.im.2003.11.002.
31 50. Fakhri M, Hamzehgardeshi Z, Hajikhani Golchin N, Komili A. Promoting menstrual health among
32 persian adolescent girls from low socioeconomic backgrounds: a quasi-experimental study. *BMC*
33 *Public Health*. 2012; 12:193. DOI:10.1186/1471-2458-12-193.
34 51. Su JJ, Lindell D. Promoting the menstrual health of adolescent girls in China. *Nursing and Health*
35 *Sciences*. 2016:481–487. DOI:10.1111/nhs.12295.
36 52. Tokolahi E, Hocking C, Kersten P. Development and Content of a School-Based Occupational
37 Therapy Intervention for Promoting Emotional Well-Being in Children. *Occupational Therapy In*
38 *Mental Health*. 2016; 32(3):245-258. DOI:10.1080/0164212X.2015.1129522.
39 53. Humphrey-Murto S, Varpio L, Gonsalves C, Wood TJ. Using consensus group methods such as
40 Delphi and Nominal Group in medical education research *. *Medical Teacher*. 2017; 39(1):14-19.
41 DOI:10.1080/0142159X.2017.1245856.
42 54. Abel T, Hofmann K, Ackermann S, Bucher S, Sakarya S. Health literacy among young adults: a
43 short survey tool for public health and health promotion research. *Health Promotion International*.
44 2015; 30(3):725-735. DOI:10.1093/heapro/dat096.
45 55. Davis TC, Wolf MS, Arnold CL, Byrd RS, Long SW, Springer T, et al. Development and validation of
46 the Rapid Estimate of Adolescent Literacy in Medicine (REALM-Teen): a tool to screen adolescents
47 for below-grade reading in health care settings. *Pediatrics*. 2006; 118(6):e1707. DOI:
48 10.1542/peds.2006-1139.
49 56. McDonald F, Patterson P, Costa D, Shepherd H. Validation of a Health Literacy Measure for
50 Adolescents and Young Adults Diagnosed with Cancer. *Journal of Adolescent and Young Adult*
51 *Oncology*. 2016; 5(1):69-75. DOI:10.1089/jayao.2014.0043.
52
53
54
55
56
57
58
59
60

- 1
2
3 57. Osborne R, Batterham R, Elsworth G, Hawkins M, Buchbinder R. The grounded psychometric
4 development and initial validation of the Health Literacy Questionnaire (HLQ). *BMC Public Health*.
5 2013; 13:658. DOI:10.1186/1471-2458-13-658.
- 6 58. Bradley-Klug K, Shaffer-Hudkins E, Lynn C, Jeffries Deloatche K, Montgomery J. Initial
7 development of the Health Literacy and Resiliency Scale: Youth version. *Journal of Communication in*
8 *Healthcare*. 2017; 10(2):100-107. DOI:10.1080/17538068.2017.1308689.
- 9 59. Aflaq F, Jami H. Experiences and Attitudes Related to Menstruation among Female Students.
10 *Pakistan Journal of Psychological Research*. 2012; 27(2):201-224.
- 11 60. Brooks-Gunn J, Ruble DN. The menstrual attitude questionnaire. *Psychosomatic medicine*. 1980;
12 42(5):503.
- 13 61. Marván ML, Ramírez-Esparza D, Cortés-Iniestra S, Chrisler JC. Development of a new scale to
14 measure Beliefs about and Attitudes Toward Menstruation (BATM): data from Mexico and the
15 United States. *Health care for Women International*. 2006; 27(5):453.
16 DOI:10.1080/07399330600629658
- 17 62. Morse JM, Kieren D, Bottorff J. The adolescent menstrual attitude questionnaire, part I: Scale
18 construction. *Health care for Women International*. 1993; 14(1):39-62.
19 DOI:10.1080/07399339309516025
- 20 63. DeMaria EP, Mikulas WL. Women's Awareness of Their Menstrual Cycle. *International Journal of*
21 *Sexual Health*. 1992; 4(3):71-82. DOI:10.1300/J056v04n03_05.
- 22 64. Byers P, Zeller R, Byers B. Focus group methods. In: Weiderman M, Whitley B, editors. *Handbook*
23 *for conducting research on human sexuality*; 2002. p. 173-193.
- 24 65. Tong A, Sainsbury P, Carter S, Hall B, Harris D, Walker R, et al. Patients' priorities for health
25 research: focus group study of patients with chronic kidney disease. *Nephrology Dialysis*
26 *Transplantation*. 2008; 23:3206-3214. DOI:10.1093/ndt/gfn207.
- 27 66. Greene S, Hogan D. *Researching children's experiences : methods and approaches*. London:
28 London : SAGE; 2005.
- 29 67. McBride N. *Intervention research : a practical guide for developing evidence-based school*
30 *prevention programmes*. Singapore: Springer; 2016.
- 31 68. Glenton C, Carlsen B. What about N? A methodological study of sample-size reporting in focus
32 group studies. *BMC Medical Research Methodology*. 2011; 11(1):26. DOI:10.1186/1471-2288-11-26.
- 33 69. Liamputtong P. *Research methods in health : foundations for evidence-based practice*. Second
34 edition.. ed: South Melbourne, Victoria, Australia : Oxford University Press; 2013.
- 35 70. Liamputtong P. *Qualitative research methods*. 4th ed. Melbourne: Oxford University Press; 2013.
- 36 71. Corbin JM, Strauss AL. *Basics of qualitative research : techniques and procedures for developing*
37 *grounded theory*. 3rd ed.. ed. Thousand Oaks, Calif.: Thousand Oaks, Calif. : Sage Publications, Inc.;
38 2008.
- 39 72. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a
40 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*.
41 2007; 19(6):349-357. DOI: 10.1093/intqhc/mzm042.
- 42 73. Chiou M-H, Wang H-H, Yang Y-H. Effect of Systematic Menstrual Health Education on
43 Dysmenorrheic Female Adolescents' Knowledge, Attitudes, and Self-Care Behavior. *Kaohsiung*
44 *Journal of Medical Sciences*. 2007; 23(4):183-190. DOI:10.1016/S1607-551X(09)70395-X.
- 45 74. Janssen EHC, Singh AS, van Nassau F, Brug J, van Mechelen W, Chinapaw MJM. Test-retest
46 reliability and construct validity of the DOIT (Dutch Obesity Intervention in Teenagers) questionnaire:
47 measuring energy balance-related behaviours in Dutch adolescents. 2014; 17(2):277-286.
48 DOI:10.1017/S1368980012005253.
- 49 75. Flisher AJ, Evans J, Muller M, Lombard C. Brief Report: Test-Retest Reliability of Self-Reported
50 Adolescent Risk Behaviour. *Journal of Adolescence*. 2004; 27(2):207-212.
51 DOI:10.1016/j.adolescence.2001.10.001.
- 52 76. Kiliç S. Cronbach's alpha reliability coefficient. *Journal of Mood Disorders*. 2016; 6(1):47-8.
53 DOI:10.5455/jmood.20160307122823.
- 54
55
56
57
58
59
60

- 1
2
3 77. Bowen G. Naturalistic inquiry and the saturation concept: a research note. *Qualitative Research*. 2008; 8(1):137-152. DOI:10.1177/1468794107085301.
- 4
5 78. Burns S, Cross D, Maycock B. "That Could Be Me Squishing Chips on Someone's Car." How
6 Friends Can Positively Influence Bullying Behaviors. *The Journal of Primary Prevention*. 2010;
7 31(4):209-222. DOI:10.1007/s10935-010-0218-4.
- 8 79. Boeije HR. A purposeful approach to the constant comparative method in the analysis of
9 qualitative interviews. *Quality and Quantity*. 2002; 36:391-5177. DOI: 10.1023/A:1020909529486
- 10 80. Harris T. Grounded theory. *Nursing Standard*. 2015; 29(35):32. DOI:10.7748/ns.29.35.32.e9568.
- 11 81. Burns S, Maycock B, Cross D, Brown G. The Power of Peers: Why Some Students Bully Others to
12 Conform. *Qualitative Health Research*. 2008; 18(12):1704. DOI:10.1177/1049732308325865.
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14 **ACKNOWLEDGEMENTS**

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16 None

17 **AUTHORS' CONTRIBUTIONS**

18
19 This protocol paper describes a supervised doctoral research project. Its results
20 will be used by FR to obtain a Doctor of Philosophy. All authors contributed to
21 development and conceptualisation of the protocol. FR was responsible for
22 drafting and coordinating the authors' contributions. SB, HJC and JH were
23 responsible for editing and guidance on the paper. All authors were
24 responsible for critically revising the paper. All authors approved the final
25 version of this paper.

26 **FUNDING STATEMENT**

27
28 This research project is funded through the Australian Government Research
29 Training Program Scholarship as administered through the doctoral program
30 run at Curtin University's School of Public Health.

31 **COMPETING INTERESTS STATEMENT**

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33 None declared

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BMJ Open

Developing and trialling a school-based ovulatory-menstrual health literacy program for adolescent females: a quasi-experimental mixed method protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-023582.R1
Article Type:	Protocol
Date Submitted by the Author:	24-Nov-2018
Complete List of Authors:	Roux, Felicity; Curtin University - Perth City Campus, School of Public Health Burns, Sharyn; Curtin University, Western Australian Centre for Health Promotion Research, School of Public Health Chih, Hui; Curtin University - Perth City Campus, School of Public Health Hendriks, Jacqueline; Curtin University - Perth City Campus, School of Public Health
Primary Subject Heading:	Public health
Secondary Subject Heading:	Paediatrics, Reproductive medicine, Obstetrics and gynaecology
Keywords:	school-based intervention, health literacy, menstruation, dysmenorrhoea, abnormal uterine bleeding, premenstrual syndrome

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TITLE

Developing and trialling a school-based ovulatory-menstrual health literacy program for adolescent females: a quasi-experimental mixed method protocol.

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Keywords: school-based intervention; health literacy; menstruation; dysmenorrhoea; abnormal uterine bleeding; premenstrual syndrome

Total Word Count: 3916 words

ABSTRACT

Introduction

A review of international and Australian school-based resources suggests that teaching of the ovulatory-menstrual (OM) cycle is predominantly couched in biology. A whole person framework that integrates the spiritual, intellectual, social and emotional dimensions with the physical changes of the OM cycle is needed to facilitate adolescent OM health literacy. This paper describes the protocol for a study that aims to develop and trial an intervention for 13-16-year-old adolescent females which enhances positive attitudes towards OM health coupled with developing skills to monitor and self-report OM health. These skills aim to foster acceptance of the OM cycle as a “vital sign” and facilitate confident communication of common OM disturbances (namely, dysmenorrhoea, abnormal uterine bleeding and premenstrual syndrome), which are noted to impact on school and social activities.

Methods and Analysis

Phase One will comprise a Delphi panel of women’s health specialists, public health professionals and curriculum consultants, and focus groups with adolescent females, teachers and school healthcare professionals. This will inform the development of an intervention to facilitate OM health literacy. The

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Delphi panel will also inform the development of a valid and reliable questionnaire to evaluate OM health literacy. Phase Two will trial the intervention with a convenience sample of at least 175 adolescent females from one single-sex school. The mixed methods evaluation of the intervention will include a pre- and post-intervention questionnaire. One-on-one interviews with teachers and school healthcare professionals will expand understanding of the barriers, enablers and suitability of implementation of the intervention in a school-based setting. Finally, focus groups with purposively selected trial participants will further refine the intervention.

Ethics and dissemination

The study's findings will be disseminated through local community seminars, conferences, peer-review articles and media channels where appropriate. The Curtin University of Human Research Ethics Committee has approved this study (approval HRE2018-0101).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The Delphi panel comprising of experts from multiple disciplines adds rigour to the development of the school-based OM health literacy intervention.
- A consumer-centred study that engages multiple stakeholders.
- The mixed methods approach allows for triangulation of quantitative and qualitative data.
- The risk of bias and limited generalisability are present as participant recruitment in the Phase Two trial will be restricted to a single-sex private school and exclude parental inputs.
- Limited funds restrict implementing and evaluating trials in a larger sample of schools.

Developing and trialling a school-based ovulatory-menstrual health literacy program for adolescent females: a quasi-experimental mixed method protocol.

Felicity Roux, Sharyn Burns, Hui Jun Chih, Jacqui Hendriks

INTRODUCTION

The American College of Obstetricians & Gynecologists' Committee for Adolescent Health Care and the American Academy of Pediatrics' Committee on Adolescence have jointly and repeatedly recommended that the ovulatory-menstrual (OM) cycle is to be considered a "vital sign" in assessing overall health.^{1, 2} For all young girls, menarche is the culmination of a sustained intricate hormonal interplay which is governed by the hypothalamic-pituitary-ovarian axis.³ As this ongoing cyclical process matures slowly,^{4, 5} disturbances can present such as dysmenorrhoea, abnormal uterine bleeding (AUB) and premenstrual syndrome (PMS).⁶

Studies in Australia suggest the prevalence of dysmenorrhoea in adolescent females ranges from 80% to 93%.⁷⁻¹⁰ International studies suggest similar rates of prevalence: 68% in Italy,¹¹ 69% in Nigeria,¹² 73% in Brazil¹³ and 83% in Singapore.¹⁴ Globally, the rates for girls missing school because of dysmenorrhoea range from 12% to 37%.^{7, 9, 11, 13} For women subsequently diagnosed with endometriosis, a recent literature review suggests considerable direct financial costs associated with this chronic disease, ranging from USD 1109 (£682) to USD 12 118 (£6170) per patient per year in Canada and the USA respectively.¹⁵ In Australia, the Government has indicated its intention to create a National Action Plan for Endometriosis to provide support for women facing this medical condition.¹⁶

AUB menstrual disturbance can occur at both ends of reproductive life. Studies suggest prevalence ranges for adolescent females from 21% in Egypt¹⁷ and Brazil,¹³ and 40% in Australia.⁹ The costs of investigating and managing this condition are estimated around AUD 6 million (£2.65 million) per annum.¹⁸

Another common OM disturbance is PMS. A report of global studies posits its prevalence at 51-86%, and comments that severe cases are disabling and can interfere with schooling and relationships.¹⁹ An early study found that a PMS diagnosis was associated with an average annual increase of USD 59 (£30) in direct costs and USD 4333 (£2271) in indirect costs per patient compared with patients without PMS.²⁰

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In Australian studies, the prevalence of adolescent females consulting a healthcare professional about their menstrual disturbance ranged from 18% to 34%.^{7, 9, 10} Without diagnosis and treatment, cycle disorders worsen over time, as does any underlying pathology.²¹

Adolescent health literacy is an emerging field, and knowledge about it is not as extensive as that of adult health literacy.²² Nutbeam's Health Outcome Model²³ offers a framework to explore adolescent health literacy. It begins by situating health literacy as a key outcome of health education. In this Model, health literacy is realised after sequentially acquiring three core skills: functional skills (such as information searching and comprehension), interactive skills (including personal application of health knowledge, engagement with health caregivers, decision making and self-confidence) and critical skills to appraise information.²³ Coincidentally, the progression from functional to critical health literacy skills aligns with the trajectory of adolescent cognitive and social development.²⁴ Qualitative research in Britain applied the functional and interactive skills of Nutbeam's Model²³ to understand how children make meaning of health information through their own embodied experience.²⁵ One Canadian exploratory study extended the first two core skills of Nutbeam's Model²³ to the final core skill of critical health literacy by using task-oriented measurements of evaluation.²⁶ The three core skills of Nutbeam's Model²³ will be used as a framework in this study to develop and evaluate OM health literacy in adolescents.

As girls grow, develop and begin assuming responsibility for their health, they are still minors: firstly, under the close care of parents and family, and secondly under the wider care of healthcare professionals and teachers. Schools play an important role in developing health literacy because of curriculum requirements around personal development^{27, 28} and the time children spend in education.

However, in Australia, many teachers lack training and confidence to facilitate contemporary relationships and sexuality education (RSE). In primary schools, qualitative studies have observed a tendency of teachers to outsource puberty education^{29, 30} and that less than half of female teachers felt very confident in teaching menstruation.³¹ In primary and secondary schools, a lack of confidence has been noted in teachers to deliver RSE programs.^{32, 33} A synthesis of international qualitative reviews of school-based RSE programs suggests that teachers are best placed to fulfil the needs for continuity and

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3 meeting key curriculum outcomes. It was noted that some teachers were
4 embarrassed teaching RSE, which may be linked to their poor training.³⁴ In
5 Australia, RSE training is not mandatory for pre-service teachers, and so not all
6 teachers may have received this training.³⁵ This could negatively impact on
7 supporting girls to develop their OM health literacy.
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11 Furthermore, available educational resources in Australia about OM cycles
12 focus predominantly on ovulation and menstruation as biological events.³⁶⁻³⁹
13 The resources contain limited information about ovulation as the governing
14 event of the OM cycle. In some regions of New Zealand, a school-based
15 menstrual health education program on endometriosis (the *me* program) has
16 been delivered annually since 1997.⁴⁰ The *me* program is delivered in one 60-
17 minute session, which is akin to the vaccination model.²⁹ This short time frame
18 is problematic in equipping adolescents with the skills to recognise their own
19 OM cycle patterns because the OM cycle is complex, highly individualised and
20 fluctuates over weeks. Additionally, the *me* program focuses on only one
21 common OM disturbance, and it is predicated on a negative OM experience
22 rather than framing OM health positively. The Australian Rite Journey
23 program⁴¹ was adapted for girls and it could be considered to overcome these
24 drawbacks through its fertility awareness challenge of charting one cycle to
25 identify the individual's unique OM pattern.⁴² No data exist to measure if
26 teachers are equipped to teach OM health, or if this aspect of the program is
27 offered. These programs do not promote the OM cycle as a "vital sign" and its
28 use as a personal health monitor to identify common OM disturbances,^{1, 2} or its
29 place within the core skill set of critical health literacy.²³ In addition, there is no
30 evidence of their effect on girls' attitudes to the OM cycle, or measures of their
31 confidence in explaining their OM experiences to healthcare professionals.
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44 **METHODS AND ANALYSIS**

45 **Research objectives**

46
47 This study aims to develop and trial an OM health literacy intervention for
48 delivery to female students aged 13-16 years. The study's objectives will be
49 completed in two phases:
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53 **Phase One: Development**

- 54
55 1. To develop a school-based adolescent OM health literacy intervention
56 after consultation with experts in health and education, and with the
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3 primary (adolescent females) and secondary (teachers and school
4 healthcare professionals) target groups.

- 5
6 2. To develop a valid and reliable questionnaire to measure adolescent OM
7 health literacy.
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10 Phase Two: Intervention Trial

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12 1. To trial the intervention in one single-sex secondary school.
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14 2. To refine the intervention after consultation with the primary and
15 secondary target groups.
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17 3. To provide recommendations regarding the future utility of the
18 intervention.
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20 **Patient and Public Involvement**

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22 The students, teachers and school healthcare professionals who will be invited
23 to participate in this study were not involved in the development of the
24 research question, study design or the outcome measures. The schools
25 involved in this study will be provided a summary of the research findings. The
26 results will also be published in peer-review journals.
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30 **Research setting**

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32 The study will be based in Perth, Western Australia. In Phase One, five schools
33 will be invited to offer female students, teachers and school healthcare
34 professionals the opportunity to participate in focus groups. Both private and
35 public schools will be approached. Representation across various
36 sociodemographic backgrounds will be sought based on schools' Index of
37 Community Socio-Educational Advantage values.⁴³ The setting for Phase Two
38 will be one purposively selected single-sex school in the Perth metropolitan
39 area. Only private schools will be approached in this phase because there are
40 no single-sex public schools in Perth. The school will be single-sex rather than
41 co-educational of mixed sexes in order to eliminate any study burden of
42 occupying male students. Subsequent studies may explore the efficacy of this
43 intervention in a co-educational setting. To avoid possible testing effects,
44 schools in Phase One will not be approached for Phase Two.
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54 **Phase One: Development**

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56 The development phase of the OM health literacy intervention and
57 questionnaire is illustrated in Figure 1:
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A Systematic Literature Review (SLR) of OM health programs for adolescent females

The SLR will include an assessment of previous reviews of OM health programs and primary studies published in English using the PRISMA flow diagram and check list.⁴⁴ The inclusion dates extend from the present back to 1980, which is when a mainstream book that used Odeblad's findings⁴⁵ to describe OM cycle phases was published.⁴⁶ The key search words will include: [adolescen* OR teen?age*] AND [menstrua* OR menarch*, ovulat* OR fertil* OR reproduc*] AND [educat* OR teach* OR school*] AND [chart* OR record* OR track* OR diary] AND [knowledge OR aware* OR "health literacy"] AND [attitude OR opinion OR "body image" OR confidence]. Initial databases to be used are CINAHL, Informit, Ovid, Proquest, Science Direct, Medline and Web of Science. The SLR aims to identify components that would enhance the opportunity for changes in knowledge, attitude and help-seeking behaviours in adolescent females. Studies which do not demonstrate review from a healthcare professional or are not school-based will be excluded. Each study will be assessed on how it addresses:

1. The primary target population (adolescent females aged 13-16 years), and consideration of:
 - a. Comprehensiveness (such as coverage of common complaints, evidence of program development by fertility specialists and the guidance for participants to identify personal OM cycle phases);
 - b. Fostering a positive attitude towards the OM cycle (e.g. the Australian Medical Association has suggested a relationship between education and body image);⁴⁷ and
 - c. Fostering an improvement in confidence to communicate with healthcare professionals.
2. The secondary target population (teachers and school healthcare professionals), and consideration of content and integration within the curricula, ease and comfort of the program delivery, training, efficacy of delivery in school-based settings, dissemination and program evaluation.

The expected outcome from conducting the SLR is that it will inform the draft development of the intervention which will then be submitted to the Delphi panel for further development.

Delphi study

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A Delphi study offers a consensus building method through group communication and feedback from a panel of experts in the field.⁴⁸ For this study's purposes, the classes of experts have been identified⁴⁹ as women's health specialists, public health professionals and curriculum consultants. Delphi studies do not rely upon statistical power, but rather group dynamics for achieving consensus, with the literature suggesting 10-18 experts.⁴⁹ The panel's first task will be to inform the development of the intervention by collecting their feedback on how the intervention can:

- 15 1. be mapped to the mandated Health & Physical Education curriculum for
16 Grades 9 and 10 (ages 13-16 years) in Western Australia;²⁷ and
- 17 2. incorporate the whole person framework for the following dimensions
18 of human being: spiritual, physical, intellectual, social and emotional;
19 and
20 21
22
- 23 3. address the needs of:
 - 24 a. the Primary target group (such as materials, and the format,
25 number and length of class sessions, which the literature for
26 school-based menstrual health and well-being promotional
27 interventions has preliminarily indicated);⁵⁰⁻⁵² and
 - 28 b. the Secondary target group (such as material guides and a
29 professional support and development plan).

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The Delphi panel's feedback on the intervention's development will be collated as a preliminary draft. In its review, members will be able to suggest items that might not have been initially considered.⁴⁹ Subsequent iterations will identify and rank the most important factors until members achieve 70% consensus on the draft intervention.^{49, 53}

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The Delphi panel's second task will be to refine the questionnaire to measure OM health literacy using existing valid and reliable items and scales to test:

1. adolescent health literacy^{22, 26, 54-58} and
2. knowledge, attitudes and experiences of menstruation.⁵⁹⁻⁶³

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The Delphi panel will be asked to evaluate how the items and scales meet the study's aims and objectives, and to make alternative contributions. Their feedback will be collated as a preliminary draft questionnaire, which will be reviewed and ranked in an iterative process to identify and rank the items,⁴⁹ with consensus achieved at 70%,⁵³ which will provide content validation.⁴⁸

Focus groups of the Primary Target Population

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3 Focus groups with adolescent females will be conducted to gain insight on⁶⁴
4 and to elicit priorities for issues⁶⁵ to be included in the intervention. To reduce
5 the possibility of distress, 16-year-old girls will be approached because most
6 will have already been menstruating for up to three years and are more likely
7 to be familiar with the responsibilities and experience of their OM cycles.
8 Personal information will not be solicited, but rather what the participants
9 believe to be important for adolescent OM health in general. This creates the
10 opportunity to explore socio-ecological influences⁶⁶ that may shape an
11 adolescent's approach to OM self-management. Exploration of girls' parents or
12 guardians as enablers or barriers to OM health literacy lies however outside
13 the scope of this study. Each of the five socio-demographically diverse schools
14 will be asked to purposively select six to eight 16-year-old female students to
15 form one focus group.⁶⁷ A total of thirty to forty participants will thus be
16 allocated into five focus groups (n=6-8 per group).

25 **Focus groups of the Secondary Target Population**

26
27 Teachers from health, physical education, science and religious studies and
28 school healthcare professionals (such as nurses, psychologists and counsellors)
29 are the most likely group to implement the intervention in Phase Two and
30 beyond.⁶⁸ They may provide insight⁶⁵ into mapping the intervention to the
31 curriculum and its practical facilitation in class. The purpose is to gain an
32 understanding of the issues surrounding the program's content, delivery,
33 training and future continuation. Each of the five socio-demographically
34 diverse schools will be asked to purposively select six to eight of their teachers
35 and school healthcare professionals to form one focus group. In total, thirty to
36 forty participants will be allocated into five focus groups (n=6-8 per group).

37
38 Additional focus groups in either population may be recruited to saturation,
39 which is consistent with qualitative research.⁶⁹ The focus groups will be
40 facilitated by the research team using a semi-structured interview guide, and
41 conducted at a suitably quiet location at each school.

50 **Qualitative data analysis**

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52 Focus groups' data will be digitally recorded and transcribed verbatim. To
53 maintain dependability and determine credibility, the data will be reviewed by
54 three researchers, two of whom have extensive experience in this field.^{70, 71}
55 Data will be coded using NVivo V.10 software. A constant comparison analysis
56 will allow for the thematic discovery⁷² that is necessary to finalise the
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3 intervention's development. The 32-item Consolidated criteria for reporting
4 qualitative studies (COREQ-32)⁷³ will be used to report on the conduct,
5 method, context, findings, analysis and interpretations of the qualitative
6 studies. The key findings based on the SLR, Delphi Panel and COREQ-32 will
7 inform the refinement of the intervention in preparation for its trial. The
8 expected outcomes are improvements in the intervention's feasibility and
9 acceptability for its delivery in Phase Two.
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14 **Questionnaire Test-retest**

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16 A group of at least 120 adolescent females^{50, 74, 75} will be recruited from one
17 school to assess test-retest reliability of the questionnaire over a fortnight.⁷⁶ To
18 thank them for their time, the participants will be invited to enter a draw for a
19 AUD 30 gift voucher at each sitting. Questionnaires will be administered online
20 through Qualtrics™. Participants will enter their responses in real time from
21 either personal or school supplied devices. The test-retest reliability will be
22 deemed acceptable at Cronbach's alpha value of >0.7.⁷⁷ The research team will
23 use the findings of the test-retest process to refine the questionnaire for use in
24 Phase Two. The expected outcome is established validity and reliability for the
25 questionnaire to be administered in Phase Two.
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32 **Phase Two: Trial**

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34 The trial and evaluation of the OM health literacy intervention is shown in
35 Figure 2:
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38 One single-sex private school in Perth WA will be purposively selected. The trial
39 will be offered in-class at the school's convenience. Whilst the intervention will
40 be mapped to the Australian curriculum for Health & Physical Education,²⁷ the
41 school's preference for its delivery in other classes will be observed. For the
42 purpose of the trial, the intervention will be delivered by the first author who
43 has expertise in the facilitation of RSE programs to 13-16-year-old students. It
44 is anticipated that the trial will run for six to eight weekly sessions during one
45 school term, which reduces the risk of participant loss. Both primary and
46 secondary target populations will be recruited from the same school:
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- 52 1. The primary target population will be adolescent females aged 13-16
53 years. This age range falls in Grade 9, at which the intervention is
54 targeted and which also provides the likeliest opportunity to recruit
55 given curriculum time restrictions in more senior years. All Grade 9 girls
56 will be invited.
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- 2.
2. The secondary target population will be teachers in health, physical education, science and religious studies, as well as the school's healthcare professionals which may include the school nurses, psychologists and counsellors. These staff will be invited through convenience sampling to observe the delivery of the intervention.

Quantitative evaluation by adolescent participants

Using the questionnaire developed in Phase One, the OM health literacy scores of the 13-16-year-old adolescent females will be recorded at baseline and immediate post intervention. To detect a medium-sized difference of 4 points between the baseline score and the immediate post intervention score at 5% significance and 80% power, a sample size of at least $n=105$ is required. With a 60% retention at post measurement,⁵¹ a total of at least 175 adolescent females will be recruited.

It is expected that the OM health literacy scores will comprise of four key aspects:

1. OM health knowledge;
2. OM health attitudes;
3. self-perceived confidence to communicate OM cycle health; and
4. ability to recognise OM cycle phases.

The scores will be assessed for normality. If normally distributed, the descriptive statistics of the OM health literacy scores will be reported in mean and standard deviation. Paired t tests will be used to compare the difference between baseline and immediate post intervention. If the data are not normally distributed, descriptive statistics will be reported in median and interquartile range and transformed or analysed using Wilcoxon signed-rank test. Statistical significance will be achieved at 0.05. Data will be analysed using STATA version 14 (StataCorp LP). The expected outcomes are that the OM health knowledge and attitudes of participants will have improved, and they will have gained confidence in communicating OM cycle health by being able to recognise OM cycle phases.

Qualitative evaluation with intervention participants

All Grade 9 intervention participants aged 13-16 years will be invited to qualitatively evaluate the study. A semi-structured interview guide will be used to:

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- 3 1. explore understanding of OM health;
- 4 2. explore common attitudes towards OM health;
- 5 3. identify generic experiences of OM cycle charting; and
- 6 4. generate feedback on the course content and its structure.
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10 Approximately three focus groups (n=6-8 per group) will be conducted in a
11 quiet location at the school's convenience. Additional focus groups may be
12 recruited to saturation. This operates concurrently with sampling, data
13 collection, coding, data comparison and analysis to allow theory to emerge.⁷⁸

14 **Qualitative evaluation with teachers and school healthcare professionals**

15 The teachers and school healthcare professionals who observed the
16 intervention's trial will be invited to participate in a one-on-one semi-
17 structured interview. The interview guide will discuss opinions on:

- 18 1. the appropriateness of the program for the primary target group;
- 19 2. elements of the trial that were successful and those which need
20 modification; and
- 21 3. items required to address the efficacy of implementation in schools
22 (such as resources to implement the program, how to equip teachers
23 and school healthcare professionals to deliver the program, and how
24 well it maps to the curriculum).
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36 **Qualitative data analysis**

37 Whilst conducting the student focus groups and school staff interviews, new
38 threads of interest may arise. The discussion guides may be modified for
39 subsequent focus groups and interviews.⁷⁹ This allows for questions to be
40 modified as part of the understanding process.⁸⁰ The focus groups and
41 interviews will be conducted to saturation, which will be determined when no
42 new concepts surface from repeated data review.⁷⁸

43 The qualitative data generated from the focus groups and interviews will be
44 recorded and transcribed verbatim. Data will be coded with NVivo, then
45 discussed and reviewed by the research team. A grounded theory approach
46 has been selected because it aims to make theoretical assumptions that can be
47 verified.^{72, 81} This systematic approach accentuates the mixed methods
48 approach.⁸² The theory developed should explain variations in behaviour while
49 representing the main concerns and ideas of the participants.⁸³ Accordingly,
50 the data will be analysed by constant comparison, whereby data is continually
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3 sorted and the information is coded into commonly occurring key themes.⁸⁰
4 After final coding, the data will be thematically analysed to include the
5 perspectives that emerged and allow for an inductive development of theory.⁷²
6 This process is consistent with other qualitative based studies.^{79, 84} COREQ-32
7 will be used to report the conduct, method, context, findings, analysis and
8 interpretations of the qualitative studies.⁷³ The expected outcome is that the
9 qualitative findings will provide a richer understanding of the intervention
10 from the perspective of the students, teachers and school healthcare
11 professionals. These data will be triangulated with the quantitative findings to
12 further refine the intervention.
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19 In summary, the qualitative and quantitative instruments used in this study's
20 mixed-method approach offers a triangulation of data sources to cross-check
21 and inform the development and trialling of the intervention. Each step in
22 Phase One will inform the next step in order to progress the intervention's
23 development and to validate the questionnaire as the measurement tool. In
24 turn, Phase One provides the intervention and its validated questionnaire for
25 trial in Phase Two. The final outcome expected at the end of Phase Two is a
26 more nuanced and refined intervention for wider testing. A subsequent large
27 intervention-based trial would include focus on generalisability and
28 sustainability.
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35 **ETHICS & DISSEMINATION**

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37 Ethics approval has been obtained from Curtin University (HRE2018-0101).
38 Additional ethics approval will be sought at key milestones as stipulated by
39 HREC. Prior to participation in the study, informed written consent will be
40 obtained from parents or guardians and student participants. Each participant
41 will be informed of the voluntary nature of the study, their right to withdraw at
42 any time without prejudice and maintenance of anonymity. Confidentiality
43 procedures will include delinked data collection, direct computer entry of de-
44 identified data, and encrypted data storage on secure computers. Focus groups
45 and interviews will be held in familiar environments whilst mindful of the
46 participants' privacy and safety.
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53 The questionnaire will be administered according to a standard protocol that
54 includes eligibility checks, confidentiality, ethical consent and administering
55 incentives. Communication with participants will be age-appropriate.
56 Information about suitable support services will be given to all participants and
57 referral to a school healthcare professional will be made available for the
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3 participants if they become distressed by the focus groups, questionnaire test-
4 retest or participation in the intervention.
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7 The dissemination of results will include:
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- 9 1. a de-identified report of the study findings will be given to participating
10 schools for dissemination to their staff and families for having
11 generously participated;
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- 13 2. dissemination of the study's findings to healthcare professionals,
14 educationalists and academics through local community, health and
15 education conferences and international peer-reviewed journals;
16
- 17 3. presentations at school-based professional development workshops and
18 community-based seminars including web-based setting, where
19 appropriate, to encourage the integration of the study's findings into
20 public health and education policies; and
21
- 22 4. dissemination of the study's questionnaire for use by researchers
23 developing interventions for adolescent reproductive health literacy,
24 and by teachers delivering puberty programs as part of sexuality and
25 relationship education in accordance with curricula requirements.
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31 LIST OF FIGURES

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33 Figure 1: Flowchart of Phase One – Development of the OM health literacy
34 intervention
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36
37 Figure 2: Flowchart of Phase Two – Trial of the OM health literacy intervention
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39 REFERENCES

- 40
41 1. American Academy of Pediatrics Committee on Adolescence and American College of
42 Obstetricians & Gynecologists Committee on Adolescent Health Care. Menstruation in girls and
43 adolescents: using the menstrual cycle as a vital sign. *Pediatrics*. 2006; 118(5):2245-50.
44 DOI:10.1542/peds.2006-2481.
45
- 46 2. American College of Obstetricians & Gynecologists Committee. Opinion No. 651: Menstruation in
47 girls and adolescents: using the menstrual cycle as a vital sign. *Obstet Gynecol*. 2015; 126(6):e143-
48 e146. DOI:10.1097/AOG.0000000000001215.
49
- 50 3. Marshall WA, Tanner JM. Variations in pattern of pubertal changes in girls. *Arch Dis Child*. 1969;
51 44(235):291. DOI:10.1136/adc.44.235.291.
52
- 53 4. Quint EH, Smith YR. Abnormal uterine bleeding in adolescents. *J Midwifery Womens Health*. 2003;
54 48(3):186-91. DOI:10.1016/S1526-9523(03)00061-8.
55
- 56 5. Hillard PA. Menstruation in adolescents. *Ann N Y Acad Sci*. 2008; 1135(1):29-35.
57 DOI:10.1196/annals.1429.022.
58
- 59 6. Jamieson MA. Disorders of menstruation in adolescent girls. *Pediatr Clin North Am*. 2015; 62(4).
60 DOI:10.1016/j.pcl.2015.04.007.

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- 2
- 3
- 4 7. Hillen T, Grbavac S, Johnston P, Straton J, Keogh J. Primary dysmenorrhoea in young Western
- 5 Australian women: prevalence, impact and knowledge of treatment. *J Adolesc Health*. 1999;
- 6 25(1):40-5. DOI:10.1016/S1054-139X(98)00147-5.
- 7 8. Pitts MK, Ferris JA, Smith AMA, Shelley JM, Richters J. Prevalence and correlates of three types of
- 8 pelvic pain in a nationally representative sample of Australian women. *Med J Aust*. 2008; 189(3):138.
- 9 9. Parker M, Sneddon A, Arbon P. The menstrual disorder of teenagers (MDOT) study: determining
- 10 typical menstrual patterns and menstrual disturbance in a large population-based study of Australian
- 11 teenagers. *BJOG*. 2010; 117(2):185-92. DOI:10.1111/j.1471-0528.2009.02407.x.
- 12 10. Subasinghe AK, Happo L, Jayasinghe YL, Garland SM, Wark JD. Prevalence and severity of
- 13 dysmenorrhoea, and management options reported by young Australian women. *Aust Fam*
- 14 *Physician*. 2016; 45(11):829-34.
- 15 11. Zannoni L, Giorgi M, Spagnolo E, Montanari G, Villa G, Seracchioli R. Dysmenorrhoea, absenteeism
- 16 from school, and symptoms suspicious for endometriosis in adolescents. *J Pediatr Adolesc Gynecol*.
- 17 2014; 27(5):258-65. DOI:doi.org/10.1016/j.jpag.2013.11.008.
- 18 12. Nwankwo TO, Aniebue UU, Aniebue PN. Menstrual disorders in adolescent school girls in Enugu,
- 19 Nigeria. *J Pediatr Adolesc Gynecol*. 2010; 23(6):358-63. DOI:10.1016/j.jpag.2010.04.001.
- 20 13. Pitanguí AC, Gomes M, Lima A, Schwingel P, Albuquerque A, Cappato de Araujo R. Menstruation
- 21 disturbances: prevalence, characteristics, and effects on the activities of daily living among
- 22 adolescent girls from Brazil. *J Pediatr Adolesc Gynecol*. 2013; 26:148-52.
- 23 DOI:10.1016/j.jpag.2010.04.001.
- 24 14. Agarwal A, Venkat A. Questionnaire study on menstrual disorders in adolescent girls in
- 25 Singapore. *J Pediatr Adolesc Gynecol*. 2009; 22:365-71. DOI:10.1016/j.jpag.2009.02.005.
- 26 15. Soliman AM, Yang H, Du EX, Kelley C, Winkel C. The direct and indirect costs associated with
- 27 endometriosis: a systematic literature review. *Hum Reprod*. 2016; 31(4):712-22.
- 28 DOI:10.1093/humrep/dev335.
- 29 16. Hunt, G. National action plan on endometriosis. Canberra: Commonwealth of Australia; 2017.
- 30 [http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-](http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt130.htm)
- 31 [hunt130.htm](http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt130.htm) (accessed Apr 2018).
- 32 17. Nooh AM, Abdul-Hady A, El-Attar N. Nature and prevalence of menstrual disorders among
- 33 teenage female students at Zagazig University, Zagazig, Egypt. *J Pediatr Adolesc Gynecol*. 2015;
- 34 29:137-42. DOI:10.1016/j.jpag.2015.08.008.
- 35 18. Hickey M, Karthigasu K, Agarwal S. Abnormal Uterine Bleeding: a Focus on Polycystic Ovary
- 36 Syndrome. *Women's Health*. 2009; 5(3):313-324. DOI:10.2217/WHE.09.20.
- 37 19. Rapkin A, Mikacich J. Premenstrual dysphoric disorder and severe premenstrual syndrome in
- 38 adolescents. *Paediatr Drugs*. 2013; 15(3):191-202. DOI:10.1007/s40272-013-0018-4.
- 39 20. Borenstein EJ, Dean BB, Yonkers AK, Endicott AJ. Using the daily record of severity of problems as
- 40 a screening instrument for premenstrual syndrome. *Obstet Gynecol*. 2007; 109(5):1068-75.
- 41 DOI:10.1097/01.AOG.0000259920.73000.3b.
- 42 21. Vigil P, Ceric F, Cortés ME, Klaus H. Usefulness of monitoring fertility from ,enarche. *J Pediatr*
- 43 *Adolesc Gynecol*. 2006; 19(3):173-9. DOI:10.1016/j.jpag.2006.02.003.
- 44 22. Manganello JA, Devellis RF, Davis TC, Schottler-Thal C. Development of the health literacy
- 45 assessment scale for adolescents (HAS-A). *J Commun Healthc*. 2015; 8(3):172-84.
- 46 DOI:10.1179/1753807615Y.0000000016.
- 47 23. Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health
- 48 education and communication strategies into the 21st century. *Health Promot Int*. 2000; 15(3):259-
- 49 67.
- 50 24. Sansom-Daly U, Lin M, Robertson E, Wakefield CE, McGill B, Girgis A, et al. Health literacy in
- 51 adolescents and young adults: an updated review. *J Adolesc Young Adult Oncol*. 2016; 5:106-18.
- 52 DOI:10.1089/jayao.2015.0059.
- 53 25. Fairbrother H, Curtis P, Goyder E. Making health information meaningful: children's health
- 54 literacy practices. *SSM Popul Health*. 2016; 2:476-84. DOI:10.1016/j.ssmph.2016.06.005.
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- 3
- 4 26. Wu AD, Begoray DL, Macdonald M, Wharf Higgins J, Frankish J, Kwan B, et al. Developing and
- 5 evaluating a relevant and feasible instrument for measuring health literacy of Canadian high school
- 6 students. *Health Promot Int*. 2010; 25(4):444-52. DOI:10.1093/heapro/daq032.
- 7 27. School Curriculum and Standards Authority. Health & Physical Education Curriculum Pre-Primary
- 8 to Year 10. Perth, Government of Western Australia; 2017.
- 9 [https://k10outline.scsa.wa.edu.au/home/p-10-curriculum/curriculum-browser/health-and-physical-](https://k10outline.scsa.wa.edu.au/home/p-10-curriculum/curriculum-browser/health-and-physical-education)
- 10 [education](https://k10outline.scsa.wa.edu.au/home/p-10-curriculum/curriculum-browser/health-and-physical-education) (accessed Apr 2018).
- 11 28. Family Planning Alliance Australia. Position Statement: Relationship and Sexuality Education in
- 12 Schools. Australia: FPPA; 2016. [http://familyplanningallianceaustralia.org.au/wp-](http://familyplanningallianceaustralia.org.au/wp-content/uploads/2017/04/FPAA-Schools-Education_Position-Statement_001_v2c.pdf)
- 13 [content/uploads/2017/04/FPAA-Schools-Education_Position-Statement_001_v2c.pdf](http://familyplanningallianceaustralia.org.au/wp-content/uploads/2017/04/FPAA-Schools-Education_Position-Statement_001_v2c.pdf) (accessed Apr
- 14 2018).
- 15 29. Goldman JDG. External providers' sexuality education teaching and pedagogies for primary
- 16 school students in Grade 1 to Grade 7. *Sex Educ*. 2011; 11(2):155-74.
- 17 DOI:10.1080/14681811.2011.558423.
- 18 30. Johnson RL, Sendall MC, McCuaig LA. Primary schools and the delivery of relationships and
- 19 sexuality education: the experience of Queensland teachers. *Sex Educ*. 2014; 14(4):359-74.
- 20 DOI:10.1080/14681811.2014.909351.
- 21 31. Duffy B, Fotinatos N, Smith A, Burke J. Puberty, health and sexual education in Australian
- 22 regional primary schools: Year 5 and 6 teacher perceptions. *Sex Educ*. 2013; 13(2):186-203.
- 23 DOI:10.1080/14681811.2012.678324.
- 24 32. Smith A, Schlichthorst M, Mitchell A, Walsh J, Lyons A, Blackman P, et al. Sexuality education in
- 25 Australian secondary schools 2010: results of the 1st national survey of Australian secondary
- 26 teachers of sexuality education. Melbourne: Australian Research Centre in Sex Health & Society, La
- 27 Trobe University; 2011. DOI:10.4225/50/557E5B09832EB.
- 28 33. Burns S, Hendriks J. Sexuality and relationship education training to primary and secondary
- 29 school teachers: an evaluation of provision in Western Australia. *Sex Educ*. 2018; 18(6):672-88. DOI:
- 30 10.1080/14681811.2018.1459535.
- 31 34. Pound P, Langford R, Campbell R. What do young people think about their school-based sex and
- 32 relationship education? A qualitative synthesis of young people's views and experiences. *BMJ Open*.
- 33 2016; 6(9) DOI:10.1136/bmjopen-2016-011329.
- 34 35. Carman M, Mitchell A, Schlichthorst M, Smith A. Teacher training in sexuality education in
- 35 Australia: how well are teachers prepared for the job? *Sex Health*. 2011; 8(3):269-71.
- 36 DOI:10.1071/SH10126.
- 37 36. New South Wales Education. The Menstrual Cycle. Sydney, Australia: Intel Corporation; 2013.
- 38 37. Walsh J. Talk soon. Talk often: a guide for parents talking to their kids about sex. Victoria:
- 39 Australian Research Centre in Sex Health & Society, La Trobe University; 2011.
- 40 38. Department of Health Western Australia. Puberty: Menstrual Cycle. Growing & Developing
- 41 Healthy Relationships: curriculum support materials. Perth: Government of Western Australia; 2016.
- 42 http://www.healthywa.wa.gov.au/Articles/N_R/Puberty-things-that-change-for-girls (accessed Apr
- 43 2018)
- 44 39. Department of Health Western Australia. Girls and Puberty. Perth: Government of Western
- 45 Australia; 2007.
- 46 40. Bush D, Brick E, East MC, Johnson N. Endometriosis education in schools: a New Zealand model
- 47 examining the impact of an education program in schools on early recognition of symptoms
- 48 suggesting endometriosis. *Aust N Z J Obstet Gynaecol*. 2017; 57(4):452-7. DOI:10.1111/ajo.12614.
- 49 41. Lines A, Gallasch G. The Rite Journey: Rediscovering Rites of Passage for Boys. *Thymos*. 2009;
- 50 3(1):74-89. DOI:10.3149/thy.0301.74.
- 51 42. Lines A, Gallasch G, Hobbs A, Bennett J. The rite journey for girls: a rite of passage programme
- 52 for adolescents. Adelaide, Australia: Authenticity; 2018.
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60

- 1
2
3 43. Australia Curriculum Assessment and Reporting Authority. Guide to understanding 2013 Index of
4 Community Socio-educational Advantage (ICSEA) values. Sydney, ACARA; 2013.
5 www.myschool.edu.au (accessed Apr 2018)
6
7 44. Moher D, Liberati A, Tetzlaff J, Altman DG. The PRISMA Group. Preferred reporting items for
8 systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med*. 2009; 6(7):e1000097.
9 DOI:10.1371/journal.pmed.1000097.
10
11 45. Odeblad E. The functional structure of human cervical mucus. *Acta Obstetrica et Gynecologica*
12 *Scandinavia*. 1968; 47:57.
13
14 46. Billings E, Westmore A. The Billings method: controlling fertility without drugs or devices.
15 Richmond, Victoria: Anne O'Donovan; 1980.
16
17 47. Australian Medical Association. Position statement: health in the context of education. Barton,
18 ACT: AMA; 2014. www.ama.com.au (accessed Apr 2017)
19
20 48. Keeney S, Hasson F, McKenna HP. The Delphi technique in nursing and health research.
21 Chichester, West Sussex: Wiley-Blackwell; 2011.
22
23 49. Okoli C, Pawlowski SD. The Delphi method as a research tool: an example, design considerations
24 and applications. *Inf Manag*. 2004; 42(1):15-29. DOI:10.1016/j.im.2003.11.002.
25
26 50. Fakhri M, Hamzehgardeshi Z, Hajikhani Golchin N, Komili A. Promoting menstrual health among
27 Persian adolescent girls from low socioeconomic backgrounds: a quasi-experimental study. *BMC*
28 *Public Health*. 2012; 12:193. DOI:10.1186/1471-2458-12-193.
29
30 51. Su JJ, Lindell D. Promoting the menstrual health of adolescent girls in China. *Nurs Health Sci*.
31 2016;481-7. DOI:10.1111/nhs.12295.
32
33 52. Tokolahi E, Hocking C, Kersten P. Development and content of a school-based occupational
34 therapy intervention for promoting emotional well-being in children. *Occup Ther Ment Health*. 2016;
35 32(3):245-58. DOI:10.1080/0164212X.2015.1129522.
36
37 53. Humphrey-Murto S, Varpio L, Gonsalves C, Wood TJ. Using consensus group methods such as
38 Delphi and nominal group in medical education research. *Med Teach*. 2017; 39(1):14-9.
39 DOI:10.1080/0142159X.2017.1245856.
40
41 54. Abel T, Hofmann K, Ackermann S, Bucher S, Sakarya S. Health literacy among young adults: a
42 short survey tool for public health and health promotion research. *Health Promot Int*. 2015;
43 30(3):725-35. DOI:10.1093/heapro/dat096.
44
45 55. Davis TC, Wolf MS, Arnold CL, Byrd RS, Long SW, Springer T, et al. Development and validation of
46 the rapid estimate of adolescent literacy in medicine (REALM-Teen): a tool to screen adolescents for
47 below-grade reading in health care settings. *Pediatrics*. 2006; 118(6):e1707.
48 DOI:10.1542/peds.2006-1139.
49
50 56. McDonald F, Patterson P, Costa D, Shepherd H. Validation of a health literacy measure for
51 adolescents and young adults diagnosed with cancer. *J Adolesc Young Adult Oncol*. 2016; 5(1):69-75.
52 DOI:10.1089/jayao.2014.0043.
53
54 57. Osborne R, Batterham R, Elsworth G, Hawkins M, Buchbinder R. The grounded psychometric
55 development and initial validation of the health literacy questionnaire (HLQ). *BMC Public Health*.
56 2013; 13:658. DOI:10.1186/1471-2458-13-658.
57
58 58. Bradley-Klug K, Shaffer-Hudkins E, Lynn C, Jeffries Deloatche K, Montgomery J. Initial
59 development of the health literacy and resiliency scale: youth version. *J Commun Healthc*. 2017;
60 10(2):100-7. DOI:10.1080/17538068.2017.1308689.
61
62 59. Aflaq F, Jami H. Experiences and attitudes related to menstruation among female students.
63 *Pakistan Journal of Psychological Research*. 2012; 27(2):201-24.
64
65 60. Brooks-Gunn J, Ruble DN. The menstrual attitude questionnaire. *Psychosomatic medicine*. 1980;
66 42(5):503.
67
68 61. Marván ML, Ramírez-Esparza D, Cortés-Iniestra S, Chrisler JC. Development of a new scale to
69 measure beliefs about and attitudes toward menstruation (BATM): data from Mexico and the United
70 States. *Healthc Women Int*. 2006; 27(5):453. DOI:10.1080/07399330600629658.

- 1
2
3 62. Morse JM, Kieren D, Bottorff J. The adolescent menstrual attitude questionnaire, part I: scale
4 construction. *Healthc Women Int.* 1993; 14(1):39-62. DOI:10.1080/07399339309516025.
5
6 63. DeMaria EP, Mikulas WL. Women's awareness of their menstrual cycle. *Int J Sex Health.* 1992;
7 4(3):71-82. DOI:10.1300/J056v04n03_05.
8 64. Byers P, Zeller R, Byers B. Focus group methods. In: Weideman M, Whitley B, editors. *Handbook*
9 *for conducting research on human sexuality*; 2002. p. 173-93.
10 65. Tong A, Sainsbury P, Carter S, Hall B, Harris D, Walker R, et al. Patients' priorities for health
11 research: focus group study of patients with chronic kidney disease. *Nephrology Dialysis*
12 *Transplantation.* 2008; 23:3206-14. DOI:10.1093/ndt/gfn207.
13 66. Bronfenbrenner U. *The Ecology of Human Development.* Cambridge MA: Harvard University
14 Press; 1979.
15 67. Greene S, Hogan D. *Researching children's experiences: methods and approaches.* London: SAGE;
16 2005.
17 68. McBride N. *Intervention research : a practical guide for developing evidence-based school*
18 *prevention programmes.* Singapore: Springer; 2016.
19 69. Glenton C, Carlsen B. What about N? A methodological study of sample-size reporting in focus
20 group studies. *BMC Med Res Methodol.* 2011; 11(1):26. DOI:10.1186/1471-2288-11-26.
21 70. Liamputtong P. *Research methods in health: foundations for evidence-based practice.* 2nd ed.
22 Melbourne: Oxford University Press; 2013.
23 71. Liamputtong P. *Qualitative research methods.* 4th ed. Melbourne: Oxford University Press; 2013.
24 72. Corbin JM, Strauss AL. *Basics of qualitative research: techniques and procedures for developing*
25 *grounded theory.* 3rd ed. Thousand Oaks CA: Sage Publications Inc.; 2008.
26 73. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a
27 32-item checklist for interviews and focus groups. *Int J Qual Health Care.* 2007; 19(6):349-57.
28 DOI:10.1093/intqhc/mzm042.
29 74. Chiou M-H, Wang H-H, Yang Y-H. Effect of systematic menstrual health education on
30 dysmenorrheic female adolescents' knowledge, attitudes, and self-care behavior. *Kaohsiung J Med*
31 *Sci.* 2007; 23(4):183-90. DOI:10.1016/S1607-551X(09)70395-X.
32 75. Janssen EHC, Singh AS, van Nassau F, Brug J, van Mechelen W, Chinapaw MJM. Test-retest
33 reliability and construct validity of the DOiT (Dutch obesity intervention in teenagers) questionnaire:
34 measuring energy balance-related behaviours in Dutch adolescents. *Public Health Nutr.* 2014;
35 17(2):277-86. DOI:10.1017/S1368980012005253.
36 76. Flisher AJ, Evans J, Muller M, Lombard C. Brief report: test-retest reliability of self-reported
37 adolescent risk behaviour. *J Adolesc.* 2004; 27(2):207-12. DOI:10.1016/j.adolescence.2001.10.001.
38 77. Kılıç S. Cronbach's alpha reliability coefficient. *J Mood Disord.* 2016; 6(1):47-8.
39 DOI:10.5455/jmood.20160307122823.
40 78. Bowen G. Naturalistic inquiry and the saturation concept: a research note. *Qual Res.* 2008;
41 8(1):137-52. DOI:10.1177/1468794107085301.
42 79. Burns S, Cross D, Maycock B. "That could be me squishing chips on someone's car": how friends
43 can positively influence bullying behaviors. *J Prim Prev.* 2010; 31(4):209-22. DOI:10.1007/s10935-
44 010-0218-4.
45 80. Boeije HR. A purposeful approach to the constant comparative method in the analysis of
46 qualitative interviews. *Qual Quan.* 2002; 36:391-5177. DOI:10.1023/A:1020909529486.
47 81. Harris T. Grounded theory. *Nursing Standard.* 2015; 29(35):32. DOI:10.7748/ns.29.35.32.e9568.
48 82. Bluff R. *Grounded Theory: The Methodology.* In: Holloway I, editor. *Qualitative Research in*
49 *Health Care.* Berkshire, UK: Open University Press, McGraw-Hill; 2005.
50 83. Glaser B. *Basics of Grounded Theory Analysis.* Mill Valley, CA: Sociology Press; 1992.
51 84. Burns S, Maycock B, Cross D, Brown G. The power of peers: why some students bully others to
52 conform. *Qual Health Res.* 2008; 18(12):1704-16. DOI:10.1177/1049732308325865.
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AUTHORS' CONTRIBUTIONS

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3 This protocol paper describes a supervised doctoral research project. All
4 authors contributed to development and conceptualisation of the protocol. FR
5 was responsible for drafting and coordinating the authors' contributions. SB, JC
6 and JH were responsible for editing and guidance on the paper. All authors
7 were responsible for critically revising the paper. All authors approved the final
8 version of this paper.
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13 **FUNDING STATEMENT**

14
15 This research project is funded through the Australian Government Research
16 Training Program Scholarship as administered through the doctoral program
17 run at Curtin University's School of Public Health.
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20 **COMPETING INTERESTS STATEMENT**

21 None declared
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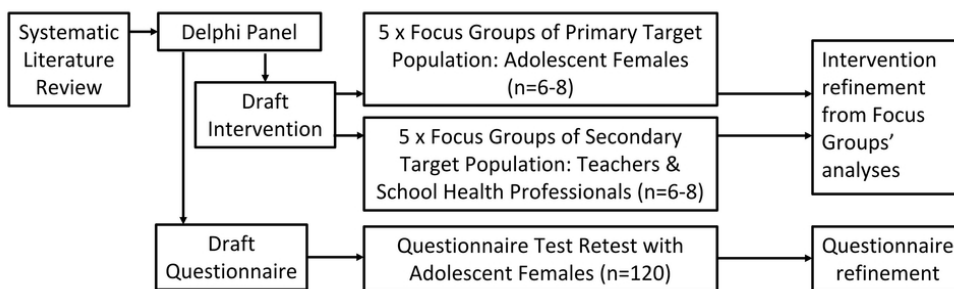


Figure 1: Flowchart of Phase One – Development of the OM health literacy intervention

41x13mm (600 x 600 DPI)

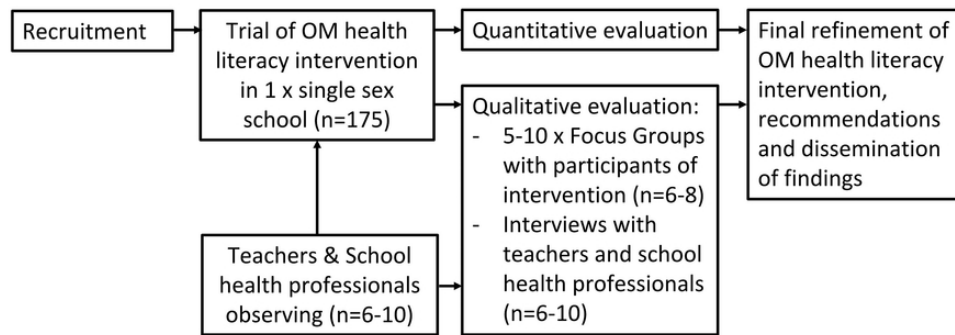


Figure 2: Flowchart of Phase Two – Trial of the OM health literacy intervention

38x14mm (600 x 600 DPI)

BMJ Open

Developing and trialling a school-based ovulatory-menstrual health literacy program for adolescent females: a quasi-experimental mixed method protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-023582.R2
Article Type:	Protocol
Date Submitted by the Author:	29-Jan-2019
Complete List of Authors:	Roux, Felicity; Curtin University, School of Public Health Burns, Sharyn; Curtin University, School of Public Health Chih, HuiJun; Curtin University, School of Public Health Hendriks, Jacqueline; Curtin University, School of Public Health
Primary Subject Heading:	Public health
Secondary Subject Heading:	Paediatrics, Reproductive medicine, Obstetrics and gynaecology
Keywords:	school-based intervention, health literacy, menstruation, dysmenorrhoea, abnormal uterine bleeding, premenstrual syndrome

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Manuscripts

TITLE

Developing and trialling a school-based ovulatory-menstrual health literacy program for adolescent females: a quasi-experimental mixed method protocol.

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Keywords: school-based intervention; health literacy; menstruation; dysmenorrhoea; abnormal uterine bleeding; premenstrual syndrome

Total Word Count: 3925 words

ABSTRACT

Introduction

A review of international and Australian school-based resources suggests that teaching of the ovulatory-menstrual (OM) cycle is predominantly couched in biology. A whole person framework that integrates the spiritual, intellectual, social and emotional dimensions with the physical changes of the OM cycle is needed to facilitate adolescent OM health literacy. This paper describes the protocol for a study that aims to develop and trial an intervention for 13-16-year-old adolescent females which enhances positive attitudes towards OM health coupled with developing skills to monitor and self-report OM health. These skills aim to foster acceptance of the OM cycle as a “vital sign” and facilitate confident communication of common OM disturbances (namely, dysmenorrhoea, abnormal uterine bleeding and premenstrual syndrome), which are noted to impact on school and social activities.

Methods and Analysis

Phase One will comprise a Delphi panel of women's health specialists, public health professionals and curriculum consultants, and focus groups with adolescent females, teachers and school healthcare professionals. This will inform the development of an intervention to facilitate OM health literacy. The Delphi panel will also inform the development of a valid and reliable questionnaire to evaluate OM health literacy. Phase Two will trial the intervention with a convenience sample of at least 175 adolescent females from one single-sex school. The mixed methods evaluation of the intervention will include a pre- and post-intervention questionnaire. One-on-one interviews with teachers and school healthcare professionals will expand understanding of the barriers, enablers and suitability of implementation of the intervention in a school-based setting. Finally, focus groups with purposively selected trial participants will further refine the intervention.

Ethics and dissemination

The study's findings will be disseminated through local community seminars, conferences, peer-review articles and media channels where appropriate. The Curtin University of Human Research Ethics Committee has approved this study (approval HRE2018-0101). This project is registered with the "Australian and New Zealand Clinical Trials Registry". The trial registration number is ACTRN12619000031167

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The Delphi panel comprising of experts from multiple disciplines adds rigour to the development of the school-based OM health literacy intervention.
- A consumer-centred study that engages multiple stakeholders.
- The mixed methods approach allows for triangulation of quantitative and qualitative data.
- The risks of bias and limited generalisability are present as participant recruitment in the Phase Two trial will be restricted to a single-sex private school and exclude parental inputs.
- Limited funds restrict implementing and evaluating trials in a larger sample of schools.

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3 **Developing and trialling a school-based ovulatory-menstrual health literacy**
4 **program for adolescent females: a quasi-experimental mixed method**
5 **protocol.**
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22 **INTRODUCTION**

23
24 The American College of Obstetricians & Gynecologists' Committee for
25 Adolescent Health Care and the American Academy of Pediatrics' Committee
26 on Adolescence have jointly and repeatedly recommended that the ovulatory-
27 menstrual (OM) cycle is to be considered a "vital sign" in assessing overall
28 health.^{1, 2} For all young girls, menarche is the culmination of a sustained
29 intricate hormonal interplay which is governed by the hypothalamic-pituitary-
30 ovarian axis.³ As this ongoing cyclical process matures slowly,^{4, 5} disturbances
31 can present such as dysmenorrhoea, abnormal uterine bleeding (AUB) and
32 premenstrual syndrome (PMS).⁶
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39 Studies in Australia suggest the prevalence of dysmenorrhoea in adolescent
40 females ranges from 80% to 93%.⁷⁻¹⁰ International studies suggest similar rates
41 of prevalence: 68% in Italy,¹¹ 69% in Nigeria,¹² 73% in Brazil¹³ and 83% in
42 Singapore.¹⁴ Globally, the rates for girls missing school because of
43 dysmenorrhoea range from 12% to 37%.^{7, 9, 11, 13} For women subsequently
44 diagnosed with endometriosis, a recent literature review suggests considerable
45 direct financial costs associated with this chronic disease, ranging from USD
46 1109 (£682) to USD 12 118 (£6170) per patient per year in Canada and the USA
47 respectively.¹⁵ In Australia, the Government has indicated its intention to
48 create a National Action Plan for Endometriosis to provide support for women
49 facing this medical condition.¹⁶
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56 AUB menstrual disturbance can occur at both ends of reproductive life. Studies
57 suggest prevalence ranges for adolescent females from 21% in Egypt¹⁷ and
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3 Brazil,¹³ and 40% in Australia.⁹ The costs of investigating and managing this
4 condition are estimated around AUD 6 million (£2.65 million) per annum.¹⁸

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7 Another common OM disturbance is PMS. A report of global studies posits its
8 prevalence at 51-86%, and comments that severe cases are disabling and can
9 interfere with schooling and relationships.¹⁹ An early study found that a PMS
10 diagnosis was associated with an average annual increase of USD 59 (£30) in
11 direct costs and USD 4333 (£2271) in indirect costs per patient compared with
12 patients without PMS.²⁰

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14
15 In Australian studies, the prevalence of adolescent females consulting a
16 healthcare professional about their menstrual disturbance ranged from 18% to
17 34%.^{7, 9, 10} Without diagnosis and treatment, cycle disorders worsen over time,
18 as does any underlying pathology.²¹

19
20
21 Adolescent health literacy is an emerging field, and knowledge about it is not
22 as extensive as that of adult health literacy.²² Nutbeam's Health Outcome
23 Model²³ offers a framework to explore adolescent health literacy. It begins by
24 situating health literacy as a key outcome of health education. In this Model,
25 health literacy is realised after sequentially acquiring three core skills:
26 functional skills (such as information searching and comprehension),
27 interactive skills (including personal application of health knowledge,
28 engagement with health caregivers, decision making and self-confidence) and
29 critical skills to appraise information.²³ Coincidentally, the progression from
30 functional to critical health literacy skills aligns with the trajectory of
31 adolescent cognitive and social development.²⁴ Qualitative research in Britain
32 applied the functional and interactive skills of Nutbeam's Model²³ to
33 understand how children make meaning of health information through their
34 own embodied experience.²⁵ One Canadian exploratory study extended the
35 first two core skills of Nutbeam's Model²³ to the final core skill of critical health
36 literacy by using task-oriented measurements of evaluation.²⁶ The three core
37 skills of Nutbeam's Model²³ will be used as a framework in this study to
38 develop and evaluate OM health literacy in adolescents.

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41 As girls grow, develop and begin assuming responsibility for their health, they
42 are still minors: firstly, under the close care of parents and family, and secondly
43 under the wider care of healthcare professionals and teachers. Schools play an
44 important role in developing health literacy because of curriculum
45 requirements around personal development^{27, 28} and the time children spend
46 in education.

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However, in Australia, many teachers lack training and confidence to facilitate contemporary relationships and sexuality education (RSE). In primary schools, qualitative studies have observed a tendency of teachers to outsource puberty education^{29, 30} and that less than half of female teachers felt very confident in teaching menstruation.³¹ In primary and secondary schools, a lack of confidence has been noted in teachers to deliver RSE programs.^{32, 33} A synthesis of international qualitative reviews of school-based RSE programs suggests that teachers are best placed to fulfil the needs for continuity and meeting key curriculum outcomes. It was noted that some teachers were embarrassed teaching RSE, which may be linked to their poor training.³⁴ In Australia, RSE training is not mandatory for pre-service teachers, and so not all teachers may have received this training.³⁵ This could negatively impact on supporting girls to develop their OM health literacy.

Furthermore, available educational resources in Australia about OM cycles focus predominantly on ovulation and menstruation as biological events.³⁶⁻³⁹ The resources contain limited information about ovulation as the governing event of the OM cycle. In some regions of New Zealand, a school-based menstrual health education program on endometriosis (the *me* program) has been delivered annually since 1997.⁴⁰ The *me* program is delivered in one 60-minute session, which is akin to the vaccination model.²⁹ This short time frame is problematic in equipping adolescents with the skills to recognise their own OM cycle patterns because the OM cycle is complex, highly individualised and fluctuates over weeks. Additionally, the *me* program focuses on only one common OM disturbance, and it is predicated on a negative OM experience rather than framing OM health positively. The Australian Rite Journey program⁴¹ was adapted for girls and it could be considered to overcome these drawbacks through its fertility awareness challenge of charting one cycle to identify the individual's unique OM pattern.⁴² No data exist to measure if teachers are equipped to teach OM health, or if this aspect of the program is offered. These programs do not promote the OM cycle as a "vital sign" and its use as a personal health monitor to identify common OM disturbances,^{1, 2} or its place within the core skill set of critical health literacy.²³ In addition, there is no evidence of their effect on girls' attitudes to the OM cycle, or measures of their confidence in explaining their OM experiences to healthcare professionals.

METHODS AND ANALYSIS

Research objectives

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3 This study aims to develop and trial an OM health literacy intervention for
4 delivery to female students aged 13-16 years. The study's objectives will be
5 completed in two phases:
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8 Phase One: Development 9

- 10 1. To develop a school-based adolescent OM health literacy intervention
11 after consultation with experts in health and education, and with the
12 primary (adolescent females) and secondary (teachers and school
13 healthcare professionals) target groups.
14
- 15 2. To develop a valid and reliable questionnaire to measure adolescent OM
16 health literacy.
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20 Phase Two: Intervention Trial 21

- 22 1. To trial the intervention in one single-sex secondary school.
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- 24 2. To refine the intervention after consultation with the primary and
25 secondary target groups.
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- 27 3. To provide recommendations regarding the future utility of the
28 intervention.
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31 Patient and Public Involvement 32

33 The students, teachers and school healthcare professionals who will be invited
34 to participate in this study were not involved in the development of the
35 research question, study design or the outcome measures. The schools
36 involved in this study will be provided a summary of the research findings. The
37 results will also be published in peer-review journals.
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41 Research setting 42

43 The study will be based in Perth, Western Australia. In Phase One, five schools
44 will be invited to offer female students, teachers and school healthcare
45 professionals the opportunity to participate in focus groups. Both private and
46 public schools will be approached. Representation across various
47 sociodemographic backgrounds will be sought based on schools' Index of
48 Community Socio-Educational Advantage values.⁴³ The setting for Phase Two
49 will be one purposively selected single-sex school in the Perth metropolitan
50 area. Only private schools will be approached in this phase because there are
51 no single-sex public schools in Perth. The school will be single-sex rather than
52 co-educational of mixed sexes in order to eliminate any study burden of
53 occupying male students. Subsequent studies may explore the efficacy of this
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3 intervention in a co-educational setting. To avoid possible testing effects,
4 schools in Phase One will not be approached for Phase Two.
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7 **Phase One: Development**

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9 The development phase of the OM health literacy intervention and
10 questionnaire is illustrated in Figure 1:
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12

13 **A Systematic Literature Review (SLR) of OM health programs for adolescent** 14 **females**

15
16 The SLR will include an assessment of previous reviews of OM health programs
17 and primary studies published in English using the PRISMA flow diagram and
18 check list.⁴⁴ The search time period spans 39 years, dating from 1st January
19 1980 to 31st December 2018. The year 1980 marks the publication of a
20 mainstream book which used Odeblad's findings⁴⁵ to describe OM cycle
21 phases.⁴⁶ The key search words will include: [adolescen* OR teen?age*] AND
22 [menstrua* OR menarch*, ovulat* OR fertil* OR reproduc*] AND [educat* OR
23 teach* OR school*] AND [chart* OR record* OR track* OR diary] AND
24 [knowledge OR aware* OR "health literacy"] AND [attitude OR opinion OR
25 "body image" OR confidence]. The databases to be searched are CINAHL,
26 Informit, Ovid, Proquest, Science Direct, Medline, Web of Science and Scopus.
27 The SLR aims to identify components that would enhance the opportunity for
28 changes in knowledge, attitude and help-seeking behaviours in adolescent
29 females. Studies which do not demonstrate review from a healthcare
30 professional or are not school-based will be excluded. Each study will be
31 assessed on how it addresses:
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- 41 1. The primary target population (adolescent females aged 13-16 years),
42 and consideration of:
 - 43 a. Comprehensiveness (such as coverage of common complaints,
44 evidence of program development by fertility specialists and the
45 guidance for participants to identify personal OM cycle phases);
 - 46 b. Fostering a positive attitude towards the OM cycle (e.g. the
47 Australian Medical Association has suggested a relationship
48 between education and body image);⁴⁷ and
 - 49 c. Fostering an improvement in confidence to communicate with
50 healthcare professionals.
- 51 2. The secondary target population (teachers and school healthcare
52 professionals), and consideration of content and integration within the
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3 curricula, ease and comfort of the program delivery, training, efficacy of
4 delivery in school-based settings, dissemination and program evaluation.
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7 The expected outcome from conducting the SLR is that it will inform the draft
8 development of the intervention which will then be submitted to the Delphi
9 panel for further development.
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12 **Delphi study**

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14 A Delphi study offers a consensus building method through group
15 communication and feedback from a panel of experts in the field.⁴⁸ For this
16 study's purposes, the classes of experts have been identified⁴⁹ as women's
17 health specialists, public health professionals and curriculum consultants.
18 Delphi studies do not rely upon statistical power, but rather group dynamics
19 for achieving consensus, with the literature suggesting 10-18 experts.⁴⁹ The
20 panel's first task will be to inform the development of the intervention by
21 collecting their feedback on how the intervention can:
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- 26 1. be mapped to the mandated Health & Physical Education curriculum for
27 Grades 9 and 10 (ages 13-16 years) in Western Australia;²⁷ and
- 28 2. incorporate the whole person framework for the following dimensions
29 of human being: spiritual, physical, intellectual, social and emotional;
30 and
31
- 32 3. address the needs of:
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34 a. the Primary target group (such as materials, and the format,
35 number and length of class sessions, which the literature for
36 school-based menstrual health and well-being promotional
37 interventions has preliminarily indicated);⁵⁰⁻⁵² and
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39 b. the Secondary target group (such as material guides and a
40 professional support and development plan).
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46 The Delphi panel's feedback on the intervention's development will be collated
47 as a preliminary draft. In its review, members will be able to suggest items that
48 might not have been initially considered.⁴⁹ Subsequent iterations will identify
49 and rank the most important factors until members achieve 70% consensus on
50 the draft intervention.^{49, 53}
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54 The Delphi panel's second task will be to refine the questionnaire to measure
55 OM health literacy using existing valid and reliable items and scales to test:
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- 58 1. adolescent health literacy^{22, 26, 54-58} and
- 59 2. knowledge, attitudes and experiences of menstruation.⁵⁹⁻⁶³
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3 The Delphi panel will be asked to evaluate how the items and scales meet the
4 study's aims and objectives, and to make alternative contributions. Their
5 feedback will be collated as a preliminary draft questionnaire, which will be
6 reviewed and ranked in an iterative process to identify and rank the items,⁴⁹
7 with consensus achieved at 70%,⁵³ which will provide content validation.⁴⁸
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11 **Focus groups of the Primary Target Population**

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13 Focus groups with adolescent females will be conducted to gain insight on⁶⁴
14 and to elicit priorities for issues⁶⁵ to be included in the intervention. To reduce
15 the possibility of distress, 16-year-old girls will be approached because most
16 will have already been menstruating for up to three years and are more likely
17 to be familiar with the responsibilities and experience of their OM cycles.
18 Personal information will not be solicited, but rather what the participants
19 believe to be important for adolescent OM health in general. This creates the
20 opportunity to explore socio-ecological influences⁶⁶ that may shape an
21 adolescent's approach to OM self-management. Exploration of girls' parents or
22 guardians as enablers or barriers to OM health literacy lies however outside
23 the scope of this study. Each of the five socio-demographically diverse schools
24 will be asked to purposively select six to eight 16-year-old female students to
25 form one focus group.⁶⁷ A total of thirty to forty participants will thus be
26 allocated into five focus groups (n=6-8 per group).
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36 **Focus groups of the Secondary Target Population**

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38 Teachers from health, physical education, science and religious studies and
39 school healthcare professionals (such as nurses, psychologists and counsellors)
40 are the most likely group to implement the intervention in Phase Two and
41 beyond.⁶⁸ They may provide insight⁶⁵ into mapping the intervention to the
42 curriculum and its practical facilitation in class. The purpose is to gain an
43 understanding of the issues surrounding the program's content, delivery,
44 training and future continuation. Each of the five socio-demographically
45 diverse schools will be asked to purposively select six to eight of their teachers
46 and school healthcare professionals to form one focus group. In total, thirty to
47 forty participants will be allocated into five focus groups (n=6-8 per group).
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54 Additional focus groups in either population may be recruited to saturation,
55 which is consistent with qualitative research.⁶⁹ The focus groups will be
56 facilitated by the research team using a semi-structured interview guide, and
57 conducted at a suitably quiet location at each school.
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Qualitative data analysis

Focus groups' data will be digitally recorded and transcribed verbatim. To maintain dependability and determine credibility, the data will be reviewed by three researchers, two of whom have extensive experience in this field.^{70, 71} Data will be coded using NVivo V.10 software. A constant comparison analysis will allow for the thematic discovery⁷² that is necessary to finalise the intervention's development. The 32-item Consolidated criteria for reporting qualitative studies (COREQ-32)⁷³ will be used to report on the conduct, method, context, findings, analysis and interpretations of the qualitative studies. The key findings based on the SLR, Delphi Panel and COREQ-32 will inform the refinement of the intervention in preparation for its trial. The expected outcomes are improvements in the intervention's feasibility and acceptability for its delivery in Phase Two.

Questionnaire Test-retest

A group of at least 120 adolescent females^{50, 74, 75} will be recruited from one school to assess test-retest reliability of the questionnaire over a fortnight.⁷⁶ To thank them for their time, the participants will be invited to enter a draw for a AUD 30 gift voucher at each sitting. Questionnaires will be administered online through Qualtrics™. Participants will enter their responses in real time from either personal or school supplied devices. The test-retest reliability will be deemed acceptable at Cronbach's alpha value of >0.7.⁷⁷ The research team will use the findings of the test-retest process to refine the questionnaire for use in Phase Two. The expected outcome is established validity and reliability for the questionnaire to be administered in Phase Two.

Phase Two: Trial

The trial and evaluation of the OM health literacy intervention is shown in Figure 2:

One single-sex private school in Perth WA will be purposively selected. The trial will be offered in-class at the school's convenience. Whilst the intervention will be mapped to the Australian curriculum for Health & Physical Education,²⁷ the school's preference for its delivery in other classes will be observed. For the purpose of the trial, the intervention will be delivered by the first author who has expertise in the facilitation of RSE programs to 13-16-year-old students. It is anticipated that the trial will run for six to eight weekly sessions during one

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3 school term, which reduces the risk of participant loss. Both primary and
4 secondary target populations will be recruited from the same school:
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- 7 1. The primary target population will be adolescent females aged 13-16
8 years. This age range falls in Grade 9, at which the intervention is
9 targeted and which also provides the likeliest opportunity to recruit
10 given curriculum time restrictions in more senior years. All Grade 9 girls
11 will be invited.
12
- 13 2. The secondary target population will be teachers in health, physical
14 education, science and religious studies, as well as the school's
15 healthcare professionals which may include the school nurses,
16 psychologists and counsellors. These staff will be invited through
17 convenience sampling to observe the delivery of the intervention.
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23 **Quantitative evaluation by adolescent participants**

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25 Using the questionnaire developed in Phase One, the OM health literacy scores
26 of the 13-16-year-old adolescent females will be recorded at baseline and
27 immediate post intervention. To detect a medium-sized difference of 4 points
28 between the baseline score and the immediate post intervention score at 5%
29 significance and 80% power, a sample size of at least n=105 is required. With a
30 60% retention at post measurement,⁵¹ a total of at least 175 adolescent
31 females will be recruited.
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36 It is expected that the OM health literacy scores will comprise of four key
37 aspects:
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- 40 1. OM health knowledge;
- 41 2. OM health attitudes;
- 42 3. self-perceived confidence to communicate OM cycle health; and
- 43 4. ability to recognise OM cycle phases.
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47 The scores will be assessed for normality. If normally distributed, the
48 descriptive statistics of the OM health literacy scores will be reported in mean
49 and standard deviation. Paired t tests will be used to compare the difference
50 between baseline and immediate post intervention. If the data are not
51 normally distributed, descriptive statistics will be reported in median and
52 interquartile range and transformed or analysed using Wilcoxon signed-rank
53 test. Statistical significance will be achieved at 0.05. Data will be analysed using
54 STATA version 14 (StataCorp LP). The expected outcomes are that the OM
55 health knowledge and attitudes of participants will have improved, and they
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3 will have gained confidence in communicating OM cycle health by being able
4 to recognise OM cycle phases.
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7 **Qualitative evaluation with intervention participants**

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9 All Grade 9 intervention participants aged 13-16 years will be invited to
10 qualitatively evaluate the study. A semi-structured interview guide will be used
11 to:
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- 14 1. explore understanding of OM health;
- 15 2. explore common attitudes towards OM health;
- 16 3. identify generic experiences of OM cycle charting; and
- 17 4. generate feedback on the course content and its structure.
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21 Approximately three focus groups (n=6-8 per group) will be conducted in a
22 quiet location at the school's convenience. Additional focus groups may be
23 recruited to saturation. This operates concurrently with sampling, data
24 collection, coding, data comparison and analysis to allow theory to emerge.⁷⁸
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28 **Qualitative evaluation with teachers and school healthcare professionals**

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30 The teachers and school healthcare professionals who observed the
31 intervention's trial will be invited to participate in a one-on-one semi-
32 structured interview. The interview guide will discuss opinions on:
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- 35 1. the appropriateness of the program for the primary target group;
- 36 2. elements of the trial that were successful and those which need
37 modification; and
- 38 3. items required to address the efficacy of implementation in schools
39 (such as resources to implement the program, how to equip teachers
40 and school healthcare professionals to deliver the program, and how
41 well it maps to the curriculum).
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47 **Qualitative data analysis**

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49 Whilst conducting the student focus groups and school staff interviews, new
50 threads of interest may arise. The discussion guides may be modified for
51 subsequent focus groups and interviews.⁷⁹ This allows for questions to be
52 modified as part of the understanding process.⁸⁰ The focus groups and
53 interviews will be conducted to saturation, which will be determined when no
54 new concepts surface from repeated data review.⁷⁸
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3 The qualitative data generated from the focus groups and interviews will be
4 recorded and transcribed verbatim. Data will be coded with NVivo, then
5 discussed and reviewed by the research team. A grounded theory approach
6 has been selected because it aims to make theoretical assumptions that can be
7 verified.^{72, 81} This systematic approach accentuates the mixed methods
8 approach.⁸² The theory developed should explain variations in behaviour while
9 representing the main concerns and ideas of the participants.⁸³ Accordingly,
10 the data will be analysed by constant comparison, whereby data is continually
11 sorted and the information is coded into commonly occurring key themes.⁸⁰
12 After final coding, the data will be thematically analysed to include the
13 perspectives that emerged and allow for an inductive development of theory.⁷²
14 This process is consistent with other qualitative based studies.^{79, 84} COREQ-32
15 will be used to report the conduct, method, context, findings, analysis and
16 interpretations of the qualitative studies.⁷³ The expected outcome is that the
17 qualitative findings will provide a richer understanding of the intervention
18 from the perspective of the students, teachers and school healthcare
19 professionals. These data will be triangulated with the quantitative findings to
20 further refine the intervention.
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31 In summary, the qualitative and quantitative instruments used in this study's
32 mixed-method approach offers a triangulation of data sources to cross-check
33 and inform the development and trialling of the intervention. Each step in
34 Phase One will inform the next step in order to progress the intervention's
35 development and to validate the questionnaire as the measurement tool. In
36 turn, Phase One provides the intervention and its validated questionnaire for
37 trial in Phase Two. The final outcome expected at the end of Phase Two is a
38 more nuanced and refined intervention for wider testing. A subsequent large
39 intervention-based trial would include focus on generalisability and
40 sustainability.
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48 **ETHICS & DISSEMINATION**

49 Ethics approval has been obtained from Curtin University (HRE2018-0101).
50 Additional ethics approval will be sought at key milestones as stipulated by
51 HREC. Prior to participation in the study, informed written consent will be
52 obtained from parents or guardians and student participants. Each participant
53 will be informed of the voluntary nature of the study, their right to withdraw at
54 any time without prejudice and maintenance of anonymity. Confidentiality
55 procedures will include delinked data collection, direct computer entry of de-
56 identified data, and encrypted data storage on secure computers. Focus groups
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3 and interviews will be held in familiar environments whilst mindful of the
4 participants' privacy and safety.
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8 The questionnaire will be administered according to a standard protocol that
9 includes eligibility checks, confidentiality, ethical consent and administering
10 incentives. Communication with participants will be age-appropriate.
11 Information about suitable support services will be given to all participants and
12 referral to a school healthcare professional will be made available for the
13 participants if they become distressed by the focus groups, questionnaire test-
14 retest or participation in the intervention.
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19 The dissemination of results will include:

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1. a de-identified report of the study findings will be given to participating schools for dissemination to their staff and families for having generously participated;
 2. dissemination of the study's findings to healthcare professionals, educationalists and academics through local community, health and education conferences and international peer-reviewed journals;
 3. presentations at school-based professional development workshops and community-based seminars including web-based setting, where appropriate, to encourage the integration of the study's findings into public health and education policies; and
 4. dissemination of the study's questionnaire for use by researchers developing interventions for adolescent reproductive health literacy, and by teachers delivering puberty programs as part of sexuality and relationship education in accordance with curricula requirements.

43 LIST OF FIGURES

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46 Figure 1: Flowchart of Phase One – Development of the OM health literacy
47 intervention
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49 Figure 2: Flowchart of Phase Two – Trial of the OM health literacy intervention
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51 REFERENCES

52
53
54 1. American Academy of Pediatrics Committee on Adolescence and American College of
55 Obstetricians & Gynecologists Committee on Adolescent Health Care. Menstruation in girls and
56 adolescents: using the menstrual cycle as a vital sign. *Pediatrics*. 2006; 118(5):2245-50.
57 DOI:10.1542/peds.2006-2481.
58
59
60

2. American College of Obstetricians & Gynecologists Committee. Opinion No. 651: Menstruation in girls and adolescents: using the menstrual cycle as a vital sign. *Obstet Gynecol.* 2015; 126(6):e143-e146. DOI:10.1097/AOG.0000000000001215.
3. Marshall WA, Tanner JM. Variations in pattern of pubertal changes in girls. *Arch Dis Child.* 1969; 44(235):291. DOI:10.1136/adc.44.235.291.
4. Quint EH, Smith YR. Abnormal uterine bleeding in adolescents. *J Midwifery Womens Health.* 2003; 48(3):186-91. DOI:10.1016/S1526-9523(03)00061-8.
5. Hillard PA. Menstruation in adolescents. *Ann N Y Acad Sci.* 2008; 1135(1):29-35. DOI:10.1196/annals.1429.022.
6. Jamieson MA. Disorders of menstruation in adolescent girls. *Pediatr Clin North Am.* 2015; 62(4). DOI:10.1016/j.pcl.2015.04.007.
7. Hillen T, Grbavac S, Johnston P, Straton J, Keogh J. Primary dysmenorrhoea in young Western Australian women: prevalence, impact and knowledge of treatment. *J Adolesc Health.* 1999; 25(1):40-5. DOI:10.1016/S1054-139X(98)00147-5.
8. Pitts MK, Ferris JA, Smith AMA, Shelley JM, Richters J. Prevalence and correlates of three types of pelvic pain in a nationally representative sample of Australian women. *Med J Aust.* 2008; 189(3):138.
9. Parker M, Sneddon A, Arbon P. The menstrual disorder of teenagers (MDOT) study: determining typical menstrual patterns and menstrual disturbance in a large population-based study of Australian teenagers. *BJOG.* 2010; 117(2):185-92. DOI:10.1111/j.1471-0528.2009.02407.x.
10. Subasinghe AK, Happo L, Jayasinghe YL, Garland SM, Wark JD. Prevalence and severity of dysmenorrhoea, and management options reported by young Australian women. *Aust Fam Physician.* 2016; 45(11):829-34.
11. Zannoni L, Giorgi M, Spagnolo E, Montanari G, Villa G, Seracchioli R. Dysmenorrhoea, absenteeism from school, and symptoms suspicious for endometriosis in adolescents. *J Pediatr Adolesc Gynecol.* 2014; 27(5):258-65. DOI:doi.org/10.1016/j.jpag.2013.11.008.
12. Nwankwo TO, Aniebue UU, Aniebue PN. Menstrual disorders in adolescent school girls in Enugu, Nigeria. *J Pediatr Adolesc Gynecol.* 2010; 23(6):358-63. DOI:10.1016/j.jpag.2010.04.001.
13. Pitangui AC, Gomes M, Lima A, Schwingel P, Albuquerque A, Cappato de Araujo R. Menstruation disturbances: prevalence, characteristics, and effects on the activities of daily living among adolescent girls from Brazil. *J Pediatr Adolesc Gynecol.* 2013; 26:148-52. DOI:10.1016/j.jpag.2010.04.001.
14. Agarwal A, Venkat A. Questionnaire study on menstrual disorders in adolescent girls in Singapore. *J Pediatr Adolesc Gynecol.* 2009; 22:365-71. DOI:10.1016/j.jpag.2009.02.005.
15. Soliman AM, Yang H, Du EX, Kelley C, Winkel C. The direct and indirect costs associated with endometriosis: a systematic literature review. *Hum Reprod.* 2016; 31(4):712-22. DOI:10.1093/humrep/dev335.
16. Hunt, G. National action plan on endometriosis. Canberra: Commonwealth of Australia; 2017. <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt130.htm> (accessed Apr 2018).
17. Nooh AM, Abdul-Hady A, El-Attar N. Nature and prevalence of menstrual disorders among teenage female students at Zagazig University, Zagazig, Egypt. *J Pediatr Adolesc Gynecol.* 2015; 29:137-42. DOI:10.1016/j.jpag.2015.08.008.
18. Hickey M, Karthigasu K, Agarwal S. Abnormal Uterine Bleeding: a Focus on Polycystic Ovary Syndrome. *Women's Health.* 2009; 5(3):313-324. DOI:10.2217/WHE.09.20.
19. Rapkin A, Mikacich J. Premenstrual dysphoric disorder and severe premenstrual syndrome in adolescents. *Paediatr Drugs.* 2013; 15(3):191-202. DOI:10.1007/s40272-013-0018-4.
20. Borenstein J, Chiou CF, Dean B, Wong J, Wade S. Estimating direct and indirect costs of premenstrual syndrome. *J Occup Environ Med.* 2005; 47(1):26-33. DOI:10.1097/01.jom.0000150209.44312.d1
21. Vigil P, Ceric F, Cortés ME, Klaus H. Usefulness of monitoring fertility from menarche. *J Pediatr Adolesc Gynecol.* 2006; 19(3):173-9. DOI:10.1016/j.jpag.2006.02.003.

22. Manganello JA, Devellis RF, Davis TC, Schottler-Thal C. Development of the health literacy assessment scale for adolescents (HAS-A). *J Commun Healthc*. 2015; 8(3):172-84. DOI:10.1179/1753807615Y.0000000016.
23. Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot Int*. 2000; 15(3):259-67.
24. Sansom-Daly U, Lin M, Robertson E, Wakefield CE, McGill B, Girgis A, et al. Health literacy in adolescents and young adults: an updated review. *J Adolesc Young Adult Oncol*. 2016; 5:106-18. DOI:10.1089/jayao.2015.0059.
25. Fairbrother H, Curtis P, Goyder E. Making health information meaningful: children's health literacy practices. *SSM Popul Health*. 2016; 2:476-84. DOI:10.1016/j.ssmph.2016.06.005.
26. Wu AD, Begoray DL, Macdonald M, Wharf Higgins J, Frankish J, Kwan B, et al. Developing and evaluating a relevant and feasible instrument for measuring health literacy of Canadian high school students. *Health Promot Int*. 2010; 25(4):444-52. DOI:10.1093/heapro/daq032.
27. School Curriculum and Standards Authority. Health & Physical Education Curriculum Pre-Primary to Year 10. Perth, Government of Western Australia; 2017. <https://k10outline.scsa.wa.edu.au/home/p-10-curriculum/curriculum-browser/health-and-physical-education> (accessed Apr 2018).
28. Family Planning Alliance Australia. Position Statement: Relationship and Sexuality Education in Schools. Australia: FPPA; 2016. http://familyplanningallianceaustralia.org.au/wp-content/uploads/2017/04/FPAA-Schools-Education_Position-Statement_001_v2c.pdf (accessed Apr 2018).
29. Goldman JDG. External providers' sexuality education teaching and pedagogies for primary school students in Grade 1 to Grade 7. *Sex Educ*. 2011; 11(2):155-74. DOI:10.1080/14681811.2011.558423.
30. Johnson RL, Sendall MC, McCuaig LA. Primary schools and the delivery of relationships and sexuality education: the experience of Queensland teachers. *Sex Educ*. 2014; 14(4):359-74. DOI:10.1080/14681811.2014.909351.
31. Duffy B, Fotinatos N, Smith A, Burke J. Puberty, health and sexual education in Australian regional primary schools: Year 5 and 6 teacher perceptions. *Sex Educ*. 2013; 13(2):186-203. DOI:10.1080/14681811.2012.678324.
32. Smith A, Schlichthorst M, Mitchell A, Walsh J, Lyons A, Blackman P, et al. Sexuality education in Australian secondary schools 2010: results of the 1st national survey of Australian secondary teachers of sexuality education. Melbourne: Australian Research Centre in Sex Health & Society, La Trobe University; 2011. DOI:10.4225/50/557E5B09832EB.
33. Burns S, Hendriks J. Sexuality and relationship education training to primary and secondary school teachers: an evaluation of provision in Western Australia. *Sex Educ*. 2018; 18(6):672-88. DOI: 10.1080/14681811.2018.1459535.
34. Pound P, Langford R, Campbell R. What do young people think about their school-based sex and relationship education? A qualitative synthesis of young people's views and experiences. *BMJ Open*. 2016; 6(9) DOI:10.1136/bmjopen-2016-011329.
35. Carman M, Mitchell A, Schlichthorst M, Smith A. Teacher training in sexuality education in Australia: how well are teachers prepared for the job? *Sex Health*. 2011; 8(3):269-71. DOI:10.1071/SH10126.
36. New South Wales Education. The Menstrual Cycle. Sydney, Australia: Intel Corporation; 2013.
37. Walsh J. Talk soon. Talk often: a guide for parents talking to their kids about sex. Victoria: Australian Research Centre in Sex Health & Society, La Trobe University; 2011.
38. Department of Health Western Australia. Puberty: Menstrual Cycle. Growing & Developing Healthy Relationships: curriculum support materials. Perth: Government of Western Australia; 2016. http://www.healthywa.wa.gov.au/Articles/N_R/Puberty-things-that-change-for-girls (accessed Apr 2018)

- 1
- 2
- 3
- 4 39. Department of Health Western Australia. *Girls and Puberty*. Perth: Government of Western
- 5 Australia; 2007.
- 6 40. Bush D, Brick E, East MC, Johnson N. Endometriosis education in schools: a New Zealand model
- 7 examining the impact of an education program in schools on early recognition of symptoms
- 8 suggesting endometriosis. *Aust N Z J Obstet Gynaecol*. 2017; 57(4):452-7. DOI:10.1111/ajo.12614.
- 9 41. Lines A, Gallasch G. *The Rite Journey: Rediscovering Rites of Passage for Boys*. Thymos. 2009;
- 10 3(1):74-89. DOI:10.3149/thy.0301.74.
- 11 42. Lines A, Gallasch G, Hobbs A, Bennett J. *The rite journey for girls: a rite of passage programme*
- 12 *for adolescents*. Adelaide, Australia: Authenticity; 2018.
- 13 43. Australian Curriculum Assessment and Reporting Authority. *Guide to understanding 2013 Index*
- 14 *of Community Socio-educational Advantage (ICSEA) values*. Sydney, ACARA; 2013.
- 15 www.myschool.edu.au (accessed Apr 2018)
- 16 44. Moher D, Liberati A, Tetzlaff J, Altman DG. The PRISMA Group. Preferred reporting items for
- 17 systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med*. 2009; 6(7):e1000097.
- 18 DOI:10.1371/journal.pmed.1000097.
- 19 45. Odeblad E. The functional structure of human cervical mucus. *Acta Obstetrica et Gynecologica*
- 20 *Scandinavia*. 1968; 47:57.
- 21 46. Billings E, Westmore A. *The Billings method: controlling fertility without drugs or devices*.
- 22 Richmond, Victoria: Anne O'Donovan; 1980.
- 23 47. Australian Medical Association. *Position statement: health in the context of education*. Barton,
- 24 ACT: AMA; 2014. www.ama.com.au (accessed Apr 2017)
- 25 48. Keeney S, Hasson F, McKenna HP. *The Delphi technique in nursing and health research*.
- 26 Chichester, West Sussex: Wiley-Blackwell; 2011.
- 27 49. Okoli C, Pawlowski SD. The Delphi method as a research tool: an example, design considerations
- 28 and applications. *Inf Manag*. 2004; 42(1):15-29. DOI:10.1016/j.im.2003.11.002.
- 29 50. Fakhri M, Hamzehgardeshi Z, Hajikhani Golchin N, Komili A. Promoting menstrual health among
- 30 Persian adolescent girls from low socioeconomic backgrounds: a quasi-experimental study. *BMC*
- 31 *Public Health*. 2012; 12:193. DOI:10.1186/1471-2458-12-193.
- 32 51. Su JJ, Lindell D. Promoting the menstrual health of adolescent girls in China. *Nurs Health Sci*.
- 33 2016:481-7. DOI:10.1111/nhs.12295.
- 34 52. Tokolahti E, Hocking C, Kersten P. Development and content of a school-based occupational
- 35 therapy intervention for promoting emotional well-being in children. *Occup Ther Ment Health*. 2016;
- 36 32(3):245-58. DOI:10.1080/0164212X.2015.1129522.
- 37 53. Humphrey-Murto S, Varpio L, Gonsalves C, Wood TJ. Using consensus group methods such as
- 38 Delphi and nominal group in medical education research. *Med Teach*. 2017; 39(1):14-9.
- 39 DOI:10.1080/0142159X.2017.1245856.
- 40 54. Abel T, Hofmann K, Ackermann S, Bucher S, Sakarya S. Health literacy among young adults: a
- 41 short survey tool for public health and health promotion research. *Health Promot Int*. 2015;
- 42 30(3):725-35. DOI:10.1093/heapro/dat096.
- 43 55. Davis TC, Wolf MS, Arnold CL, Byrd RS, Long SW, Springer T, et al. Development and validation of
- 44 the rapid estimate of adolescent literacy in medicine (REALM-Teen): a tool to screen adolescents for
- 45 below-grade reading in health care settings. *Pediatrics*. 2006; 118(6):e1707.
- 46 DOI:10.1542/peds.2006-1139.
- 47 56. McDonald F, Patterson P, Costa D, Shepherd H. Validation of a health literacy measure for
- 48 adolescents and young adults diagnosed with cancer. *J Adolesc Young Adult Oncol*. 2016; 5(1):69-75.
- 49 DOI:10.1089/jayao.2014.0043.
- 50 57. Osborne R, Batterham R, Elsworth G, Hawkins M, Buchbinder R. The grounded psychometric
- 51 development and initial validation of the health literacy questionnaire (HLQ). *BMC Public Health*.
- 52 2013; 13:658. DOI:10.1186/1471-2458-13-658.
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- 4 58. Bradley-Klug K, Shaffer-Hudkins E, Lynn C, Jeffries Deloatche K, Montgomery J. Initial
- 5 development of the health literacy and resiliency scale: youth version. *J Commun Healthc*. 2017;
- 6 10(2):100-7. DOI:10.1080/17538068.2017.1308689.
- 7 59. Aflaq F, Jami H. Experiences and attitudes related to menstruation among female students.
- 8 *Pakistan Journal of Psychological Research*. 2012; 27(2):201-24.
- 9 60. Brooks-Gunn J, Ruble DN. The menstrual attitude questionnaire. *Psychosomatic medicine*. 1980;
- 10 42(5):503.
- 11 61. Marván ML, Ramírez-Esparza D, Cortés-Iniestra S, Chrisler JC. Development of a new scale to
- 12 measure beliefs about and attitudes toward menstruation (BATM): data from Mexico and the United
- 13 States. *Healthc Women Int*. 2006; 27(5):453. DOI:10.1080/07399330600629658.
- 14 62. Morse JM, Kieren D, Bottorff J. The adolescent menstrual attitude questionnaire, part I: scale
- 15 construction. *Healthc Women Int*. 1993; 14(1):39-62. DOI:10.1080/07399339309516025.
- 16 63. DeMaria EP, Mikulas WL. Women's awareness of their menstrual cycle. *Int J Sex Health*. 1992;
- 17 4(3):71-82. DOI:10.1300/J056v04n03_05.
- 18 64. Byers P, Zeller R, Byers B. Focus group methods. In: Weideman M, Whitley B, editors. *Handbook*
- 19 *for conducting research on human sexuality*; 2002. p. 173-93.
- 20 65. Tong A, Sainsbury P, Carter S, Hall B, Harris D, Walker R, et al. Patients' priorities for health
- 21 research: focus group study of patients with chronic kidney disease. *Nephrology Dialysis*
- 22 *Transplantation*. 2008; 23:3206-14. DOI:10.1093/ndt/gfn207.
- 23 66. Bronfenbrenner U. *The Ecology of Human Development*. Cambridge MA: Harvard University
- 24 Press; 1979.
- 25 67. Greene S, Hogan D. *Researching children's experiences: methods and approaches*. London: SAGE;
- 26 2005.
- 27 68. McBride N. *Intervention research : a practical guide for developing evidence-based school*
- 28 *prevention programmes*. Singapore: Springer; 2016.
- 29 69. Glenton C, Carlsen B. What about N? A methodological study of sample-size reporting in focus
- 30 group studies. *BMC Med Res Methodol*. 2011; 11(1):26. DOI:10.1186/1471-2288-11-26.
- 31 70. Liamputtong P. *Research methods in health: foundations for evidence-based practice*. 2nd ed.
- 32 Melbourne: Oxford University Press; 2013.
- 33 71. Liamputtong P. *Qualitative research methods*. 4th ed. Melbourne: Oxford University Press; 2013.
- 34 72. Corbin JM, Strauss AL. *Basics of qualitative research: techniques and procedures for developing*
- 35 *grounded theory*. 3rd ed. Thousand Oaks CA: Sage Publications Inc.; 2008.
- 36 73. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a
- 37 32-item checklist for interviews and focus groups. *Int J Qual Health Care*. 2007; 19(6):349-57.
- 38 DOI:10.1093/intqhc/mzm042.
- 39 74. Chiou M-H, Wang H-H, Yang Y-H. Effect of systematic menstrual health education on
- 40 dysmenorrhic female adolescents' knowledge, attitudes, and self-care behavior. *Kaohsiung J Med*
- 41 *Sci*. 2007; 23(4):183-90. DOI:10.1016/S1607-551X(09)70395-X.
- 42 75. Janssen EHC, Singh AS, van Nassau F, Brug J, van Mechelen W, Chinapaw MJM. Test-retest
- 43 reliability and construct validity of the DOiT (Dutch obesity intervention in teenagers) questionnaire:
- 44 measuring energy balance-related behaviours in Dutch adolescents. *Public Health Nutr*. 2014;
- 45 17(2):277-86. DOI:10.1017/S1368980012005253.
- 46 76. Flisher AJ, Evans J, Muller M, Lombard C. Brief report: test-retest reliability of self-reported
- 47 adolescent risk behaviour. *J Adolesc*. 2004; 27(2):207-12. DOI:10.1016/j.adolescence.2001.10.001.
- 48 77. Kılıç S. Cronbach's alpha reliability coefficient. *J Mood Disord*. 2016; 6(1):47-8.
- 49 DOI:10.5455/jmood.20160307122823.
- 50 78. Bowen G. Naturalistic inquiry and the saturation concept: a research note. *Qual Res*. 2008;
- 51 8(1):137-52. DOI:10.1177/1468794107085301.
- 52 79. Burns S, Cross D, Maycock B. "That could be me squishing chips on someone's car": how friends
- 53 can positively influence bullying behaviors. *J Prim Prev*. 2010; 31(4):209-22. DOI:10.1007/s10935-
- 54 010-0218-4.
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3 80. Boeije HR. A purposeful approach to the constant comparative method in the analysis of
4 qualitative interviews. *Qual Quan.* 2002; 36:391-5177. DOI:10.1023/A:1020909529486.
5 81. Harris T. Grounded theory. *Nursing Standard.* 2015; 29(35):32. DOI:10.7748/ns.29.35.32.e9568.
6 82. Bluff R. Grounded Theory: The Methodology. In: Holloway I, editor. *Qualitative Research in*
7 *Health Care.* Berkshire, UK: Open University Press, McGraw-Hill; 2005.
8 83. Glaser B. *Basics of Grounded Theory Analysis.* Mill Valley, CA: Sociology Press; 1992.
9 84. Burns S, Maycock B, Cross D, Brown G. The power of peers: why some students bully others to
10 conform. *Qual Health Res.* 2008; 18(12):1704-16. DOI:10.1177/1049732308325865.
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13 **AUTHORS' CONTRIBUTIONS**

14
15 This protocol paper describes a supervised doctoral research project. All
16 authors contributed to development and conceptualisation of the protocol. FR
17 was responsible for drafting and coordinating the authors' contributions. SB,
18 HJC and JH were responsible for editing and guidance on the paper. All authors
19 were responsible for critically revising the paper. All authors approved the final
20 version of this paper.
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23 **FUNDING STATEMENT**

24
25 This research project is funded through the Australian Government Research
26 Training Program Scholarship as administered through the doctoral program
27 run at Curtin University's School of Public Health.
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30 **COMPETING INTERESTS STATEMENT**

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32 None declared
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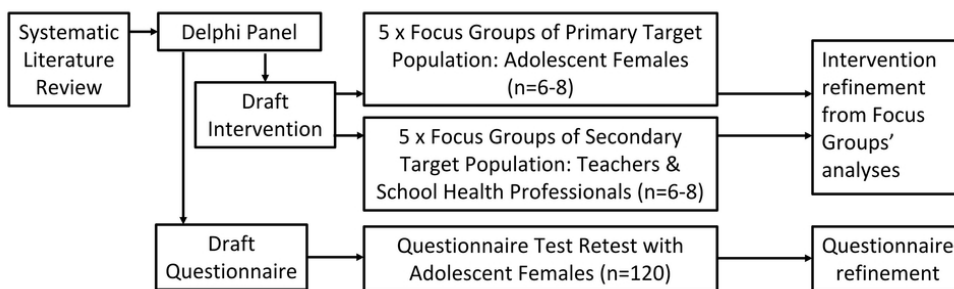


Figure 1: Flowchart of Phase One – Development of the OM health literacy intervention

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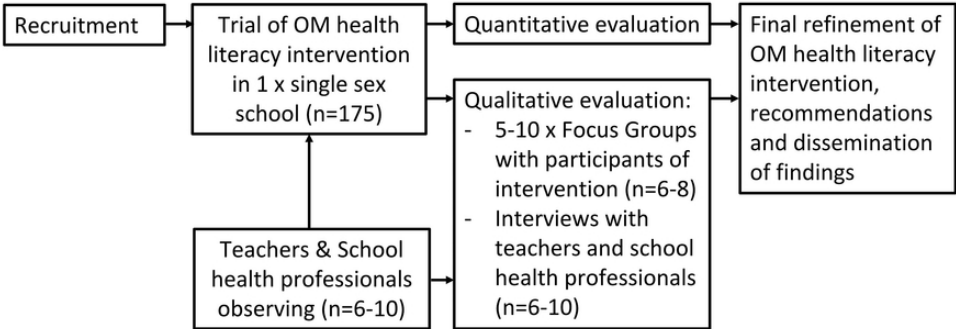


Figure 2: Flowchart of Phase Two – Trial of the OM health literacy intervention

38x14mm (600 x 600 DPI)