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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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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

inform the development of an intervention to facilitate OM health literacy. The Delphi panel will also inform the development of a valid questionnaire to evaluate OM health literacy, which will be assessed for test-retest reliability. Phase Two will trial the intervention with a convenience sample of 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

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

ARTICLE SUMMARY

Strengths and Limitations of this study

- To our knowledge, this will be the first study aimed at the whole person OM health literacy of adolescent females, which aims to raise OM health awareness and confidence to address OM health disturbances.
- A consumer-empowered study that engages multiple stakeholders.
- The selection of a single-sex school may reduce the intervention's generalisability.
- The risk of bias is present as participant recruitment will be restricted to private schools.
- Limited funds restrict implementing and evaluating trials in a larger sample of other schools.

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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 Brazil[13] 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 Egypt[17] 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]

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 Model[23] 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 Model[23] 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 Model[23] to the final core skill of critical health literacy by using task-oriented measurements of evaluation.[26] The three core skills of Nutbeam's Model[23] 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

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 program[41] 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:

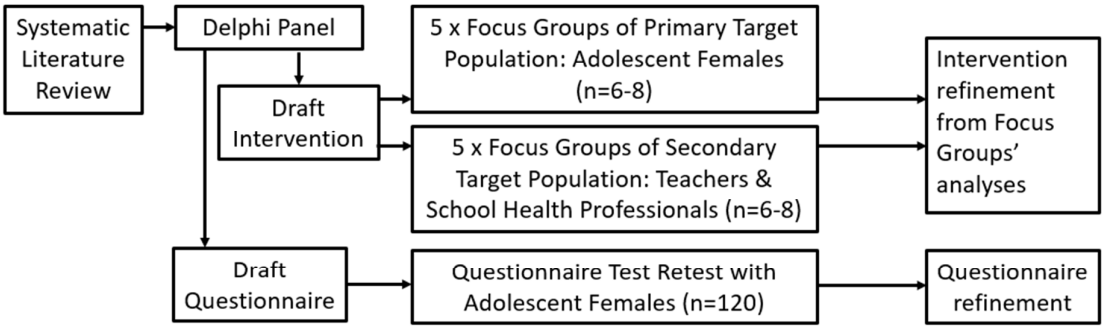

Figure 1: Flowchart of Phase One - Development

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

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 the Odeblad's findings[45] 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 age 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.

Delphi study

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 identified[49] 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:

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

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]

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]

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

Focus groups with adolescent females will be conducted to gain insight on[64] and to elicit priorities for issues[65] to be included in the intervention. To reduce the possibility of distress, 16-year-old girls will be approached because most will have already attained up to three years of gynaecological age and are more likely to be familiar with the responsibilities and experience of their OM cycles. Personal information will not be solicited, but rather what the

participants believe to be important for adolescent OM health in general. Each of the five socio-demographically diverse schools will be asked to purposively select six to eight 16 year old female students to form one focus group.[66] A total of 30-40 participants will thus be allocated into five focus groups (n= 6 to 8 per group).

Focus groups of the Secondary Target Population

Teachers from health, physical education, science and religious studies and school healthcare professionals (such as nurses, psychologists and counsellors) are the most likely group to implement the intervention in Phase Two and beyond.[67] They may provide insight[65] into mapping the intervention to the curriculum and its practical facilitation in class. The purpose is to gain an understanding of the issues surrounding the program's content, delivery, training and future continuation. Each of the five socio-demographically diverse schools will be asked to purposively select 6 to 8 of their teachers and healthcare professionals to form one focus group. In total, 30-40 participants will be allocated into five focus groups (n= 6 to 8 per group).

Additional focus groups in either population may be recruited to saturation, which is consistent with qualitative research.[68] The focus groups will be facilitated by the research team using a semi-structured interview guide, and conducted at a suitably quiet location at each school.

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.[69, 70] Data will be coded using NVivo V.10 software. A constant comparison analysis will allow for the thematic discovery[71] that is necessary to finalise the intervention's development. The 32-item Consolidated criteria for reporting qualitative studies (COREQ-32)[72] 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.

Questionnaire Test-retest

A group of at least 120 adolescent females[50, 73, 74] will be recruited from one school to assess test-retest reliability of the questionnaire over a fortnight.[75] 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.[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:

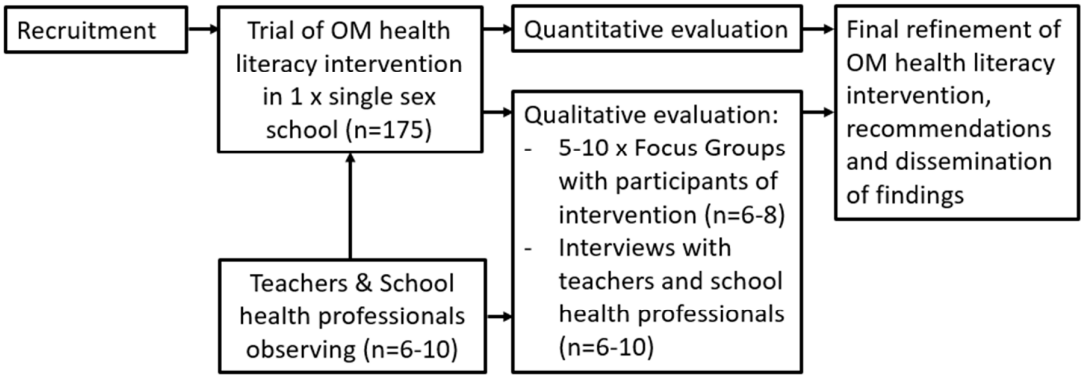

Figure 2: Flow chart of Phase Two - Trial of the OM health literacy intervention

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

Ethics approval has been obtained from Curtin University (HRE2018-0101). Additional ethics approval will be sought at key milestones as stipulated by HREC. Prior to participation in the study, informed written consent will be obtained from parents or guardians and student participants. Each participant will be informed of the voluntary nature of the study, their right to withdraw at any time without prejudice and maintenance of anonymity. Confidentiality procedures will include delinked data collection, direct computer entry of de-identified data, and encrypted data storage on secure computers. Focus groups and interviews will be held in familiar environments whilst mindful of the participants' privacy and safety.

The questionnaire will be administered according to a standard protocol that includes eligibility checks, confidentiality, ethical consent and administering incentives. Communication with participants will be age-appropriate. Information about suitable support services will be given to all participants and referral to a school healthcare professional will be made available for the participants if they become distressed by the focus groups, questionnaire test-retest or participation in the intervention.

The dissemination of results will include:

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.

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

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

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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).

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 Brazil[13] 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 Egypt[17] 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]

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 Model[23] 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 Model[23] 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 Model[23] to the final core skill of critical health literacy by using task-oriented measurements of evaluation.[26] The three core skills of Nutbeam's Model[23] 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

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 program[41] 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.

Patient and Public Involvement

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

Research setting

The study will be based in Perth, Western Australia. In Phase One, five schools will be invited to offer female students, teachers and school healthcare professionals the opportunity to participate in focus groups. Both private and public schools will be approached. 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 single-sex school in the Perth metropolitan area. Only private schools will be approached in this phase because there are no single-sex public schools in Perth. The school will be single-sex rather than co-educational of mixed sexes in order to eliminate any study burden of occupying male students. Subsequent studies may explore the efficacy of this intervention in a co-educational setting. 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:

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 findings[45] 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

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 identified[49] 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:

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

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]

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]

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

Focus groups with adolescent females will be conducted to gain insight on[64] and to elicit priorities for issues[65] to be included in the intervention. To reduce the possibility of distress, 16-year-old girls will be approached because most will have already been menstruating for up to three years and are more likely to be familiar with the responsibilities and experience of their OM cycles. Personal information will not be solicited, but rather what the participants believe to be important for adolescent OM health in general. This creates the opportunity to explore socio-ecological influences[66] that may shape an adolescent's approach to OM self-management. Exploration of girls' parents or guardians as enablers or barriers to OM health literacy lies however outside the scope of this study. Each of the five socio-demographically diverse schools will be asked to purposively select six to eight 16-year-old female students to form one focus group.[67] A total of thirty to forty participants will thus be allocated into five focus groups (n=6-8 per group).

Focus groups of the Secondary Target Population

Teachers from health, physical education, science and religious studies and school healthcare professionals (such as nurses, psychologists and counsellors) are the most likely group to implement the intervention in Phase Two and beyond.[68] They may provide insight[65] into mapping the intervention to the curriculum and its practical facilitation in class. The purpose is to gain an understanding of the issues surrounding the program's content, delivery, training and future continuation. Each of the five socio-demographically diverse schools will be asked to purposively select six to eight of their teachers and school healthcare professionals to form one focus group. In total, thirty to forty participants will be allocated into five focus groups (n=6-8 per group).

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

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 discovery[72] 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 school term, which reduces 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.

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:

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.[78]

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 school 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.[79] This allows for questions to be modified as part of the understanding process.[80] The focus groups and interviews will be conducted to saturation, which will be determined when no new concepts surface from repeated data review.[78]

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. A grounded theory approach has been selected because it aims to make theoretical assumptions that can be verified.[72, 81] This systematic approach accentuates the mixed methods approach.[82] The theory developed should explain variations in behaviour while representing the main concerns and ideas of the participants.[83] Accordingly, the data will be analysed by constant comparison, whereby data is continually

sorted and the information is coded into commonly occurring key themes.[80] After final coding, the data will be thematically analysed to include the perspectives that emerged and allow for an inductive development of theory.[72] This process is consistent with other qualitative based studies.[79, 84] COREQ-32 will be used to report the conduct, method, context, findings, analysis and interpretations of the qualitative studies.[73] The expected outcome is that the qualitative findings will provide a richer understanding of the intervention from the perspective of the students, teachers and school healthcare professionals. These data will be triangulated with the quantitative findings to further refine the intervention.

In summary, the qualitative and quantitative instruments used in this study's mixed-method approach offers a triangulation of data sources to cross-check and inform the development and trialling of the intervention. Each step in Phase One will inform the next step in order to progress the intervention's development and to validate the questionnaire as the measurement tool. In turn, Phase One provides the intervention and its validated questionnaire for trial in Phase Two. The final outcome expected at the end of Phase Two is a more nuanced and refined intervention for wider testing. A subsequent large intervention-based trial would include focus on generalisability and sustainability.

ETHICS & DISSEMINATION

Ethics approval has been obtained from Curtin University (HRE2018-0101). Additional ethics approval will be sought at key milestones as stipulated by HREC. Prior to participation in the study, informed written consent will be obtained from parents or guardians and student participants. Each participant will be informed of the voluntary nature of the study, their right to withdraw at any time without prejudice and maintenance of anonymity. Confidentiality procedures will include delinked data collection, direct computer entry of de-identified data, and encrypted data storage on secure computers. Focus groups and interviews will be held in familiar environments whilst mindful of the participants' privacy and safety.

The questionnaire will be administered according to a standard protocol that includes eligibility checks, confidentiality, ethical consent and administering incentives. Communication with participants will be age-appropriate. Information about suitable support services will be given to all participants and referral to a school healthcare professional will be made available for the

participants if they become distressed by the focus groups, questionnaire test-retest or participation in the intervention.

The dissemination of results will include:

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.

LIST OF FIGURES

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

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

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AUTHORS' CONTRIBUTIONS

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

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COMPETING INTERESTS STATEMENT

None declared

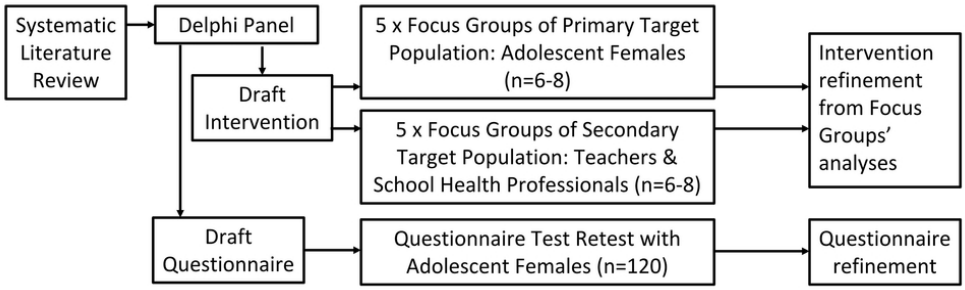

Figure 1: Flowchart of Phase One – Development of the OM health literacy intervention

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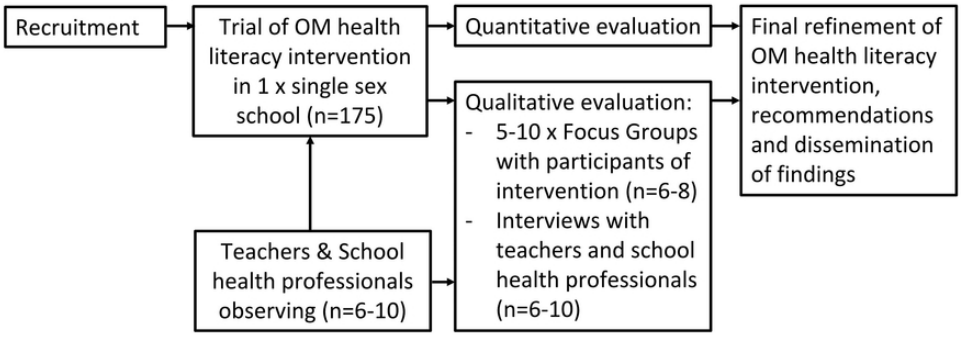

Figure 2: Flowchart of Phase Two – Trial of the OM health literacy intervention

38x14mm (600 x 600 DPI)

BMJ Open

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

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Secondary Subject Heading:	Paediatrics, Reproductive medicine, Obstetrics and gynaecology
Keywords:	school-based intervention, health literacy, menstruation, dysmenorrhoea, abnormal uterine bleeding, premenstrual syndrome

TITLE

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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.

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

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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 Brazil[13] 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 Egypt[17] 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]

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 Model[23] 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 Model[23] 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 Model[23] to the final core skill of critical health literacy by using task-oriented measurements of evaluation.[26] The three core skills of Nutbeam's Model[23] 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 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 program[41] 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.

Patient and Public Involvement

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

Research setting

The study will be based in Perth, Western Australia. In Phase One, five schools will be invited to offer female students, teachers and school healthcare professionals the opportunity to participate in focus groups. Both private and public schools will be approached. 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 single-sex school in the Perth metropolitan area. Only private schools will be approached in this phase because there are no single-sex public schools in Perth. The school will be single-sex rather than co-educational of mixed sexes in order to eliminate any study burden of occupying male students. Subsequent studies may explore the efficacy of this

intervention in a co-educational setting. 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:

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 search time period spans 39 years, dating from 1st January 1980 to 31st December 2018. The year 1980 marks the publication of a mainstream book which used Odeblad's findings[45] to describe OM cycle phases.[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]. The databases to be searched are CINAHL, Informit, Ovid, Proquest, Science Direct, Medline, Web of Science and Scopus. 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

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 identified[49] 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:

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

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]

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]

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

Focus groups with adolescent females will be conducted to gain insight on[64] and to elicit priorities for issues[65] to be included in the intervention. To reduce the possibility of distress, 16-year-old girls will be approached because most will have already been menstruating for up to three years and are more likely to be familiar with the responsibilities and experience of their OM cycles. Personal information will not be solicited, but rather what the participants believe to be important for adolescent OM health in general. This creates the opportunity to explore socio-ecological influences[66] that may shape an adolescent's approach to OM self-management. Exploration of girls' parents or guardians as enablers or barriers to OM health literacy lies however outside the scope of this study. Each of the five socio-demographically diverse schools will be asked to purposively select six to eight 16-year-old female students to form one focus group.[67] A total of thirty to forty participants will thus be allocated into five focus groups (n=6-8 per group).

Focus groups of the Secondary Target Population

Teachers from health, physical education, science and religious studies and school healthcare professionals (such as nurses, psychologists and counsellors) are the most likely group to implement the intervention in Phase Two and beyond.[68] They may provide insight[65] into mapping the intervention to the curriculum and its practical facilitation in class. The purpose is to gain an understanding of the issues surrounding the program's content, delivery, training and future continuation. Each of the five socio-demographically diverse schools will be asked to purposively select six to eight of their teachers and school healthcare professionals to form one focus group. In total, thirty to forty participants will be allocated into five focus groups (n=6-8 per group).

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

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 discovery[72] 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

school term, which reduces 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.
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:

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.[78]

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 school 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.[79] This allows for questions to be modified as part of the understanding process.[80] The focus groups and interviews will be conducted to saturation, which will be determined when no new concepts surface from repeated data review.[78]

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. A grounded theory approach has been selected because it aims to make theoretical assumptions that can be verified.[72, 81] This systematic approach accentuates the mixed methods approach.[82] The theory developed should explain variations in behaviour while representing the main concerns and ideas of the participants.[83] Accordingly, the data will be analysed by constant comparison, whereby data is continually sorted and the information is coded into commonly occurring key themes.[80] After final coding, the data will be thematically analysed to include the perspectives that emerged and allow for an inductive development of theory.[72] This process is consistent with other qualitative based studies.[79, 84] COREQ-32 will be used to report the conduct, method, context, findings, analysis and interpretations of the qualitative studies.[73] The expected outcome is that the qualitative findings will provide a richer understanding of the intervention from the perspective of the students, teachers and school healthcare professionals. These data will be triangulated with the quantitative findings to further refine the intervention.

In summary, the qualitative and quantitative instruments used in this study's mixed-method approach offers a triangulation of data sources to cross-check and inform the development and trialling of the intervention. Each step in Phase One will inform the next step in order to progress the intervention's development and to validate the questionnaire as the measurement tool. In turn, Phase One provides the intervention and its validated questionnaire for trial in Phase Two. The final outcome expected at the end of Phase Two is a more nuanced and refined intervention for wider testing. A subsequent large intervention-based trial would include focus on generalisability and sustainability.

ETHICS & DISSEMINATION

Ethics approval has been obtained from Curtin University (HRE2018-0101). Additional ethics approval will be sought at key milestones as stipulated by HREC. Prior to participation in the study, informed written consent will be obtained from parents or guardians and student participants. Each participant will be informed of the voluntary nature of the study, their right to withdraw at any time without prejudice and maintenance of anonymity. Confidentiality procedures will include delinked data collection, direct computer entry of de-identified data, and encrypted data storage on secure computers. Focus groups

and interviews will be held in familiar environments whilst mindful of the participants' privacy and safety.

The questionnaire will be administered according to a standard protocol that includes eligibility checks, confidentiality, ethical consent and administering incentives. Communication with participants will be age-appropriate. Information about suitable support services will be given to all participants and referral to a school healthcare professional will be made available for the participants if they become distressed by the focus groups, questionnaire test-retest or participation in the intervention.

The dissemination of results will include:

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.

LIST OF FIGURES

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

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

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AUTHORS' CONTRIBUTIONS

This protocol paper describes a supervised doctoral research project. All authors contributed to development and conceptualisation of the protocol. FR was responsible for drafting and coordinating the authors' contributions. SB, HJC and JH were responsible for editing and guidance on the paper. All authors were responsible for critically revising the paper. All authors approved the final version of this paper.

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COMPETING INTERESTS STATEMENT

None declared

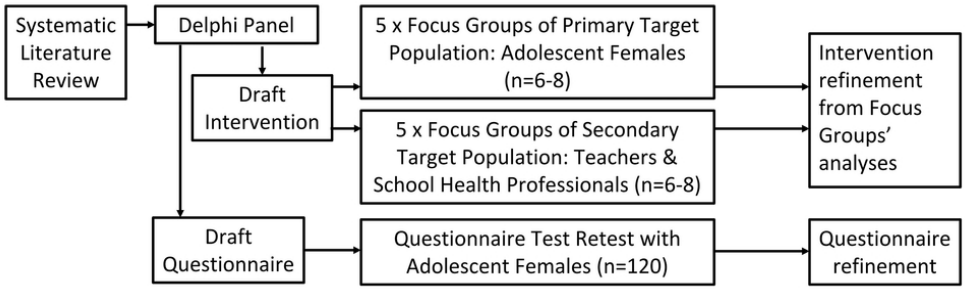

Figure 1: Flowchart of Phase One – Development of the OM health literacy intervention

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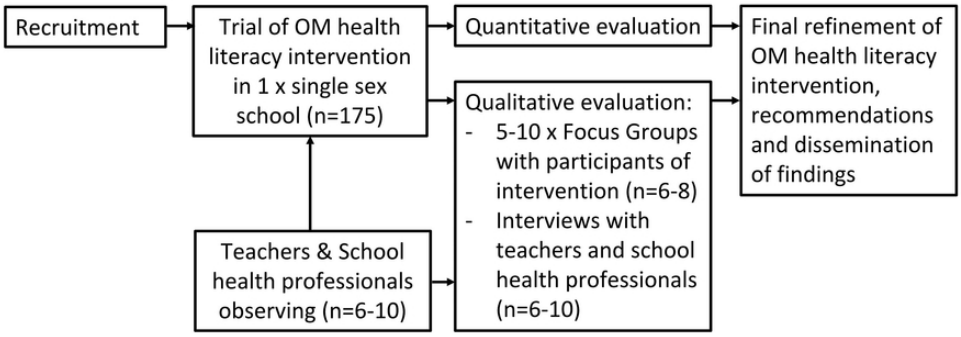

Figure 2: Flowchart of Phase Two – Trial of the OM health literacy intervention

38x14mm (600 x 600 DPI)