'Diagnosis and treatment of vulval skin disease: A survey study'

STUDY PERSONNEL AND CONTACT DETAILS

Chief investigator: Dr Rosalind Simpson

Associate Professor of Dermatology

Centre of Evidence Based Dermatology

Lifespan and Population Health

School of Medicine
University of Nottingham

Applied Health Services Research Building (Building number 42),

University Park Campus,

Nottingham

NG7 2RD

Phone: 0115 8232436

Email: Rosalind.simpson@nottingham.ac.uk

Co-investigators: Dr Louise Clarke

Lifespan and Population Health

School of Medicine
University of Nottingham

Applied Health Services Research Building (Building number 42),

University Park Campus,

Nottingham

NG7 2RD

Email: louise.clarke1@nottingham.ac.uk

BMedSci student: Arabella Crew

School of Medicine

University of Nottingham

Study Statistician: N/A

Study Coordinating Centre: Centre of Evidence Based Dermatology

Study Background information and rationale

Background:

Lichen Sclerosus (LS) affects up to 3% of adult women (1) and is the most common inflammatory vulval skin condition. It is primarily found in post-menopausal women but can be found in all age groups, including infants. It causes significant discomfort, scarring and irreversible vulval anatomical changes, as well as increasing lifetime vulval cancer risk by up to 22 times (2). Vulval skin diseases can also affect psychological wellbeing which can lead to self-harm and suicidal thoughts (3). In a recent interview study, women with vulval dermatoses described symptoms 'all-encompassing' and treatment a 'burden,' with limitations to daily activities, diminished sexual pleasure and a wide range of negative feelings as a result (4). Vulval LS (VLS) specifically, has been associated with higher rates of depression, decreased work productivity and decreased sexual quality of life (5). Potent topical corticosteroid treatment can reduce symptoms, sequelae, occurrence of vulval cancer and improve quality of life (6). Serious complications of VLS can be avoided with early potent topical corticosteroid treatment, with some skin changes completely reversible (6). Women with a longer duration of symptoms have more severe hyperkeratosis, increased likelihood of scarring and increased risk of being

subsequently diagnosed with vulval cancer (7). This suggests timely diagnosis is important for symptom relief, prevention of scarring and decreasing risk of vulval cancer. However, diagnostic delay and misdiagnosis is common. Women often attribute these to negative interactions with healthcare professionals (HCPs) and poor overall knowledge amongst wider medical personnel (8).

Women who have experienced a delay in diagnosis report dismissive and insensitive attitudes of HCPs (8), not being examined when indicated and frequent misdiagnosis (9) which includes symptoms being ascribed to mental health or self-harm (10). In addition, women report personal embarrassment when seeking a diagnosis for vulval symptoms which may contribute to further diagnostic delay. All qualitative studies to date have found patient participants with VLS and vulval dermatoses to have consistently negative interactions with HCPs in both community and hospital settings when seeking diagnosis and treatment of their vulval symptoms (8, 9, 10 and 11). This has both psychological and physical ramifications. As a result of unsatisfactory interactions and delay in diagnosis, women reported feelings of concern, anger, further embarrassment, and mourning (9, 10 and 11). Diagnostic delay leads to increased physical burden of disease with increased rates of serious complications in patients who have not received early potent topical steroid treatment (7).

Awareness and understanding of vulval skin disease is variable amongst HCPs working within UK primary care, the setting in which most patients are diagnosed. A 2007 study in the UK found that follow up in primary care, in the 12 months following discharge from vulval clinic, was carried out 62% of the time. This study called for better education in primary care to enable standard requirements of care for women with VLS (12). There is currently no pre-existing research regarding diagnosis of VLS in primary care from an HCP's perspective. This survey will collect data on HCP's experience of examining female genitalia, identifying vulval skin disease, education on vulval skin disease, and opinions on barriers to diagnosis and treatment of VLS in primary care. In addition, the survey will ask questions on how helpful HCPs would find diagnostic criteria and in which format this would be most useful. This will compliment an ongoing study at the Centre for Evidence Based Dermatology.

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STUDY OBJECTIVES

PRIMARY OBJECTIVE

To investigate primary care HCPs perception of confidence in identifying and managing vulval skin conditions with focus on lichen sclerosus by establishing:

1. their confidence in examining female genitalia and identifying vulval skin disease
2. their confidence in diagnosing and treating of VLS
3. their opinions on the possible barriers to diagnosis and treatment of VLS.

SECONDARY OBJECTIVE

To establish the level of education and training of HCPs on vulval skin disease.

TERTIARY OBJECTIVE

To determine whether having a diagnostic criteria for VLS is perceived as helpful by HCPs and in which format they would prefer a diagnostic tool to be available.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: September 2023-January 2024 (5 months)

Participant Duration: The online or paper survey will take participants approximately 10 minutes to complete. The survey will only be completed once by individual participants.

End of the Study: End of the study will be the end of the online survey.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment:

Recruitment for the online study will take place through advertisements via professional bodies, e-mail via relevant professional networks and social media posts on relevant professional groups. Recruitment will also take place via distributing paper copies at relevant professional events and meetings.

Eligibility criteria

Informed consent will be assumed if a participant responds to the survey (online and paper surveys) and ticks the 'check box' on the survey for consent (online version only).

Inclusion criteria:

- Healthcare professionals working in primary care that may examine female genitalia as part of their job role.
- Ability to complete the online survey
- Ability to give informed consent
- Ability to understand written English

HCPs working in primary care that may examine female genitalia as part of their job role include, but are not limited to:

• General Practitioners

• General Practice trainees

• Advanced Nurse Practitioners

• Advanced Care Practitioners

• Practice Nurses

• Health Care Assistants

• Midwives

Exclusion criteria:

HCPs not working in primary care or HCPs who do not examine female genitalia as part of their job role.

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the investigator. The participants will be made aware that this will not affect their future career or eligibility to take part in future research. Participants will be made aware (via the information sheet) that should they withdraw, the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

Completion of all or part of the online or paper survey will be taken as informed consent and separate written informed consent will not be sought. Written participant information will be combined with a short online consent process for the online survey. Written participant information will be distributed with the paper copy of the survey.

At the beginning of the online survey, participants will be asked to read the participant information and 'check a box' to give their consent to participate in the survey. For the paper survey, participants will be asked to read the participant information and consent will be assumed if all or part of the survey is completed. Participants will be provided with contact details for the study team and the investigator and/or a member of the study team will answer any questions that the participant has concerning study participation.

STUDY REGIMEN

Recruitment

Potential participants will be invited via professional bodies, e-mail via relevant professional networks and social media posts on relevant professional groups. Recruitment may take place via distributing paper copies at relevant

professional events and meetings. Stakeholder groups will include all HCPs in primary care that examine female genitalia as part of their job role including, but not limited to GPs, GP trainees, nurses, midwives and health care assistants.

Compliance

The survey will be kept as succinct as possible to aid completion of the survey by participants.

Criteria for terminating the study

It is not anticipated that this study will need to be terminated early. If recruitment from certain stakeholder groups is poor, this will be addressed by targeting specific networks to boost numbers of those who are underrepresented.

ANALYSES

Methods

Data will be downloaded or manually inputted into Excel, SPSS and NVivo and analysed using mixed methods. Descriptive statistics will be used to analyse demographic information and quantitative survey data, and Spearman's rank tests will be used to explore relationships between confidence levels and other variables. Qualitative survey responses will be analysed using thematic analysis with a semantic approach, with codes strictly driven by the data.

Sample size and justification

No sample size calculation has been carried out for this study as there will be no formal statistical tests required, only descriptive statistics. It is anticipated that up to 200 health professionals will complete the surveys. The study team will promote and disseminate the survey for the duration that it is open to maximise responses.

ADVERSE EVENTS

The occurrence of an adverse event because of participation within this study is not expected and no adverse event data will be collected.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol and participant information sheets have received approval / favourable opinion from the University of Nottingham Ethics committee.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION

Healthcare professional and patient surveys

Completion of the combined participant information/consent form and subsequent return of questionnaires will be taken as informed consent. For paper copies, completion and return of the all or part of the questionnaires will be taken as informed consent.

RECORDS

The online survey will be filled in electronically using Microsoft Forms. The paper forms will be kept in a locked filing cabinet in a secure building at the earliest opportunity following collection. They will be disposed of via confidential waste once the data has been inputted in Microsoft Excel.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The survey will only collect the minimum required information for the purposes of the study. Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method).

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

Paper copies of the survey will be transferred to a locked filing cabinet in a secure building at the earliest opportunity. They will then be disposed of via confidential waste after the data has been transferred onto Microsoft Excel.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

STUDY DATA

Study data and evidence of monitoring and systems audits will be made available for inspection by the University of Nottingham Ethics Committee as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

Dissemination to health care professionals will be through presentations at clinical conferences and via publication in a peer reviewed journals. The research data will form part of the dissertation for the BMedSci degree of Arabella Crew. Participants will not be identifiable in any written, presented or published material.

All participants involved in the research will be informed of the study outcomes if they opt in to receive a newsletter and all will be able to access study updates on the Centre of Evidence Based Dermatology website.

USER AND PUBLIC INVOLVEMENT

This study was developed with input from the Centre of Evidence Based Dermatology vulval patient panel, a group consisting of patients and professionals with an interest in vulval skin disease.

Researchers used their established relationships with professional colleagues for PPI input and will do for ongoing PPI input as needed.

STUDY FINANCES

Funding source and conflict of interest:

This project has not received any funding.

Dr Rosalind Simpson has no conflicts of interest to declare.

Dr Louise Clarke has no conflicts of interest to declare.

Arabella Crew has no conflicts of interest to declare.

Participant stipends and payments:

Participants will not be paid to participate in the study.