



Development and Psychometric Evaluation of the Sexual and Reproductive Health Questionnaire for Women With Type 1 Diabetes Mellitus: A Study Protocol for a Sequential Exploratory Mixed-Methods Study

Nasrin Azimi^{1,2}, Giti Ozgoli^{3,4*}, Abbas Ebadi^{5,6}, Hamid Alavi Majd⁷, Assadollah Rajab⁸, Fatemeh Jalali Chimeh⁹, Samiyeh Kazemi²

Abstract

Objectives: Type 1 diabetes mellitus (T1DM) can profoundly influence different dimension of health such as sexual and reproductive health (SRH). The aim of this study is to develop and evaluate the psychometric properties of the Sexual and Reproductive Health Questionnaire for Women with Type 1 Diabetes Mellitus (SRHQ-WT1DM).

Materials and Methods: This protocol for a sequential exploratory mixed-methods study has two phases. Conducting a literature review, the first phase of the study will develop the items of SRHQ-WT1DM. Data analysis in this phase will be performed using directed content analysis and according to the framework proposed by the United Nations Population Fund (UNFPA) and the World Health Organization (WHO) for SRH in women. The second phase will evaluate the psychometric properties of SRHQ-WT1DM through a methodological study. Face and content validity will be evaluated both qualitatively and quantitatively, and construct validity will be done by exploratory factor analysis and convergent validity. The questionnaire's reliability and stability will be examined using internal consistency (by Cronbach's alpha calculation) and test-retest method (by Intra class correlation coefficient calculation), respectively. Descriptive statistics, Pearson correlation coefficient, and independent t-test will also be used. Women with T1DM who are of childbearing age and have unknown mental disorders will be selected as participants in the study from the Iranian Diabetes Society.

Discussion: Development and psychometric evaluation of a specific tool for SRH assessment in women will help identify and fulfill their SRH-related needs and improve dimensions of their SRH.

Keywords: Sexual health, Reproductive health, Women, Type 1 diabetes mellitus, Protocol, Psychometrics properties

Introduction

Type 1 diabetes mellitus (T1DM) is considered to be a critical public health problem (1). It is a metabolic disorder caused by chronic hyperglycemia following the autoimmune destruction of pancreatic beta cells and subsequent absolute deficiency of insulin (2). Recently, the statistics by the International Diabetes Federation (IDF) showed that 463 million adults worldwide have diabetes mellitus. The prevalence of diabetes mellitus (DM) among Iranian adults is about 9.6% (3). Around 10% of people with DM suffer from T1DM (4). Currently, more than 1.1 million kids and adolescents (under 20-years-old) suffer from T1DM. In Iran, the prevalence of T1DM among this age group is 7.8 cases per 1000 (5) and 36% of diabetes among Iranian is T1DM (6).

The most important complications of DM for women

are limb amputation, decreased self-esteem due to body image, and concerns over marital relationships and sexual and reproductive health (SRH) (6). Chronic insulin deficiency and hyperglycemia exert serious negative effects on reproductive system (7,8) and causes menstrual disorders, delayed menarche, early menopause, infertility (9) and sexual dysfunction in women (8). Pregnant women suffering from T1DM are more likely to be at risk of hypertension, overweight, inadequate blood glucose control, preeclampsia, infections, and delivery through cesarean section. Furthermore, their neonates are more likely to experience congenital defects, prematurity, early neonatal death, macrosomia, dystocia, and damages to the brachial nerve plexus (10).

A key step in improving SRH among women with T1DM is to assess their SRH through valid and reliable

Received 10 May 2021, Accepted 23 September 2021, Available online 20 June 2022

¹Department of Midwifery, Karaj Branch, Islamic Azad University, Karaj, Iran. ²Student Research Committee, Shahid Beheshti University of Medical Sciences, Tehran, Iran. ³Midwifery and Reproductive Health Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran. ⁴Department of Midwifery and Reproductive Health, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran. ⁵Behavioral Sciences Research Center, Life style institute, Baqiyatallah University of Medical Sciences, Tehran, Iran. ⁶Department of Nursing Management, Faculty of Nursing, Baqiyatallah University of Medical Sciences, Tehran, Iran. ⁷Department of Biostatistics, School of Allied Medical Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran. ⁸Iranian Diabetes Society, Tehran, Iran. ⁹School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

*Corresponding Author: Giti Ozgoli, Tel: +982188202512, Email: g.ozgoli@gmail.com



Key Messages

- ▶ The onset of childhood T1DM has profound and long-lasting effects on a person's health.
- ▶ The first step in improving SRH of women with T1DM is to recognize the current situation using a valid and reliable tool.
- ▶ Although numerous studies and questionnaires have examined different dimensions of SRH of these women, the items of these questionnaires do not cover all the components of the concepts of SRH for this group.
- ▶ These questionnaires are not designed specifically for these people, are not adequately comprehensive, and focus more on the control of the patient's blood sugar status, nutrition, physical care measures in diabetes, exercise and the like.
- ▶ The design and psychometric evaluation of SRH assessment tools for women with type 1 diabetes mellitus will be performed for the first time by directed content analysis method on existing texts.
- ▶ The review study will be of the literature review type and based on the WHO and UNFPA classification of the concept of women SRH, the articles will be analyzed based on thematic similarity and the initial matrix will be formed.

instruments. As World Health Organization (WHO) and the United Nations Population Fund (UNFPA) have suggested, women's SRH can be divided into the six main categories of safe motherhood (11,12), family planning (11,12), sexually transmitted diseases (12), human immunodeficiency virus and acquired immunodeficiency syndrome (11,12), sexual history and function (13), and sexual and gender-based violence (11). There are different measurement tools which address some aspects of these six main dimensions. Some of the more common tools are as follows

- The 39-item Diabetes questionnaire (Diabetes-39) covers dimensions such as energy and mobility, DM control, anxiety, social burden, and sexual functioning (13).
- The Female Sexual Function Index (FSFI) measures the sexual function of women in six dimensions of sexual desire, subjective arousal, vaginal lubrication, orgasm, sexual satisfaction, and dyspareunia (14).
- The Golombok-Rust Inventory of Sexual Satisfaction (GRISS) has four dimensions of marital satisfaction, marital relationships, marital interests, trust, and respect (15).
- The Female Sexual Distress Scale (FSDS) contains items on sexual distress, sexual dissatisfaction, and shame over sexual problems (16).
- Diabetes Quality of Life (DQOL) has items on the two main dimensions of caring behaviors and satisfaction with DM management (17).
- The Audit of Diabetes-Dependent Quality of Life (ADDQOL) has items on social and family life, nutrition, and physical exercise (18).

- The Hudson Index of Sexual Satisfaction has items of this index measure the level, severity, and marital problems in couples (19).
- The Sexual and Reproductive Needs Assessment Questionnaire: This questionnaire was developed and psychometrically evaluated in Zimbabwe by the New Dimension Consulting (NEDICO) and UNFPA (20) includes several items on demographic characteristics as well as 114 items in six main dimensions .

None of the mentioned tools are found to be comprehensive for assessing SRH of women with T1DM. Moreover, some of them are too lengthy, or assess blood glucose control, nutrition, and routine DM care, DM effects on employment, caring behaviors, physical exercise, and satisfaction with DM status with limited items, if any, in SRH. The questionnaire developed by NIDECO is also a general questionnaire and does not address the specific aspects of DM effects on SRH. For example, it does not include the uses and complications of contraceptive methods for women with DM, DM-related problems in pregnancy, DM-related birth complications, and the long-term impacts of DM on various aspects of SRH such as puberty and menstruation. Given the non-comprehensiveness of the existing SRH assessment questionnaires for women with T1DM and the gap in this regard, it is essential to develop valid and reliable tools in this area. Therefore, the present study will be conducted to reduce this gap. This study aims to develop and evaluate the psychometric properties of the Sexual and Reproductive Health Questionnaire for Women with Type 1 Diabetes Mellitus (SRHQ-WT1DM).

Materials and Methods

Study Setting and Participants

This study will be conducted in the central building of the Iranian Diabetes Society in Tehran, Iran. Eligible participants will be married women of reproductive ages (15–49 years), those whose T1DM was diagnosed at least one year before the study (the members of the Iranian Diabetes Society), and women with at least one child. Purposive sampling method will be used in this study.

This exploratory sequential mixed methods study will have two phases. The first phase develops the SRHQ-WT1DM based on the results obtained for review of literature and using directed content analysis. The second phase will be a quantitative methodological study for evaluation of the psychometric properties of SRHQ-WT1DM.

Phase 1. SRHQ-WT1DM Development

Waltz et al (21) have proposed a four-step approach for instrument development. The four steps of this approach are selection of a conceptual model, explaining the objectives for the scale, development of the blueprint, and construction of the tool. In the present study,

1. The conceptual model of SRHQ-WT1DM will be developed using the results of literature review which will be analyzed through a directed content analysis based on the WHO and UNFPA theoretical framework of SRH in women.
2. The objectives will be designed based on the dimensions of SRH of women with T1DM.
3. The blueprint will contain the more specific dimensions of the concept, i.e., its subcategories, as well as a primary estimation of the necessary items for each subcategory.
4. The most appropriate and relevant items will be produced and grouped into categories and subcategories according to their similarities. Figure 1 shows the algorithm of the design tools of the study.

Development of the Conceptual Model and Production of the Item Pool

In order to develop the conceptual model and produce the item pool, the related literature will be reviewed to access the literature on the concept of SRH in women with T1DM. The model will be developed based on the SRH model of WHO and UNFPA and the collected data will be analyzed and categorized based on this model.

Search Strategy

The intended keywords identified based on the model of WHO and UNFPA for SRH (Table 1). Search queries will be searched in the English databases of PubMed, Web of Science, SCOPUS, and Embase, and the search engine Google Scholar and Persian databases of Magiran, SID and IranDoc. The search protocol will be limited to the 2000–2019 period and Boolean operators “AND” and “OR” will be used to combine search results. Inclusion criteria will be the articles published in English or Persian, the articles published between 2000 and 2019, and those whose full texts are available. Documents will not be included if they have addressed the complications of chronic DM for vital body organs, SRH in men, type 2 DM or gestational DM, comparison of pharmacological methods and laboratory findings, women of non-productive years, and epidemiologic trends of DM. The characteristics of the retrieved documents will be entered into the EndNote software and duplicate records will be removed. Then, the titles and the abstracts of the remaining documents will be

assessed based on the objectives of the study and the most appropriate documents will be identified.

Data Analysis

Eligible documents included in the study will be analyzed through directed content analysis based on the SRH model of WHO and UNFPA. In directed content analysis, data coding starts using the theory or the findings of former relevant studies (22). In some cases, there is an incomplete theory about a phenomenon and, hence, directed content analysis is used to further develop it (23). Models or theories used in directed content analysis help us have a structured process of analysis (24) and identify the primary categories (25). The included documents and instruments will be assessed and the primary items of SRHQ-WT1DM will be constructed and divided into subcategories and categories according to their similarities and, thereby, the primary version of the questionnaire will be developed. A panel of experts in SRH, endocrinology, and gynecology will be formed to assess the appropriateness of the items.

Phase 2. Psychometric Evaluation

This phase, using a methodological study, will assess the psychometric properties of SRHQ-WT1DM. These properties will include face, content, and construct validity as well as reliability.

Content Validity Evaluation

Qualitatively evaluating the content validity, twenty pediatricians, SRH, endocrinology, and gynecology will be asked to evaluate and provide written feedback on the wording, grammar, and items allocation

Quantitatively investigating the content validity, content validity ratio (CVR) and content validity index (CVI) will be calculated (21). For CVR calculation, the same experts will be asked to rate the essentiality of each item based on a 3-point scale (1-3): “Essential”, “Useful but not essential”, and “Unessential”. Then, CVR will be calculated using the following formula, $CVR = (ne - N/2) / (N/2)$, where Ne is the number of experts who rate an item “Essential” and N is the total number of experts. Lawshe and others pointed that when the number of experts is twenty, the items with a CVR greater than 0.42 are considered to be appropriate (26).

In order to calculate CVI, the same experts will be

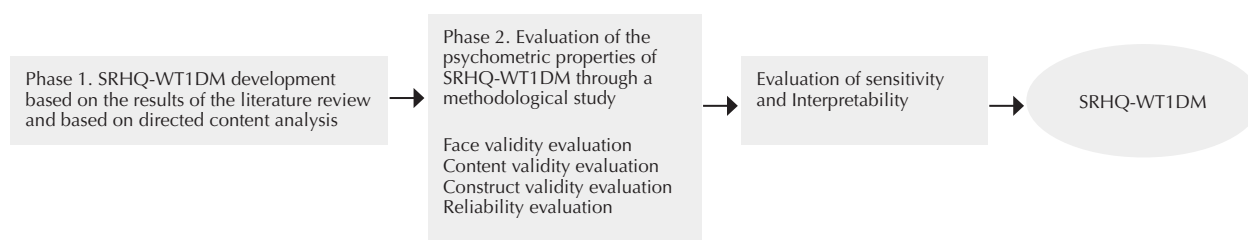


Figure 1. Algorithm of Tool Design Steps.

Table 1. Keywords in Search Strategy Based on the MeSH Terms and Classification of the WHO and UNFPA* in Non-Iranian Databases

| Safe Motherhood | Family Planning | HIV, AIDS | Sexually Transmitted Diseases | Sexual Function | Gender-Based Violence |
|-----------------------|---------------------------------|------------------|-------------------------------|----------------------------------|-----------------------|
| Fertility | Contraceptive agents | | | Sex counseling | |
| Reproduction | Family planning services | | | Sex education | |
| Reproductive medicine | Family planning education | HIV | | Sexual health | |
| Reproductive health | Oral or hormonal contraceptives | Human | | Sexual behavior | |
| Maternal welfare | Condoms, female | immunodeficiency | Sexually transmitted diseases | Sexual dysfunction | Gender-based violence |
| Maternal outcomes | Contraceptive effectiveness | virus | | Physiological sexual dysfunction | |
| Pregnancy outcomes | Family planning | AIDS | | Marital quality of life | |
| Neonatal outcomes | Contraception | | | Sexual health | |
| Prenatal measures | Contraceptive pills | | | Sexual function | |
| | Uterine devices | | | | |

* The keywords of “psychometric evaluation”, “questionnaire”, and “diabetes mellitus” will be combined with the keywords in the table.

asked to rate the relevant items based on a 4-point scale (1-4): “Irrelevant”, “Needs major revision”, “Relevant but needs revision”, and “Completely relevant”. Then, the CVI of each item will be calculated by dividing the number of experts rated it 3 or 4 by the total number of the experts. CVI value is interpreted as follows: less than 0.7: unacceptable; 0.7-0.79: items need revision; and more than 0.79: acceptable (21).

The assessment of content validity will also be done by calculating Kappa and weighted Kappa. Kappa is used to assess intra-rater and inter-rater agreement. It considers chance agreements and adjusts agreement for them (27). Therefore, it is preferable to a simple agreement coefficient. Kappa will be calculated via the following formula, $K = [\text{Pr}(a) - \text{Pr}(e)] / [1 - \text{Pr}(e)]$, where $\text{Pr}(a)$ is the actual observed agreement and $\text{Pr}(e)$ is chance agreement. Kappa coefficient ranges from 0 (“Disagreement”) to 1 (“Complete agreement”) and is interpreted as excellent (>0.74), good (0.60–0.74), and relatively good (0.40–0.59). In the present study, Kappa values that are more than 0.7 are acceptable.

Face Validity Evaluation

In the qualitative face validity evaluation, 10 women with T1DM will be interviewed about the difficulty, appropriateness, and clarity of the items and, then they will be revised according to their comments (28). In quantitative face validity evaluation, we will ask 10 other women with T1DM to rate the significance of each item based on a 5-point scale. Their rating scores will be used to calculate item impact score multiplying the significance of the item by the number of women rated the intended item 4 or 5. Item impact scores higher than 1.5 will be considered acceptable (29).

Item analysis: Item analysis is a method for face validity evaluation and is performed through item difficulty coefficient, discriminant coefficient, and the Loop method. The Loop method will be used in the present study. In this method, the reliability coefficients of all items and the total reliability coefficient of the scale are

calculated. Then, the scale’s total reliability coefficient is calculated after excluding each item one by one. If the exclusion of an item leads to a significant decrease in the total reliability coefficient, that item is considered to be an important and essential one (30). Item analysis in the present study will be performed in a pilot study on 35 women with T1DM in which reliability coefficient will be calculated after the exclusion of each item, and the results will be used to judge about the item significance. Reliability coefficients greater than 0.7 will be considered acceptable.

Construct Validity Evaluation

Construct validity is defined as the degree showing the appropriateness of an instrument for the measurement of the intended construct (31). The construct validity of SRHQ-WT1DM will be assessed using exploratory factor analysis (EFA) and convergent validity evaluation.

In EFA, sampling adequacy will be assessed using the Kaiser-Meyer-Olkin (KMO) method and a KMO statistic greater than 0.8 will be considered acceptable. Data appropriateness for EFA will also be evaluated using the Bartlett’s Sphericity test. Factors will primarily be extracted through Varimax rotation based on eigenvalues greater than 1 and scree plot. The minimum factor loading will be 0.4 (32). The minimum sample size for EFA will be considered to be 200 (32) or 5-10 participants per item (33). Finally, five T1DM-afflicted women will be selected per item from the Iranian Diabetes Society to complete SRHQ-WT1DM. Their data will be used for EFA using the SPSS software.

Convergent Validity Evaluation

The 8-item Short Form Survey (SF-8) will be used for the convergent validity evaluation of SRHQ-WT1DM. The SF-8 is the short form of Health-Related Quality of Life Profile and can be used for health assessment in people with chronic disease (34). Participants will be asked to complete SRHQ-WT1DM and SF-8 and, then, Pearson’s correlation analysis will be used to assess the correlation

between the scores of these two instruments. A correlation coefficient of more than 0.7 will be considered acceptable.

Reliability Evaluation

Reliability refers to the extent to which the apparent differences in the scores of a test are due to actual differences in the studied characteristics, and to what extent the differences can be attributed to random error (35). The reliability of SRHQ-WT1DM and measurement stability will be evaluated using internal consistency and test-retest methods.

Internal Consistency Evaluation

In internal consistency evaluation, items are evaluated in terms of their conceptual appropriateness by using methods such as Cronbach's alpha, split-half, and Kuder-Richardson (36). In the present study, Cronbach's alpha will be calculated for SRHQ-WT1DM and all its dimensions. The possible range for Cronbach's alpha is 0–1, with higher scores showing greater internal consistency (21).

Evaluation of Stability by Test-Retest

This method determines whether the score of a person for a scale remains stable over time. Intra class correlation coefficient (ICC) is usually used for methods with repeated measurements such as test-retest. This coefficient tests the stability over time and is sensitive to systematic error in the data (36). In this study, for the evaluation of the stability, SRHQ-WT1DM will be completed by 30 women two times and in an interval of two weeks. Then, ICC will be calculated for the questionnaire and its dimensions using the SPSS software. Coefficients greater than 0.7 will be considered acceptable.

Responsiveness

Responsiveness is defined as the ability of an instrument in detecting changes when they happen (37, 38). The responsiveness of SRHQ-WT1DM will be assessed by calculating the standard error of measurement (SEM) and the minimum detectable changes (MDC).

SEM calculation: SEM will be calculated using the following formula, $SEM = SD_{\text{pooled}}(1-R)$, where R is an estimation of reliability (either Cronbach's alpha or ICC) and SD_{pooled} is calculated by dividing the sum score of SD_1 and SD_2 by 2 (i.e., $SD_{\text{pooled}} = [SD_1 + SD_2]/2$). In the present study, SD_1 and SD_2 will be the standard deviations of the scores of the test and the pretest measurements for stability assessment, while R will be the total ICC of the questionnaire.

MDC calculation: MDC will be calculated using the following formula, $MDC = SEM * 1.96 * 2$.

Interpretability

Interpretability is the minimal important change (MIC) in the score of the intended instrument or the degree to which the change in the score of the instrument is meaningful.

In other words, MIC is the lowest change in the score of the instrument which indicates an improvement or aggravation of patients' conditions in response to a specific therapeutic intervention and leads to changes in the treatment process (39). The interpretability of SRHQ-WT1DM will be determined by assessing sampling adequacy, calculating MIC, and determining ceiling and floor effects.

Sampling adequacy assessment: Sampling adequacy will be determined using KMO method. This method assesses the proportion of variance among variables, with lower proportion showing more appropriate data for EFA (40). KMO varies from 0 to 1. A KMO value greater than 0.8 will be considered acceptable in the present study.

MIC calculation: MIC is the lowest change in the mean score of an instrument which is considered important by respondents (41). It is calculated using the following formula, $MIC = 0.5 * SD$ of Δ score, where Δ score is the deviation of changes between the test and the retest measurements and 0.5 is a moderate effect size (36). An MIC greater than MDC shows that the intended instrument has acceptable responsiveness (42,43).

Ceiling and Floor Effects

Ceiling and floor effects happen when most respondents obtain high and low scores, respectively, for the intended instrument (44). The value of ceiling and floor effects should be less than 20% (45). In our study, ceiling and floor effects will be determined by calculating the percentage of participants who obtain the highest and lowest scores, respectively, for SRHQ-WT1DM.

Scoring

An instrument can be scored using a Likert scale and a standard 0–100 scale (21). The SRHQ-WT1DM will be scored based on a 5-point Likert scale, in which the higher the scores, the better SRH. Moreover, scores will be altered into the 0–100 scale through the following formula (46).

Score in the 0-100 scale

$$= \frac{\text{The raw score} - \text{The lowest possible raw score}}{\text{The highest possible raw score} - \text{The lowest possible raw score}}$$

The 0–100 score of SRHQ-WT1DM also can be interpreted as follows: scores 0–25: poor SRH; scores 25–50: moderate SRH; scores 50–75: good SRH; and scores 75–100: excellent SRH.

Data Analysis

All of the statistical analysis in the psychometric evaluation phase will be performed using the Statistical Package for the Social Sciences software (SPSS, version 23.0 for Windows; SPSS Inc., Chicago, IL). The descriptive statistics of mean, standard deviation, absolute frequency, and relative frequency will be used for data description. The Pearson's correlation analysis, independent *t* test, intra

class correlation coefficient, Cronbach's alpha, and EFA will be used for data analysis. In all statistical analyzes, the significance level of P-value will be less than 0.05.

Discussion

This study aims to develop SRHQ-WT1DM and its constructive dimensions through a literature review and evaluate its psychometric properties through a methodological study. Articles extracted from selected databases are analyzed based on the research objectives and according to WHO and UNFPA classifications of SRH based on the thematic similarity. The items obtained from the final articles, sub-categories and categories will form the concept of SRH in women with T1DM. In the next step, standard steps of psychometrics will be performed and the opinions of the target group will be used.

Reproductive system disorders are very common in women with T1DM and up to 40% of them develop reproductive system problems at some point in their lives (9). Chronic hyperglycemia and absolute lack of insulin, in addition to toxic effects on the surface of the brain and ovaries, affect the function of the reproductive and sexual systems by damaging the walls of arteries and the autonomic nervous system (7, 8) and consequently lead to late puberty, menstrual cycle disorders, infertility, adverse pregnancy complications and premature menopause (47,48). Sexual function is affected by T1DM because of changes in blood flow, increased incidence of vaginal infections, decreased vaginal lubrication, and long-term complications such as neuropathy (49,50). Pre-gestational diabetes is associated with an increased risk of adverse maternal and fetal outcomes (51). Hypertension (52,53), preeclampsia (54-56), increased body mass index and obesity (57-59), blood sugar disorder (66), Seizure (59), emergency cesarean section (58,60,61), infections (69,59), post-partum hemorrhage (62) and death (63,64) increase in pregnant women with T1DM. Common problems in fetuses of mothers with T1DM include low birth weight (55,65), macrosomia (65,66) and shoulder dystocia (67), intrauterine growth restriction (68), congenital malformations (69-71), preterm labor(61,72-74), icterus and death (53,67).

The effects of types 1 and 2 DM on reproduction are different and can be distinguishable from each other. As T1DM starts in childhood, it has profound effects on SRH. However, most SRH assessment instruments used for women with T1DM are general health assessment instruments which focus on the general aspects of SRH and are appropriate for general populations. Moreover, SRH assessment is usually neglected in health assessments. A careful SRH assessment using SRH-specific valid and reliable instruments can affect and be affected by DM management. Using SRHQ-WT1DM in DM care centers can facilitate the identification of the challenges in providing care services for patients with T1DM and help improve their SRH.

One of the limitations of the present study is the widespread concept of SRH among women, which will result in retrieving a large number of documents in the literature review phase of the study and will require a great amount of effort for screening and selecting the most appropriate documents. In addition, only Persian and English articles whose full texts are available will be examined.

In summary, T1DM is increasing among women who are in their reproductive age, and its effects on the health and functions of the reproductive and sexual systems are observable. To assess the current situation and plan effective measures to improve the reproductive health of women with T1DM, it is necessary to design a specific tool with appropriate validity and reliability. The present study is a protocol for designing of this tool.

Authors' Contribution

NA, GO, AE and HAM designed the study and conducted the research. NA, GO, AE, AR, SK and FJCH monitored, evaluated, and analyzed the result of the study. Further, NA, GO, AE and HAM reviewed the article. All authors approved the final manuscript and took responsibility for the integrity of the data.

Conflict of Interests

The authors declare that they have no competing interests.

Ethical Issues

This study has been approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran. (Reference no: IR.SBMU.PHARMACY.REC.1399.218).

Financial Support

This research has received support from Vice-Chancellor in Research Affairs -Shahid Beheshti University of Medical Sciences.

Acknowledgements

The authors would like to express their gratitude to the Student Research Committee and Vice-Chancellor in Research Affairs -Shahid Beheshti University of Medical Sciences

References

1. Al-Lawati JA. Diabetes Mellitus: A Local and Global Public Health Emergency! Oman Med J. 2017;32(3):177-179. doi:10.5001/omj.2017.34
2. Insel RA, Dunne JL, Atkinson MA, et al. Staging presymptomatic type 1 diabetes: a scientific statement of JDRF, the Endocrine Society, and the American Diabetes Association. *Diabetes Care*. 2015;38(10):1964-1974.
3. Saeedi P, Petersohn I, Salpea P, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9th edition. *Diabetes Res Clin Pract*. 2019;157:107843. doi:10.1016/j.diabres.2019.107843
4. Tuomilehto J, Ogle GD, Lund-Blix NA, Stene LC. Update on Worldwide Trends in Occurrence of Childhood Type 1 Diabetes in 2020. *Pediatr Endocrinol Rev*. . 2020;17(Suppl 1):198-209.
5. Atlas DJIDA, 9th edn. Brussels, Belgium: International Diabetes Federation. International Diabetes Federation; 2019.
6. Zamani N, Rezaee Jamaloe H, Behboodi Moghadam Z, Moshki M, Peikari HR. On the Health Concerns of Women with Diabetes: A Combined Study 2018. *Journal of Diabetes Nursing*. 2019;7(3):857-876.
7. Basmatzou T, Hatziveis K. Diabetes mellitus and influences on human fertility. *International Journal of Caring Sciences*.

- 2016;9(1):371-379.
8. Enzlin P, Mathieu C, Van den Bruel A, Bosteels J, Vanderschueren D, Demyttenaere KJDC. Sexual dysfunction in women with type 1 diabetes: a controlled study. *Diabetes Care*. 2002;25(4):672-677.
 9. Codner E, Merino P, Tena-Sempere M. Female reproduction and type 1 diabetes: from mechanisms to clinical findings. *Hum Reprod Update*. 2012;18(5):568-585.
 10. Abell SK, Nankervis A, Khan KS, Teede HJ. Type 1 and Type 2 diabetes preconception and in pregnancy: health impacts, influence of obesity and lifestyle, and principles of management. Paper presented at: Seminars in reproductive medicine; 2016.
 11. Sexual & reproductive health. <https://www.unfpa.org/sexual-reproductive-health>. Published August 2019. Accessed August 15, 2019.
 12. Sexual and Reproductive Health. <https://www.who.int/reproductivehealth/en/>. Published August 2019. Accessed August 15, 2019.
 13. Boyer JG, Earp JALJMc. The development of an instrument for assessing the quality of life of people with diabetes: *Diabetes-Care*. 1997;35(5):440-453. doi:10.1097/00005650-199705000-00003
 14. Rosen R, Brown C, Heiman J, et al. The Female Sexual Function Index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. *J Sex Marital Ther*. 2000;26(2):191-208. doi:10.1080/009262300278597
 15. Rust J, Golombok S. The Golombok-Rust Inventory of Sexual Satisfaction (GRISS). *Br J Clin Psychol*. 1985;24 (Pt 1):63-64. doi:10.1111/j.2044-8260.1985.tb01314.x
 16. Derogatis LR, Rosen R, Leiblum S, Burnett A, Heiman J. The Female Sexual Distress Scale (FSDS): Initial validation of a standardized scale for assessment of sexually related personal distress in women. *J Sex Marital Ther*. 2002;28(4):317-330.
 17. Rubin RR, Peyrot M. Quality of life and diabetes. *Diabetes Metab Res Rev* 1999;15(3):205-218.
 18. Bradley C, Todd C, Gorton T, Symonds E, Martin A, Plowright R. The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. *Qual Life Res*. 1999;8(1-2):79-91.
 19. Hudson WW, Harrison DF, Crosscup PC. A short-form scale to measure sexual discord in dyadic relationships. *J Sex Res*. 1981;17(2):157-174.
 20. Sexual and reproductive health (SRH) needs assessment among mobile and vulnerable population (MPV) communities in Zimbabwe. Study report. Harare, Zimbabwe: NEDICO & UNFPA; 2008.
 21. Waltz CF, Strickland OL, Lenz ER. *Measurement in Nursing and Health Research*. 4th ed. New York: Springer; 2010.
 22. Iman MT, Noshadi MR. Qualitative content analysis. *Pazhuhesh*. 2011;3(2):15-44.
 23. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. 2005;15(9):1277-1288. doi:10.1177/1049732305276687
 24. Hickey G, Kipping C. A multi-stage approach to the coding of data from open-ended questions. *Nurse Res*. 1996;4(1):81-91.
 25. Potter WJ, Levine-Donnerstein D. Rethinking validity and reliability in content analysis. *Journal of Applied Communication Research*. 1999;27:258-285.
 26. Brinkman W-P. Design of a questionnaire instrument. *Handbook of mobile technology research methods*. Nova Publishers; 2009:31-57.
 27. McHugh ML. Interrater reliability: the kappa statistic. *Biochemia Medica*. 2012;22(3):276-282.
 28. Mohammadbeigi A, Mohammadsalehi N, Aligol M. Validity and reliability of the instruments and types of measurements in health applied researches (Persian). *Journal of Rafsanjan University of Medical Sciences*. 2015;13(12):1153-1170.
 29. Hajizadeh E, Asghari M. *Statistical methods and analyses in health and biosciences a research methodological approach*. Tehran: Jahade Daneshgahi Publications; 2011:395-410.
 30. Ebadi A, Taghizadeh Z, Montazeri A, Shahvari Z, Tavousi M, Bagherzadeh R. Translation, development and psychometric properties of health related measures-Part 2: construct validity, reliability and responsiveness. *Payesh (Health Monitor)*. 2017;16(4):445-455.
 31. Guion RM. On Trinitarian doctrines of validity. *Professional Psychology*. 1980;11(3):385.
 32. Plichta SB, Kelvin EA, Munro BH. *Munro's statistical methods for health care research*. 6th ed. LWW; 2013.
 33. Williams JC, Lynn SJ. Acceptance: An historical and conceptual review. *Imagin Cogn Pers*. 2010;30(1):5-56.
 34. Turner-Bowker DM, Bayliss MS, Ware JE, Kosinski M. Usefulness of the SF-8™ Health Survey for comparing the impact of migraine and other conditions. *Qual Life Res*. 2003;12(8):1003-1012.
 35. Ebadi A, Rakhshan M, Zareian A, Sharif nia H, Mojahedi M. *Principles of Scale Development in Health Science*. 1st ed. Tehran: Jame-e-negar; 2017.
 36. Ebadi A, Zarshenas L, Rakhshan M, Zareian A, Sharifnia S, Mojahedi M. *Principles of scale development in health science*. Tehran: Jamee Negar; 2017.
 37. De Bruin A, Diederiks J, De Witte L, Stevens F, Philipsen H. Assessing the responsiveness of a functional status measure: the Sickness Impact Profile versus the SIP68. *J Clin Epidemiol*. 1997;50(5):529-540.
 38. Hays R, Anderson R, Revicki D. Psychometric considerations in evaluating health-related quality of life measures. *Qual Life Res*. 1993;2(6):441-449.
 39. Shirinabadi Farahani A, Rassouli M, Yaghmaei F, Alavi Majd H. Index for selecting an appropriate instrument to conduct research in health sciences: Introducing the COSMIN checklist. *J Health Promot Manag*. 2015;4(4):1-13.
 40. Dodge Y. *The concise encyclopedia of statistics*. New York: Springer; 2008.
 41. Polit D, F. *Measurement and the Measurement of Change*. LWW; 2015.
 42. Guyatt G, Walter S, Norman G. Measuring change over time: assessing the usefulness of evaluative instruments. *Journal of Chronic Diseases*. 1987;40(2):171-178.
 43. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol*. 2007;60(1):34-42.
 44. Dilorio CK. *Measurement in health behavior: methods for research and evaluation*. 1st ed. John Wiley & Sons; 2006.
 45. Yekaninejad M, Mohammadi Zeidi I, Akaberi A, Golshan A. Validity and reliability of the kidney disease quality of life-short form (KDQOL-SF™ 1.3) in Iranian patients. *Journal of North Khorasan University of Medical Sciences*. 2012;4(2):261-272.
 46. Ibrahim EM, Madian A. Impact of hepatitis C on health-related quality of life in Egypt. *J Am Sci*. 2011;7(11):430-439.
 47. Sjöberg L, Pitkäniemi J, Haapala L, Kaaja R, Tuomilehto J. Fertility in people with childhood-onset type 1 diabetes. *Diabetologia*. 2013;56(1):78-81.
 48. Lin Y-H, Chen K-J, Peng Y-S, Chen P-C, Yang Y-H. Type 1 diabetes impairs female fertility even before it is diagnosed. *Diabetes Res Clin Pract*. 2018;143:151-158.
 49. Barnard KD, Naranjo D, Johnson N, et al. Diabetes and female sexual health: an ongoing challenge. *Practical Diabetes*. 2019;36(5):165-169. doi:10.1002/pdi.2238
 50. Maiorino M, Bellastella G, Castaldo F, Petrizzo M, Giugliano D, Esposito KJ. Sexual function in young women with type 1 diabetes: the METRO study. *J Endocrinol Invest*. 2017;40(2):169-177.
 51. Owens LA, Egan AM, Carmody L, Dunne F. Ten years of optimizing outcomes for women with type 1 and type 2 diabetes in pregnancy - The Atlantic DIP experience. *J Clin Endocrinol Metab*. 2016;101(4):1598-1605. doi:10.1210/jc.2015-3817
 52. Chico A, Saigi I, García-Patterson A, et al. Glycemic control and perinatal outcomes of pregnancies complicated by type 1 diabetes: Influence of continuous subcutaneous insulin infusion and lispro insulin. *Diabetes Technol Ther*. 2010;12(12):937-945.

- doi:10.1089/dia.2010.0111
53. Stone RG, Troy E, Scully P, et al. An audit of pregnancy outcomes in women with childhood onset type 1 diabetes mellitus. *Arch Dis Child Educ Pract Ed.* 2019;104:A274-A275. doi:10.1136/archdischild-2019-epa.643
 54. Cilingir IGU. Pregnancy outcomes in women with strictly controlled type 1 diabetes mellitus. *Indian J Endocrinol Metab.* 2019;22(6):798-800. doi:10.4103/ijem.IJEM_139_18
 55. Vangen S, Stoltenberg C, Holan S, et al. Outcome of pregnancy among immigrant women with diabetes. *Diabetes Care.* 2003; 26(2):327-332. doi:10.2337/diacare.26.2.327
 56. Wotherspoon AC, Young IS, Patterson CC, McCance DR, Holmes VA; Diabetes and Pre-eclampsia Intervention Trial (DAPIT) Study Group. Effect of pregnancy planning on maternal and neonatal outcomes in women with Type 1 diabetes. *Diabet Med.* 2017;34(9):1303-1308. doi:10.1111/dme.13398
 57. Klemetti M, Nuutila M, Tikkanen M, Kari MA, Hiilesmaa V, Teramo K. Trends in maternal BMI, glycaemic control and perinatal outcome among type 1 diabetic pregnant women in 1989-2008. *Diabetologia.* 2012;55(9):2327-2334. doi:10.1007/s00125-012-2627-9
 58. Abell SK, Boyle JA, de Courten B, et al. Impact of type 2 diabetes, obesity and glycaemic control on pregnancy outcomes. *Aust N Z J Obstet Gynaecol.* 2017;57(3):308-314. doi:10.1111/ajo.12521
 59. Timur BB, Timur H, Tokmak A, Isik H, Eyi EGY. The influence of maternal obesity on pregnancy complications and neonatal outcomes in diabetic and nondiabetic women. *Geburtshilfe und Frauenheilkunde.* 2018;78(4):400-406. doi:10.1055/a-0589-2833
 60. Stogianni A, Lendahls L, Landin-Olsson M, Thunander M. Obstetric and perinatal outcomes in pregnancies complicated by diabetes, and control pregnancies, in Kronoberg, Sweden. *BMC Pregnancy and Childbirth.* 2019;19(1). doi:10.1186/s12884-019-2269-8
 61. Persson M, Norman M, Hanson U. Obstetric and perinatal outcomes in type 1 diabetic pregnancies: A large, population-based study. *Diabetes Care.* 2009;32(11):2005-2009. doi:10.2337/dc09-0656
 62. BI Y, XU Q, LU J, HU J, LI J, GE Z, et al. Maternal and Neonatal Outcomes in Pregnancy Complicated by Type 1 Diabetes Mellitus. *Diabetes.* 2018;67(Supplement_1).
 63. Negrato CA, Mattar R, Gomes MB. Adverse pregnancy outcomes in women with diabetes. *Diabetology and Metabolic Syndrome.* 2012;4(1):1-6. doi:10.1186/1758-5996-4-41
 64. Campbell KH, Savitz D, Werner EF, et al. Maternal morbidity and risk of death at delivery hospitalization. *Obstet Gynecol.* 2013;122(3):627-633. doi:10.1097/AOG.0b013e3182a06f4e
 65. Lin S-F, Kuo C-F, Chiou M-J, Chang S-H. Maternal and fetal outcomes of pregnant women with type 1 diabetes, a national population study. *Oncotarget.* 2017;8(46):80679.
 66. Jensen DM, Damm P, Moelsted-Pedersen L, et al. Outcomes in type 1 diabetic pregnancies: a nationwide, population-based study. *Diabetes Care.* 2004;27(12):2819-2823. doi:10.2337/diacare.27.12.2819
 67. Mitrović M, Stojić S, Tešić DS, et al. The impact of diabetes mellitus on the course and outcome of pregnancy during a 5-year follow-up. *Vojnosanitetski Pregled.* 2014;71(10):907-914. doi:10.2298/VSP1410907M.
 68. Haeri S, Khoury J, Kovilam O, Miodovnik M. The association of intrauterine growth abnormalities in women with type 1 diabetes mellitus complicated by vasculopathy. *Am J Obstet Gynecol.* 2008;199(3):278. e271-278. e275.
 69. Costacou T, Rubinstein D, Orchard TJ. Prediction of adverse pregnancy outcomes among women with type 1 diabetes. *Diabetes.* 2018;67:A436.
 70. Dunne FP, Brydon PA, Proffitt M, Smith T, Gee H, Holder RL. Fetal and maternal outcomes in Indo-Asian compared to caucasian women with diabetes in pregnancy. *QJM.* 2000;93(12):813-818. doi:10.1093/qjmed/93.12.813.
 71. Sharpe PB, Chan A, Haan EA, Hiller JE. Maternal diabetes and congenital anomalies in South Australia 1986-2000: a population-based cohort study. *Birth Defects Res A Clin Mol Teratol.* 2005;73(9):605-611. doi:10.1002/bdra.20172
 72. Murphy HR, Steel SA, Roland JM, et al. Obstetric and perinatal outcomes in pregnancies complicated by Type 1 and Type 2 diabetes: influences of glycaemic control, obesity and social disadvantage. *Diabet Med.* 2011;28(9):1060-1067. doi:10.1111/j.1464-5491.2011.03333.x
 73. John C, Alegbeleye J, Otoide A. Foeto-maternal outcome of diabetes in a tertiary health facility in Nigeria. *African Journal of Diabetes Medicine Vol.* 2015;23(2):13-16.
 74. Dorfman H, Srinath M, Rockhill K, Hogue C. The Association Between Diabetes Mellitus Among American Indian/Alaska Native Populations with Preterm Birth in Eight US States from 2004-2011. *Maternal and Child Health Journal.* 2015;19(11):2419-2428. doi:10.1007/s10995-015-1761-7

Copyright © 2022 The Author(s); This is an open-access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.