Assessing sexual and reproductive health dimensions tools in women with type 1 diabetes mellitus with regard to Consensus-based Standards for the selection of health status Measurement Instruments checklist

Nasrin Azimi¹₂, Abbas Ebadi³⁴, Hamid Alavi Majd⁵, Assadollah Rajab⁶, Giti Ozgoli⁷⁸

Abstract:
A valid tool is of paramount importance in determining women's sexual and reproductive health status, meeting their health needs, and recognizing the effectiveness of some interventions. This review study aimed to assess sexual and reproductive health dimensions tools in women with type 1 diabetes mellitus with regard to Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) checklist. In this review study, in addition to Iranian databases (MagIran, Sid, Irandoc), non-Iranian databases (PubMed, Scopus, Embase, and Web of Science) and Google Scholar search engine were considered. The mentioned databases were searched for articles in English and Persian published within 2000–2019, using the search strategy for each database and Boolean operators along with appropriate keywords according to the MESH term. Articles with nonresearcher-made tools measuring the sexual and reproductive health concepts and dimensions were included in the present study. Afterward, the psychometric properties of the tools were assessed according to the COSMIN checklist. In the selected articles, there were 14 psychometrically valid tools to be assessed from 151 articles containing the sexual and reproductive health dimensions; among which, seven tools were evaluated with regard to COSMIN. None of the tools also had all the features noted in COSMIN. Moreover, all the concerned scales were not interpretable and accountable; however, a majority of them had internal consistency and construct validity. In this study, there was no valid and specific tool for measuring sexual-reproductive health status in this population group. Therefore, it is necessary to develop a valid tool according to the dimensions and needs of specific reproductive health in type 1 diabetes.

Keywords:
Consensus-based Standards for the selection of health status Measurement Instruments, sexual and reproductive health, type 1 diabetes mellitus

Introduction
Type 1 diabetes mellitus is recognized as a complex metabolic disorder in which chronic hyperglycemia is caused by the absolute absence of insulin secretion.¹⁻² According to the latest statistics...
of the International Diabetes in 2019, 463 million adults aged 20–79 years worldwide have diabetes; in Iran, this number is 9.6% of this population. Concerning younger ages, 1.1 million children and adolescents under 20 years have type 1 diabetes worldwide, regarding which 7.8 per 1000 people of this age group are in Iran.²

Although diabetes affects men and women equally, women are more severely impacted by its consequences.³ For women, this long-term condition poses challenges throughout life, particularly in relation to sexual and reproductive health.² All human beings possess the rights to sexual and reproductive health.⁶ According to the World Health Organization (WHO)⁷ and the United Nations Population and Development Fund (UNFPA),⁸ the general dimensions of sexual and reproductive health can be summarized in terms of safe motherhood, family planning,⁷,⁸ sexually transmitted diseases,⁷ AIDS and HIV,⁷,⁸ sexual function, sexual violence, and gender-based violence.⁸

Type 1 diabetes is associated with long-term sexual complications and problems of the reproductive system.⁹ Hyperglycemic hormonal disorders affect fertility and cause complications in the internal reproductive system, leading to menstrual disorders, early menarche, premature menopause, and infertility.¹⁰ Sexual function secondary to changes in blood flow increases the risk of vaginal infections and reduces vaginal lubrication, and long-term complications such as neuropathy are affected.¹¹ In pregnant women with type 1 diabetes, the risk of high blood pressure, overweight, inability to control blood sugar, preeclampsia, cesarean section, and infection increases. Newborns of these mothers are more likely to have congenital anomalies, preterm infancy, macrosomia, and early infant death, and their brachial plexus is damaged.¹²

In studies on some aspects of sexual and reproductive health in diabetes, there are tools addressing and measuring some of the sexual-reproductive health dimensions. Some qualities of life tools in diabetes include 39-item diabetes, Diabetes Quality of Life, Assessment of Diabetes Quality of Life Questionnaire, Diabetes Quality of Life Measurement Scale, Diabetes Health Pack, Barriers to Physical Activity in Diabetes, Diabetes Treatment Satisfaction, and Diabetes Self-Management Quality Questionnaire focused on physical aspects of the disease, patient care behaviors, and disease control using their own concepts, and there is no dimension or an item that may contain concepts related to sexual-reproductive health, according to the definitions put forth by the WHO⁷ and the UNFPA.⁸ To obtain some valid and specific information on the sexual-reproductive health status of women with type 1 diabetes, the valid instrument(s) encompassing more comprehensive dimensions of the sexual and reproductive health should be developed according to an authentic and international benchmark so that the results can be specific and reliable.

A large number of articles have suggested different benchmarks to evaluate the questionnaires. The most well known and the most comprehensive of which is Consensus-based Standards for the Selection of health status Measurement Instruments (COSMIN).¹³ According to the COSMIN, in addition to validity and reliability, accountability and interpretability are also considered as the other main features of a tool. COSMIN checklist encompasses 12 distinct domains and examines psychometric properties during four stages.¹⁴ It was the goal of this study to assessing the tools including concepts associated with sexual-reproductive health dimensions in type 1 diabetes mellitus in accordance with COSMIN.

Materials and Methods

This study was a review study aimed at comparing sexual and reproductive health dimension tools in women with type 1 diabetes mellitus with regard to the COSMIN checklist. First, based on the MESH term, a list of appropriate keywords were extracted for accessing articles related to sexual and reproductive health dimensions of women with type 1 diabetes. Since the word sexual and reproductive health is a general word to access all the articles that have evaluated the concepts and to subset the related ones to sexual and reproductive health, the dimensions of sexual and reproductive health were classified by the WHO and UNFPA as safe motherhood, family planning, sexually transmitted diseases, AIDS, sexual function, and gender-based violence dimensions.²,⁷,⁸ The MESH term was also prepared based on these dimensions. Keywords of this study were Psychometrics Surveys, Questionnaires, diabetes mellitus, and words which were grouped according to Table 1.

The search was conducted on the non-Iranian databases of PUBMED, SCOPUS, EMBASE, Web of Science, and search engine Google Scholar for articles in English and Persian published within 2000–2019 using the search strategy for each database and Boolean operators along with appropriate keywords according to the MESH term. In each database, appropriate filters were selected to restrict and refine the search, such as age, sex, and year. Articles with no access to the full text were excluded.

The PRISMA Flow Diagram 1 illustrates the process of obtaining and selecting articles related to research goals to determine and modify sexual and reproductive health dimensions in type 1 diabetes. Articles with topics addressing issues such as chronic complications of diabetes in vital organs such as the heart and kidney, male participants, type 2 diabetes and gestational
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Table 1: Keywords* in search strategy based on the Mesh term and Classification of World Health Organization and United Nations Population Fund

| Gender base violence | Sexual function | Sexual transmitted disease | HIV, AIDS | Family planning | Safe motherhood |
|----------------------|-----------------|----------------------------|-----------|-----------------|-----------------|
| Gender-based violence | Sex counseling | Sexual transmitted disease | HIV       | Contraceptive agents | Fertility       |
|                      | Sex education   |                           |           | Family planning services | Reproduction    |
|                      | Sexual health   |                           |           | Family planning education | Reproductive medicine |
|                      | Sexual behavior |                           |           | Contraceptive agents   | Reproductive health |
|                      | Sexual dysfunctions |                     |           | female              | Maternal welfare |
|                      | physiological   |                           |           | Contraceptives oral, hormonal | Pregnancy outcomes |
|                      | Sexual dysfunctions |                     |           |                       |                 |
|                      | psychological   |                           |           | Condoms, female |                 |
|                      |                   |                           |           | Contraceptive effectiveness |                 |

Keywords for search strategy in Non-Iranian databases

| Keywords for search strategy in Iranian databases |
|--------------------------------------------------|
| Infertility and violence                         |
| Marital quality of life                          |
| Sexual health                                    |
| Sexual function                                  |
| Sexual counseling                                |
| Sexual dysfunction                               |
| Sexual function questionnaire                    |
| Sexual transmitted infections                    |
| AIDS                                             |
| Family planning                                  |
| Family planning education                        |
| Contraception                                    |
| Contraceptive pills                              |
| Uterine devices                                  |
| Condoms                                          |
| *The words Psychometrics Surveys, Questionnaires, diabetes mellitus were used in combination with the keywords in the search strategy according to [Table 1]. HIV=Human Immunodeficiency virus, UNFPA=United Nations Population Fund |

Results

In this study, the full text of 151 articles was reviewed. These articles examined the sexual and reproductive health dimensions of women with type 1 diabetes mellitus. The concerned dimensions were safe maternal dimension with themes such as prenatal care, specific pregnancy considerations, maternal pregnancy outcomes, fetal and neonatal outcomes, maternal delivery outcomes; family planning dimensions with themes such as comparison of effectiveness, complications and patterns of consumption, specific considerations in using methods; sexual diseases dimension with themes such as sexual herpes, vaginal candidiasis, and sexual wart; reproductive system dimension with themes such as menstrual disorders, maturation, ovarian problems, menopause, and infertility; and sexual and reproductive health with themes such as sexual satisfaction and performance.

In the majority of the studies, the data collection tools included researcher-made questionnaires along with data recorded in hospital database systems, blood indices measurement, and observations. In these articles, the questionnaires were not available, and their statistical data were on the sexual and reproductive health concepts in women with type 1 diabetes; hence, it was not possible to evaluate the tools according to the COSMIN checklist (due to the lack of psychometric procedures). In this regard, eight articles had 14 valid and nonresearcher-made tools, seven of which had tools somehow addressing one of the aspects of sexual and reproductive health in women with type 1 diabetes.
mellitus. Since this study aimed to compare the tools in terms of sexual and reproductive health dimensions according to the WHO and UNFPA classifications, the seven tools were included to be reviewed and evaluated with regard to the COSMIN checklist.

Table 2 has presented the specifications of the authentic and valid articles using psychometric assessments, which were included in this review study.

In some cases, the articles had adopted similar tools so that they were excluded with regard to the purpose of this comparative study. These seven tools contained dimensions and items specific and relevant to sexual and reproductive health, as defined by the WHO and the UNFPA. For example, Maiorino et al. examined female sexual functioning using both the SF36 and Female Sexual Distress Scale (FSDS). The latter tool was evaluated in accordance with the COSMIN psychometric checklist since it dealt with sexual and reproductive health dimensions. Table 3 has listed the specifications of the seven tools with regard to the COSMIN.

### Reproductive Health Attitudes and Behavior Questionnaire

In this study, participants in the age range of 16–22 years with type 1 diabetes were selected from the Pediatric Diabetes Clinic in St. Petersburg, Pennsylvania. The questionnaire consisted of three theories focused on reproductive health in these individuals. The items were extracted directly or adjustably from a validated questionnaire, i.e., “Pregnancy and Diabetes Interview Schedule.” The predicted behavioral goals in developing this questionnaire were prenatal care with three main themes focusing on achieving normal blood glucose, receiving prenatal counseling, and using effective contraceptive methods. The questionnaire encompassed 3 main models, 10 scales, and 48 items. The models, which were scored based on a Likert scale, were as follows: (1) health belief model (with...
five scales of sensitivity, severity of barriers, and action signs), (2) rational function model (with two scales of personal attitude and subjective standards), and (3) social cognition model (with two scales of self-efficacy and expectation of results). Regarding the content validity, the descriptive analysis results of the scales from three theories revealed that a majority of the scores at different scales ranged from moderate to high, indicating moderate-to-high level of individuals’ basic beliefs and attitudes toward the reproductive health constructs in this questionnaire. Following the factor analysis, 42 items revealed the greatest variance, resulting in 21 items for health belief, 11 items for rational function, and 10 items for social cognition. The internal consistency of the questionnaire was assessed using Cronbach’s alpha to be $\alpha = 0.65–0.83$.\(^{[18]}\)

**Female Sexual Distress Scale**

To evaluate the validity and reliability of this questionnaire and determine the final number of items, a pilot clinical trial was conducted. Approximately 500 women participated in these three studies. The first draft of this questionnaire consisted of 20 items, and its scoring scale ranged from always to never (0–4).

The first study was a pilot study conducted to evaluate and reduce the number of items, analyze the principal components of the tool’s dimensions, and evaluate the reliability of this instrument using test–retest reliability and divergent validity. Following the factor analysis, 12 items predicted more than 73% of the variance. Furthermore, internal consistency of the 12 items was above 0.8 and its reliability was estimated to be $r = 0.91$.

The second study was a randomized clinical trial aimed at offering a drug intervention for 174 female patients with sexual arousal disorder. FSDS was used to primarily evaluate the participants. Furthermore, the internal consistency of the tool was $\alpha = 0.93$, and its test–retest reliability was estimated to be $r = 0.8$.

The third study was also a clinical trial on 145 women with decreased libido and 102 healthy women. The sensitivity of the FSDS tool in detecting these individuals was 0.86, and its specificity was 0.93. Reliability was high in the three studies, and the tool had a high discrimination power to distinguish women with healthy and sexual dysfunction. Moreover, the internal consistency of the tool was $\alpha = 0.86$, and its test–retest reliability was estimated to be $r = 0.91$. In addition, this scale revealed high sensitivity and specificity in detecting female sexual anxiety.\(^{[23]}\)

**Female Sexual Function Index**

The first phase was to meet the basic psychometric criteria, i.e., to reach clear and comprehensible items with comprehensive options of 30 items to assess the aforementioned dimensions. The questionnaire was then submitted to 30 female volunteers. The respondents’ feedbacks were reviewed by the expert panel to comment on modifying, removing, or adding new items.

The second phase aimed at evaluating the Female Sexual Function Index (FSFI) for construct validity (factor analysis, discriminant validity, and divergence validity) and reliability (internal consistency and test–retest). The divergent validity of the 29-item questionnaire was obtained using factor analysis and varimax rotation. Following the varimax rotations for all the items, 19 items were detected to have acceptable eigenvalues in 6 dimensions. Its divergent validity was assessed using Locke-Wallace’s Marital Adjustment Test score.\(^{[37]}\) Differential validity (discriminant validity), which shows the capability of a scale to distinguish between healthy and unhealthy populations, was assessed using the comparison between the mean scores obtained for the patients with sexual dysfunction and the control group ($P \geq 0.001$). The reliability of the questionnaire was assessed using test–retest reliability, and high correlations were observed for all the dimensions ($r = 0.79–0.86$) and for the whole scale ($r = 0.88$). The internal consistency of the questionnaire was also estimated using Cronbach’s alpha ($\alpha \leq 0.82$).\(^{[23]}\)

**Diabetes 39 (D39)**

The project consisted of two stages. In the first phase, using information extracted from literature review, existing quality of life tools, and interviews with health professionals and diabetics, the first draft of this scale was developed and consisted of 92 items on important aspects of these patients’ lives and addressed 10 dimensions, including diabetes medicine (9 items), diabetes control (23 items), anxiety and concern (13 items), energy and mobility (11 items), sleeping (3 items), limited diet (6 items), self-acceptance (4 items), social pressure and peer group (14 items), other diseases (8 items), and sexual function (3 items). Then, this questionnaire was sent to 1000 people with diabetes (aged 18 years and above). Fifty items were then deleted. In the second phase, the 42-item questionnaire was completed by 427 diabetic patients. Following the factor analysis and data analysis, three other items were removed. The final instrument contained 39 items and dealt with six dimensions of the patients’ lives: energy and mobility, diabetes control, anxiety and concern, social pressure and peer group, and sexual function. The construct validity of the questionnaire was assessed by discriminant validity and convergent validity using SF-36 ($P \geq 0.05$), and its internal consistency was confirmed using Cronbach’s alpha ($\alpha = 0.81–0.92$).\(^{[29]}\)
## Table 3: Tools assessing sexual and reproductive health dimension in women with Type 1 diabetes mellitus with regard to the Consensus-based Standards for the selection of health status Measurement Instruments Checklist

| Tool | Country | Age group | Dimensions | Number of items | Content validity | Face validity | Construct validity | Reliability | Responsiveness |
|------|---------|-----------|------------|----------------|-----------------|---------------|-------------------|-------------|----------------|
| RHAB [18] | Russia and USA 2006 | 16-22 years | 10 | 42 | Based on pregnancy and diabetes Interview schedule [22] | No information | No information | Factor analysis | No information | Test re test $r$ $\geq$0.91 | No information | $\alpha$=0.65-0.83 |
| FSDS [23] | USA 2002 | 40±0.06 years | 1 | 12 | No information | No information | Yes [24] | Factor analysis | No information | Test re test $r$ 0.91 | No information | $\alpha$=0.86 |
| FSFI [25] | USA 2000 | Case: 21-69 years Control: 29-69 years | 6 | 19 | Yes | By expert panel | Yes [26] | Factor analysis | Discriminant validity Divergent validity (marital adjustment test) [27] Control/case group $r$=0.53 versus $r$=0.22 | No information | Test re test 0.80 | No information | $\alpha$=0.82 |
| D39 [29] | UK 1997 18 ≤ years | 6 | 39 | No information | By patients [30] | Yes [31] | Discriminant validity Factor analysis Convergent validity (SF-36) $P<0.05$ | Test re test | No information | No information | $\alpha$=0.81-0.92 |
| GRISS [31] | UK 1983 No information | 4 | 56 | No information | No information | Yes [32] | Factor analysis Discriminant validity For men, $r$=0.79 For women, $r$=0.63 | Test re test | $\alpha$=0.74 | Female: 0.60-0.83 and male: 0.44-0.78 |

Contd...
Golombok and Rust’s Sexual Satisfaction Questionnaire

The first version of the questionnaire contained 96 items (48 items for women and 48 items for men). In the pilot study, 51 couples with sexual dysfunction and 36 couples with no disorders from a hospital in London were included. Following factor analysis, 56 items on marital satisfaction, marital communication, common interests, respect, and trust showed the highest percentage of variance. The validity of the tool with discriminant validity was $r = 0.37$ for men, and $r = 0.63$ for women. Test–retest reliability also revealed $P < 0.01$ and $r = 0.76$ for men and $P < 0.01$ and $r = 0.65$ for women. Split-half testing also showed the reliability of the questionnaire to be $r = 0.94$.\[31\]

Derogatis Sexual Functioning Inventory

It is a self-report list of one’s recent sexual function and encompasses 254 items and 10 scales. The items are scored with regard to yes/no and Likert scales.

The scales of this questionnaire are (1) information (26 items about the anatomy and physiology of sexual), (2) experiences (24 items, the range of sexual behaviors), (3) stimulation (refers to asexual actions), (4) attitudes, (5) psychological signs (stressful aspects and individual’s concerns), (6) effects (40 items, refers to effects of sex), (7) defining sex roles (15 items), (8) fantasy (20 items), (9) body image (15 items), and (10) sexual satisfaction. To evaluate the validity and reliability of this questionnaire, a sample of 230 college students in the United States with an average age of 32 participated in the study. The reliability of the questionnaire was assessed using test–retest ($r ≤ 0.7$), and internal consistency was confirmed using Cronbach’s alpha ($\alpha = 0.6–0.97$).\[33\]

Dyadic Adjustment Scale

To this end, 218 couples included in this study. The first draft of the questionnaire encompassed 40 items, and factor analysis was used to determine the dimensions and number of the final items. The items addressed about four or five dimensions, including satisfaction, double cohesion, double consensus, and expression of affection. Finally, eight items with unacceptable eigenvalues were deleted and 32 items remained. Content validity was assessed based on the experts’ judgment. The result of $t$-test was also significant in dyadic adjustment in married and divorced groups ($P \geq 0.001$). Convergent validity (using Locke-Wallace’s Dyadic Adjusted Scale) was also used to evaluate the construct validity of the tool as such that they had $r = 0.86$ and $r = 0.88$ for the married and divorced groups at $P \geq 0.001$, respectively. Using test–retest technique, the reliability of the questionnaire was also determined to be $r = 0.96$ at $P \geq 0.001$. Internal consistency was also calculated to be $\alpha = 0.96$.\[35\]
Discussion

Most of the valid tools used in researches related to the sexual and reproductive health in women with type 1 diabetes, which are also used in the general and healthy population. Due to the specific consequence of type 1 diabetes on the sexual and reproductive health dimensions of affected women and significant differences in their needs, it is necessary to design psychometric specific tools for measuring the sexual and reproductive health for this group.

Nowadays, one of the main contemporary topics in research studies is how to select appropriate and relevant measurement tools, and this is as important as the research and the provision of scientific documentation. Before using a tool, its psychometric features must be adequately evaluated and considered. COSMIN checklist is one of the most comprehensive criteria in selecting a suitable tool, which examines psychometric properties in four phases, and the measurable criteria of the tools of this checklist include reliability, validity, responsiveness, and accountability.

According to the search results, 14 valid tools were detected in the methodology of these articles, seven of which encompassed items addressing sexual-reproductive health dimensions. In the next step, the tools were assessed psychometrically, and their features were evaluated based on the COSMIN checklist.

Although most of the articles did not refer to the COSMIN checklist, all of them considered the main indices of consistency (internal consistency and reliability) and validity. An in-depth review of the concerned articles showed that the number of dimensions and items was specified in all the articles. The construct validity of the questionnaires was determined using factor analysis, differential validity, divergent validity, and convergent validity, and the results were acceptable. All the aforementioned tools had acceptable stability, which was determined using internal consistency (Cronbach’s alpha coefficient) and reliability (test-retest and r > 0.7). High levels of internal consistency indicated the high correlation among the items, suggesting that the concerned tool was most likely to measure the concept under study. Factor analysis was used in all of the questionnaires to determine and select the most appropriate final items. Moreover, the internal consistency results for all the questionnaires reported high values of Cronbach’s alpha, indicating that they are suitable for the concerned purpose. The research studies can lead to credible results if they employ culture-adapted tools.

Conclusion

Type 1 diabetes mellitus can affect the sexual and reproductive life of women, influencing many of their choices relating to contraception, pregnancy, and menopause. In this study, it was realized that most of the tools that could be evaluated in accordance with COSMIN checklist had acceptable validity and reliability, but when focusing on the sexual and reproductive dimension, there was an indication of the inappropriateness of the available tools for a comprehensive assessment of sexual and reproductive health in women with type 1 diabetes. Therefore, further studies on the development and psychometric evaluation of other dimensions of sexual and reproductive health in women with type 1 diabetes are recommended since sexual and reproductive health also includes other aspects, structures, and items not addressed in these tools. Using a valid tool, it is possible to find the current situation, health gaps, and thus plan for the suitable action to improve the sexual-reproductive health of women with type 1 diabetes.

Limitations of the study

Regarding the comprehensiveness of sexual-reproductive health and its dimensions and subscales, a larger number of keywords and search terms should have been used. This enhanced the number of detected articles and prolonged the screening and selection of relevant articles.

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Conflicts of interest

There are no conflicts of interest.

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