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NURSING

Validation of the Italian version of the SexContraKnow instrument

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Keywords

Validation study • Contraception • Sex education • Adolescent • Health literacy

Summary

Introduction. A large proportion of all pregnancies worldwide occur in young adolescent women, and almost all these pregnancies are unintentional. To address effective educational interventions, it is necessary to assess adolescents' literacy on this topic. The aim of this study was to translate and validate the Italian version of the SexContraKnow instrument.

Methods. This was a methodological study. The validation of the instrument was performed following the EORTC Quality of Life Group translation procedure. The process consisted of four phases: translation, content validation, face validation, and pilot test. Data were collected between May and September 2021. The STROBE guidelines were followed for this study.

Results. After performing forward and backward translations, we

evaluated content validity (Scale-Content Validity Index = 0.91) and face validity. We then conducted a pilot test, test re-test, with 10 students (Cronbach α = 0.928; Pearson's R = 0.991).

Conclusion. The Italian Version of the SexContraKnow instrument has a good level of validation and reliability and can be effectively used by nurses to assess adolescents' literacy about the use of contraceptives and to develop targeted educational interventions. This instrument will help to evaluate the effectiveness of education programmes about health literacy about safe sex and contraception. The attention of nurses should be actively directed towards the process of health literacy among adolescents, in the perspective of a society focused on the empowerment of the population.

Introduction

Health literacy is a set of skills that improve people's ability to process information that enables to live in a healthier way. Such skills include reading, writing, listening, talking, calculating, and critical analysis, as well as communication and interaction [1]. Health literacy is an important social benefit [2] because it reduces improper access to hospital and emergency services, drug utilization, and increases health autonomy, individuals' usage of preventive services and the development of correct health care behaviours [3]. To achieve a good level of health literacy, people should have the ability to find, select and understand healthcare information from the Internet, brochures about health, verbal or written healthcare instructions, and healthcare journals [3]. Although the process of health literacy is of undoubted relevance, today half of the adult population still have inadequate levels of health literacy and is unable to understand information about their health [4] and require more support when having to manage their health problems [5].

Similarly, in the adolescent population – meaning people of any gender aged between 10 and 19 years [6] – the situation is no better, as less than one-fifth of all European students have a high level of health

literacy [7]. This deficiency affects the broader concept of health, defined as a “state of physical, psychological and social well-being [...]” [8], but is even more true in sexual and reproductive health, defined as “...a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled” [9]. Adolescents face numerous physical, cognitive, emotional, and behavioural changes that they know very little about, as they acquire increasing autonomy and experience in many areas [10, 11]. These experiences may include alcohol use, drugs, smoking, and sexual activities, each of which may be associated with sexual and reproductive risks, such as sexually transmitted diseases and/or unintentional pregnancies [7].

In fact, 11% of all pregnancies worldwide involve young adolescent women, and almost all these pregnancies are unintentional [12]. Health literacy is especially important in adolescents because it impacts not only on the individual but also on the whole family. Education

enables individuals to change behaviours about their health habits [5]. In literature, it is widely recognised that adolescence is a critical period due to frequent incorrect health behaviours [5, 10, 12-14]. Moreover, health behaviours are acquired during adolescence, and therefore receiving correct health education at this age is an important determinant for health promotion [10]. The Health 2020 Strategy of the World Health Organization Regional Office for Europe [15] highlighted the importance of health literacy for the population and has become a key point on the European health agenda [13]. This context suggests that there is a need to increase educational interventions aimed at providing health literacy and skills regarding sexual and reproductive health, especially in adolescents. To properly design such interventions, it is necessary to understand what this population knows about this topic. Adequate literacy about sexuality and contraception is defined as the possession of training about sexuality and contraception that allows one to make informed decisions and pursue one's sexuality safely [10, 16]. Several studies have been conducted internationally and in the Italian context focusing on adolescents' literacy of safe sex and contraception, but most of them used non-validated ad-hoc tools [14, 17-20]. It is essential to use valid and reliable tools. Sebastian Sanz-Martos and his Spanish nursing research group of the University of Jean in 2019 developed an instrument to evaluate health literacy about sexuality and contraceptive methods in young university students. The *SexContraKnow* instrument proved to have sufficient validity and reliability and could be used in future research also to evaluate the effect of educational interventions or develop future educational programmes [5].

Methods

AIM

The purpose of this study is to provide a valid and reliable Italian instrument to assess adolescents' health literacy about contraception and develop an effective educational program. We selected the *SexContraKnow* instrument [5], translated it (Appendix 1) in Italian, adapted it to the adolescent population (aged between 14 and 19 years) and validated it.

METHODOLOGY

For the validation of the *SexContraKnow* instrument, we followed the EORTC *Quality of Life Group* guidelines [21]. The validation process consisted of four phases: translation, content validation, face validation, pilot test.

To translate the instrument, we used the *forward-backward translation* method. We asked two different Italian mother-tongue translators with a good knowledge of the Spanish language to independently translate the questionnaire. They had not been previously informed of the study or the content of the questionnaire. The two

translations were reconciled into one through an online meeting with the two translators and the researchers. This final version was translated back into Spanish by a native Spanish translator with a good knowledge of the Italian language.

To validate the content of the instrument, we submitted it to a group of experts and asked them to rate the relevance of the 15 items of the questionnaire. These were scored using a four-point *Likert* scale, from 1 (not-relevant at all) to 4 (very relevant). Then we calculated the Content Validity Index (CVI) for each item and for the whole instrument. Following the recommendation on an acceptable indicator of content validity [22] we determined that each item-CVI (I-CVI) had to be at least ≥ 0.78 to be considered item relevant. The scale-CVI (S-CVI) had to be at least ≥ 0.90 for the entire instrument to be valid.

To test the face validity, we asked a group of volunteer high school students (between 14 and 19 years) to evaluate the questionnaire and then we performed a qualitative analysis of their answers. We asked them whether the 15 items were difficult to understand, confusing, contained difficult words, contained offensive words, or needed to be rephrased. At the end of this phase, we considered all the changes proposed by the students and performed the cultural adaptation.

To test the internal consistency, we performed a pilot *test re-test* and calculated *Cronbach's alpha* and the *Pearson correlation coefficient* (*Pearson's r*). We asked a convenience sample of high school students to complete the questionnaire (T0) and then to repeat this after one week (T1). During the week, the students did not receive any further information or education.

PARTICIPANTS

Sample sizes were consistent with the EORTC *Quality of Life Group* guidelines [21]. Throughout the phases, we used a convenience sample. The content of the questionnaire was validated by a group of 9 experts of adolescent sexual health. For face validity, we invited 12 volunteer high school students (between 14 and 19 years) whose mean age was 16.5 years (SD = 1.78) to evaluate the questionnaire. For the pilot test, the sample included 10 volunteer high school students (between 14 and 19 years) with a mean age of 18.1 years (SD = 1.6).

DATA COLLECTION

The data across all the phases were collected using a Google Forms® link. The link was sent to the participants via email. For content validity, the data were collected in May 2021. We gave the participants two weeks' time to answer the questionnaire. For face validity, the data were collected in July 2021 and the students had two weeks to answer. For internal consistency, instead, the data were collected in September 2021. The first administration of the questionnaire took place on the 21st of September 2021 and the second on the 28th of September 2021. The high school students had to complete the questionnaire within the day after it was emailed to them on both occasions.

DATA ANALYSIS

For content and face validity the data we collected were codified and analysed using a Microsoft Excel® spreadsheet. I-CVI was obtained using the mean relevance score of each item. S-CVI was obtained using the computed mean of all the I-CVIs. Face validity was qualitatively analysed. The data relating to the pilot test were entered in a Microsoft Excel sheet and analysed using the Jamovi® software version 2.2.2. We calculated Cronbach's alpha to assess internal consistency and Pearson's r value to assess internal reliability.

THE INSTRUMENT

The purpose of the *SexContraKnow* instrument is to verify the level of health literacy about safe sex and contraception in university students [5]. It was validated on a population of university students aged 19-24 years, attending the faculty of nursing and the faculty of law. The instrument contains 15 items about sex and contraception. The possible answers for each question are: "true", "false", "I don't know". The third possible answer is useful to identify the least known subjects and therefore develop an educational intervention. The highest possible score is 15 and the average completion time was about 10 minutes.

ETHICAL CONSIDERATIONS

The questionnaire was translated only after obtaining the approval of the authors for use. This pilot study was part of a larger study about health literacy approved by the Ethical Regional Committee of Liguria (156/2019). Participation was voluntary. The students aged over 18 signed a consent form, whereas, for students who were still minors, the consent form was signed also by their

parents. The collected data were stored in a password-protected computer. Only the researchers of the study could access the data.

Results

CONTENT AND FACE VALIDITY

We invited a group of experts to evaluate the instrument. The experts were all females (mean age 43.7; SD = 14.7): 5 high school teachers, 2 midwives, 1 gynaecologist, and 1 healthcare assistant. All the healthcare professionals involved were employed in a counselling centre. We calculated the Content Validity Index (CVI) for each item (I-CVI) and for the entire questionnaire (S-CVI). The S-CVI score was 0.91, meaning that the Italian experts found the instrument to be relevant to evaluate adolescents' health literacy. All the I-CVI scores are reported in Table I. Only one item had an I-CVI score < 0.78 but, since the S-CVI score was ≥ 0.90, it was not excluded from the instrument. At the end of this phase, the questions were transformed into sentences, as suggested by the group of experts. For the face validation, a convenience sample of 12 high school students was invited to evaluate the instrument. The sample consisted of 6 males and 6 females, and the mean age was 16.5 years (SD = 1.78). None of the items was considered offensive. The questions that were considered confusing or containing difficult words were modified and reformulated based on the students' suggestions.

INTERNAL CONSISTENCY

To verify the internal consistency of the instrument we performed a pilot test re-test on 10 volunteer students.

Tab. I. Item-Content Validity Index values.

| SexContraKnow items | I-CVI [§] |
|---|--------------------|
| N. 1 - There is a risk of pregnancy when you have unprotected sex in the 2 days before or after ovulation | 1.00 |
| N. 2 - The male condom is safe if placed just before ejaculation, even if penetration has occurred previously | 0.89 |
| N. 3 - The "calendar method" (calculating the fertile period to not have sexual intercourse within this period) is effective in preventing pregnancy | 1.00 |
| N. 4 - When you start taking the birth control pill, it is effective from day one | 1.00 |
| N. 5 - Hormonal contraceptive methods of birth control (for example, the birth control pill or vaginal ring) are recommended for adolescents | 1.00 |
| N. 6 - When the contraceptive pill is not taken at the correct time due to forgetfulness, the pill can be taken without loss of effectiveness as long as no more than 12 hours have passed since the correct time | 1.00 |
| N. 7 - The "dual contraceptive method" consists of the simultaneous use of a barrier contraceptive method (e.g., male condom) and a hormonal contraceptive method (e.g., contraceptive pill) | 1.00 |
| N. 8 - If the contraceptive pill is started after the 5 th day of the menstruation cycle, the use of another contraceptive method for one week is recommended | 1.00 |
| N. 9 - The regimen for taking the contraceptive pill is one pill per day for 21 days starting from the 1st day of the cycle, followed by a week of rest or use of 7 placebo pills during this rest period | 0.78 |
| N. 10 - The contraceptive skin patch must be applied on the first day of the menstruation cycle | 0.78 |
| N. 11 - The birth control skin patch should be replaced only when the patch detaches itself | 0.78 |
| N. 12 - The contraceptive skin patch should be placed on the buttocks, lower abdomen, upper back, or outer arms | 0.67 |
| N. 13 - It is necessary to see a specialist for the placement of the vaginal ring | 0.78 |
| N. 14 - The vaginal ring can be removed for 2 hours during sexual intercourse without risk of pregnancy | 1.00 |
| N. 15 - The vaginal ring should be left in place for 21 days, followed by a week of rest | 1.00 |

[§] Item-content validity index.

Tab. II. Characteristics of the test-retest sample (N = 10).

| Characteristics | High school students | |
|--------------------------------------|----------------------|-------------|
| | N (%) | Mean (SD) |
| Gender | | |
| Males | 2 (20) | |
| Females | 8 (80) | |
| Age | | |
| | | 18.1 (1.66) |
| High school classes | | |
| First year | 1 (10) | |
| Fourth year | 2 (20) | |
| Fifth year | 7 (70) | |
| Parents' relationship | | |
| Married/cohabiting | 7 (70) | |
| Separated/divorced | 3 (30) | |
| Parents working in healthcare | | |
| Yes | 3 (30) | |
| No | 7 (70) | |
| Older siblings | | |
| Yes | 5 (50) | |
| No | 5 (50) | |

The majority were females (80%) with a mean age of 18.1 years (SD = 1.6) (Tab. II).

After the second administration of the instrument, we analysed the data and calculated Cronbach's alpha ($\alpha = 0.928$) and Pearson's r ($r = 0.991$).

DESCRIPTIVE DATA

We performed a descriptive analysis on the answers of the students at T0 and T1. After calculating the mean score between T0 and T1, the items with the highest score were Item 1, "There is a risk of pregnancy when you have sex without any protection in the two days before or after ovulation.", and Item 3, The "calendar method (calculating the fertile period for not having sex during this period) is effective to avoid a pregnancy". The item with the lowest score was Item 13: "For the placement of the vaginal ring it is necessary to consult a medical specialist". The items the students were least knowledgeable about were: Item 10, "The contraceptive skin patch must be applied on the first day of menstrual cycle", and Item 12, "The contraceptive skin patch should preferably be applied on the buttock, to the lower abdomen, on the upper back or the outer arms". All the answers are summarized in Table III.

Discussion

The results we obtained, following the EORTC *Quality of Life Group* guidelines [21], showed that the reliability and validity of the Italian version of the *SexContraKnow* instrument were acceptable. Therefore, this instrument could be reliably used to explore adolescents' literacy about safe sex and contraception. The original instrument also showed good fit and reliability [5]. The invariability of the 15 items of the scale was assessed for differences across gender (male/female), previously training in

Tab. III. Descriptive analysis of the items (N = 10).

| SexContraKnow items | Percentage of success | | Percentage of mistakes | | Percentage of "don't know/no answer" responses | |
|---------------------|-----------------------|-----|------------------------|-----|--|-----|
| | T0 | T1 | T0 | T1 | T0 | T1 |
| 1 | 90% | 90% | 0 | 0 | 10% | 10% |
| 2 | 60% | 60% | 20% | 20% | 20% | 20% |
| 3 | 90% | 90% | 10% | 0 | 0 | 10% |
| 4 | 70% | 60% | 10% | 20% | 20% | 20% |
| 5 | 70% | 80% | 0 | 0 | 30% | 20% |
| 6 | 70% | 70% | 10% | 10% | 20% | 20% |
| 7 | 80% | 80% | 0 | 0 | 20% | 20% |
| 8 | 40% | 40% | 0 | 0 | 60% | 60% |
| 9 | 70% | 60% | 10% | 10% | 20% | 30% |
| 10 | 30% | 30% | 10% | 0 | 60% | 70% |
| 11 | 30% | 30% | 10% | 10% | 60% | 60% |
| 12 | 40% | 30% | 0 | 0 | 60% | 70% |
| 13 | 40% | 40% | 40% | 50% | 20% | 10% |
| 14 | 20% | 20% | 30% | 20% | 50% | 60% |
| 15 | 60% | 60% | 10% | 10% | 30% | 30% |

using the questionnaire (yes/no) and academic degree discipline (nursing/law). The Bonferroni-adjusted α value ($0.05/15 = 0.0033$) showed no significance. The reliability of the scale was 0.99 for items and 0.74 for people. Both values indicate the fitness of the items to adequately rank people on the latent trait. The temporal stability of the scale was calculated using test-retest, obtaining a value of 0.81 (CI 0.692-0.888).

A descriptive analysis of the answers given to the instrument was also performed by the Spanish research group. Considering that the maximum score is 15 points, the mean score of all the answers was 7.47 (SD = 3.16). The item that obtained the highest percentage (93%) of correct answers was Item 2, "The male condom is safe if placed just before ejaculation, even if penetration has occurred previously", while the lowest (15.8%) was Item 14, "During sexual intercourse, the vaginal ring can be removed for 2 hours without risk of pregnancy". The most unknown item (73.9%) was Item 10, "The contraceptive skin patch must be applied on the first day of menstrual cycle" [5]. Although we validated the Italian version of the *SexContraKnow* Instrument on a high school population, the results were comparable to those obtained from the Spanish nursing research group of the University of Jean. We found that teenagers had more health literacy about the contraceptive methods they used most, in accordance with the National Survey on Contraception carried out by the Spanish Society of Contraception in 2018 [23].

For the Italian context, we found that it was essential to have this instrument for the adolescent population. The Ministry of Health in Italy performed several surveys on adolescents' health, including sexual health, but the instruments used were old [19] or non-specific for contraceptive methods and safe sex [20, 24]. Thanks to the validation of this instrument, Italian researchers

now have a new validated and reliable tool that could be used also in combination with the surveys that will be conducted by the Italian Ministry of Health in the future. It is important to improve health literacy through formal health education provided in schools. Health literacy provided through formal health education, improves people's self-efficacy, knowledge, and correct health behaviours [3, 12, 25]. People with a high level of health literacy can educate their children and help them adopt correct health behaviours, and adolescents would be more conscious about safe sex and contraception [2]. Nurses are the healthcare professionals who mostly interact with people and are the key to improving health literacy in the society [10]. Nurses play an active role because they can understand how to address appropriate educational interventions and how to transfer correct health information to adolescents [2, 12]. In particular, public health nurses and school nurses have the responsibility to promote health programs for adolescents [10].

LIMITATIONS

This study has some limits. First, the sample size for the pilot test-retest was limited to 10 participants because the validated instrument was intended to be used for a secondary larger study. Second, all the participants were from the same city. Third, we selected a sample aged between 14-19 years (high school population) so that more parents would accept their children's participation in our study. It would have been interesting to evaluate contraceptive health literacy in an even younger population.

Conclusions

The Italian version of the *SexContraKnow* instrument showed evidence of acceptable reliability and validity. It can be reliably used in Italy to assess adolescents' (high school students) health literacy about safe sex and contraception. It could be useful to test the instrument with younger or older populations than high school students. To further confirm its validity and reliability, it would be useful to conduct a multicentre nationwide study. This instrument could also be used to evaluate the effectiveness of educational programs currently available in Italy and promote the implementation of the most effective ones.

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Conflict of interest statement

The author declares no conflict of interest.

Authors' contributions

All authors contributed to the study conception and design. Material preparation and data collection were performed by VR, FN, and GC. Data analyses were performed by VR, FN, and MC. The first draft of the manuscript was written by VR, FN, MC, MH, RW, and GA. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Appendix 1

Di seguito, troverai una serie di affermazioni sulla sessualità, sulla gravidanza e sui metodi anticoncezionali. Alcune affermazioni sono vere e altre sono false, indica in ogni caso l'opzione che ritieni più corretta. Indichiamo una terza opzione di risposta, non sa/ non risponde. Nel caso non si conosca se l'affermazione è vera o falsa, per favore indicacelo tramite l'opzione NS/NC e non rispondere a caso.

| | | | |
|--|---|---|-------|
| 1 - C'è rischio di gravidanza quando si hanno rapporti sessuali senza alcuna protezione nei due giorni precedenti o posteriori all'ovulazione | V | F | NS/NC |
| 2 - Il preservativo maschile è sicuro se si mette giusto prima di eiaculare, anche se precedentemente ci sia stata una penetrazione | V | F | NS/NC |
| 3 - Il "metodo del calendario" (calcolare il periodo fertile per non avere rapporti sessuali durante questo periodo) è efficace per evitare una gravidanza | V | F | NS/NC |
| 4 - La pillola anticoncezionale è efficace sin dal primo giorno | V | F | NS/NC |
| 5 - I metodi anticoncezionali ormonali (per esempio, la pillola anticoncezionale o l'anello vaginale) sono raccomandabili per gli adolescenti | V | F | NS/NC |
| 6 - Quando ci si dimentica di assumere la pillola anticoncezionale all'ora corretta, si può prendere entro 12 ore senza perdita di efficacia | V | F | NS/NC |
| 7 - Il "doppio metodo anticoncezionale" consiste nell'utilizzo simultaneo di un anticoncezionale di barriera (per esempio, preservativo) e uno ormonale (per esempio, pillola anticoncezionale) | V | F | NS/NC |
| 8 - Se l'inizio dell'assunzione della pillola anticoncezionale è dopo il 5° giorno del ciclo, è raccomandabile usare un altro metodo anticoncezionale per una settimana | V | F | NS/NC |
| 9 - Lo schema di assunzione della pillola anticoncezionale è giornaliero partendo dal 1° giorno del ciclo, per 21 giorni con una settimana di riposo. Per mantenere l'abitudine alcune aziende hanno inserito la possibilità di assumere una pastiglia placebo in tale settimana | V | F | NS/NC |
| 10 - Il cerotto cutaneo anticoncezionale si deve applicare sin dal primo giorno di ciclo | V | F | NS/NC |
| 11 - La sostituzione del cerotto cutaneo anticoncezionale si deve fare solo quando questo si stacca in autonomia | V | F | NS/NC |
| 12 - Il cerotto cutaneo anticoncezionale si deve applicare preferibilmente sul gluteo, sulla zona del basso ventre, sulla parte superiore della schiena o esterna delle braccia | V | F | NS/NC |
| 13 - Per la collocazione dell'anello vaginale è necessario rivolgersi a un medico specialista | V | F | NS/NC |
| 14 - Durante un rapporto sessuale, l'anello vaginale si può rimuovere per 2 ore senza che ci sia il rischio di gravidanza | V | F | NS/NC |
| 15 - L'anello vaginale si deve lasciare inserito per 21 giorni, lasciando successivamente una settimana di pausa | V | F | NS/NC |