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The health needs of women prisoners: an Italian field survey

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Abstract

Introduction. Health care in prisons represents an important part of public health due to the interaction between prisons and society. Women prisoners have needs that distinguish them from male prisoners, however little is known about how those needs are met. The aim of the study was to gather information about the needs of women in prison and to identify which of their needs are the most or the least met.

Methods. This study investigated the needs of detained women using a newly developed Questionnaire based on Gordon's model. In this descriptive study, data were collected from a convenient sample of women recruited from two Italian prisons. Data analysis used descriptive statistics.

Results. Fifty-five women (response rate = 92%) completed the self-reported questionnaire. Our findings showed that physical needs are met worse than psychological and social needs. The majority of physical needs were related to the inability to meet food preferences and the difficulty in respecting food requirements related to disease and by religion. The women experienced a loss of privacy, and they need more time for improving the quality of their relationships. The majority of the participants (65%) declared that they suffer from psychological disorders with an alarming percentage (29%) stating that they had thoughts of self-harm. They commonly consume tobacco (87.3%), and abuse substances (20%).

Discussion and conclusions. The recognition of multi-dimensional women's needs is of primary importance to create opportunities to support incarcerated women and to build health-promoting gender-sensitive interventions.

Key words

- prisoners
- incarceration
- women's health
- public health
- health needs

INTRODUCTION

The state of health of the prison population is an important part of public health, due to the interaction that occurs between prison institutions and the society in which they operate [1], the investigation of the health status of prisoners is essential to all public health authorities whose purpose is to benefit the health of society as a whole. Detainees are not a homogeneous segment of society because many of them live outside the norm of society and come from socio-economic disadvantaged backgrounds. Their level of health, prior to entry into prison is on average lower than that of the general population, and for these reasons, they are more vulnerable and fragile [2].

State detention often exacerbates latent and manifest health issues and fails sufficiently to ensure the right to the protection of health. In such situations, it is essential to ensure that prisoners have equal opportunities to access good health treatment on an equal basis to the population as a whole.

It is important to consider that the deprivation of liberty is a serious detriment to health especially concerning social and psychological components. One factor of invasive institutionalization is the loss of the individual's privacy and ability to control the environment of everyday life, which often translates into a sense of loss of identity and a perception of insecurity [3].

Globally, recent decades have seen a rapid and unrelenting growth in the use of imprisonment as a response to crime and social disorder. Today, well over 10 million people are imprisoned worldwide [4], with women

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making up approximately 7% of the worldwide prison population [5, 6]. In parallel to the global growth rate of incarceration, there is increasing attention to the physical, psychological, and social conditions that characterize women in detention and their specific needs. However, women are a small minority within the overall total of the prison population, and the majority of international and national research has focused to the date upon the prison population as a whole, and not specifically the female sub-group [7-9].

Women in the correctional system are a population at risk and one of the greatest risks they face is increased vulnerability to health problems such as communicable diseases, substance abuse, and mental health issues [10]. According to a WHO report, complex health needs of female prisoners include: 1) mental health problems; 2) suicidal behavior; 3) substance use problems; 4) reproductive health [11].

It has also been shown that a history of incarceration may influence detainees' access to healthcare. Specifically, incarcerated women are less likely to have a regular source of healthcare or to receive routine care than the general population [12]. Furthermore, this vulnerable population of women subsists within a penal system designed primarily for men; a system that does not adequately address women's unique needs. This may lead to ineffective treatment, poor healthcare outcomes, and wasted healthcare resources [13, 14].

These considerations suggest that it is important to consider gender when planning interventions to enable the allocation of resources in the most efficient way and for ensuring the optimal level of appropriateness [15].

In Italy, information on the health of women prisoners is scarce. For this reason, the need to carry out a careful assessment of the health needs of women inmates in Italian prisons is of primary importance for public health.

This study represents an exploratory study aimed at describing the health needs of the female prison population in Italy. In this context, a thorough survey of the female prison population will help decrease inequalities through a clear recognition of women's' specific needs.

MATERIALS AND METHODS

Instrument

The research team used a specific tool, named "Questionnaire for the survey of the health needs of the female prison population".

The Questionnaire was developed in original, as no validated tools formally existed.

The draft tool used the Gordon model [16], which is based on the type of functional health patterns, related to a specific classification for establishing a comprehensive needs assessment. It is one of the best-known classifications of human needs applied in the field of Nursing. The Gordon model has a holistic nature and is applied to the care recipient (in a group or in the community) regardless of the context in which the healthcare is required and is independent of age and any context of the health-disease continuum [17].

In order to obtain a set of information that could be managed via a data matrix, the research group formulated the Questionnaire with items in closed-answer mode and pre-coded. Specifically, the team used this formula for three reasons, primarily related to the complexity of the instrument itself:

1) to use the self-administration of the survey instrument, a technique that avoids the disruption of the object of investigation;
2) to speed up compilation by the respondents of a very complex questionnaire;
3) to avoid excessive interpretation of those interviewed.

To establish the psychometric proprieties of the new instrument we evaluated the face and content validity of the Questionnaire [18, 19], and its reliability through test-retest and Cronbach's alpha.

The items of the Questionnaire were generated to include all of the Gordon model criteria consistent with the existing literature. Then, through two focus groups, a panel of experts (a psychologist, a physician, a nurse, a social worker and a midwife) were asked to evaluate whether the items covered all-important criteria or if there were missing components. In the second, the focus was on the relevance and clarity of the questions as well as their significance and completeness.

To assess the face validity of the Questionnaire we contacted five female prisoners, and two nurses with advanced experience in caring for prisoners. These participants had to determine whether they understood what they were asked in the Questionnaire if they thought the questions were adequately described and whether or not they observed other important aspects not included in the list.

Participants also received a form in which they had to write their comments and demographic characteristics. Changes were made to the Questionnaire in adherence to these results.

Based on the comments expressed by the five prisoners, the research team concluded that the new search tool has good face validity, since its reading made intuitive sense, and its content sufficiently covered the health needs of the female prison population. Thus, the first version of the Questionnaire was draft.

Lastly, to establish the content validity of the first version of the Questionnaire a rigorous judgment quantification process by Lynn [20] was used. The panel of experts involved in the previous focus groups was asked to express their opinion independently from each other on the items of the modified version of the instrument using a Likert Scale from 1 = "not relevant" to 4 = "very relevant", over a period of five weeks.

Evaluations of each of their results were subjected to cross-analysis at the beginning of subsequent weekly sessions.

At the end of the process, the feedback of the expert panel added a degree of satisfaction of convergence with a content validity index for the whole scale of 0.92.

The stability of the Questionnaire was established with test-retest measure. This was achieved by recruiting fifteen female inmates on a voluntary basis and held at the House Female Prison of Rome-Rebibbia and by providing them with the Questionnaire at time T1 and

T2, with a time interval between the first and second participation of seven days.

The resulting two sets of results showed a strong evidence of test-retest reliability (r = 0.98).

The internal consistency examined with Cronbach's alpha was 0.96.

Based on these results, the final version of the Questionnaire was drafted and divided into 14 sections, of which 11 investigate needs according to Gordon's functional health patterns (Health Perception-Health Management, Nutritional-Metabolic, Elimination, Activity-Exercise, Sleep-Rest, Cognitive-Perceptual, Self-perception/Self-concept, Role-Relationship, Sexuality-Reproductive, Coping-Stress Tolerance, and Value-Belief) and three related to socio-demographic variables, general information in regards to the general health status, and the overall level of satisfaction of the care provided.

Sample

Participants were consecutively recruited from a pool of 60 women prisoners. A total of 55 prisoners were enrolled during the study period with a response rate of 92%, from the Rome-Rebibbia (n = 36) and the Perugia-Capanne (n = 19) prisons respectively.

The inmates had to meet the following inclusion criteria:

- an understanding of the Italian language;
- unimpaired cognitive function;
- self-sufficiency in daily living activities;
- voluntary participation in the study.

The prison authorities excluded all those prisoners awaiting trial due to the necessity of requesting judicial authorization to participate.

The sample was guaranteed by researchers to respect privacy and anonymity, and all prisoners gave explicit written informed consent to participate in the research.

Data analysis

The data were first entered into a database, prepared with Excel for Microsoft Office 2007, and processed with the statistical program SPSS for Windows - v. 16.0.

Descriptive statistics were used to describe the inmate's characteristics. Then, to analyze the physical, psychological and social dimensions the following phenomena were considered: for the physical dimension, feeding preferences, intestinal function, the availability of physical exercise in prison, sexual preferences and sleeping problems; for the physical dimension, feeding preferences, intestinal function, the availability of physical exercise in prison, sexual preferences and sleeping problems; for the psychological dimension, the availability of a comfortable detention room and privacy, personal hygiene, and any occurrence of self-injurious actions. Finally for the social dimension, the availability and comfort for and public areas, positive and negative relationships with other prisoners, penitentiary police, and health professionals, the satisfaction of inmates spiritual needs and the availability of work.

Results were described as frequency and as mean score per each dimension. The scores were created by summing the positive answer for each variable in the same dimension.

The missing values were replaced by the mean of the values of the other variables for the same woman in the same dimension. The score ranged from 0 to 10 (theoretical range) for physical dimension, 0 to 6 for psychological dimension and from 0 to 7 for social dimension with higher values indicating more satisfaction by the women for each dimension.

For comparison, the three scores were categorized as "high levels of needs unmet" and "low levels of needs unmet" as based on the mean of the distribution of the single dimension.

Setting

The administration of the Questionnaire took place in special rooms made available by the prison administrations of the participating institutions.

The context in which the interviews were held led the research team to thoroughly prepare the meetings, and in particular, to focus on guaranteeing a climate favorable to the administration of the Questionnaire by promoting cooperation between the inmates and the research team.

Procedures

On the days assigned by the prison authorities, the women who arrived for the interview with the researchers, in groups of four at a time, showed willingness and were very eager to communicate and to contribute to the discussion. The inmates specified that they would complete the Questionnaire only if they could to return it directly to the researcher; therefore, they felt free to answer the questions truthfully without fear of any interference by the prison administration. Having received the necessary assurances, they all agreed to participate in the project and signed an informed consent, in which they stated that they understood the purpose of research.

ETHICAL CONSENSUS

Researchers guaranteed anonymity and confidentiality by assigning a numeric code to inmates. An official "Form of Consent" was requested before administering the Questionnaire. In the informed consent, it was reiterated that the research had not been prepared by the Penitentiary Administration, which does not take any responsibility for the outcome of the same.

This study was approved by the ethical review board of the two prisons involved in the study (authorization n. 64587/2013 and n. 010220/119/2013).

RESULTS

The 55 respondents had an average age of 39.6 ± 10 years. In our sample, 43 (78.2%) were Italian, while the others 12 (21.8%) came from Former Yugoslavia (Macedonia, Serbia, Bosnia and Croatia) (n = 4; 33.4%), Romania (n = 3; 25%), Africa (Ghana, Morocco, Tunisia) (n = 3; 25%), Bulgaria (n = 1; 8.3%), and Russia (n = 1; 8.3%), respectively.

About half of the sample (n = 31; 56.3%) were unmarried or divorced and had at least one child (n = 40; 72.7%).

Of the women 13 (23.6%) achieved a low level of education, while 3 (5.4%) held a Bachelor or Master degree.

Forty-two (76.4%) women were Catholic.

Table 1 shows in detail the socio-demographic characteristics of the sample.

Overall, the most frequent crime was drug trafficking 21 (38.2%), followed by criminal association 7 (12.7%), theft 6 (10.9%), and robberies 5 (9.2%).

Forty-seven (85.5%) of the detainees were serving a sentence of up to 5 years, while 50 (90.9%) had a penalty that was still outstanding.

The inmates showed a high consumption of tobacco 48 (87.3%), with a daily average of 19 cigarettes.

Eleven (20%) of the women prisoners in the sample group regularly used drugs such as cocaine (n= 9; 81.8%), cannabis (n = 6; 54.5%), heroin (n = 5; 45.5%) and hashish/marijuana (n = 3; 27.3%).

Only 4 (8.3%) of the women interviewed claimed to consume alcohol.

For the purpose of the study, and to increase the legibility of the data, the Questionnaire was divided into the three health dimensions designated by the World Health Organization (WHO)'s definition ("physical", "psychological" and "social" respectively) [21].

Table 1
Socio-demographic characteristics of the sample

Age	**N**	**%**
≤ 30	10	18.2
31-40	24	43.6
41-50	15	27.3
≥ 51	6	10.9
Nationality		
Italian	43	78.2
Other	12	21.8
Marital status		
Unmarried	20	36.3
Married	5	9.2
Divorced	11	20.0
Other	11	20.0
Missing	8	14.5
Children		
Yes	40	72.7
No	15	28.0
Highest educational level		
None	3	5.4
Primary School	10	18.2
Lower Secondary	34	61.8
Upper Secondary	5	9.2
Bachelor or Master degree	3	5.4
Religion		
Catholic	42	76.4
Not Catholic	13	23.6

The percentage of women who had more than a half of their needs met was lower for the physical dimension (9%) and higher for psychological and social dimension (49%) *(Table 2)*.

Based on the percentage of women who attained a score higher than the mean score for each dimension, the comparison between "high levels of needs unmet" and "low levels of needs unmet" was graphically drafted in *Figure 1*.

In every dimension, the percentage of the "high levels of needs unmet" is higher than that of the "low levels of needs unmet", with the worst situation for the physical dimension.

In general, 42 women (76.4%) in the sample considered their state of health as satisfactory.

Unfortunately, 46 (83.6%) were not satisfied by the healthcare provided by the prison, in fact, 21 (45.7%) of them claimed to be affected by an illness that causes continuing pain without proper pain management. Furthermore, 36 (65.5%) women of the sample said that they suffered from psychological disorders and 14 of them (38.9%) were not satisfied by the psychological assistance provided by the prison.

With regard to the physical dimension in reference to nutrition, 45 women (81.8%) of the sample declared that they were unable to meet their food preference in relation to its variety, quantity, and quality.

In addition, the prison system had substantially changed their dietary habits, making it difficult to respect food requirements related to disease (n = 18; 75%) and by religion (n = 11; 20%).

Their appetite and weight had undergone significant changes (n = 23; 46%).

Intestinal function was irregular for 24 (43.6%) women of the test sample.

Thirty-two (58.2%) women in the sample slept less than 7 hours a night, while 29 (52.7%) used hypnotics to sleep better. Most of the inmates (n = 37; 67.3%) said they noticed changes in their normal pattern of sleep, because of difficulties falling asleep (n = 14; 25.9%), frequent nocturnal awakenings (n = 15; 40.5%) and nightmares (n = 8; 14.8%).

More than half of the detainees did not practice any kind of physical activity (n = 31; 56.4%), and among those who did (n = 24; 43.6%) only 10 (41.7%) claim to be satisfied.

In prison 47 (85.5%) women do not have sexual activity.

With regards to psychological needs, the investigation showed that the totality of the sample experienced a loss of personal space due to sharing a room with other inmates, with 36 (65.5%) of respondents sharing a unit of three, a lack of comfort of the same (n = 47; 85.5%), a dissatisfaction with the respect for privacy during routine hygienic care (n = 33; 60%), and during visiting times with family and friends (n = 24; 100%).

Sixteen (29.1%) of the inmates had thoughts of self-harm, while 12 (75%) of them had harmed themselves.

With regard to social needs, and in reference to roles and relationships, almost all of the sample (n = 51; 92.7%) complained about the lack of suitable public areas, where they found shortcomings in both environ-

Table 2
Descriptive statistics of the three dimensions

Physical dimension											
Mean (SD)	3.47 (1.6)										
Theoretical range	0	1	2	3	4	5	6	7	8	9	10
Actual range N (%)	1 (1.8)	4 (7.2)	9 (16.3)	17 (30.9)	11 (20.0)	8 (14.5)	2 (3.6)	2 (3.6)	1 (1.8)	0 (0)	0 (0)
Needs met > 5.5 Needs met ≤ 5.5	5 (9) 50 (91)										
Psychological dimension											
Mean (SD)	3.31 (1.07)										
Theoretical range	0	1	2	3	4	5	6				
Actual range N (%)	0 (0)	3 (5.4)	10 (18.1)	15 (27.2)	21 (38.1)	6 (10.9)	0 (0)				
Needs met > 3.5 Needs met ≤ 3.5	27 (49) 28 (51)										
Social dimension											
Mean (SD)	4.60 (1.21)										
Theoretical range	0	1	2	3	4	5	6	7			
Actual range N (%)	0 (0)	0 (0)	1 (1.8)	9 (16.3)	18 (32.7)	14 (25.4)	9 (16.3)	4 (7.2)			
Needs met > 4 Needs met ≤ 4	27 (49) 28 (51)										

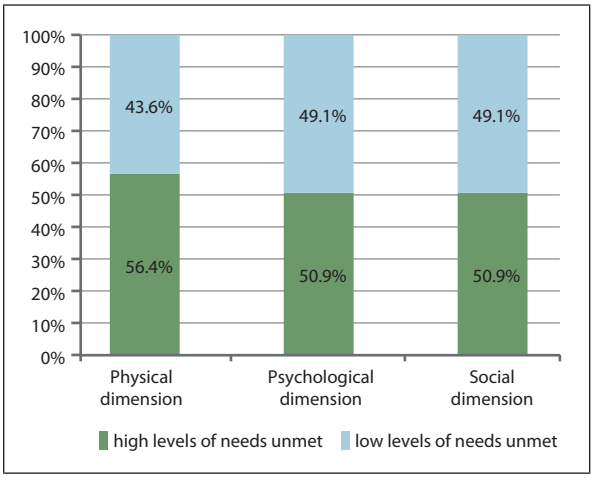

Figure 1
Percentage of women who attained a high/low score.

mental factors (lighting, heating) and logistics (capacity, noise). They also complained about the time available for socialization activities (n = 42; 79.2%).

Twenty (36.4%) women in the sample said that the relationships between the inmates were negative, while 24 (43.6%) said they had negative relationships with the care staff. Only 5 (9.1%) of the detainees experienced a negative relationship with the police personnel.

Forty-two (76.4%) of the women interviewed said that they were able to satisfy their spiritual needs: with the main causes of dissatisfaction as a shortage of suitable places of worship (n = 5; 38.5%), spiritual guidance (n = 5; 38.5%) and religious services (n =3; 23.1%).

Thirty-three (60.0%) prisoners were not engaged in work activities.

Table 3 shows in details the participants' response to the Questionnaire.

DISCUSSION AND CONCLUSIONS

Over the past two decades, the incarceration rate for women has steadily increased [22].

Deprivation of liberty subsequent to state detention may represent a serious obstacle to the maintenance of satisfactory health levels while increasing the risk of developing health problems [23].

Describing the needs of women subjected to restriction of personal freedom is an essential tool in which to understand which areas to target efforts to preserve and/or restore a good state of health.

The data concerning the crimes perpetrated by the inmates of the sample seems to confirm what has already been described in the literature [24], according to which the crimes for which women are imprisoned are generally not violent crimes, but more often property crimes, and drug possession. Furthermore, detention is usually short-term and tends not to be an isolated episode. Consequently, there is a high turnover of female prisoners, resulting in challenges in regards to health interventions, and it determines several transitions between the prison, the community, and wider society. In such a situation, the continuity of care is important in regards to the post-release service for any health problems identified during imprisonment while healthcare in prison should encourage prisoners to adopt health behaviors that are continued on release.

The respondents' smoking reaches alarming levels when compared to the average population as a whole, specifically 87.3% *versus* 15.8% [25]. Ninety % of pris-

Table 3
Participants' response to the Questionnaire

			Yes N (%)	No N (%)
General questions		Satisfactory general state of health	42 (76.4)	13 (23.6)
		Satisfaction of healthcare	9 (16.4)	46 (83.6)
		illness that causes pain	-	21 (45.7)
		Psychic suffering	36 (65.5)	19 (34.5)
		satisfaction of psychological assistance	14 (38.9)	-
Physical dimension	Feeding preferences	1. food variety, quantity and quality	10 (18.2)	45 (81.8)
		2. adequate to the disease	6 (25.0)	18 (75.0)
		3. respect for religious indications	33 (60.0)	11 (20.0)
		4. changes in the appetite and weight	23 (46.0)	32 (54.0)
	Elimination	5. intestinal function	29 (52.7)	24 (43.6)
	Rest and sleep	6. hours of sleep < 7 hours a night	32 (58.2)	23 (41.8)
		7. use of hypnotic to sleep	29 (52.7)	26 (47.3)
		8. changes in the habitual pattern of sleep	37 (67.3)	16 (29.1)
		difficulty falling asleep	14 (25.9)	-
		frequent nocturnal awakenings	15 (40.5)	-
		nightmares	8 (14.8)	-
	Physical activity	9. practicing subjects	24 (43.6)	31 (56.4)
		satisfied subjects	10 (41.7)	-
	Sexuality	10. sexual activity	3 (5.5)	47 (85.5)
Psychological dimension	Comfort	1. single room	-	55 (100)
		sharing a room (≥ 3 persons)	-	36 (65.5)
		2. room comfort	6 (10.9)	47 (85.5)
		3. privacy during personal hygiene	22 (40.0)	33 (60.0)
		4. interviews with family members	24 (43.6)	31 (56.4)
		loss of privacy during visiting times	24 (100)	-
	Self-injurious actions	5. thoughts of self-harm	16 (29.1)	39 (70.9)
		6. actions against themselves	12 (75.0)	-
Social dimension	Comfort	1. common spaces comfort	2 (3.6)	51 (92.7)
		2. time for socialization activities	11 (20.8)	42 (79.2)
	Good interpersonal relationships	3. *versus* inmates	35 (63.6)	20 (36.4)
		4. *versus* health personnel	31 (56.4)	24 (43.6)
		5. *versus* prison police personnel	50 (90.9)	5 (9.1)
	Spirituality	6. spiritual activities	42 (76.4)	13 (23.6)
		shortage of suitable places of worship	-	5 (38.5)
		shortage of spiritual guidance	-	5 (38.5)
		shortage of religious services	-	3 (23.1)
	Work activities	7. practicing subjects	21 (38.2)	33 (60.0)

oners smoke [26], and the ready availability of tobacco and lack of diversionary activities can seriously hinder smoking cessation in prison.

Concerning drug addiction, our data did not differ from other Italian surveys conducted on the prevalence of use of drugs in Italian prisons [27].

The literature demonstrates how prisoners' health during detention is influenced by opportunities to make healthy choices and barriers to achieve them [28].

Our results highlighted the low level of met needs especially in reference to the physical dimension. These findings contrast with the common idea that the state of detention impairs mostly the psychological and social dimensions [29, 30]. A reasonable explanation could be connected with the fact that satisfaction levels of prisoners' needs correlate with personal experience and ex-

pectations [31, 32]. Therefore, inmates probably do not expect to have their psychological and social needs met, but they have a greater expectation for their physical needs. When their high expectation of such needs is not met, their satisfaction level decreases.

The state of detention changed inmates' habits, especially with respect to physical needs. Several prisoners stated that they suffer from sleep disorders, and were dissatisfied especially about feeding choices and physical activities.

Diet, physical activities, and adequate rest are important determinants of health, so when promoting health these aspects need to be taken into consideration. Unfortunately, there are several barriers within the prison system that impede healthcare including, overcrowding, a poor environment, underfunded health resource, and a prison timetable that is not generally organized on inmates' needs but rather on those of the organization [33]. This fact is confirmed by the low satisfaction level on the healthcare provided to our sample, and especially concerning pain control [34].

Furthermore, a basic problem is that, while the practice of health promotion is founded upon the concepts of empowerment and choice, prisoners have an inevitable decrement in their autonomy within the prison regime. They represent an archetypal group who have restricted control over their lives [35].

Individual values and needs are progressively replaced by those dictated by the prison organization, resulting in a process of loss of self and identity, which entails changes in the prisoners self-perception and self-identity; the so-called "prisoner syndrome" [36], where people might not feel in control of their environment or their personal conditions [37].

Prison conditions appear to have a greater impact also in regards to relationships and the lack of confidentiality and privacy was of great concern to many [38].

The low level of good relationships is a problem that should not be underestimated. From an operational point of view, however, raising confidence levels is a challenge not easily overcome, especially due to the high turnover of detainees and the short duration of detention.

Trust and strong emotional bonds, love or friendship, mutual intimacy, and sympathy characterize the definition of "good relationships". All good interpersonal relationships are based on trust and because of the nature of trust, it requires time to develop. Consequently, low confidence levels among the detainees are probably related to the lack of trusting relationships, which exacerbates feelings of uncertainty over contingent events and experiences. Thus, an increase in the opportunity for social interaction would contribute to a more collaborative environment, help the development of fiduciary relationships, and encourage levels of sociality [39], and reduce self-harm action [40].

These findings provide some insight into the challenging aspects of women's needs. One key finding is that women suffer more due to not being able to meet their physical needs and that they may benefit from regular health promotion interventions which make them more adapted to live in prison. More emphasis on maintaining physical needs could, therefore, reinforce the psychological and social dimension. Additional research is needed to explore inmates' needs at an early stage and throughout the detention period, in order to offer additional insight into the changes and impacts that the state of detention has upon them. Specifically, further efforts should be directed toward specific concerns that relate for example to reproductive health, breast examinations, human papillomavirus infection and the presence of children [41].

LIMITATIONS

The most important limitation of the study is the small sample size, which may not be considered a representative sample of inmates admitted to Italian prisons. This could represent a biased selection, which could be resolved by future multi-center studies with larger sampling.

A second limitation is that our data derived from the self-report Questionnaire, with the possibility of response bias.

Finally, the Questionnaire describes the subjective perception of the inmates without merging them with other more objective measures.

Despite these limitations, the results represent a starting point in defining the complex health care needs of women in the correctional system on which to plan health-promoting interventions.

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Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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