**Abstract**

*Aims.* The aim of this study is to validate the Italian version of the Mental Health Knowledge Schedule (MAKS-I).

*Methods.* The validation process included: linguistic validation; analysis of the feasibility; face validity; internal consistency; floor and the ceiling effects; divergent validity. Multiple linear regression was performed to examine the relationship between mental health knowledge and independent variables.

*Results.* MAKS-I was administered to 453 people. The linguistic validation was successful and face validity of the questionnaire showed no critical issues. The estimated composite reliability was 0,638. Divergent validity was supported by lack of statistical significant correlation between MAKS-I and RIBS-I with a positive correlation index. Participation in seminars or conferences related to the issue of mental health stigma, gender, qualification and having a first or second-degree relatives with a psychiatric disorder can be considered possible predictors of the MAKS-I score.

*Conclusions.* MAKS-I is a reliable questionnaire to assess mental health knowledge and familiarity with psychiatric clinical conditions in Italian language.

**Key words:** Mental Illness Stigma, Discrimination, Validation Study, Psychometrics

**Introduction**

One of the main objectives of anti-stigma campaigns is to increase Mental Health Literacy (MHL) in different populations (Henderson et al., 2016, Stuart & Sartorius, 2017); several psychometric instruments have been validated to measure the level of knowledge of the general population. Several tools are validated in Italian language for the evaluation of stereotypes, attitudes and stigmatizing behaviours (Buizza, Ghilardi, & Ferrari, 2017; Pingani, Catellani, et al., 2016; Pingani, Evans-Lacko, et al., 2016; Pingani, Forghieri, Ferrari, Ben-Zeev, & ..., 2012; Serra et al., 2013), but no instrument has been validated for assessing knowledge and recognition of mental health disorders. For this reason, in this study we aimed to validate the Italian version of the Mental Health Knowledge Schedule (MAKS-I) (S. Evans-Lacko, Little, et al., 2010), which was developed in UK (S Evans-Lacko et al., 2014; Sara Evans-Lacko, Henderson, & Thornicroft, 2013; Henderson et al., 2016; Sampogna et al., 2017) and has been adapted in Ireland (Beirne, Mohungoo, & Buckley, 2013), Sweden (L. Hansson, Stjernswärd, & Svensson, 2016; Lars Hansson & Markström, 2014; Mårtensson, Jacobsson, & Engström, 2014), China (J. Li, Thornicroft, & Huang, 2014), India (De Silva et al., 2016), Nepal (De Silva et al., 2016), United States (Sideras, McKenzie, Noone, Dieckmann, & Allen, 2015), Canada (Dimoff, Kelloway, & Burnstein, 2016) and Oceania (Sweeney, Donovan, March, & Laurenson, 2015).

In 1997, Jorm and colleagues (Jorm et al., 1997) proposed an innovative construct for defining the concept of mental health literacy (MHL): the definition “…refers to knowledge and beliefs about mental disorders which aid their recognition, management or prevention”. MHL can be articulated at three levels (O’Connor, Casey, & Clough, 2014): recognition (ability to recognize a specific mental disorder), knowledge (about risk factors, possibility of asking for information, about the causes of mental illness, self-treatment and help provided by health professionals) and attitudes (which promote recognition or appropriate help seeking behaviours). These three different components (recognition, knowledge and attitudes) are present in the cognitive model that describes stigma in mental health (Corrigan & Watson, 2002; Pingani et al., 2012): stereotypes (as lack of recognition and knowledge) activate the emergence of prejudices as cognitive and emotional responses (attitudes) subsequently lead to the behavioural reaction of discrimination (Corrigan & Watson, 2002; Pingani et al., 2012).

Three different interventions have been described in literature to reduce stigma: education, protest and contact (Corrigan et al., 2001). Education is characterized by the provision of evidence-based information about specific mental illnesses and their treatments (Brown, 2017). Protest aims to eliminate the negative stereotypes through public statements, media reports, or advertisements (Rüsch, Angermeyer, & Corrigan, 2005), but does not necessarily provide a positive alternative that can replace the negative stereotype. Direct contact with people with mental disorders has been shown to be an effective way to fight stigma by reducing anxiety and allowing people to check the untruthfulness of their prejudice (Chen, Koller, Krupa, & Stuart, 2016; S. Evans-Lacko et al., 2013; S. Evans-Lacko, Brohan, Mojtabai, & Thornicroft, 2012).

**Worldwide, several campaigns have been undertaken to fight stigma based on the latest evidence: Time to Change (England), Opening Minds (Canada), One of Us (Denmark), and other elsewhere. Unfortunately, the Italian situation is not positive in this respect: as Zoppei and Lasalvia have pointed out (Zoppei & Lasalvia, 2011), although there have been at least 71 anti-stigma initiatives, a shared database is not available, there is no exchange of information between the various professionals involved, and often outcomes are not measured.**

Three recent reviews (O’Connor et al., 2014; Wei, McGrath, Hayden, & Kutcher, 2015, 2016) have shown that, from 1999 to present, there are 13 to 16 validated questionnaires measuring the MHL or mental health knowledge in general.

The MAKS can be adapted to different contexts, and it can be used not only among the general population (S. Evans-Lacko et al., 2013; Sara Evans-Lacko et al., 2013; Henderson et al., 2016), but also with specific target groups including aviation (Jones et al., 2014) and police personnel (Lars Hansson & Markström, 2014), educational institutions (K. Chisholm et al., 2016; K. E. Chisholm, Patterson, Torgerson, Turner, & Birchwood, 2012; De Silva et al., 2016; Dimoff et al., 2016; Friedrich et al., 2013; Sideras et al., 2015), custodial institutions (Wright, Twardzicki, Gomez, & Henderson, 2014), family members of people with mental disorders (Sin, Henderson, Pinfold, & Norman, 2013; Sin, Murrells, Spain, Norman, & Henderson, 2016; Sweeney et al., 2015), community mental health staff (J. Li et al., 2014; Jie Li et al., 2015; Mårtensson et al., 2014). The{Chisholm, 2012, A randomised controlled feasibility trial for an educational school-based mental health intervention: study protocol} MAKS has shown an excellent content validity, a “fair” reliability, and a “poor” the internal consistency.

**Methods**

***Instrument description***

The 12 items of the MAKS are scored on a Likert scale (from 1: “Strongly Disagree” to 5: “Strongly Agree”). “Don’t know” is coded as neutral (value of 3). The MAKS questionnaire is articulated into two parts. The first six statements are related to mental health knowledge, and it gives the possibility to calculate a total score. Items from 7 to 12 refer to six clinical conditions to identify the levels of recognition and familiarity with those clinical situations. Items 6, 8, and 12 must be reversed (S. Evans-Lacko, Little, et al., 2010).

***Linguistic validation of the questionnaire***

The validation process included three stages: a) five native Italian speakers, fluent in English, independently translated the questionnaire into Italian. Based on the five translations, a unique Italian version was created with the approval of all translators; b) the Italian version was re-translated into English by an English native speaker not involved in the previous step. From the comparison between the back-translation and the first Italian translation, an initial draft of the Italian questionnaire was produced; c) the first Italian translation was administered to 25 university students who voluntarily agreed to participate in the study. To evaluate the face validity, for each item the following questions were asked: "Is the statement clear?"; "Do you think it could be formulated more clearly?"; "Did you find it difficult to choose an appropriate response option for the statement?".

Based on students’ responses and on the supervision by the author of the English version of the questionnaire (SEL), the beta version of the MAKS-I was developed. The beta version was then validated into Italian and administered to the general population.

***Sample recruitment***

The beta version of the MAKS-I questionnaire was administered by health professionals to the general population in public places (shopping centres, markets, squares, cinema, etc.) in two different Italian cities (Reggio Emilia and Napoli). The inclusion criteria were: a) being 18 years of age or more; b) having the ability to provide an informed consent to take part to the study. One criteria was taken into account to define the sample size for the validation of the questionnaire: a number of respondents not less than 100 units (Hair, Anderson, Tatham, & Black, 1998; Hatcher, 1994). The goal was to administer 500 questionnaires expecting a response rate above 75% largely satisfying the minimum sample size required. To all eligible responders the purpose of the study, the institutions promoting the study and the characteristics of the questionnaire were clearly explained and discussed.

***Statistical analysis***

Descriptive statistics, including frequency distributions, means and standard deviation were computed for each MAKS-I item and for all collected socio-demographic variables. The feasibility was verified by analysing the time used to compile the questionnaire by the first 40 people involved in the study while face validity was performed on a sample of 25 students from the University of Modena and Reggio Emilia.

The internal consistency of the questionnaire was tested using the Composite Reliability of the first 6 items. This is because the last 6 items were only designed to assess the knowledge of specific clinical conditions (S. Evans-Lacko, Little, et al., 2010). A threshold of 0.6 was considered the acceptable minimum value of the Composite Reliability (Raykov, 1997). The standardized loading was defined using an exploratory factory analysis (Varimax rotation) defining a single factor to extract. The floor and the ceiling effects (Portney & Watkins, 2000) (percentage less or more the 20% of the answer) were defined, for each item, calculating the percentage of responses attributed to the first and last point of the Likert scale. Divergent validity was examined in relation to the RIBS-I (Pingani, Evans-Lacko, et al., 2016) using the Pearson’s correlation coefficient (Kendall & Stuart, 1973). A multiple linear regression was performed in order to identify possible predictors of mental health knowledge using five independent variables (age, sex, participation in seminars or conferences related to the issue of stigma in psychiatry, to have a first or second-degree relatives with a psychiatric disorder, qualification) (Freedman, 2009). The Statistical Package Social Sciences (SPSS) version 22.0 and Data Analysis and Statistical Software (STATA) version 12.0 were used for data analysis.

According to the Internal Review Board, the ethical approval for this study was not necessary because it did not involve cases nor patients. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. Authors certify their responsibility for the manuscript: they accept responsibility for the conduct of the study and for the analysis and interpretation of the data; they helped write the manuscript and agree with the decisions about it; they meet the definition of an author as stated by the International Committee of Medical Journal Editors; they have seen and approved the final manuscript. The authors declare that neither the article nor any essential part of it, including tables and figures, will be published or submitted elsewhere before appearing in the Journal.

**Results**

***Sample characteristics***

The Italian version of MAKS was administered to 500 people but only 453 (90.60%) agreed to participate in the study and had given consent for their data to be used/published in the research. **Most of those who did not agree to participate said they were not interested in the topic and did not want to spend time on it.** The mean age of the sample was almost forty years (39.95; SD=±18.03) and 58.72% of the respondents (266/453) are female. Most respondents had a high school diploma (211/453; 46.58%) (Table 1).

***Face validity***

The 25 university students were on average 25.90 years, mainly female (N=15; 60%). Items 2, 4, 5, 7, 8, 9, 10, 11, and 12 were considered clear and understandable by the entire sample. Item 1 (“Most people with mental health problems want to have paid employment”) was found to be clear by all respondents; only one participant pointed out that they it would be good to emphasize is the question refers to having a job paid fairly and not with symbolic salaries. Regarding statement 3, one respondent pointed out that the term "medication" was too general; and that it would be more useful to indicate specific psycho-pharmacological categories. The term “health care professional” used in item 6 (“Most people with mental health problems go to a healthcare professional to get help”) raised doubts in two respondents: who felt that healthcare professional was too broad.

***Psychometric properties***

The composite reliability analysis is shown in Table 2. The value of estimated composite reliability was 0,638. Table 3 shows all frequencies and percentage related to the answers given to each item. Item 1 (“Most people with mental health problems want to have paid employment”) and 5 (“People with severe mental health problems can fully recover”) present the highest percentage of "Don’t know" responses (21.85% and 22.74%). The floor effect was found only for item 5 (23.84%), while items 6 (“Most people with mental health problems go to a healthcare professional to get help”) and 11 (“Drug addiction”) had a score near to 20% (19.43% and 19.21%). There were no ceiling effects for items 5 (5.52%) and 6 (15.01%). The percentages of the other items were significant (>20%): the minimum was 27.37% for item 2 (“If a friend had a mental health problem, I know what advice to give them to get professional help”), the maximum is 86.98% for item 9 (“Schizophrenia”). Divergent validity is supported by lack of significant correlations (Table 4) between MAKS-I and RIBS-I. The time taken to complete the questionnaire, was calculated based on the first 40 people who agreed to be involved in the study. Completion time ranged from a minimum of 57 seconds to a maximum of 7 minutes and 11 seconds. The average administration time was 1 minute and 38 seconds.

***Possible predictors of mental health knowledge***

There is only one dependent variable significant in the two models defined using the multiple linear regression (table 5): participation in seminars or conferences related to the issue of mental health stigma is associated with an increase in the score obtained in the MAKS-I questionnaire (β=0.16 for total score items 1-6 and β=0.12 for total score items 7-12). Greater mental health knowledge (total score items 1-6) was also associated with the female population (β=0.12; p=0.02) and having a first or second-degree relatives with a psychiatric disorder (β=0.11; p<0.01). The levels of recognition and familiarity with various conditions (total score items 7-12) were also associated with a higher level of education in the general population (β=0.11; p=0.03).

**Discussion**

The feasibility of the questionnaire overlapped with the study of the original version (S. Evans-Lacko, Little, et al., 2010): 1 minute and 30 seconds for the Italian version and 1 minute and 23 seconds for the English version. The MAKS-I was found to be an easy to administer and feasible assessment instrument, which can be easily used on large scale population.

In the present study, the Italian version of the MAKS was translated and validated. The face validity was tested in a sample of 25 students, for confirming the comprehension of the questionnaire. The suggestion that were made by one respondent on the item 1. This observation is based on reality because very often people with mental illness perform work with very low salaries or are employed in occupations that have the sole purpose of spending time with an activity. For this suggestion is not necessary a significant modification of the instrument.

Regarding the divergent validity, no statistical significance was found between the correlation of the RIBS-I (items 5-8) and the MAKS-I. However, the value of the correlation coefficient (ρ) for both correlations are between 0 and 1, thus indicating a directly proportional association between the two variables. This positive correlation, although not statistically significant, has already been identified in previous researches (J. Li et al., 2014).

Finally, in relation to predictors of knowledge of mental disorders, our findings have shown that participation in scientific events on the topic of stigma in mental health can be considered a possible predictor of a greater knowledge of mental illness. Our result confirms previous Italian studies (Pingani, Catellani, et al., 2016; Pingani, Evans-Lacko, et al., 2016): however, extreme caution is needed in the comparison of results related to educational strategies as they are extremely heterogeneous for content and organizational modalities (Gronholm, Henderson, Deb, & Thornicroft, 2017).

Previous studies demonstrates that knowing someone with a mental health problem is strongly associated with mental health-related knowledge, attitudes and behaviour (S. Evans-Lacko, London, Little, Henderson, & Thornicroft, 2010; Sara Evans-Lacko et al., 2013): our results confirm this association with a greater mental health knowledge (total score items 1-6) in respondents who have a relative with a psychiatric disorder. However, it is interesting to note that there is no association between having a family member with mental health and knowledge of different clinical conditions (total score items 7-12): we can hypothesize that closeness can lead to an increase in the knowledge of the "status" and rights of a person with mental illness but not to an increase in the knowledge of different clinical conditions. The levels of recognition and familiarity with various conditions (total score items 7-12) it is also associated with a higher level of school qualification (β=0.11; p=0.03). Greater mental health knowledge (total score items 1-6) is associated, as just describe in literature (Angermeyer, Matschinger, & Holzinger, 1998; Sara Evans-Lacko et al., 2013), to female respondents.

One of the main strengths of this study is the large sample size and the adoption of a multicentre design, which aids generalizability of our findings. On the other hand, we must acknowledge the unsatisfying reliability score. It must be considered that even the English version does not show a high reliability score. In fact, the MAKS cannot be used as scale and the internal consistency is not so relevant since people’s knowledge may be domain specific; therefore, even in the Italian version we have decided to calculate it to emphasize the value obtained as an indicator of trends in responses (S. Evans-Lacko, Little, et al., 2010).

**Although the results obtained from the validation of the instrument are encouraging, it is necessary to highlight how the study has some limitations. In particular, the opportunistic nature of the sample, which has not been subjected to any stratification (sex, age and title of study), may limit generalizability of results. In order for the results to be generalizable it is necessary to test the psychometric qualities of the instrument also in larger samples and in specific populations (for example students, other professionals, etc.).**

Challenging stigma is one of the most relevant priorities for research in the mental health field (Pingani et al., 2014). Over the last twenty years, several anti-stigma campaigns have been promoted in different countries: a scoping review identified anti-stigma campaigns in 21 different European different countries (Borschmann, Greenberg, Jones, & Henderson, 2014).

Several psychometric instruments were developed during “Time to Change” campaign (Mental Illness Knowledge Scale – MAKS (S. Evans-Lacko, Little, et al., 2010) and Reported and Intended Behaviour Scales – RIBS (S. Evans-Lacko, Rose, & Little, 2011)) or from “SAPPHIRE - Research Programme on Stigma and Discrimination in Mental Health” used for evaluating several stigma-related outcomes (Discrimination and Stigma Scale - DISC, Questionnaire on Anticipated Discrimination – QUAD (Jheanell Gabbidon, Brohan, Clement, Henderson, & Thornicroft, 2013), Mental Illness Clinicians’ Attitudes – MICA (J. Gabbidon et al., 2013; Kassam, Glozier, Leese, Henderson, & Thornicroft, 2010) and Barriers to Access to Care Evaluation scale – BACE (Clement et al., 2012)).

The assessment of knowledge as one component of analysing the process of stigmatization (and the effectiveness of antistigma interventions) is essential. Several studies have shown that mental health-related knowledge can influence the development of negative attitudes and discriminatory behaviours. The MAKS can be used to understand the relationship between knowledge, attitudes, and behaviours related to mental health stigma. Moreover, evaluating the different types of knowledge regarding mental health issues can be useful to understand the development of stereotypes and discriminating behaviours. Since the Italian version of the RIBS (evaluating the behavioural component of stigma process) is already available (Pingani, Evans-Lacko, et al., 2016), it has been fundamental to validate the Italian version of the MAKS, as well. RIBS as well as RIBS-I can be used to evaluate the paradigm of stigma development in the general population in combination with the level of knowledge. The availability of the MAKS also in Italian can be useful to make cross-national comparisons of level of knowledge in the general population. **Thanks to these two instruments it will be possible to begin to evaluate, in the Italian context, the presence of stereotypes and behaviours associated with mental illness in different contexts: school, work, health and sports (just to give some examples). The MAKS-I can be used to evaluate outcome of antistigma interventions – used in combination with the RIBS-I – with the aim to understand how to best improve their effectiveness (Sampogna et al., 2017; Winkler et al., 2017).**

In Italy, a critical review of the literature was published (Zoppei & Lasalvia, 2011). It highlighted that several intervention programs have been promoted, differing in theoretical background and implementation systems. The evaluation of the interventions made were so poor that it was not possible to carry out a quantitative analysis of the outcomes.

To avoid a significant waste of time and resources (human and financial) it is necessary to proceed with greater caution and to use easy, feasible and reliable assessment tools for evaluating the effectiveness of anti-stigma programs. The MAKS-I has the above-mentioned features and can be used for evaluating the stigma process in the Italian population and - hopefully in the next future - the effectiveness of Italian national antistigma campaigns.

**Availability of Data and Materials**

All data used for this study are available upon request addressed to the corresponding author.

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**Conflict of Interest**

The authors declare that there is no conflict of interest regarding the publication of this article.