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REGULAR RESEARCH PAPER

The European Academy for Cognitive Behavioural Therapy for Insomnia: An initiative of the European Insomnia Network to promote implementation and dissemination of treatment

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Abstract

Insomnia, the most prevalent sleep disorder worldwide, confers marked risks for both physical and mental health. Furthermore, insomnia is associated with considerable direct and indirect healthcare costs. Recent guidelines in the US and Europe unequivocally conclude that cognitive behavioural therapy for insomnia (CBT-I) should be the first-line treatment for the disorder. Current treatment approaches are in stark contrast to these clear recommendations, not least across Europe, where, if any treatment at all is delivered, hypnotic medication still is the dominant therapeutic modality. To address this situation, a Task Force of the European Sleep Research Society and the European Insomnia Network met in May 2018. The Task Force proposed establishing a European CBT-I Academy that would enable a Europe-wide system of standardized CBT-I training and training centre accreditation. This article summarizes the deliberations of the Task Force concerning definition and ingredients of CBT-I, preconditions for health professionals to teach CBT-I, the way in which CBT-I should be taught, who should be taught CBT-I and to whom CBT-I should be administered. Furthermore, diverse aspects of CBT-I care and delivery were discussed and incorporated into a stepped-care model for insomnia.

KEYWORDS
CBT-I, cognitive behavioural therapy for insomnia, European CBT-I Academy, insomnia, stepped-care

1 | A SUMMARY OF PRESENT GUIDELINES

In the last 2 years, four national/international guidelines have been published concerning the diagnosis and treatment of insomnia. The focus of the present article will be on treatment.

The American College of Physicians, in a series of three articles (Brasure et al., 2016; Qaseem, Kansagara, Forciea, Cooke, & Denberg, 2016; Wilt et al., 2016) and an editorial (Kathol & Arnedt, 2016), came to the conclusion that cognitive behavioural therapy for insomnia (CBT-I) should be considered the first-line treatment for all adult patients presenting with insomnia: "ACP recommends that all adult patients receive cognitive behavioral therapy for insomnia (CBT-I) as the initial treatment for chronic insomnia disorder (Grade: strong recommendation, moderate quality evidence)". Furthermore, for adults with chronic insomnia, for whom CBT-I was either unsuccessful or unavailable, a shared decision approach, which includes a discussion of benefits and costs for the short-term use of medication, was suggested.

Wilt et al. (2016), from the same series of articles, focused on pharmacological treatment and concluded that zopiclone, zolpidem and suvorexant may have a short-term positive effect on sleep outcomes in adults with insomnia, but the comparative effectiveness and long-term efficacy of pharmacotherapies are unknown. Furthermore, undesirable side-effects of hypnotic medications were stressed.

The American Academy of Sleep Medicine (AASM; Sateia, Buysse, Krystal, Neubauer, & Heald, 2017) focused exclusively on the pharmacological treatment of insomnia and concluded that even for short-term pharmacological treatment the evidence for all investigated substances (including benzodiazepines, Z-drugs, melatoninergic agonists, suvorexant and others) is at best "weak".

For Europe in general and Germany specifically, independently published guidelines (Riemann, Baglioni, et al., 2017; Riemann, Baum, et al., 2017) for the diagnosis and treatment of insomnia mirror the conclusions of the American College of Physicians. Based on a thorough analysis of all meta-analyses published in the field, these guidelines stated that CBT-I should be the first-line treatment for insomnia and that pharmacological treatment should only be considered when CBT-I was unsuccessful or not available. In the UK, the British Association for Psychopharmacology (BAP) consensus statement has (since 2010) recommended that "CBT-based treatment packages for chronic insomnia, including sleep restriction and stimulus control, are effective; and should be offered to patients as a first-line treatment" (strength of evidence A: directly based on category I evidence) (Wilson et al., 2010, 2019). The BAP also stated that increased availability of this therapy is required.

Comparing these statements to earlier published guidelines (for example Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008), the present guidelines reflect a complete shift in recommendations towards CBT-I as the first-line treatment, and away from the use of sleeping pills. However, as Morin (2017) in his editorial about the European guideline (Riemann, Baglioni, et al., 2017) noted, the central

challenge is the implementation of these clinical practice guidelines for the management of chronic insomnia within the various healthcare systems of Europe. Data from different sources indicate that at present, CBT-I is offered only to a very small proportion of patients suffering from chronic insomnia (e.g., Koffel, Bramoweth, & Ulmer, 2018). Furthermore, pharmacotherapy is still by far the most prevalent intervention for insomnia in routine healthcare worldwide. Given the unequivocal guideline recommendation of CBT-I as the first-line treatment for insomnia, and the fact that it is seldom available in practice, it felt timely to appoint a Task Force of the European Sleep Research Society and the European Insomnia Network with the aim of establishing a European CBT-I Academy. The Academy's aims will be to (a) define key aspects of CBT-I and (b) enable a Europe-wide system of CBT-I training and training centre accreditation. This should in turn promote the availability of CBT-I, to similar standards and with comparable levels of dissemination, across Europe. This paper summarizes the deliberations of the Task Force, including an overview of current data on the prevalence of insomnia in Europe and experts' estimation of CBT-I availability in the 12 European countries of the founding members of the Academy (Austria, Estonia, Finland, France, Germany, Italy, Norway, Poland, Sweden, Switzerland, the Netherlands and the UK).

2 | AN INTRODUCTION TO INSOMNIA DISORDER IN EUROPE: EPIDEMIOLOGY AND COSTS

Table 1 provides an overview of epidemiological studies conducted in adult populations (age ≥ 18 years) that were identified through PubMed and PsycInfo searches, using “insomnia” AND “prevalence” OR “epidemiol*” as keywords and focusing on prevalence of insomnia in European countries.

Epidemiological data for 25 European countries were identified. These studies were grouped according to whether they considered night-time insomnia symptoms exclusively, night-time plus daytime insomnia symptoms, or more conservatively, insomnia diagnoses as defined using diagnostic manuals (e.g., International Classification of Diseases (ICD)-10, Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV, DSM-5, International Classification of Sleep Disorders (ICSD)-2 or ICSD-3). As can be seen, by any metric, insomnia is very common. Although estimates vary, the median European prevalence for insomnia with night-time symptoms alone is 24.8%, 12.5% for night-time together with daytime symptoms and 10.1% for full insomnia diagnosis.[1] When looking at the percentage of insomnia diagnoses across different countries, Germany with 5.7% and the UK with 5.8% seem to have the lowest percentage, whereas Norway, France and Russia, with percentages, respectively, of 20%, 19% and 23.1%, show the highest values.

Recent data from Germany (Marschall, Nolting, Hildebrandt-Heene, & Sydow, 2017), based on longitudinal epidemiological data from more than 5,000 representative participants, indicate an increase in the prevalence of insomnia from 2009 to 2016, and a marked increase in hypnotic prescriptions. Comparing 2009–2016, the prevalence of adults who had taken hypnotic medication at least once a year increased from 13.5% to 17.3%. The intake of hypnotic medication in the last 3 months prior to investigation increased from 4.7% to 9.2% for the whole sample. Data from this detailed report indicate that 38% of adults suffering from insomnia received a recommendation for psychotherapy. However, it remains unclear what type of psychotherapy was recommended and whether it was actually received. Similar data have been published for Norway (Pallesen et al., 2001; Pallesen, Sivertsen, Nordhus, & Bjorvatn, 2014). In a Norwegian study, 80% of patients who used sleeping medications in the past reported a preference for a non-pharmacological treatment alternative (Omvik et al., 2010). However, less than 10% of these patients had actually been offered anything other than sleeping medications.

In Austria there was a report of a slight decrease in diagnoses of some sleep disorders from 1997 to 2007 (Zeitlhofer et al., 2010). However, there are no data on how many patients receive a recommendation for psychotherapy, how many actually receive psychotherapy and what kinds of psychotherapy are either recommended or provided. In this survey, only 7% of people suffering from sleep problems took medication and 6% sought psychotherapy. Furthermore, a recent study provided evidence that in Austria, awareness of certain sleep disorders in women seems to be lower than in men (Auer, Frauscher, Hochleitner, & Hoegl, 2018).

In an internet study conducted by *The Dutch Brain Foundation*, 14% of people with sleep complaints were reported to seek help from their general practitioner (GP), 5% sought the help of a psychologist or other therapist and about 4% contacted a sleep centre (van der Velden & Wester, 2015). In line with these data, it has also been reported that about 60% of the patients who received a preliminary sleep disorder diagnosis from their GP went on to receive a benzodiazepine prescription (Hoebert, Souverein, Mantel-Teeuwisse, Leufkens, & Dijk, 2012). These data suggest that only a small proportion of people with insomnia receive CBT-I in the Netherlands. Nevertheless, in the Netherlands a decrease in the use of hypnotics and tranquilizers has also been documented (Van Laar, 2017). A similar decreasing trend emerged in Finland (Kronholm, Markkula, & Virta, 2012; The Social Insurance Institution of Finland, 2016). In Sweden, around 7% of adults use sleep medication, a figure that has slowly decreased in the past 10 years (The Swedish National Board of Health & Welfare, 2018). A survey among 600 GPs (response rate, 58.7%) showed that 95% prescribed sleeping medication to their insomnia patients, even though 31% believed that sleeping medication was more harmful than the sleep problem itself. Moreover, 80% claimed that they often referred insomnia patients for CBT and 24% reported sometimes referring patients for CBT. However, details on the execution, content and quality of these CBT interventions remain unknown (Swedish Agency for Health Technology Assessment & Assessment of Social Services, 2010). In France, 53% of patients with severe insomnia who were surveyed sought help for their insomnia (Léger, Guilleminault,

[1]For those studies reporting different prevalence values, e.g. for women and for men separately, the mean was calculated.

TABLE 1 Prevalence of insomnia disorder in European countries

Country	Author (year)	Sample size	% Insomnia symptoms (the presence of night-time symptoms)	% Insomnia syndrome (the presence of night-time and daytime symptoms)	% Insomnia diagnosis (insomnia diagnoses as outlined for example by ICD-10, DSM-IV, DSM-5, ICSD-2 or ICSD-3)
Austria	Soldatos, Allaert, Ohta, and Dikeos (2005)[#,*]	490	19.0%	9.8%	
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	20.5%		
	Zeitlhofer et al. (2010)	1,000 (women, *n* = 522; men, *n* = 478)	18%	17%	
Belgium	Soldatos et al. (2005)[#,*]	6,832	36.0%	16.0%	
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	27.0%		
Czech Republic	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	25.0%		
Denmark	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	16.6%		
Estonia	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	30.5%		
Finland	Ohayon and Partinen (2002)*	982	37.6%	15.0%	11.7%
	Hublin, Partinen, Koskenvuo, and Kaprio (2011)	12,126	12% (daily or almost daily) 40% (weekly)		
	Kronholm et al. (2016)	4,852–6,031 (different samples over 6 years)	9.0%–9.6% (often) 40.3–45.3 (sometimes)		
	Lallukka et al. (2016)[#]	1,885 (men) 1,875 (women)	8.1% (frequent) 24.0% (occasional) 9.2% (frequent) 23,5% (occasional)		
France	Léger, Guilleminault, Dreyfus, Delahaye, and Paillard (2000)*	12,778	29.0%		19.0%
	Léger et al. (2011)	1,004			12.0%
	Chan-Chee et al. (2011)				15.0%–20.0%
	Beck, Richard, and Leger (2013)	27,653			15.8%
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	28.0%		
Germany	Schlack, Hapke, Maske, Busch, and Cohrs (2013)	7,988			5.7%
	Soldatos et al. (2005)[#,*]	2,016	17.4%	5.2%	
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	26.7%		
	Schlarb, Kulessa, & Gulewitsch, 2012	2,196	16%		7.7%
Greece	Paparrigopoulos et al. (2010)	254	25.3%		
Hungary	Novak, Mucsi, Shapiro, Rethelyi, and Kopp (2004)	12,643	47.0%		9.2%
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	28.1%		
Italy	Ohayon and Smirne (2002)*	3,970	27.6%		7.0%
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	16.6%		

(Continues)

TABLE 1 (Continued)

Country	Author (year)	Sample size	% Insomnia symptoms (the presence of night-time symptoms)	% Insomnia syndrome (the presence of night-time and daytime symptoms)	% Insomnia diagnosis (insomnia diagnoses as outlined for example by ICD-10, DSM-IV, DSM-5, ICSD-2 or ICSD-3)
Lithuania	Lallukka et al. (2016)[#,*]	600 (men) 1,002 (women)	24.0% 30.0%		
Netherlands	Kerkhof (2017)	2,089			8.2% (men, 6.8%; women, 9.5%)
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	16.8%		
Norway	Bjorvatn, Waage, and Pallesen (2018)	1,001			20.0%
	Pallesen et al. (2001), Pallesen et al. (2014)	2,001 2,000			11.7% 15.5%
	Sivertsen et al. (2009)*	47,000	13.5%		
	Uhlig, Sand, Ødegård, and Hagen (2014)	40,535			7.9%
	Lallukka et al. (2016)[#,*]	2,378(men) 3,858 (women)	4.0% 7.0%		
Poland	Nowicki et al. (2016)	2,413	50.5%		
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	31.2%		
	Kiejna, Wojtyniak, Rymaszewska, and Stokwiszewski (2003)	47,924 (non-institutionalized, adult respondents)	23.7%		
Portugal	Ohayon and Paiva (2005)*	1,858	28.1%		10.1%
	Soldatos et al. (2005)[#,*]	784	21.2%	6.2%	
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	29.8%		
Romania	Voinescu and Szentágotai (2013)	588	27.6%		15.8%
Russia	Averina et al. (2005)*	1,968 (men) 1,737 (women)			11.3% 34.8%
Slovakia	Soldatos et al. (2005)[#,*]	502	32.0%	11.1%	
Slovenia	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	22.7%		
Spain	Ohayon and Sagales (2010)	4,065	20.8%		6.4%
	Soldatos et al. (2005)[#,*]	1,999	22.4%	8.2%	
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	24.3%		
Sweden	Mallon, Broman, Akerstedt, and Hetta (2014)	1,128	24.6%		10.5%
	Ohayon and Bader (2010)	1,209	32.1% (women, 38.3%; men, 26.1%)		
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	19.0%		
Switzerland	Stringhini et al. (2015)	3,391	Women, 34.5%; men, 26.6%		
	van de Straat and Bracke (2015)[#]	54,722 (total sample size)	17.4%		
Turkey	Benbir et al., (2015)	4,758	51.0%		12.2%

(Continues)

TABLE 1 (Continued)

Country	Author (year)	Sample size	% Insomnia symptoms (the presence of night-time symptoms)	% Insomnia syndrome (the presence of night-time and daytime symptoms)	% Insomnia diagnosis (insomnia diagnoses as outlined for example by ICD-10, DSM-IV, DSM-5, ICSD-2 or ICSD-3)
United Kingdom	Calem et al., (2012)	5,425	38.6%	13.9%	5.8%
	Ellis, Perlis, Neale, Espie, and Bastien (2012)[#]	1,095			7.9%
	Morphy, Dunn, Lewis, Boardman, and Croft (2007)*	2,363		37.0%	

ICD, International Classification of Diseases; DSM, Diagnostic and Statistical Manual of Mental Disorders; ICSD, International Classification of Sleep Disorders.

*Data from prior to 2010.

[#]Multinational study that included other countries as well as the country of relevance.

Bader, Lévy, & Paillard, 2002) and 10.8% of adults reported regularly taking medication to sleep (Léger, Poursain, Neubauer, & Uchiyama, 2008). In an observational epidemiological survey, it was reported that, in Italy, insomnia symptoms are undertreated and GPs prefer the pharmacological approach, which is four times more frequent than any non-pharmacological therapy (78.6% vs. 18.2%, Terzano, Cirignotta, Mondini, Ferini-Strambi, & Parrino, 2006).

Insomnia is a costly condition. At present, it has been shown, on a meta-analytic level, to convey increased risks of cardiovascular diseases (Li, Zhang, Hou, & Tang, 2014; Sofi et al., 2014; Spiegelhalder, Scholtes, & Riemann, 2010), obesity and development of diabetes (Anothaisintawee, Reutrakul, Van Cauter, & Thakkinstian, 2016; Chan, Levsen, & McCrae, 2018), depression (Baglioni et al., 2011; Hertenstein et al., 2019), anxiety (Hertenstein et al., 2019) and suicide (Norra & Richter, 2013; Pigeon, Pinquart, & Conner, 2012). Wickwire (2019) reported that untreated insomnia is associated with increased all-causes healthcare utilization based on a randomly selected and nationally representative sample from the USA. Norwegian studies clearly indicate that insomnia significantly predicts sick leave and disability pension (Overland et al., 2008; Sivertsen, Krokstad, Øverland, & Mykletun, 2009). In fact, insomnia has been shown to be a stronger predictor of disability pension than depression (Overland et al., 2008). In a Finnish nationally representative study it was concluded that direct costs due to sickness absence could decrease by up to 20% if sleep disturbances could be fully addressed (Lallukka et al., 2014).

In Europe, data for Germany (Thiart et al., 2016) have shown that direct and indirect costs for insomnia are around €40–50 billion annually. In France, direct costs were estimated at $2 billion USD in 1995 (Léger, Levy, & Paillard, 1999). Indirect costs are estimated at €77 per employee per year for costs of absenteeism and €1,062 for productivity loss (Léger & Bayon, 2010; Leger, Massuel, Metlaine, & SYSYPHE Study Group, 2006). Data from Sweden indicate lower direct and indirect costs of insomnia compared to Germany and France, around €325 million annually (Swedish Agency for Health Technology Assessment and Assessment of Social Services, 2010). This discrepancy between countries shows the heterogeneity of European health systems concerning insomnia care and probably a difference in calculation of indirect costs. Similar data are also available for the USA and Canada. Annual direct and indirect costs for insomnia have been estimated to be around $150 billion in the USA (Reynolds & Ebben, 2017), being mainly related to indirect costs such as increased healthcare utilization, poorer performance at work and enhanced risk of accidents (Wickwire, Shaya, & Scharf, 2016). A Canadian study (Daley, Morin, LeBlanc, Grégoire, & Savard, 2009) reported total annual costs for insomnia disorder alone to be around $6.5 billion and underlined that the highest costs were for alcohol consumed as a sleep aid (58%) and consultations for insomnia (33%). The study also indicated that, similar to the data from the USA, insomnia is associated with significant morbidity in terms of health problems, health care utilization, work absenteeism, reduced productivity and risk of non-motor-vehicle accidents. Despite individual differences between countries, in all regions direct and indirect costs are a heavy burden on society and general health budgets. Data from the Sleep Health Foundation in Australia in 2017 (Adams et al., 2017; Sleep Health Foundation Report by Deloitte Access Economics, 2017) estimated that 7.4 million Australian adults experienced poor sleep, resulting in both insufficient sleep and excessive daytime sleepiness. This was associated with a cost of AUS$26.2 billion in 2016–2017: AUS$1.8 billion associated with health system costs, AUS$17.9 billion associated with productivity losses, AUS$0.6 billion with informal care costs and AUS$5.9 billion with other financial costs. In addition to these costs, a further AUS$40.1 billion was associated with decreases in well-being. Improving accessibility to an effective, brief and relatively low-cost treatment such as CBT-I is thus strongly warranted.

3 | AN INTRODUCTION TO COGNITIVE BEHAVIOURAL THERAPY FOR INSOMNIA (CBT-I)

Cognitive behavioural therapy for insomnia (CBT-I) largely targets those factors that may maintain insomnia over time, such as dysregulation of the sleep drive, sleep-interfering behaviours and cognitions,

attempts to control the sleep process and sleep-related anxiety. It typically consists of stimulus control therapy, sleep restriction therapy and a range of cognitive therapeutics, supplemented by psychoeducation/sleep hygiene and relaxation training (Riemann & Perlis, 2009). Table 2 summarizes the main interventional strategies included in a CBT-I protocol.

The efficacy of CBT-I for ameliorating night-time symptoms of insomnia alone or when it presents as comorbid with other mental and somatic disorders has been shown in 14 meta-analyses (Geiger-Brown et al., 2015; Ho et al., 2015; Irwin, Cole, & Nicassio, 2006; Johnson et al., 2016; Koffel, Koffel, & Gehrman, 2015; Miller et al., 2014; Montgomery & Dennis, 2004; Morin, Culbert, & Schwartz, 1994; Murtagh & Greenwood, 1995; Okajima, Komada, & Inoue, 2011; Pallesen, Nordhus, & Kvale, 1998; Tang et al., 2015; Trauer, Qian, Doyle, Rajaratnam, & Cunnington, 2015; Wu, Appleman, Salazar, & Ong, 2015). In seven meta-analyses the efficacy of CBT-I was demonstrated for daytime or comorbid symptoms (Ballesio et al., 2018; Belleville, Cousineau, Levrier, & St. Pierre-Delorme, 2011; Ho et al., 2015; Johnson et al., 2016; Koffel et al., 2015; Tang et al., 2015; Wu et al., 2015). CBT-I is as effective as sedative hypnotics during acute treatment (4–8 weeks; Smith et al., 2002) and is more effective in the long term (Morin, Colecchi, Stone, Sood, & Brink, 1999). CBT-I is associated with an average treatment effect of about 50% improvement, with large effect sizes that are reliably around 1.0 (Perlis, Jungquist, Smith, & Posner, 2005). Follow-up studies showed that CBT-I promotes stable changes for sleep onset latency and wake after sleep onset and slower but substantial improvements for total sleep time (Perlis et al., 2005).

Most clinical research on CBT-I focuses on the general adult population, including older adults. Traditionally, research has focused on recruited participants meeting criteria for insomnia but not necessarily representative of more complex or typical clinical cases. These cases might include young, working and older adults with insomnia that is comorbid with different mental and somatic disorders, paediatric populations presenting with developmental disabilities, pregnant women, women at postpartum, women going through the menopause, shift workers and those entering retirement. Recently, research has also focused on the efficacy and clinical effectiveness of CBT-I in adults whose insomnia is comorbid with a wide range of mental and somatic disorders. Findings from such studies have afforded greater confidence in the applicability of CBT-I to insomnia disorder, wherever and however it presents. Likewise, CBT-I appears to be applicable to paediatric populations, including infants, toddlers, preschoolers, school-age children, adolescents and young adults. Less evidence is available on CBT-I's applicability to some specific populations, such as pregnant women, women going through the menopause, older adults with cognitive impairment, children with developmental disabilities and shift workers.

4 | INSOMNIA: SCOPE OF THE PROBLEM AND CURRENT CLINICAL PRACTICE IN EUROPE

Although insomnia is prevalent and costly, there is a lack of investment in evidence-based first-line treatment (CBT-I). This may, in part,

TABLE 2 CBT-I ingredients

CBT-I strategy	Description
Sleep restriction	*Behavioural strategy*: A method which aims to strengthen homeostatic sleep pressure and stabilize circadian control of sleep and wakefulness, by decreasing the opportunity to sleep over successive nights. Patients are instructed to restrict their time in bed to match their average (self-report in sleep diaries) total sleep duration. The time in bed is then gradually increased until it reaches patients' optimal sleep need. An alternative method, called *sleep compression*, involves gradual constriction of time in bed, which is then similarly increased until reaching the optimal sleep need
Stimulus control	*Behavioural strategy*: A set of instructions that aim to strengthen the bed as a cue for sleep, weakening it as a cue for activities that might interfere with sleep, and helping the insomniac acquire a consistent sleep rhythm, based on operant conditioning model: (1) Lie down to go to sleep only when you are sleepy. (2) Do not use your bed for anything except sleep and sexual activity. (3) If you find yourself unable to fall asleep, get up and go to another room. Stay up as long as you wish, and come back to bed when you feel sleepy. (4) If you still cannot fall asleep, repeat step 3. Do this as often as is necessary throughout the night. (5) Set your alarm and get up at the same time every morning irrespective of how much sleep you got during the night. (6) Do not nap during the daytime
Sleep hygiene education	*Behavioural and educational strategy*: General health instructions about internal and external factors that might influence sleep (e.g., sport, light, temperature, etc.)
Relaxation	*Behavioural and cognitive strategy*: A set of methods that aim to reduce somatic or cognitive hyperarousal (e.g., progressive muscle relaxation, autogenic training, imagery training, meditation)
Cognitive reappraisal	*Cognitive strategy*: Strategies designed to reduce dysfunctional beliefs, attitudes, concerns, and false beliefs about the cause of insomnia and about the inability to sleep
Cognitive control/ Worry time	*Cognitive strategy*: The patient is instructed to sit comfortably in an armchair and write down a list of worries alongside plans for the next day. The rationale of this strategy is to prevent emotionally loaded intrusive thoughts during the sleep-onset period, as all worries have been "already" processed before going to bed
Paradoxical intention	*Cognitive strategy*: Strategy aimed at reducing the anticipatory anxiety at the time of falling asleep. Patients are instructed to remain still in bed with their eyes closed and to try to stay awake as long as they can. This reduces sleep effort, which in turn often leads to falling asleep quicker

be linked to a current lack of standardization of CBT-I, such that the treatment, although generally effective, can vary considerably in content and duration from clinician to clinician. Moreover, primary care practitioners are often poorly informed on sleep disorders, which remain underdiagnosed and sub-optimally managed (Grandner & Chakravorty, 2017; Grandner & Malhotra, 2015). This is despite it being well documented that the prevalence of insomnia in primary care patients is higher than that in the general population (Bjorvatn, Meland, Flo, & Mildestvedt, 2017; Grandner & Chakravorty, 2017). In an Italian observational epidemiological survey, insomnia was reported by 64% of 3,284 interviewed patients under 738 GPs, with 20% reporting both night-time and daytime symptoms and 44% complaining of night-time symptoms only (Terzano et al., 2004).

There is a high degree of variability in both CBT-I availability and clinical administration across Europe. Alongside a severe shortage of European CBT-I experts, this variability calls for greater efficiency and standardized certification of CBT-I clinicians through examination and supervised practice of CBT-I's core evidence-based components. To address this situation, the Task Force group collected information on current availability of CBT-I education and practice in the 12 countries of the founding members of the Academy (Austria, Estonia, Finland, France, Germany, Italy, Norway, Poland, Sweden, Switzerland, the Netherlands and the UK; see Table 3).

It should be stressed that each European country has its own specific national healthcare system and there is no overarching European healthcare system at an EU level. For example, in the UK, the National Health Service (NHS) covers all medical and health-related issues. The NHS is a central health service organized by the government through the Department of Health and Social Care; everyone who lives in the UK has equal access to the NHS and its benefits and the NHS is financed by the taxpayer. In France, the healthcare system also provides universal cover for all citizens irrespective of age or socioeconomic status. The costs are covered by a combination of central government funding, employment fees and healthcare users, who generally pay a low percentage of the cost of the healthcare (e.g. medication and visits to physician) they receive. The Italian health system works in a similar manner to its French equivalent. In contrast, the German healthcare system consists of a mixture of highly regulated institutions/processes organized through the government and a semi-private system linked to hospitals and private practices. There are several hundred health insurance companies, including so-called "private" health insurance, and premiums to health insurance are paid by employers and employees on an equal basis. In Sweden, public health care, which includes CBT-I, is financed through taxes and available to all. The maximum fee paid by the individual per year for healthcare is approximately €100/person. There is a similar system for medication, which includes approved sleeping medications. In addition to the public healthcare system, a separate private system exists. Here companies often provide a "healthcare" service to their employees for problems that might be related to or might affect work performance. These "corporate healthcare facilities" quite often have "CBT therapists" (sometimes psychologists or psychotherapists, not necessarily licensed, and usually not specifically trained in sleep medicine), who will handle sleep problems (e.g., insomnia symptoms, as these are often related to work stress and might affect work performance). Some facilities offer e-versions of "CBT-I" provided by private companies, although these are rarely evaluated or quality controlled.

Exact data for the number of patients treated with CBT-I per year were not available publicly for any of the 12 countries. In many European countries this is mainly dependent on individual psychotherapists who may offer CBT-I and for whom data are hard to estimate. Where possible, experts' estimations suggest that CBT-I is very seldom available for insomnia patients in Europe. In each country, only data from specialized clinical centres, either in hospitals or in universities, could be tracked. Via these institutions, sleep or CBT-I experts offer or could offer training for health professionals. Another complication is that countries within Europe adhere to differing professional and legal systems regulating the delivery of clinical care, including treatment of insomnia. First of all, psychotherapists, clinical psychologists, other applied psychologists with a licence to practice recognized by the national healthcare system and physicians (mainly from neurology and psychiatry) are involved in insomnia treatment. Sleep specialists in sleep centres may also be involved.

It needs to be emphasized that in many European countries GPs have a central role in health care organization and are seen as the key navigators of most healthcare systems. Thus, GPs have a pivotal role in treating patients with insomnia. Despite this, available data indicate that GPs rarely prescribe or are able to offer CBT-I to patients with insomnia (e.g., Everitt et al., 2014; Koffel et al., 2018). In the Netherlands, according to national GP standards, GPs should offer certain aspects of CBT-I. This is often delivered by a 'practice assistant' for mental healthcare at the GP's office through internet-based therapy modules. In Sweden, Norway, Finland and the UK, insomnia is mainly a primary care and/or occupational health issue and managed principally by medication. In the UK, however, digital CBT-I (dCBT-I)[2] is currently being piloted (2018/2019) in the southeast of England, with access made available to patients, free at the point of delivery, through NHS primary care services. In Finland, a public sleep disorder outpatient clinic that also focuses on complex insomnia cases and the delivery of CBT-I was established in 2016.

However, it is clear that most patients with insomnia in Europe are never referred to sleep centres. In any case, these centres do not typically treat insomnia, and if they do treat it, do not typically provide CBT-I. Although insomnia is supposed to be handled in primary care, in Sweden it is rarely formally diagnosed and patients who complain of sleep problems are generally prescribed sleeping medication. A few primary care centres have clinicians who can provide CBT-I, but this varies between regions, with greater access in larger city regions (similarly to the IAPT [Improving Access to Psychological Therapies] services in the UK). Some regions may offer dCBT-I. For instance, Stockholm County Public Health has an internet treatment clinic (the Internet Psychiatry Clinic), which

[2]Many authors use the term Internet CBT (ICBT). In this paper, we will use dCBT-I to refer to all digital internet-delivered CBT for insomnia.

TABLE 3 Current availability of CBT-I education and practice in the 12 countries of the founding members of the CBT-I Academy

Countries	How many patients have been treated with CBT-I in the last years?	Who treats insomnia with CBT-I? How many centres/therapists offer CBT-I specifically?	Who can teach CBT-I?	Who is entitled to practice CBT-I?	Reimbursement for CBT-I?
Austria	No exact data are available. However, CBT-I is certainly not sufficiently offered to insomnia patients. Estimates of 10–20 patients per year at Innsbruck Medical University; around 20 patients at the Institution for Dream and Consciousness Research, around 10–20 in private practices and some sleep laboratories	Approx. three to five Centres for Sleep Medicine and Sleep Research, one Medical University and a few private psychotherapists	Experts in insomnia and CBT-I; sleep experts, sleep coaches, sleep coaches certified by the Medical University of Vienna	Clinical and health psychologists, psychotherapists, psychiatrists, neurologists, paediatricians, geriatricians, sleep coaches certified by the Medical University of Vienna	No reimbursement for CBT-I in the basic healthcare system. If psychotherapists offer CBT-I, it is partially reimbursed (depending on insurance)
Estonia	Approx. 1,000 patients per year	Approx. three well-established teams offer CBT-I as a component of multidisciplinary sleep disorders management. 30 CBT therapists – clinical psychologists, psychiatrists – use at least some techniques	CBT therapists (MDs and clinical psychologists) who have also had CBT-I training, about five CBT-I experts who could teach clinicians, experienced mental health nurses with CBT-I training, (four such nurses currently in practice)	Clinical psychologists, MDs who have received training in CBT and in CBT-I, mental health nurses with training in CBT-I (under supervision)	Reimbursed as psychotherapy if delivered by clinical psychologists or psychiatrists, or as a nurse's outpatient visit in public medical system; limited reimbursement in private medical system if referred by GP and psychotherapy delivered by a clinical psychologist
Finland	Approx. >1,000 patients per year	Approx. 100 occupational and public health centres (delivery by trained nurses), the Finnish Sleep Association (FSA), one to two private sleep centers and 20 private therapists offer CBT-I	About 5–10 experts could teach CBT-I to clinicians	Psychologists, psychotherapists, psychiatrists, medical doctors and nurses who have received training in CBT-I	Totally or almost totally reimbursed in public and occupational health systems and in the FSA. Partly reimbursed as part of private psychotherapy, no reimbursement in other private sector systems
France	No exact data are available. However, CBT-I is certainly not sufficiently available to insomnia patients	Estimated at about 15–30 centres in France, mostly academic hospitals with a sleep clinic	Psychologists, psychotherapists, psychiatrists and medical doctors who have received training in CBT-I	Psychologists, psychotherapists, psychiatrists and medical doctors who have received training in CBT-I	In principal, only psychiatrist treatment is reimbursed in France. However, anticipated changes may allow for psychologist treatment to be (partially) reimbursed
Germany	Approx. >1,000 patients per year	Approx. 10 sleep centres. Not possible to estimate the number of private psychotherapists offering CBT-I	Experts in insomnia and CBT-I in about 10 sleep centres around Germany	Psychologists, psychotherapists and psychiatrists	Reimbursed as psychotherapy

(Continues)

TABLE 3 (Continued)

Countries	How many patients have been treated with CBT-I in the last years?	Who treats insomnia with CBT-I? How many centres/therapists offer CBT-I specifically?	Who can teach CBT-I?	Who is entitled to practice CBT-I?	Reimbursement for CBT-I?
Italy	Approx. 300 patients in 2017. Of those treated in medical centres, the vast majority also received pharmacological intervention	Five hospital centres for sleep medicine, one university clinical centre and a few private therapists	About 15 experts could teach CBT-I to clinicians	Psychologists, psychotherapists and psychiatrists	Reimbursed by private health insurances as psychotherapy
Norway	Approx. 600 patients per year: 100 at Bergen Sleep Disorders Centre, 500 in clinical studies, mostly via guided Internet treatments	Three to four specialized centres	About 10 experts could teach CBT-I to clinicians	Medical doctors (not only psychiatrists), psychologists, nurses	Not for private clinics, but if GPs offer CBT-I, treatment is subsidized by the government
Poland	Approx. 400 patients per year	Three specialized sleep medicine centres and 10–15 CBT psychotherapists in private practices around Poland	Experts in insomnia and CBT, about 10 experts from three specialized sleep medicine centres	CBT-I trained psychologists, physicians and nurses. In practice, CBT-I is delivered mostly by CBT psychotherapists and psychiatrists	Reimbursed as psychotherapy in public mental health services; not reimbursed in other public healthcare settings and for private practices
Sweden	Approx. 2,000–3,000 in total. Approx. 1,000 of these in clinical studies, mostly via guided Internet treatments	Internet treatment providers, a few primary care facilities, a few psychologists and psychotherapists in private practice and nurses. No specialized sleep centres offer CBT-I	About 10–15 experts could teach CBT-I to clinicians, mostly psychologists	The practice of CBT is not regulated other than within the public healthcare system where CBT for any condition could be carried out by licensed personnel with adequate training. This means CBT-I can be provided by licensed CBT-I-trained psychologists, psychotherapists, physicians, psychiatrists or nurses	Within the public healthcare system, CBT-I is reimbursed in the same way as other forms of treatment. Within private practice it is reimbursed if the practitioner is linked to the public healthcare system, otherwise not
Switzerland	No exact data are available, estimate of approx. 150 patients	Approx. seven centres	About 15 experts could teach CBT-I to clinicians	Psychiatrists and psychologists	Reimbursement as psychotherapy
The Netherlands	No exact data are available. Estimated that approx. 2,000–3,000 patients receive face-to-face CBT-I	Two tertiary care sleep centres, several secondary care sleep centres, one specific sleep centre for psychiatric patients, healthcare psychologists in basic mental health care, practice assistants for mental healthcare in the general practitioners office, a few internet treatment providers	Psychologists, nurse practitioners. Healthcare psychologists, clinical psychologists, clinical neuropsychologists, psychotherapists and psychiatrists	Healthcare psychologists, clinical psychologists, psychotherapists, psychiatrists, nurse practitioner, psychologists	Besides CBT-I delivered by a mental healthcare assistant at the GP there is no reimbursement for CBT-I in the basic mental healthcare system (primary care). In secondary and tertiary care sleep centres there is no reimbursement for CBT-I (there are no diagnosis-related groups for insomnia)

(Continues)

TABLE 3 (Continued)

Countries	How many patients have been treated with CBT-I in the last years?	Who treats insomnia with CBT-I? How many centres/therapists offer CBT-I specifically?	Who can teach CBT-I?	Who is entitled to practice CBT-I?	Reimbursement for CBT-I?
United Kingdom	No exact data are available	Typically provided by specialist clinical psychologists, psychiatrists and CBT therapists (both NHS and private). Although not widely provided by the NHS, a small number of specialist sleep disorders centres may provide CBT-I for some patients (e.g., Guy's and St Thomas' Sleep Disorders Centre). Some patients may also access group CBT-I through Improving Access to Psychological Therapies (IAPT) centres but not provided uniformly across all regions of the country	Appropriately trained experts in CBT-I (including clinical psychologists, practitioner psychologists, psychiatrists and other physicians), CBT therapists (psychotherapists) and nurses	Clinical psychologists, psychiatrists, and CBT therapists (psychotherapists)	Any NHS treatment is provided by the UK government. Private treatment may be covered by private health insurance providers although this is uncommon

provides CBT-I with psychologist support via the Internet and has done so since September 2017. The service includes a full psychiatric assessment and diagnosis performed by physicians or psychologists. The internet treatment is available to all Swedes over the age of 16, through the citizens' right to choose their health centre or clinic for outpatient care. Generally speaking, however, it is a challenge to provide CBT-I in primary care. In the UK, there has been some recent project-based implementation funding to offer digital (web/mobile) dCBT-I (Sleepio™) to large populations (e.g., 8 million people in London for a time-limited period). The intention behind this is to find a pathway to deliver dCBT-I to mainstream services. In France, the majority of patients with insomnia are prescribed sleeping medication by their GP, whereas a minority of patients are referred to a sleep clinic for their insomnia complaints. However, the National Sleep Foundation (SFRMS), the foundation *Sommeil et Santé* and the *Morphée Network* (*Reseau Morphée*) make efforts to address the needs of those with insomnia by providing treatment and specialist information online. *Reseau Morphée* even offers free treatment to severe insomnia patients in the Paris region (Londe et al., 2011; Storch, Denesle, Liyan, & Lainey, 2007). In France, group therapy is also often provided and online treatment is available (Hartley et al., 2016; Lopez et al., 2017).

Whether healthcare professionals such as nurses or social workers might play a role in providing CBT-I, as suggested in previous publications (e.g., Espie et al., 2008; Espie, Inglis, Tessier, & Harvey, 2001), remains to be investigated. In Finland, for example, CBT-I is effectively delivered by trained nurses in occupational health, showing long-term improvements in insomnia symptoms (Järnefelt et al., 2014).

Although it is clear that differences in the way that healthcare is organized across Europe are not a barrier to the ubiquitous availability of pill-based solutions, the structure of health services and associated reimbursement mechanisms may play a part in 'rationing' access to CBT-I. Likewise, because CBT-I is traditionally delivered face-to-face, the shortage of training in CBT-I represents an intrinsic limitation to the scalability of CBT-I to meet population need and demand. As shown in Table 3, dCBT-I is being used to remedy this problem in some countries (e.g., Sweden) and there are large pilot schemes investigating feasibility of widespread dCBT-I provision underway (e.g., the UK and France).

5 | PRESENT SITUATION OF CBT-I TRAINING AND ITS DISSEMINATION IN EUROPE

Table 4 summarizes current availability of CBT-I education/training in the 12 founder countries (Austria, Estonia, Finland, France, Germany, Italy, Norway, Poland, Sweden, Switzerland, the Netherlands and the UK). For some countries, such as the UK and the Netherlands, for reasons of space, no comprehensive course list is provided. Here, general information on the types of courses that are available in these countries is reported instead.

TABLE 4 Current courses offered in the 12 countries represented in the CBT-I Academy

Country	Course/s	To whom is the course/s offered?	By whom is the course/s given?	Duration of the course/s	What is taught?	Does the course include teaching on clinical adaptation of CBT-I for the lifespan or special populations?	Do the course/s include interactive teaching and/or case supervision?	What is the participation's fee? Who pays?
Austria	Medical University of Vienna Sleep Coaching Course; CBT-I courses at the Institute for Dream and Consciousness Research, the CBT Society and the Austrian Sleep Research Association	MDs, medical students, clinical and health psychologists, psychotherapists, nurses, physicians, HR personnel	Sleep and dream researchers and experts, psychologists, psychotherapists	Three-semester Sleep Coaching Course (Medical University of Vienna); 2–3-day CBT-I courses	Sleep education, sleep training, sleep hygiene, relaxation techniques including self-hypnosis and dreamwork including nightmare treatment, basics of gestalt therapy including awareness training; pharmacological treatments	Sleep Coaching Course includes sleep in the elderly, menopause and children and adolescents	The Sleep Coaching Course includes interactive teaching and case supervision	The costs of the Sleep Coaching Course are €1,500, per semester; 2–3 day CBT-I courses cost around €400; Costs are borne by participants themselves, sometimes supported by their employer
Estonia	(a) Tartu University CBT-I course (Tartu University together with Nordic Sleep Centre); (b) CBT-I course Tallinn Regional Hospital; (c) CBT-I course for nurses including other sleep disorders (Tartu University); (d) Tartu University courses on sleep disorders, including CBT-I; (e) Estonian CBT school. CBT-I session	(a), (b) & (d): MDs, psychologists, psychotherapists; (c): nurses; (e): CBT therapists in training (MDs, clinical psychologists)	(a) & (d): sleep experts, MDs, psychologists; (b): psychologists; (c): mental health nurses, sleep-expert MDs; (e): CBT therapists (sleep-expert MDs, clinical psychologist)	(a), (b) & (c): 0.1 day; (d): 2 days	(a) & (d): sleep physiology; (a)–(d) sleep education; (a), (c), (d) & (e): sleep restriction; (a), (c) & (e): stimulus control; (a) & (c): relaxation; (e): cognitive techniques in CBTI; (a)–(d): tapering hypnotics; (a), (c) & (d): sleep disorders; d): pharmacotherapy of sleep disorders	(a) & (c) include specific modules on adolescent and elderly insomnia and related adaptation of the CBT-I protocol for these populations	(a)–(d): no (e): role play, supervision	About €100 for 1-day, €200 for 2-day course and €60 for 1-day nurses course. Employers or participants pay
Finland	Different courses and web-based programme to deliver CBT-based treatment in primary, secondary, and tertiary levels of healthcare	Nurses, psychologists, physicians	Psychotherapists, sleep medicine specialists, (NOSMAC, Nordic Sleep Medicine Accreditation/ESRS accreditations), psychiatrists, sleep researchers, nurses	2–3 days (16–24 hr) (some courses include clinical supervision)	Basics of sleep and sleep disorders; screening and diagnosing insomnia; pharmacological treatments; sleep education; CBT-I methods, relaxation and mindfulness techniques, hypnotic technique	Adaptation in comorbid insomnia and the menopause included. Lifespan (especially elderly) and working life perspectives (e.g., shift work) included in some courses. Special additional courses (infants, children and adolescents)	Interactive teaching, case examples, communication skills and role playing, self governed studying (textbook), internet-based material, clinical supervision and guidance	Depends on the courses, e.g. costs of the 3-day course without supervision are about €1,000/student

(Continues)

TABLE 4 (Continued)

Country	Course/s	To whom is the course/s offered?	By whom is the course/s given?	Duration of the course/s	What is taught?	Does the course include teaching on clinical adaptation of CBT-I for the lifespan or special populations?	Do the course/s include interactive teaching and/or case supervision?	What is the participation's fee? Who pays?
France	(a) Course on managing insomnia, including CBT-I, at Université Paris Descartes. (b) Training for a national diploma in behavioural therapy in which CBT-I is part of the curriculum, by AFTCC (French Association for Cognitive Behaviour Therapy). (c) Two-day course on CBT for insomnia, with an optional 1-day course for insomnia with psychiatric comorbidities (Montrouge, S. Dagneaux)	Psychologists, psychiatrists, medical doctors	Psychologists, psychiatrists, sleep medicine specialists and sleep researchers	1–3 days depending on the course	Screening and diagnosing insomnia; pharmacological treatments; sleep education; CBT-I	Yes, for instance insomnia in neurodegenerative disorders	Yes, case studies and evaluation methods are discussed in small workshops on the course	Depending on participant status and course, between €100–1,400
Germany	(a) Course on CBT-I, including information on interventions for other sleep disorders at the Sleep Laboratory of the University of Freiburg Medical Centre. (b) Four or five institutes for behavioural therapy in which CBT-I is part of the curriculum	(a) Clinical psychologists, medical doctors, and social workers. (b) Psychologists and psychiatrists	(a) Sleep, insomnia and CBT-I experts (psychologists and medical doctors) of the Sleep Laboratory of the University of Freiburg Medical Centre. (b) Psychologists	(a) 2 days. (b) Part of the curriculum	(a) Basics of sleep–wake-regulation; screening and diagnosing insomnia; comorbidities; epidemiology and aetiology of insomnia; sleep education, CBT-I methods, relaxation, pharmacotherapie; acceptance and commitment to therapy for insomnia. (b) Basics of sleep–wake-regulation; screening and diagnosing insomnia;, CBT-I methods	(a) Comorbid insomnia. (b) no	(a) Yes, communication and role playing. (b) no	(a) 400 Euro. (b) part of the curriculum

(Continues)

TABLE 4 (Continued)

Country	Course/s	To whom is the course/s offered?	By whom is the course/s given?	Duration of the course/s	What is taught?	Does the course include teaching on clinical adaptation of CBT-I for the lifespan or special populations?	Do the course/s include interactive teaching and/or case supervision?	What is the participation's fee? Who pays?
Italy	(a) Intensive 1-year CBT-I course at "Sapienza" university of Rome since 2018. (b) Annual CBT-I courses offered during the Italian Sleep Medicine Congress since 2015. (c) Annual courses hosted by the University of Pisa Psychiatric Clinic, Department of Neuroscience: each year (September/October) since 2015	(a) Psychologists, psychotherapists, medical doctors during training to become a specialist/psychotherapist. (b) Neurologists, psychiatrists, pneumologists, child and adolescent psychiatrists, physicians, psychologists. (c) neurologists, psychiatrists, pneumologists, child and adolescent psychiatrists, physicians, psychologists	(a) Psychotherapists, psychologists, medical doctors who are experts in sleep, insomnia and CBT. (b) Psychotherapists, psychologists, medical doctors, psychiatrists, child and adolescent psychiatrists who are experts in sleep and insomnia research and are part of the association of the Italian sleep medicine society. (c) Psychotherapists, psychologists, medical doctors, psychiatrists, child and adolescent psychiatrists who are experts in sleep and insomnia research and are part of the association of the Italian sleep medicine society	(a) 12 modules of 8 hr each distributed in 1 year. (b) 2 days. (c) 1 and a half days.	(a) Basics of sleep and sleep disorders; psychophysiology of insomnia; screening and diagnosing insomnia; pharmacological treatments; sleep education; CBT-I methods, relaxation, mindfulness techniques, techniques from acceptance and commitment therapy; insomnia across the lifespan: basic and clinical aspects; efficacy and limitations of CBT-I. (b) Basics of sleep and sleep disorders; psychophysiology of insomnia; screening and diagnosing insomnia; sleep education; CBT-I method. (c) Basics of sleep and sleep disorders; psychophysiology of insomnia; screening and diagnosing insomnia; sleep education; CBT-I methods practice sessions, how to apply CBT-I	(a) The course teaches CBT-I for the lifespan (infants, children, adolescents, the elderly); specific women's lifespan (pregnancy, menopausal); mental and somatic comorbidities. (b) All the courses have been on a theme and addressed CBT-I across the lifespan (i.e., infants, children, adolescents, the elderly), and in those with mental health and somatic comorbidities. (c) All the courses have been on a theme and addressed CBT-I across the lifespan (i.e., infants, children, adolescents, the elderly); also womens' specific complexities (pregnancy, the menopause); mental health and somatic comorbidities, and other sleep disorders as comorbidities	(a) Yes, the course is highly interactive including interactive teaching, role playing, and case supervision. (b) and (c) Yes, the courses include interactive teaching and activities	(a) €1,500. (The fee is payed by the participant or supported by any public or private institution; credits may be recognized for other courses (e.g. masters degree, specialization school, etc.) (b) €100/day with a discount for AIMS meeting participants (c) €100/day

(Continues)

TABLE 4 (Continued)

Country	Course/s	To whom is the course/s offered?	By whom is the course/s given?	Duration of the course/s	What is taught?	Does the course include teaching on clinical adaptation of CBT-I for the lifespan or special populations?	Do the course/s include interactive teaching and/or case supervision?	What is the participation's fee? Who pays?
Norway	One annual course in sleep medicine, in which the focus is on CBT-I. In addition, several other courses (three to five at least) given annually provide information about CBT-I to clinicians	Health professionals: GPs, psychiatrists, psychologists and other medical specialists (neurology, clinical neurophysiology, thoracic medicine, ENT), medical and psychology students at the University of Bergen	Most courses are given by Norwegian Competence Center for Sleep Disorders and/or the universities by a medical doctor and a psychologist	2-days	Sleep medicine, CBT-I methods	Yes	Yes	About €300 for a 2-day course
Poland	CBT-I training during comprehensive CBT course	Psychologists, physicians	Teaching centres accredited by Polish Association for Cognitive and Behavioural Therapy	Obligatory 10 hr of theoretical education in CBT-I for all participants. Additionally, possibility of supervision, clinical training and guided self-education for those interested	CBT-I methods	Only basic CBT-I protocol is taught, literature for CBT-I protocols in special populations (comorbid insomnia, childhood, elderly patients) is provided	Only for participants interested in sleep medicine	The fee is paid by the participant for the whole CBT course (approx. €9,000 including supervision), it is not possible to take part in CBT-I training only

(Continues)

TABLE 4 (Continued)

Country	Course/s	To whom is the course/s offered?	By whom is the course/s given?	Duration of the course/s	What is taught?	Does the course include teaching on clinical adaptation of CBT-I for the lifespan or special populations?	Do the course/s include interactive teaching and/or case supervision?	What is the participation's fee? Who pays?
Sweden	At least some CBT-I training is normally included in the university-level psychologist programmes for students on the CBT-track. Two-day courses in CBT-I are offered on an irregular basis by private and public institutes	Psychologist students	Psychologists/ sleep researchers, experts in CBT-I	On the psychologist programmes, between 0.5 and 3 days specifically for sleep and CBT-I, in addition to the general and specific CBT training within the programme	Example from Karolinska Institutet psychologist programme: Basics of sleep–wake regulation, function of sleep, psychoneuroimmunology of sleep, screening and diagnosing insomnia; specific CBT-I methods (sleep diary use, sleep restriction, stimulus control); how to use general CBT techniques in the context of insomnia (relaxation, cognitive techniques, mindfulness, etc.); the evidence base for CBT-I; limitations of CBT-I; information on pharmacological treatments and medication tapering within CBT-I	Focus on basic CBT-I. Within the Karolinska Institutet psychologist programmes, lectures/discussions on adaptations of CBT, but not specifically on CBT-I	All psychologist students have supervised clinical work with a small number of patients. Many see at least one patient with sleep problems (insomnia) as part of their problem	No fee, part of the curriculum for the psychologist programme. Private 2-day courses €300–600
Switzerland	Currently no official CBT-I course is offered in Switzerland							
The Netherlands	Several courses are delivered at tertiary care sleep centres In-company training delivered by sleep specialists for third-party education institutes Courses within the curriculum of a psychology Master's degree or post-Master's training Sleep street training for GPs: a programme which aims to instruct GP's and practice assistants for mental healthcare to evaluate and treat insomnia (complaints) in primary care. The programme has been developed by several (healthcare) organizations	Psychology students, psychologists, GZ-psychologist, clinical (neuro) psychologists, psychiatrists, nurse practitioners, GP's	Sleep specialists (GZ-psychologist or somnologists)	Mostly 1–2 days	CBT-I rationale and methods Insomnia diagnostics as well as screening/characteristics of other sleep disorders	Briefly	Interactive teaching, role playing, supervision on own cases possibilty for intervision after course, Videos	Ranging from €245 to 600 The participant, or the employer may pay part of the total cost of the education program

(Continues)

TABLE 4 (Continued)

Country	Course/s	To whom is the course/s offered?	By whom is the course/s given?	Duration of the course/s	What is taught?	Does the course include teaching on clinical adaptation of CBT-I for the lifespan or special populations?	Do the course/s include interactive teaching and/or case supervision?	What is the participation's fee? Who pays?
United Kingdom	Several workshops and brief training days on CBT-I are offered throughout the UK. Most are offered on an ad-hoc basis through the individual NHS trusts, psychological therapy training institutes and associations (e.g., BABCP) and universities (e.g. University of Oxford Online Course in Sleep Medicine contains one module on insomnia; teaching modules on doctoral training courses for trainee clinical psychologists)	Clinical psychologists, CBT therapists, medical doctors, and other health professionals	Typically, clinicians with expertise in CBT-I (principally clinical psychologists and psychiatrists)	Mostly 1 or 2-day workshops	May include information on sleep–wake regulation, models of insomnia and diagnostic criteria, CBT-I components (e.g., SRT titration, SCT instruction) and rationale for treatment, case studies and role plays, screening for other sleep disorders	May do but training seems focused principally on adult and older adult patient populations	Some courses may include role plays and case examples. Supervision is generally done within clinical teams themselves and is not by and large organised/offered through these courses	NHS employees may be able to access training at no personal cost through their NHS trusts. Private and university run courses will vary in their pricing

Several CBT-I courses are currently offered in European countries. These are generally given in sleep centres or universities and offered to psychologists, specialist physicians and psychotherapists, although GPs, nurses and/or other health professionals may also be included. Other than in Norway (one 2-day course), no courses specifically for GPs are offered. Trainers are sleep experts, both psychologists and medical doctors, or CBT experts with knowledge of insomnia. Most courses last approximately 2 days and teach core aspects of CBT-I, including CBT-I strategies and the basics of insomnia and other sleep disorders. The courses often include a module on pharmacological treatment. Three courses have a long duration, one specifically on CBT-I, one including different aspects of psychological treatment for sleep disorders and one as a module of a Sleep Medicine graduate programme. In Italy, an intensive 1-year CBT-I course has been offered at the "Sapienza" University of Rome since 2019. The course includes 12 modules (covering basics of sleep and sleep disorders, screening and diagnosis of insomnia, pharmacological treatments, sleep education, CBT-I methods, relaxation, mindfulness techniques, techniques from acceptance and commitment therapy, insomnia across the lifespan: basic and clinical aspects, insomnia across women's lifespan: basic and clinical aspects, and efficacy and limitations of CBT-I) of 8 hr each, distributed over 12 months. In Austria, a three-semester Sleep Coaching Course is offered at the University of Vienna. The course includes modules on sleep education, sleep hygiene, relaxation, self-hypnosis, dream intervention (including treatment of nightmares), basics of Gestalt therapy (including awareness training) and pharmacological treatment. Finally, at the University of Oxford in the UK, an online 2-year part-time MSc/PgDip in Sleep Medicine was established in 2016. One of the eight modules is on insomnia, with an emphasis on CBT-I as the preferred intervention. As well as the CBT-I module being available online as "standalone" CPD (continuing professional development), the University of Oxford also offers a 2-day CBT-I masterclass course delivered in person. All courses listed in Table 4 include some form of interactive teaching and some of them provide case supervision. The fee is generally paid by the participants. The list provided in Table 4 is not, however, comprehensive as it is currently difficult to gain a clear overview of all CBT-I trainings offered across Europe. Furthermore, current provision is not yet sufficient and varies consistently across countries. Current courses do not yet address the different levels of competencies between professionals in terms of both administering and being able to teach CBT-I. A main objective of the CBT-I Academy is to promote a coordinated European system of CBT-I training. which will be formed of specialist CBT-I practitioners and trainers. Furthermore, the Academy aims to compile information on current CBT-I offered in Europe and to provide a comprehensive list of accredited courses.

6 | THE CBT-I ACADEMY

The Task Force group of the European Sleep Research Society and the European Insomnia Network met in May 2018 in Freiburg (Germany)

and developed this outline proposal to establish the European CBT-I Academy to enable a Europe-wide system of homogeneous CBT-I training and training centre accreditation. Deliberations concerned: ingredients of CBT-I, how CBT-I should be administered, how to integrate CBT-I training into European healthcare systems, preconditions and qualifications for health professionals to teach CBT-I, the way in which CBT-I should be taught and to whom it should be taught.

6.1 | Ingredients of CBT-I

CBT-I should be defined as a family of evidence-based interventions, including behavioural, cognitive and educational interventions. Just as pharmacotherapy is a methodology with many drugs, CBT-I is a system of therapy, not a single therapy. This suggests that the term CBT-I is used as a convenient label but that treatment could include different evidence-based psychological interventions, such as motivational and emotional strategies, which are currently less well defined or standardized. Recently, other psychotherapeutic approaches, such as mindfulness and hypnotherapy, centring on powering emotion-regulation skills, have been empirically investigated (Gong et al., 2016; Kanen, Nazir, Sedky, & Pradhan, 2015; Lam et al., 2015) and acceptance and commitment therapy has been proposed as a possible intervention for non-responders to CBT-I (Hertenstein et al., 2014). Together with the main strategies listed in Table 2, knowledge on sleeping medication tapering or withdrawal should be considered a component of CBT-I. The insomnia research literature provides a strong evidence base, with proof of efficacy and clinical effectiveness, both for multicomponent CBT-I and also for single components, such as sleep restriction, stimulus control and relaxation therapies, and to a lesser extent cognitive therapies. The decision as to whether to apply CBT-I as a 'package' intervention or as individual components should be at the discretion of expert clinicians or defined in a stepped-care model, as discussed in the next paragraph.

6.2 | How CBT-I should be administered

6.2.1 | A stepped-care approach to insomnia

In order to increase the likelihood of sufficient evidence-based therapeutic provision for insomnia across Europe, we suggest the adoption of a stepped-care approach inspired by the model proposed by Espie (2009) and Espie, Hames, and McKinstry (2013). This model promotes the idea that the greatest numbers of patients could be managed through readily accessible self-help therapies, including dCBT-I via the internet and mobile devices, as well as books and audio resources. There is now a substantial evidence base for dCBT-I and such approaches have been incorporated into clinical guidelines (e.g., Wilson et al., 2019). Dependent upon treatment response, clinical complexity and/or treatment preference, patients may be 'stepped-up' to a more time and resource-intensive level of CBT-I; for example, including manualized treatment delivered by trained therapists. Three further steps are suggested in the model, gradually increasing the expertise of the therapist and adaptation of the intervention to the needs of the patient. These three steps range from "individual or small group CBT delivered by a graduate psychologist" to "individually tailored CBT delivered by a clinical psychologist" to "expert CBT delivered by behavioural sleep medicine expert". The purpose of the stepped-care model is twofold: first, to help individual patients find the best approach for them, and second, to develop a high-quality service at a population level that is both effective and economically viable.

Here we propose a simplification of the model proposed by Espie (2009) and Espie et al. (2013), which could be adapted for use within a given national health system. A first level includes prescriptions from GPs for behavioural treatment of insomnia or evidence-based dCBT-I developed by an expert therapist and promoted by well-known health systems. It could be that the GP or other professional recommends, or in some way 'prescribes', this solution; or it could be that the responsible health authority (such as the NHS in the UK) promotes ready access even more directly. The clear intention, however, would be to develop services in such a way that CBT-I becomes available at a scale equivalent to medication. The important point is that patients and their GPs would have immediate access to CBT-I. Of course, this is an ideal model, would take time to develop and will initially be based, where a clinician is involved, on appraisal of the patient's needs, preferences about formats of engagement, as well as what is on offer locally. Ideally, such an insomnia care pathway would also involve patients somehow being reviewed after 4–6 weeks to ascertain their degree of treatment response.

Based on patients' response to this initial step (GPs' prescriptions or dCBT-I), complexity or patients' preference and what is available locally, two higher levels of treatment are then suggested: (a) manualized CBT-I delivered by a trained therapist, either face to face or via the internet in small groups, or (b) individually tailored therapy delivered by a CBT-I expert face to face individually or through group therapy. The use of dCBT-I programmes could also be useful in these stages because one goal of CBT is to enable patients to implement effective therapy components at home in between traditional treatment sessions. The stepped-care model, therefore, reflects a pyramid of therapeutics gradually increasing the level of therapist/clinician expertise and time commitment. Stepped care therefore conserves these most expensive of human resources for those situations where they are most required, whilst optimizing the volume of patients who can be successfully and effectively treated. It is not necessary that each patient tries all steps, but rather the allocation to the best-fitting therapy would depend on insomnia severity or complexity, therapist/clinician judgement and/or patient preference. The model is summarized in Figure 1.

6.3 | How to integrate CBT-I training into the healthcare systems in Europe?

It is clear that, given the heterogeneous situation of healthcare in Europe, no unified training model can be proposed. We will,

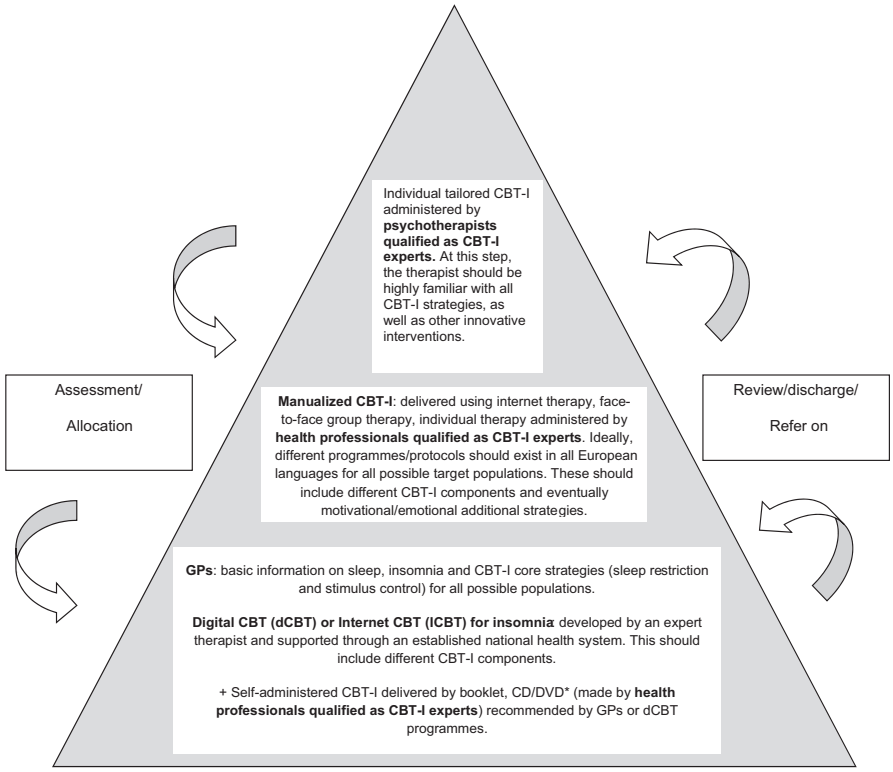

FIGURE 1 An evidence-based stepped-care model for CBT-I.

instead, suggest an 'ideal' generic model, which has the potential to be adapted to the healthcare system of each respective European country.

Here we provide a brief overview of what has been published to date about how to integrate CBT-I into general healthcare. In Appendix 1, a list of relevant publications directed at the general population in different European languages is provided.

Perlis and Smith (2008 speculated upon how to make CBT-I services more widely available, with a focus on the USA. Their approach led to the establishment of a behavioural sleep medicine specialty within the broader sleep medicine field. The behavioural sleep medicine provider is able to offer CBT-I, alongside other behavioural sleep treatments and expertise, and is affiliated to AASM-accredited sleep centres (Perlis & Smith, 2008). Curricula for CBT-I are developed and endorsed by the AASM and the BSM Committee. The authors recommended the development of intensive training opportunities for CBT-I. When one considers the ubiquitous availability of second-line treatments such as hypnotics (numbering billions of prescriptions worldwide), it is clear that CBT-I has a very long way to go to offer patients the choice of an alternative treatment path.

It is our suggestion that, in Europe, the CBT-I Academy should not be exclusively tied professionally to the field of sleep medicine. Rather, and necessarily, there should be strong connections to the field of cognitive and behavioural psychotherapy/psychiatry. Thus, expert providers of CBT-I would by definition already be health professionals with a recognized license to provide clinical psychology/psychotherapy/mental healthcare, but who have further to that obtained qualification and the associated supervised education and practice in sleep medicine and sleep clinical psychology. That is, CBT-I clinicians should be also fully licensed and insured for all of their working healthcare practice and should practice within the boundaries of their professional training. The important caveat here is that a CBT-I practitioner must already possess a license to practice clinically, and that simply undertaking a CBT-I course does not in itself confer a license to see patients.

There is a parallel here with medical management in that a licensed physician is intrinsically qualified to prescribe medication, including that not yet developed or distributed, but is likely to require further orientation to and training in a particular therapy or therapeutic approach. In the same way, a licensed clinical or practitioner psychologist, psychotherapist or psychiatrist is already qualified to see patients and to take clinical responsibility based on their national laws and professional regulations, and is best placed to extend his or her skills into the CBT/insomnia area.

6.4 | Preconditions for health professionals to teach CBT-I

One aim of the CBT-I Academy is to establish a qualification procedure; that is, professionals intending to practise CBT-I should be adequately trained. This academy approach would be expected to facilitate an increase in the number of health experts in CBT-I, to improve focus on effective clinical practice in insomnia care and to reduce treatment variability across clinicians. In order to inaugurate the academy, at the end of 2017 interested insomnia expert clinicians and members of the European Insomnia Network (EIN) were invited by e-mail to take part in the initiative. Attendees worked

together to prepare the present manuscript (the authors of this paper). At the first Academy meeting, which took place in Freiburg, Germany, on May 4th, 2018, the authors of the present paper and founding members of the Academy were declared first-generation trainers ("grandmothers and grandfathers") qualified as CBT-I trainers and practitioners. Figure 2 provides a list of the founding members of the Academy. A Steering Committee was elected during the inaugural Freiburg meeting, comprised of two chairs (D.R. and C.A.E.) and five members (E.A., C.B., S.J., A.S. and B.H.). The CBT-I Academy Steering Committee will have the task of reviewing and approving course proposals, creating a European register of CBT-I practitioners (by merging data from national registers; see below) and coordinating new initiatives to promote CBT-I education across Europe.

We assume that until this point no European country has a governing body controlling whether or not somebody is competent to practice CBT-I. On the other hand, most European countries have governing bodies controlling who is permitted to practise clinical psychology or psychotherapy, or to call themselves a psychotherapist. In establishing the CBT-I Academy our starting assumption is that eligible individuals have a legitimate license to practice in a clinical context. That is, CBT-I skills can only be an extension of a person's practising certificate. It is that certification (e.g., as a physician, clinical psychologist, health or practitioner psychologist, or psychotherapist) that provides the governance structure enabling a person to see patients, and thus to be regulated as a professional in their country of practice. The first-generation European trainers all meet these criteria, in addition to which they have recognized expertise in CBT-I, being members of the European Insomnia Network (EIN). Moreover, the foundation of the Academy could benefit from the collaboration with world-leading experts in CBT-I from the USA. The founding members have been selected as European representatives; they also represent and are in close contact with other well-established CBT-I professionals in their respective countries. Further first-generation CBT-I expert clinicians and trainers could be added to the Academy if they are established CBT-I clinical professionals with widely recognized expertise in CBT-I clinical and research aspects and are sponsored by the founding members.

Second-generation CBT-I expert clinicians and trainers will be health professionals who (a) have a licence to practice clinically and (b) have attended an accredited CBT-I course. Thus, they will be able to practise CBT-I as a form of psychological treatment.

Ideally, three levels of expertise should be considered.

1. *Expert level*: This level of expertise would allow licensed health professionals to be expert CBT-I practitioners, who are able to conduct individually tailored CBT-I. This level of expertise is suited to clinical and healthcare psychologists, psychotherapists, psychiatrists and sleep experts whose CBT-I expertise is core to their professional clinician level knowledge. They would be expected to have attended a high-quality, certified course, endorsed by the Academy, and have followed at least three cases over the course of 3–6 months under the guidance of a CBT-I qualified expert. CBT-I practitioners with certificated knowledge in sleep medicine and sleep clinical psychology could operate also as CBT-I trainers and supervisors.
2. *Advanced level*: This advanced level of expertise would allow health professionals to be trained therapists who could conduct manualized CBT-I delivered face to face or digitally, under the supervision of an expert-level CBT-I supervisor. This level of expertise would be suited to clinical and health psychology master's graduates and psychiatrists in training and, in some countries, nurses or social workers. To be entitled to an advanced level of expertise, practitioners would be expected to have attended a certified course, endorsed by the Academy, including interactive and supervising activities.

THE EUROPEAN CBT-I ACADEMY:
AN INITIATIVE OF THE EUROPEAN INSOMNIA NETWORK

STEERING COMMITTEE

Chairs: Dieter Riemann (Germany), Colin A. Espie (UK).

Members: Ellemarije Altena (France), Chiara Baglioni (Italy, Germany), Susanna Jernelöv (Sweden), Angelika Schlarb (Germany), Brigitte Holzinger (Austria).

First (founding) members of the CBT-I Academy: Ellemarije Altena (France), Chiara Baglioni (Italy, Germany), Bjørn Bjorvatn (Norway), Kerstin Blom (Sweden), Kristoffer Bothelius (Sweden), Alessandra Devoto (Italy), Colin A. Espie (UK), Lukas Frase (Germany), Dimitri Gavriloff (UK), Tuuliki Hion (Estonia), Andrea Hoflehner (Austria), Brigitte Holzinger (Austria), Heli Järnefelt (Finland), Susanna Jernelöv (Sweden), Anna F. Johann (Germany), Caterina Lombardo (Italy), Christoph Nissen (Switzerland), Laura Palagini (Italy), Geert Peeters (The Netherlands), Dieter Riemann (Germany), Angelika Schlarb (Germany), Kai Spiegelhalder (Germany), Adam Wichniak (Poland), Birgit Högl (Austria).

Non-European Members: Michael L. Perlis (USA), Donn Posner (USA).

FIGURE 2 List of founding members of the European CBT-I Academy.

3. *Foundation level*: This level of expertise is specifically suited to GPs and should reflect more basic knowledge of CBT-I behavioural strategies and sleep medicine obtained through attendance at a CBT-I Academy certified course.

The Academy will identify these three levels of expertise by classifying endorsed courses following this three-level categorization. As a consequence, trained CBT-I practitioners, depending on the course(s) attended, will then be recognized by the Academy as CBT-I practitioners at the expert, advanced or foundation level of expertise. After publication of this paper, the Steering Committee will create a register and an associated website containing all the relevant information on the processes and initiatives of the Academy. In this way, the registered list of founding, first-generation and second-generation members, their qualifications and their levels of CBT-I expertise will be in the public domain.

6.5 | The way in which CBT-I should be taught

Table 5 summarizes the CBT-I course criteria identified by the Academy. Courses for aspiring CBT-I practitioners of any level should be of a minimum of 2 days in duration and may be offered to people with pre-existing qualifications in different healthcare areas with a recognized licence to see patients in mental healthcare contexts. Courses should include teaching on sleep itself, on insomnia disorder and its assessment, as well as on core CBT-I components (such as behavioural and cognitive intervention) and additional CBT-I components (such as emotional and motivational strategies). Courses directed at a foundation level of expertise may focus specifically on CBT-I behavioural components. Courses should include conceptual elements covering sleep mechanisms and pathophysiology; theoretical underpinnings of insomnia development and maintenance; formulation of CBT as an intervention. The stepped-care model of insomnia service delivery may be also taught. Courses should cover basic principles of CBT therapy. A module on sleep medication and tapering off/withdrawing medication should be included. Depending on national laws, some health professionals may be prohibited from discussing any change in medication status with patients as they do not have the necessary professional competences. Nevertheless, any health professional dealing with patients with insomnia at a clinical level should be aware of sleep medication mechanisms and effects during intake and withdrawal. Courses should be organized to be interactive (e.g., role playing, work in small groups and difficult situations) and case supervision should be offered. It is possible that some elements of the CBT-I programme could involve interactive training and be offered online.

For the expert level, courses should comprise extensive teaching of the individual tailoring of treatment, advanced knowledge on sleep medicine, insomnia and CBT principles, and clinical experience (e.g., at least three case studies), and either have a long-term duration or include a follow-up/refresher course to discusses cases.

Trainers should all be expert-level CBT-I professionals.

TABLE 5 Template for criteria of European courses for CBT-I, which will be supported by the Academy

Courses which will provide a European Certification for CBT-I practitioners				
Duration	**Teachers**	**Participants**	**Teaching contents**	**Teaching methods**
At least 2 days Expert-level courses should be either long-term or comprise a follow-up/ refresher course after circa half a year	Expert-level CBT-I practitioners	***All expertise levels:*** Health professionals with a recognized license to provide clinical psychology/ psychotherapy/ mental health care, who received qualified and essential further supervised education in sleep medicine. CBT-I clinicians should be also fully insured for all of their working healthcare practice and should practice within the boundaries of their professional training. ***Expert level***: Psychotherapists, psychiatrists, clinical psychologists, healthcare psychologists, practitioner psychologists, sleep experts for whom insomnia and its treatments is part of their core professional expertise. ***Advanced level***: Psychotherapists, psychiatrists, clinical psychologists, healthcare psychologists, practitioner psychologists, sleep experts, clinical or healthcare master's psychologist graduates; nurses, social workers. ***Foundation level***: GPs (similar modules could be conceptualized for pediatricians, gynaecologists, or geriatrics).	***All expertise levels***: 1. Basic knowledge in sleep medicine and insomnia. 2. Core behavioural CBT-I strategies. 3. Stepped-care model and allocation issues. 4. Basic CBT principles. 5. Knowledge on sleep medication/tapering. ***Advanced and Expert levels (advanced knowledge of CBT is required)***: 1. Advanced knowledge in sleep medicine and insomnia. 2. Cognitive CBT-I components. 3. Motivational and emotional CBT-I strategies. ***Expert level***: 1. Individually tailored treatment. 2. Advanced knowledge on sleep and insomnia. 3. Advanced knowledge on CBT principles and intervention strategies.	***All expertise levels***: Courses should include interactive activities, e.g. role playing, work in small groups, discussion of difficult situations. Case supervision should be offered. Courses could be given face-to-face or online ***Expert level***: Courses should comprise clinical phases including at least three cases with supervision.

These criteria are not intended to be overly prescriptive, neither are they completely comprehensive. However, we have attempted to set expectations and minimum standards for what may be regarded as necessary and feasible.

6.6 | How courses may become endorsed

It is proposed that the qualification and training standards set by the Academy will first be approved by the ESRS and its special interest group in insomnia, the European Insomnia Network (EIN). Once this is the case, the Academy will be in a position to invite submissions with a view to reviewing them against training criteria and then to provide approval. It is hoped that this process will encourage organizations, institutions and local societies to develop high-quality curricula and that the ESRS imprimatur of endorsement will encourage health professionals to apply for and to complete CBT training.

Appendix 2 comprises a form that could be used for submitting course proposals. The form will be uploaded and updated on the ESRS website. To support the process, it is suggested that each European country designates a central National CBT-I Training Centre (i.e., centre of excellence for CBT-I). For countries where there are already several established centres, a collaborative network could be formed to support education and dissemination of CBT-I. These centres should have on board a medical specialist (general medicine, psychiatry, neurology or sleep medicine) or a clinical psychologist/psychotherapist who is accredited to practice medicine/psychiatry/psychotherapy in her/his given country. Furthermore, these persons should have accredited expertise to practise and supervise psychotherapy and CBT-I. Each country should also establish a national register of CBT-I practitioners. This could be achieved in collaboration with the national sleep society or national clinical psychology or cognitive behavioural therapy associations. In Appendix 3 a form for national registers is provided. The national registers also will be uploaded and updated on the ESRS website.

7 | CONCLUSIONS

The European guidelines for insomnia (Riemann, Baglioni, et al., 2017) highlighted that "cognitive behavioural therapy for insomnia, although being the first-line treatment for insomnia, is not easily available. It is assumed that only a minority of patients with chronic insomnia will receive this treatment in Europe. Thus, the widespread implementation of CBT-I will be a major challenge for the future." In response to this statement, European CBT-I experts from 12 different countries have instituted the CBT-I Academy, with the aim of establishing and promoting Europe-wide standards for CBT-I training and training centre accreditation. The intention is to substantially improve the availability of high-quality CBT-I in Europe within the next 10 years. In this paper, we have highlighted the very limited availability of CBT-I across Europe and summarized the current availability of training in CBT-I. Despite differences between countries, the general conclusion is that access to CBT-I for patients and training in CBT-I for health professionals are poor and require standardization. Thus, as founders of the CBT-I Academy, we have proposed minimal criteria that should be met in each country to provide adequate CBT-I training at differing expertise levels for health professionals, alongside a stepped-care approach to service delivery. This is also expected to impact clinical research standards. It is desirable that clinical trials involving CBT-I will involve CBT-I trained practitioners. This would impact very positively on the quality and comparability of CBT-I clinical studies across Europe. A closer relationship between clinical practice and research contexts would also be expected to add to the current evidence base of CBT-I, particularly with regard to the diverse groups of patients seen clinically, including children and young people, pregnant women, women at postpartum, women going through the menopause, shift workers, those with disabilities and retirees.

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CONFLICT OF INTEREST

CAE is co-founder and Chief Medical Officer of Big Health of the company that makes the digital CBT intervention, Sleepio. He has shares in the company and receives a salary from the company. DG is the director of a private CBT-I clinic and sleep medicine consultancy, Sleep Well Oxford Ltd. He is also a salaried employee of and Clinical Engagement Lead for non-employee sleep medicine consultant for Big Health (Sleepio), with shares in the company. BH reports personal fees from Abbvie, Lundbeck, Janssen Cilag, Novartis, Mundipharma, Otsuka, Illy, Inspire and AoPOrphan, personal fees from Axovant, Benevolent Bio, Roche and AoPOrphan, and other fees from Habel Medizintechnik Austria, outside the submitted work. DR reports personal fees from Heel Germany, personal fees from different publishers, personal fees from the Freiburg Training Institute for Behaviour Therapy, and personal fees from different institutes, hospitals, etc., in Germany, outside the submitted work. All other authors have nothing to disclose.

AUTHOR CONTRIBUTIONS

The first and the last authors worked together in every phase of the manuscript preparation. All authors participated in the first meeting of the European Academy for Cognitive Behavioural Therapy for Insomnia, which took place in Freiburg, Germany, on the 4th May,

2018, contributed information on a national level and to the manuscript writing.

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APPENDIX 1

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CBT-I web-based approaches

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Sleepio (https://www.sleepio.com/)
SleepWell (http://internetpsykiatri.se/behandling/somnproblem-insomni)
I-Sleep: (https://www.i-sleep.nl/)
Somnio (https://www.somnio.nl)
Somnovia (https://dak.somnovia.de/)
Therasomnia (https://www.therasomnia.com/)
Web-based therapy for insomnia (https://www.mielenterveystalo.fi/nettiterapiat/laheteohjeet/Pages/unettomuuden_lahetteet.aspx)

APPENDIX 2

CBT-I COURSE PROPOSAL FORM (TO BE SUBMITTED TO CBT-I ACADEMY STEERING COMMITTEE)

INFORMATION ON THE COURSE

Name of the course	
Person(s) in charge	
Language of the course	
Qualification of the person(s) in charge	
Institution in which the course will be delivered	
Brief description of the course	
Full duration of the course	
Modality of the course (e.g. face-to-face or online)	
Participants (to whom is the course offered)	

CONTENTS OF THE COURSE

Core CBT-I components (bedtime restriction and stimulus control)	
Cognitive CBT-I components	
Basic element of sleep mechanisms	
Insomnia pathophysiology	
Additional CBT-I components (motivational and emotional interventions)	
Modules for tapering medication	
Basic knowledge of CBT-I stepped care model	
Individual tailored treatment for patients with insomnia disorder	
Other: Specify:	

TEACHERS

Provide a full list of the course's teachers, their qualification and what topic they teach.

INTERACTIVE ACTIVITIES AND CASE SUPERVISION

Provide a detailed description of how courses will be made interactive and how case supervision will be included and done.

Journal of Sleep Research ESRS

APPENDIX 3

CBT-I NATIONAL REGISTER (TO BE SUBMITTED TO CBT-I ACADEMY STEERING COMMITTEE)

Country	

Name	Qualification	CBT-I Academy member (yes/no)	Qualification for CBT-I practice	Institution	City

The Clinical Process in Psychiatry: A Clinimetric Approach

Giovanni A. Fava, MD; Chiara Rafanelli, MD, PhD; and Elena Tomba, PhD

Objective: The aim of this review was to examine the clinical process in psychiatry, with special reference to clinimetrics, a domain concerned with the measurement of clinical phenomena that do not find room in customary taxonomy.

Data Sources: A MEDLINE search from inception to August 2010 was performed for English-language articles using the keywords *clinical judgment*, *clinimetric*, *staging*, *comorbidity*, *sequential treatment*, and *subclinical symptoms* in relation to psychiatric illness. It was supplemented by a manual search of the literature.

Study Selection: Choice of assessment strategies was based on their established or potential incremental increase in clinical information compared to use of diagnostic criteria.

Data Extraction: Contributions were evaluated according to the principles of clinimetrics.

Results: Several innovative assessment strategies were identified: the use of diagnostic transfer stations with repeated assessments instead of diagnostic endpoints, subtyping versus integration of different diagnostic categories, staging methods, and broadening of clinical information through macroanalysis and microanalysis. The most representative examples were selected.

Conclusions: Current assessment strategies in psychiatric research do not reflect the sophisticated thinking that underlies clinical decisions in practice. The clinimetric perspective provides an intellectual home for the reproduction and standardization of these clinical intuitions.

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Psychiatric diagnosis and classification have attracted considerable attention in the past decades.[1] The introduction of diagnostic criteria for the identification of psychiatric syndromes, such as the *DSM*,[2] has considerably decreased the variance of diagnoses due to different assessors and the use of inferential criteria rather than direct observation.

However, clinicians have become increasingly aware of the limitations of the current diagnostic systems[3] and concerned about future *DSM* or *ICD* developments.[4] The customary clinical taxonomy in psychiatry does not include patterns of symptoms, severity of illness, effects of comorbid conditions, timing of phenomena, rate of progression of illness, responses to previous treatments, and other clinical distinctions that demarcate major prognostic and therapeutic differences among patients who otherwise seem to be deceptively similar since they share the same psychiatric diagnosis.

Little consideration has been given to the clinical process in psychiatry, that is, how clinical judgment leading to medical decisions is formulated. The main emphasis has been given to the standardization of the assessment process by use of rating scales leading to diagnostic configuration.[5]

In 1967, Alvan Feinstein dedicated a monograph to an analysis of clinical reasoning that underlies medical evaluations, such as the appraisal of symptoms, signs, and the timing of individual manifestations.[6] In 1982, he introduced the term *clinimetrics*[7] to indicate a domain concerned with the measurement of clinical issues that do not find room in customary clinical taxonomy. Such issues include the types, severity, and sequence of symptoms; rate of progression in illness (staging); severity of comorbidity; problems of functional capacity; reasons for medical decisions (eg, treatment choices); and many other aspects of daily life, such as well-being and distress.[8] Feinstein, in his book on clinimetrics,[8] quotes Molière's bourgeois gentleman who was astonished to discover that he spoke in prose as an example of clinicians who may discover that they constantly communicate with clinimetric indices. Indeed, in clinical practice, psychiatrists weigh factors such as the progression of disease, the overall severity of the disorder, the patient's social support and adaptation, resilience and reaction to stressful life circumstances, and response to previous treatment.[9] However, current formal strategies of assessment fail to capture most of this information.

We will examine some emerging trends and perspectives in the clinical process in psychiatry, with special reference to the diagnostic process, the staging method, and the organization of information.

DATA SOURCES AND STUDY SELECTION

A review of the literature, based on a MEDLINE search from inception to August 2010 using the keywords *clinical judgment*, *clinimetric*, *staging*, *comorbidity*, *sequential treatment*, and *subclinical symptoms* in relation to psychiatric illness was performed. It was supplemented by a manual search of the literature. Choice of assessment strategies was based on clinimetric principles[8] and on the concept of incremental validity,[10] which refers to the unique contribution or incremental increase in predictive power associated with the inclusion of a particular assessment procedure in the

Clinical Points

- Exclusive reliance on diagnostic criteria has impoverished the clinical process and does not reflect the complex thinking that underlies decisions in psychiatric practice.
- The accuracy of clinical judgment can be greatly increased with specific strategies: global formulations, staging methods, and a better organization of clinical information (encompassing macroanalysis and microanalysis).
- The concept of disease is no longer adequate to guide psychiatric care; therefore, clinical decision making should be addressed to attainment of individual goals.

clinical decision process.[11,12] We will then discuss the implications that a renewed interest in these assessment strategies may entail.

DIAGNOSTIC ENDPOINTS VERSUS TRANSFER STATIONS

In most instances of diagnostic reasoning in psychiatry, the process ends with the identification of a disorder,[13] often subsumed under a rubric of the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM*). A single assessment generates the prognostic and therapeutic judgments of the clinician. A *DSM* diagnosis (eg, major depressive disorder), however, encompasses a wide range of manifestations, comorbidity, seriousness, prognosis, and responses to treatment.

The majority of patients with mood and anxiety disorders do not qualify for 1, but for several Axis I and Axis II disorders.[14] As Cloninger[15] remarks, mental disorders can be characterized as manifestations of complex adaptive systems that are multidimensional in their description and multifactorial in their origins, and they involve nonlinear interactions in their development. As a result, efforts to describe psychopathology in terms of discrete categorical diagnoses result in extensive comorbidity and do not lend themselves to adequate treatment strategies.[15]

Very seldom do comorbid diagnoses undergo hierarchical organization (eg, generalized anxiety disorder and major depression) or is attention paid to the longitudinal development of mental illnesses. There is comorbidity that wanes upon successful treatment of 1 mental disease, eg, recovery from panic disorder with agoraphobia may result in remission from co-occurring hypochondriasis, without any specific treatment for the latter.[10] Other times, treatment of 1 disorder does not result in the disappearance of comorbidity. For instance, successful treatment of depression may not affect preexisting anxiety disturbances.[16]

The diagnostic criteria are particularly helpful in setting a threshold for conditions worthy of clinical attention. Accordingly, the diagnostic criteria for a major depressive disorder identify a syndrome that may be responsive to antidepressant drugs. At least 5 of a set of 9 symptoms should be present (and 1 should be either depressed mood or loss of interest). However, according to the psychometric model, all items are weighed the same, unlike in clinical medicine, where major and minor symptoms are often differentiated (eg, Jones criteria for rheumatic fever).[7] As a result, a patient with severe and pervasive anhedonia, incapacitating fatigue, and difficulties concentrating, which make him unable to work, would not be diagnosed with a major depressive disorder, despite the clinical intuition of potential benefit from pharmacotherapy. This diagnosis could be performed in a patient who barely meets the criteria for 5 symptoms. The hidden conceptual model is psychometric: severity is determined by the number of symptoms, not by their intensity or quality, to the same extent that a score in a depression self-rating scale depends on the number of symptoms that are scored as positive.[10] This is not surprising in view of the fact that the development of psychometrics took place outside of the clinical field, mainly in educational and social areas.[17] Since the phenomena under observation in the development of psychometric principles were not clinical, they could not be automatically adapted to clinical psychology and psychiatry.

Similar considerations apply to the longitudinal development of the disorder (prodromal phase, the fully developed disorder, and residual states).[9] Detre and Jarecki[18] provided a model for relating prodromal and residual symptomatology in psychiatric illness, defined as the rollback phenomenon, ie, as the illness remits, it progressively recapitulates, even though in a reverse order, many of the stages and symptoms that were seen during the time it developed. The rollback phenomenon has been substantiated in mood and anxiety disorders.[19,20] There is limited awareness of the fact that the current patient's symptomatology may have developed over the years and have reflected previous treatments.

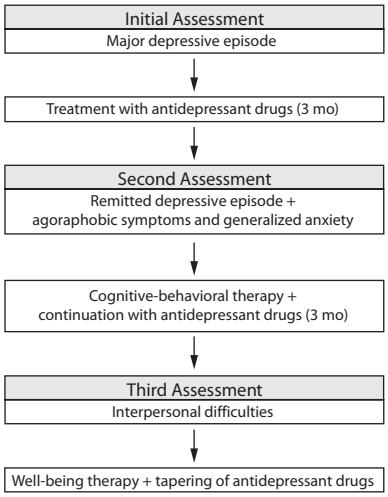
Feinstein[13] remarks that, when making a diagnosis, thoughtful clinicians seldom leap from a clinical manifestation to a diagnostic endpoint. The clinical reasoning goes through a series of "transfer stations," where potential connections between presenting symptoms and pathophysiological process are drawn. These stations are a pause for verification or change to another direction.[13] This strategy particularly applies to psychiatric disorders. An initial state of generalized anxiety may assume phobic connotations at some later point in time. If major depression then ensues, mood symptomatology may overshadow the previous anxiety disturbances, but the diagnosis of depression is only a transfer from prodromal to residual anxiety.

Some assessment strategies have been developed to overcome the flat, cross-sectional view of *DSM*.

Repeated Assessments

The use of diagnostic transfer stations has been suggested by the sequential treatment model,[21] an intensive, 2-stage approach, that includes the use of 1 treatment (eg, pharmacotherapy) after remission has been achieved. One type of treatment is thus employed to address the residual

Figure 1. Effects of Repeated Assessments on the Development of a Diagnostic Work



symptomatology that the other treatment was unable to affect. The sequential model relies on repeated assessments (after each line of treatment has been completed) that may modify an initial diagnosis (eg, preexisting anxiety disturbances may emerge after pharmacotherapy of a major depressive episode). Robins and Guze[22] developed the primary/secondary dichotomy in depression, which was based on chronology and course of follow-up. An episode of depression was defined as secondary when it was superimposed on a preexisting psychiatric or medical disease. The *DSM-IV*,[2] however, does not differentiate primary and secondary manifestations of depressive illness, as is performed in general medicine (eg, hypertension). As outlined in Figure 1, in view of the rollback phenomenon, Robins and Guze's primary/secondary distinction[22] becomes feasible: the major depressive episode appears to be superimposed on longstanding agoraphobic fears and avoidance and generalized anxiety. Symptoms are qualitatively differentiated (eg, the fact they persisted upon treatment against a background of improved symptomatology). They may be elicited by a diary or daily rating scales, which yield information that is not readily apparent in interview.

Subtyping

The need for subtyping major depressive disorder, since this category is too broad to yield meaningful treatment implications, has been recently underscored.[23,24] Lichtenberg and Belmaker,[23] for instance, differentiate between depression with anxiety (maintains functioning, positive response to favorable news or pleasurable activities) and late-life depression (no prior depressive history, reduced energy and interest, impaired cognitive function). Bech[24] has revived Robins and Guze's hierarchical primary/secondary distinction (eg, postnatal depression, poststroke late-life depression).[22] The basic assumption is that clinical manifestations that share the diagnosis of major depressive disorder may display substantial differences in prognostic and therapeutic terms.[23,24]

The underlying assumption is to increase the amount of clinical information that is conveyed by diagnosis. This requires use of instruments that yield a broad spectrum of information, such as hostility, irritable mood, and phobic avoidance, and are not ordinarily available.[24]

Building Unitary Concepts

Tyrer and associates[25] remarked that what is shared by syndromes such as anxiety, panic, phobic disturbances, and irritability may be as important as the differences between them, and conditions that are apparently comorbid could be part of the same clinical syndrome. They argued that the combination of mixed anxiety and depressive disorders together with a certain type of abnormal personality (excessive timidity, poor-self-esteem, avoidance of anxiety-provoking situations, and dependence on others) constitutes a single syndrome, the general neurotic syndrome.[25] The syndrome was shown to be associated with a poor response to treatment, frequent symptoms throughout the neurotic diagnostic spectrum, and tendency to relapse. The concept of neurosis, in its phenomenological[26] and psychodynamic[27] traditions, still has a lot to teach in terms of clinical thinking.[28]

Another example of search for unitary mechanisms of symptom formation is van Praag's Scale for Personality Disturbances.[29] On the basis of a structured interview, the rater is asked to score the following experiential qualities: (1) basic feelings of discontent with one's life situation and psychological make up, (2) unhappiness with one's personal relationships, and (3) emotional instability. The scale aims to overcome the difficulties in incorporating the I and II Axes of *DSM* and was found to allow important differentiations from residual symptomatology.[30]

The concept of allostatic load (the cumulative effects of stressful experiences in daily life) originated from basic science.[31] However, it offers another clinical opportunity of assessing the presence of a source of distress in the form of recent life events and/or chronic stress that exceed the individual's coping skills together with symptomatic manifestations encompassing psychological symptoms.[32] These approaches may be subsumed under the clinimetric rubric of global assessment indices. While the sensitivity of these methods is acknowledged in drug trials, where they often yield the most sensitive discrimination between drug and placebo effects,[33] the clinical value of these global evaluations in assessment and treatment planning is currently underestimated.

STAGING

In 1993, Fava and Kellner[9] introduced the clinimetric concept of staging in psychiatric classification. Unlike in clinical medicine, where this method had achieved wide currency (eg, the New York Heart Association Functional Classification, the Ann Arbor staging classification of Hodgkin's disease), staging was largely neglected in psychiatry. Staging

Table 1. Stages of a Psychiatric Disorder

Stage 1: Prodromal phase
Stage 2: Acute manifestations
Stage 3: Residual phase
Stage 4: Chronic (in attenuated or persistent form)

Table 2. Staging of Levels of Treatment Resistance

Stage 0: No history of failure to respond to therapeutic trial
Stage 1: Failure of at least 1 adequate therapeutic trial
Stage 2: Failure of at least 2 adequate therapeutic trials
Stage 3: Failure of 3 or more adequate therapeutic trials
Stage 4: Failure of 3 or more adequate trials including at least 1 concerned with augmentation/combination

Table 3. Staging of Loss of Therapeutic Effects During Continuation or Maintenance Treatment

Stage 0: No loss of therapeutic effect
Stage 1: Loss of therapeutic effects after adequate response in a therapeutic trial
Stage 2: Loss of therapeutic effects after adequate response in 2 therapeutic trials
Stage 3: Loss of therapeutic effects after adequate responses in 3 or more therapeutic trials

differs from the conventional diagnostic practice in that it not only defines the extent of progression of a disorder at a particular point in time but also reveals a person's current location on the continuum of the course of illness. Thus, once an index defines the existence of a particular disease state, its seriousness, extent, and longitudinal characteristics need to be evaluated.[8]

Fava and Kellner[9] developed staging methods for unipolar depression, bipolar disorder, panic disorder, and schizophrenia. Table 1 outlines the basic steps of development of a psychiatric disorder, ranging from the prodromal to the residual and chronic forms, in a longitudinal view of development of disturbances. Staging models have subsequently been refined in schizophrenia,[34] mood disorders,[35–38] and agoraphobia,[28] and they have been introduced in anorexia.[39] Staging instruments have also been developed.[40,41] In 2 randomized controlled trials,[42,43] psychotherapeutic intervention was applied according to a staging method and was found to yield long-term benefits.[44,45]

Further, the staging method has been applied to treatment response in depression.[46–48] It appears that the more information included in the method, the stronger its predictive value.[49] This information may encompass the number of trials completed,[49] the intensity/optimization of each trial,[49] issues of pseudoresistance (nonresponse to inadequate treatment in terms of duration, doses, or indications),[50] or occurrence of loss of therapeutic effects after clinical response.[51] Table 2 provides an illustration of the various levels of treatment resistance. By a clinical viewpoint, it is quite different to treat a patient with a major depressive episode who displayed positive responses to previous therapeutic trials (stage 0) and a patient who failed to respond to various adequate trials, including one concerned with augmentation/combination (stage 4). Similarly, if we encounter a depressed patient who repeatedly displayed loss of therapeutic response using various antidepressant drugs (Table 3), we should be aware that use of a new antidepressant is likely to yield the same phenomenon, probably because of a mechanism of oppositional tolerance.[51] For instance, many patients who did not respond to initial treatment in the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial and went through various types of treatments, including augmentation/combination, were characterized by a refractory state with low remission, high relapse, and high intolerance rates.[35] Accordingly, their likelihood of lasting remission would be very low, as indicated by the staging methods of Tables 2 and 3.

Motivation to treatment and changing behavior has also been submitted to a staging system and may yield valuable insights into psychological resistances of the patient.[52] Di Clemente and Prochaska[52] developed a helpful staging method: "precontemplation" (people do not recognize that a problem exists and have no intention to change), "contemplation" (individuals accept that a problem exists but are ambivalent about it), "preparation/determination" (a perceived discrepancy between current and desired study), "action," and "maintenance" of the new patterns. It is difficult to suggest a psychotherapeutic treatment, despite pertinent indications, to a patient who is in the "precontemplation" stage. However, this is seldom considered, particularly in randomized controlled trials of psychotherapy.

ORGANIZATION OF CLINICAL INFORMATION

The information we previously mentioned adds to other customary domains of the clinical evaluation, such as psychiatric history, background of alcohol and other substance abuse, general medical history, physical examination, laboratory tests, and diagnostic interviews, whether they follow specific instruments or a more personal format.[5] There are other areas, however, that need to be addressed and are currently neglected.

Subclinical Distress and Illness Behavior

A diagnostic interview and a set of criteria have been used extensively in psychosomatic research.[53–55] The Diagnostic Criteria for Psychosomatic Research allow one to translate in clinical terms the spectrum of manifestations of illness behavior, ie, the ways in which individuals experience, perceive, evaluate, and respond to their health status.[53–55] The 2 main forms of abnormal illness behavior (illness affirming and illness denying) have several common expressions in psychiatric practice. However, the psychopathology of insight—as defined by Lewis[56]—is seldom examined. When this happens, the results can be quite interesting. For instance, in a recent investigation on the spectrum of anxiety disorders in the medically ill, agoraphobia without history of panic attacks was found to be closely related to the Diagnostic Criteria for Psychosomatic Research illness denial.[57] Persistent denial of having a medical disorder and

needing treatment frequently occurs in the medical setting.[53] If panic attacks have not taken place (illness denial was not associated with panic disorder and agoraphobia), agoraphobic fears tend to be highly rationalized and do not lead individuals to seek medical attention.[57] The identification of these fears requires careful expert interviewing, well beyond the checklist use of diagnostic instruments, to overcome the denial that underlies agoraphobia and other distress manifestations. The linking between agoraphobia without history of panic attacks and Diagnostic Criteria for Psychosomatic Research illness denial provides an explanation for some discrepancies that have occurred in the literature as to the prevalence of agoraphobia in clinical samples compared to epidemiologic studies.[28] Other important constructs covered by the Diagnostic Criteria for Psychosomatic Research are demoralization,[58] irritable mood,[53] and alexithymia.[27,59]

Psychological Well-Being

An area that is currently neglected in assessment is psychological well-being, despite the availability of validated instruments and its growing importance in establishing resilience.[3,60] Dimensions such as environmental mastery, personal growth, purpose in life, autonomy, self-acceptance, and positive relations with others were found to affect vulnerability to life adversities and complex balance between positive and negative affects in mood and anxiety disorders.[60]

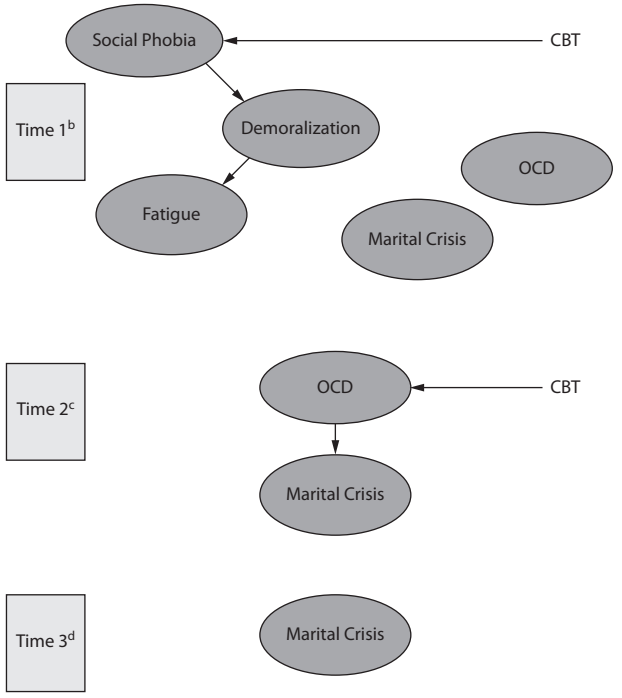
Mezzich and Salloum[3] developed the Person-centered Integrative Diagnosis, which encompasses both the positive and negative aspects of health, in an interactive way, within the person's life context. The Person-centered Integrative Diagnosis includes both the symptomatology of mental disorders and the positive aspects of health (adaptive functioning, protective factors, quality of life, etc) according to a holistic view of the person (including his/her dignity, values, and aspirations).[3] Rehabilitation of mental disorders is targeted as much on the patient's strengths and wishes as it is on alleviating symptoms and psychopathology.[61]

Macroanalysis and Microanalysis

Feinstein, when he introduced the concept of comorbidity, referred to any "additional coexisting ailment" separate from the primary disease, even if this secondary phenomenon does not qualify as a disease per se.[62] Indeed, in clinical medicine, the many methods that are available for measuring comorbidity are not limited to disease entities.[63]

A method has been developed in psychiatry for organizing clinical data as variables in clinical reasoning. Emmelkamp et al[64,65] have introduced the concept of macroanalysis (a relationship between co-occurring syndromes and problems is established on the basis of when treatment should commence). Fava and Sonino[54] have applied macroanalysis to assessing the relationship between medical and psychological variables. Macroanalysis starts from the assumption that, in most cases, there are functional relationships with other more or less clearly defined problem areas[64] and that the targets of treatment may vary during the course of disturbances.[54]

Figure 2. Example of Macroanalysis[a]



[a]A patient presents with work situational social phobia, demoralization, fatigue, obsessive-compulsive disorder (OCD) symptoms, and marital crisis.
[b]At time 1, the therapist could give priority to cognitive-behavioral therapy (CBT) of social phobia, expecting a consequent improvement in demoralization and sense of fatigue.
[c]At time 2, the therapist could decide to intervene on OCD symptoms by using CBT techniques to emphasize the negative effects of the patient's excessive preoccupation for order and precision, leading to a chronic malaise and communicative difficulties with the partner.
[d]At posttherapy assessment (time 3), the therapist could determine the relationship of OCD symptoms to marital crisis.

For instance, a patient may present with work situational social phobia (which leads him or her to avoid important opportunities for improving his or her job), demoralization (which increases his or her sense of fatigue), marital crisis (as a result of obsessional traits of mental order incompatible with that of his or her spouse), and obsessive ruminations (which lead to a chronic state of indecision). In terms of macroanalysis, the clinician, after a thorough interview with the patient, could place into a hierarchy the syndromes and symptoms of comorbidity by considering also the patient's needs. The clinician could thus give priority to the cognitive-behavioral treatment of social phobia, leaving to posttherapy assessment the determination of the relationship of social phobia to demoralization, marital crisis, and obsessional ruminations. Will they wane as anxious epiphenomena or will they persist, despite some degree of improvement? Should, in this latter case, further treatment be necessary? What type of relationship do demoralization and obsessive-compulsive symptoms entertain? If the clinical decision of tackling one syndrome may be taken during the initial assessment, the subsequent steps of macroanalysis require a reassessment after the first line of treatment has terminated (Figure 2).

The hierarchical organization that is chosen may depend on a variety of factors (urgency, availability of treatment tools, etc) that include also the patient's preferences and priorities. Macroanalysis is a tool that allows the therapist to not only increase accuracy in clinical decision making but also inform the patient about the relationship between different problem areas and motivate the patient for changing.[64,65] The concept of shared decision making is getting increasing attention in clinical medicine,[66] but it is still seldom practiced in psychiatry.[67] Macroanalysis also requires reference to the staging method, whereby a disorder is characterized according to seriousness, extension, and longitudinal development.[9] For instance, certain psychotherapeutic strategies can be deferred to a residual stage of depression when state-dependent learning has been improved by use of antidepressant drugs.[68] The planning of treatment thus requires determination of the symptomatic target of the first-line approach (eg, pharmacotherapy) and tentative identification of other areas of concern to be addressed by subsequent treatment (eg, psychotherapy).

Macroanalysis should be supplemented by microanalysis, a detailed analysis of specific symptoms (onset and course of the complaints, circumstances that worsen symptoms and consequences).[64,65] For instance, when anxiety characterizes the clinical picture, it is necessary to know under which circumstances the anxiety become manifest and how the patient responds when he/she becomes anxious, and also to know whether an avoidant behavior occurs and, if so, what are the long-term consequences of the avoidant behavior.

Targum and associates[69] have developed specific criteria (SAFER) to be used in drug trials for improving the assessment accuracy of symptoms: State versus trait (the identified symptoms must reflect the current state of illness and not long-standing traits), Accessibility, Face validity, Ecological validity, and Rule of the 3 *p*'s (symptoms must be present, persistent, and pathological). The SAFER criteria inventory constitutes a valid method of microanalysis. Microanalysis also consists of dimensional measurements, such as observer or self-rating scales for assessing anxiety and fears. Choice of these instruments is dictated by the clinimetric concept of incremental validity.[10–12] Each distinct aspect of psychological measurement should deliver a unique increase in information in order to qualify for inclusion. The concept can also be applied to the selection of instruments in a psychometric battery. In clinical research, several highly redundant scales are often used under the misguided assumption that nothing will be missed. On the contrary, violation of the concept of incremental validity leads to only conflicting results. Microanalysis is consequential and secondary to macroanalysis and leads to overcoming the assumption that there is a common assessment strategy for all clinical encounters.

CONCLUSION

Part of the challenge and, at the same time, fascination of being a clinician lies in applying scientific methods in the care of patients and in understanding disease.[70] Greater knowledge should result in significant benefits for the patients, and, in a sense, continued development on the part of the physician.[71] We are witnessing, however, a progressive detachment of clinicians from research, which is often accompanied by a sense of personal stagnation and tiredness.[71] This detachment is mainly the reflection of an intellectual crisis that has become more and more manifest in recent years.[71–73]

In 1967, Feinstein[6] urged clinicians to develop a "basic science" of their own—to study the clinical phenomena directly, to specify the importance of different types of clinical data, to create appropriate systems of taxonomy for classifying the information, and to develop intellectual models and pragmatic methods that would articulate the clinical process and use the results for quantified analyses.

More recently, Tinetti and Fried[74] have argued that time has come to abandon disease as the focus of medical care. Clinical decision making for all patients should be addressed to attainment of individual goals and identification and treatment of all modifiable and nonbiological factors, rather than solely to the diagnosis and treatment of individual diseases.[74]

Often, in their clinical practice, psychiatrists use sophisticated forms of clinical judgment that are suitable for clinical challenges but are not addressed by current research strategies. Exclusive reliance on diagnostic criteria has impoverished the clinical process and does not reflect the complex thinking that underlies decisions in psychiatric practice. The use of transfer stations with repeated assessments instead of diagnostic endpoints, the building of global formulations of clinical integration, staging methods, and a better organization of clinical information (encompassing subclinical distress, illness behavior, psychological well-being, macroanalysis, and microanalysis) may be an antidote to oversimplified models that derive from biological reductionism, neglect individual responses to treatment, and clash with clinical reality.[71,75]

The clinimetric perspective provides an intellectual home for the reproduction and standardization of the clinical intuitions. It allows the clinician to make full use of the clinical information that is available. It opens a new exciting area of research that is likely to yield improved targets for neurobiological studies and treatment trials.

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Do metacognitions mediate the relationship between irrational beliefs, eating disorder symptoms and cognitive reappraisal?

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EMPIRICAL PAPER

Do metacognitions mediate the relationship between irrational beliefs, eating disorder symptoms and cognitive reappraisal?

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Abstract

Objective: Cognitively oriented therapies, first-line treatment for eating disorders (EDs), still show room for improvement in treatment retention and outcomes. Despite the development of additional cognitive models and therapies, few studies examine the relationship between traditional and third-wave cognitive targets in EDs. The study explores the relationship between irrational beliefs (IBs) and metacognitions and their relationship with ED psychopathology and cognitive reappraisal in ED outpatients. **Method:** Seventy-seven patients (mean age 27.49 ± 12.28 years) were assessed with The Attitudes and Beliefs Scale-ABS-2, Meta-cognitions Questionnaire-MCQ-65, Eating Disorder Inventory 3-EDI-3, Eating Attitudes Test-EAT-40, Emotion Regulation Questionnaire-ERQ. **Results:** Correlational analyses showed that IBs and metacognitions significantly correlated with each other. Metacognitions partially mediated the relationship between IBs and ED-related general psychological maladjustment and completely mediated the relationship between IBs and ED symptom severity. Cognitive reappraisal was predicted only by IBs and metacognitions were not significant mediators. **Conclusions:** While IBs are sufficient in explaining ED-related psychopathology and reduced use of cognitive reappraisal, a potential integration of metacognitions about need to control thoughts in CBT models for EDs may offer incremental validity given their contribution to ED severity. Treatment implications include targeting metacognitions concerning need to control thoughts, as a potential maintenance mechanism of ED symptomatology through cognitive restructuring.

Keywords: Irrational beliefs; metacognitions; eating disorders; cognitive behavioural therapy; CBT

Clinical Significance and Methodological of this Article: A partial overlap between irrational beliefs and metacognitions is supported and integrating multiple concepts of maladaptive cognitions in the clinical assessment and psychotherapeutic treatment planning of EDs might be useful. While metacognitions may not warrant integration in CBT models of EDs in directly predicting cognitive reappraisal and ED-related psychopathology above and beyond the contribution of IBs, on the other hand, metacognitions pertaining to attempts to control and suppress thoughts may offer incremental validity to CBT models of EDs given their important contribution to ED symptom severity.

In terms of methodological significance, despite the expansion of cognitive behavioural therapy variants, this is the only study which explores more than one cognitively-oriented conceptualization of maladaptive cognition in eating disorders. It is the first that tested through mediation models the relationship between irrational beliefs, representing thought content, and metacognitions, which represent thoughts about one's thinking, in relation to cognitive reappraisal and ED symptoms.

Cognitive theory applied to eating disorders (EDs) posits that maladaptive cognitions and evaluations about the self, others, and the world generate emotional distress and perpetuate dysfunctional eating behaviours (Cooper, 2005) such as dietary restraint in anorexia nervosa (AN) and binge-eating in bulimia nervosa (BN). Indeed, EDs like all psychopathologies have been found to be marked by maladaptive thinking (Del Pozo et al., 2018; Möller & Bothma, 2001) conceptualized in second-wave cognitive models as

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irrational beliefs in Rational-Emotive Behaviour Therapy (Ellis, 1958; Vîslă et al., 2016) and cognitive distortions in Beck's (Beck & Haigh, 2014) Cognitive Behavioural Therapy, as well as being characterized by difficulties in cognitive reappraisal, the capacity to alter one's emotional state by cognitively reassessing the situation (Danner et al., 2012). Currently the most evidence-based treatment for adults with an eating disorder is the enhanced transdiagnostic cognitive behavioural therapy (CBT-E) proposed by Fairburn et al. (2003) stemming from specialized psychopathological and maintenance model for EDs.

Although cognitively-oriented therapies are considered first-line treatment in clinical guidelines for EDs (APA, 2006; National Health Service, 2017), room for improvement in treatment retention and outcomes remains, as failure to complete standard CBT-based treatment in ED outpatients is particularly high (Fairburn et al., 2012). CBT-E randomized trials, according to a recent review, do not demonstrate superiority over comparison treatments, especially in the longer-term (Atwood & Friedman, 2020). Clinicians and researchers have called for further development of cognitive models that may enhance interventions for EDs (Cooper et al., 2009; Jones et al., 2007). "Third wave" approaches such as metacognitive therapy (MT), dialectical behaviour therapy (DBT), and acceptance and commitment therapy (ACT), are currently being adapted and tested in EDs to overcome limits of traditional CBT in EDs (Linardon et al., 2017; Vann et al., 2014). Such approaches retain CBT elements but integrate new methods to improve clinical change in psychological functioning by targeting function or awareness of cognitions and emotions rather than directly targeting the content and validity of cognitive processes. Thus, third-wave therapies emphasize metacognition, acceptance, mindfulness, and psychological flexibility, and reduction of experiential avoidance (Hays & Hofmann, 2017; Linardon et al., 2017). To date, however while large pre–post symptom improvements were observed for several third-wave treatments, results on randomized controlled trials have not yet shown superiority compared to the recommended CBT treatments in EDs (Linardon et al., 2017).

Despite the expansion of the number of cognitive models (DiGiuseppe et al., 2017) few studies examine the relationship between traditional CBT and third-wave CBT cognitive targets of therapy and their role on psychological distress and dysfunctional behaviour (DiGiuseppe et al., 2016) specifically in EDs where treatment response is not optimal. While the emergence of novel approaches and psychotherapeutic options might be needed, it would be beneficial to first investigate their possible contribution to already well-validated and tested models and therapies for EDs. In particular, the possibility of integrating in CBT models for EDs the third-wave concept of metacognition which has been previously proposed (Cooper et al., 2009) remains to be investigated. Metacognition refers to the "how" we think, rather than "what" we think (Wells, 2009) and subsequently metacognitive therapy (Wells, 2009) focuses on how we judge and evaulate our thoughts, that is, metacognitions, in addition to focusing on attentional biases, and cognitive processes of worry and repetitive negative thinking (RNT) (Ehring et al., 2011; Ehring & Watkins, 2008; Nolen-Hoeksema et al., 2008). Metacognitions concerning the need to control thoughts and metacognitions about uncontrollability and danger of thoughts, have been both implicated in ED symptomatology and maintenance (Davenport et al., 2015; Olstad et al., 2015; Quattropani et al., 2016; Sun et al., 2017).

Therefore, in the current study, we investigated how the second-wave construct of irrational beliefs (IBs), rigid, absolutistic and inflexible negative thoughts about the self, the world and others (Vîslă et al., 2016), which represent the first and original conceptualization of maladaptive cognitions in the cognitive behavioural framework (Ellis, 1958; Ellis & Dryden, 2007) are related to the third-wave construct of metacognitions, the maladaptive evaluations of one's own thoughts in predicting ED symptomatology and cognitive reappraisal in ED patients. The specific aims of this cross-sectional study are to: 1) explore the relationship between IBs and metacognitions, 2) examine whether IBs in predicting ED severity, ED-related psychopathology, and cognitive reappraisal are mediated by metacognitions, specifically metacognitions about the need to control thoughts and about dangerousness and uncontrollability of thoughts. Understanding such relationships may yield important clinical information on whether they both might contribute to one latent dysfunctional cognitive variable or whether they each contribute uniquely in predicting psychopathological disturbance (DiGiuseppe et al., 2016; Tecuta et al., 2019) specifically in EDs.

Methods

The project was approved by University of Bologna Bioethics Committee and Department of Psychology Ethics Committee. Informed consent was obtained from all participants included in the study.

ED Outpatient Sample

Consecutively recruited patients (n = 79) who met diagnostic criteria for EDs (DSM 5; American

Psychiatric Association, 2013) anorexia nervosa (AN), bulimia nervosa (BN), binge-eating disorder (BED), and other specified feeding or eating disorder (OSFED) were recruited from a specialized ED treatment centre before commencing CBT-based treatment. ED diagnoses were established at intake by the consensus of a psychiatrist and a clinical psychologist independently using the Structured Clinical Interview for DSM 5 (SCID-5: First et al., 2015).

Each diagnostic interview was conducted and recorded by a clinical psychologist expert in assessment (E.T.) and subsequently reviewed by a consulting psychiatrist specialized in EDs who confirmed the diagnosis. Consent to be recorded while interviewed was obtained from all participants. Interrater reliability of ED diagnoses in terms of percent agreement was 83.11%.

With the exception of two patients who refused to participate, all invited patients took part in the study (n = 77). The inclusion criterion was the patients' age between 18 and 65 years. The exclusion criteria were comorbid drug/alcohol abuse, psychotic or neurocognitive disorders, acute suicidality, and pregnancy. The socio-demographic and clinical data of the sample appear in Table I.

Measures

The sample was assessed with the following instruments:

Attitudes and Beliefs Scale 2 (ABS-2: DiGiuseppe et al., 2018, 2020) is composed by 72 likert scale items and attempts to measure the four irrational and four rational belief processes respectively identified by Albert Ellis (1958): demandingness (DEM) versus non-demanding preferences, awfulizing (AWF) versus realisitic negative expectations, low frustration tolerance (LFT) versus high frustration tolerance, and negative global evaluation/self-downing (NGE) versus self-acceptance. The various irrational and rational belief processes are presented in three contextual areas; those that are related to issues (needs or expectations) of comfort, achievement, and affiliation. Demands represent rigid, inflexible, and nonpragmatic beliefs and reflect absolutistic "must statements." Awfulizing statements are instead excessive negative evaluations and expectations of events, while low frustration tolerance beliefs refer to thinking that one cannot tolerate an event or set of circumstances. Negative global self-evaluations/self-downing refer to generalized negative labelling and self-statements. The ABS-2 has demonstrated excellent construct validity pertaining to the four irrational and four rational belief processes (DiGiuseppe et al., 2018, 2020) and good psychometric properties including good internal consistency, divergent and convergent validity in numerous studies (DiGiuseppe et al., 2018; Macavei, 2002, 2005 Sava, 2009; Terjesen et al., 2009).

In the current study only the following four irrational belief process scales were used, all of which are composed of nine items: irrational AWF, irrational DEM, irrational NGE, and irrational LFT. The Italian translation of the ABS-2 utilized in a previous study was used (Tecuta et al., 2019). This translation has already demonstrated excellent internal consistency in the general Italian college-age population (α = 0.926) and cronbach α coefficients for the four irrational belief processes (ranging from 0.738–0.832) (Tecuta et al., 2019). In the current study, Cronbach's alphas for irrational beliefs were similarly acceptable, that is, 0.88 for AWF, 0.85 for DEM,

Table I. ED Outpatient and Control Sample Sociodemographic Data and Comparisons in ABS-2, MCQ, and ERQ-Cognitive Reappraisal Scores.

Variables	Total ED sample (N = 77)	AN group (N = 29)	BN group (N = 15)	BED group (N = 13)	OSFED group (N = 20)
Age (years)	27.49 ± 12.28	23.72 ± 10.71	30.87 ± 13.81	32.08 ± 13.56	27.45 ± 11.49
Marital Status (% single)	80.5	89.7	60	84.6	80
BMI	22.47 ± 8.27	17.53 ± 3.04	22.41 ± 3.62	35.59 ± 9.83	20.67 ± 5.20
Illness Duration (years)	8.87 ± 10.11	7.24 ± 10.23	11.31 ± 12.11	9.33 ± 9.35	9.09 ± 9.18
ABS-2 Irrational Awfulizing	19.26 ± 8.16	19.86 ± 8.90	21.80 ± 8.89	17.00 ± 7.80	17.95 ± 6.46
ABS-2 Irrational Demandingness	16.30 ± 6.68	16.59 ± 7.04	18.80 ± 8.40	13.77 ± 4.97	15.65 ± 5.30
ABS-2 Irrational Negative Global Evaluations	13.65 ± 9.86	14.69 ± 11.11	16.13 ± 9.79	9.54 ± 8.48	12.95 ± 8.50
ABS-2 Irrational Low Frustration Tolerance	19.79 ± 6.18	19.97 ± 6.98	20.67 ± 6.32	17.69 ± 6.33	20.25 ± 4.70
MCQ Positive Beliefs about Worry	35.50 ± 10.11	38.93 ± 11.31	34.87 ± 10.06	31.54 ± 8.80	33.56 ± 7.85
MCQ Negative Beliefs about Worry	42.73 ± 9.28	42.32 ± 10.41	43.67 ± 8.81	40.15 ± 8.08	44.44 ± 8.85
MCQ Cognitive Confidence	18.88 ± 7.02	17.79 ± 6.20	21.40 ± 8.27	17.31 ± 6.52	19.61 ± 7.35
MCQ Need to Control Thoughts	28.51 ± 7.45	28.32 ± 8.97	30.53 ± 8.77	26.38 ± 6.84	28.67 ± 5.12
MCQ Cognitive Self-Consciousness	18.80 ± 3.67	19.18 ± 4.32	18.87 ± 2.70	17.31 ± 3.99	19.22 ± 2.96
ERQ Cognitive Reappraisal	26.42 ± 6.74	26.64 ± 6.23	24.93 ± 7.07	28.77 ± 7.11	25.70 ± 7.00

0.93 for NGE, and 0.85 for LFT and internal consistency also was excellent ($\alpha = 0.971$) in line with validation studies (DiGiuseppe et al., 2018, 2020).

Meta-cognitions Questionnaire (MCQ-65: Cartwright-Hatton & Wells, 1997) is a self-report questionnaire with 65 likert scale items assessing five positive and negative evaluations of one's cognitive processes: positive beliefs about worry (19 items), beliefs about need to control thoughts (16 items), cognitive confidence (10 items), negative beliefs about the uncontrollability and danger of thoughts (13 items), and cognitive self-consciousness (7 items). The Italian translation of the MCQ-65 provided in Wells's (1999; Brazzelli & G. Cocchini Trans.) treatment manual for anxiety disorders was used. In the current study sample, Cronbach's alphas were 0.89 for positive beliefs about worry, 0.86 for beliefs about need to control thoughts, 0.88 for cognitive confidence, 0.87 for negative beliefs about the uncontrollability and danger of thoughts, and 0.66 for cognitive self-consciousness. Such values are in line with the validation of the original English version (Wells, 2009).

Eating Disorder Inventory 3 (EDI-3:Garner, 2008) is a self-rating 91 likert scale item questionnaire assessing clinically relevant psychological traits and constructs in EDs which has been standardized and translated in numerous languages including Italian. In the current study the Italian adaptation of the EDI-3 was used (Giannini et al., 2008). It yields 12 primary scales (three of which are ED-risk scales and nine of which are ED-related psychological scales) and the following six composite scales: eating disorder risk/severity, ineffectiveness, interpersonal problems, affective problems, overcontrol, general psychological maladjustment. Only the latter composite EDI-3 general psychological maladjustment scale was used. It is composed of the following nine psychological scales: low self-esteem (six items), personal alienation (seven items), interpersonal insecurity (seven items), interpersonal alienation (seven items), interoceptive deficits (nine items), emotion dysregulation (eight items), perfectionism (six items), asceticism (six items), and maturity fears (eight items), with a total of 64 items. This composite score represents a total global psychological functioning index and levels of ED-related psychopathology. The Italian EDI-3 adaptation has shown satisfactory internal consistency (Cronbach's alpha ranging from for subscales in 0.70-0.94 in ED patients) and validity. Specifically for the EDI-3 general psychological maladjustment scale, previously reported Cronbach alpha was 0.94 (Giannini et al., 2008) while in the current study sample it was .91.

Eating Attitudes Test-40 (EAT: Garner & Garfinkel, 1979) is a 40 likert scale item screening measure identifying behaviours and cognitive patterns associated with eating disorders where a greater total score indicates greater eating disorder severity. The measure yields a total score and three subscales scores: dieting, body and food preoccupations, and oral control. The measure shows excellent psychometric properties (Garner & Garfinkel, 1979). In this study, we used the Italian version of the EAT-40, which has been validated (Cuzzolaro & Petrilli, 1988) which also exhibits good psychometric properties with reported Cronbach alphas of 0.80 for dieting subscale, 0.70 for food and bulimic preoccupations subscale, and 0.83 for oral control subscale. In the current study only the EAT total score was used for which the reliability coefficient was .90 in the study population.

Emotion Regulation Questionnaire (ERQ: Gross & John, 2003) is a 10 likert item questionnaire that assesses emotion regulation strategies of expressive suppression and cognitive reappraisal. The ERQ is composed of two subscales: Cognitive Reappraisal and Expressive Suppression of six items and four items respectively. Validation studies presented in Gross and John (2003) showed that both subscales have an adequate internal consistency. In this study, the Italian version validated by Balzarotti et al. (2010) was used where Cronbach's alpha were 0.84 for the Reappraisal scale and 0.72 for the Suppression scale. Only the cognitive reappraisal subscale was used in the current study with Cronbach's alpha of .89 in the study population.

Clinical variables. Body mass index (kg/m^2) and illness duration were collected.

Statistical Analyses

Descriptive statistics were run for socio-demographic and clinical characteristics. Correlational analyses were conducted to examine the relationship between ABS-2 irrational beliefs and MCQ-65 meta-cognitions scores.

Using the PROCESS macro created by A. Hayes (2013), several models of mediation were tested to determine whether the relationships between IBs (ABS-2 IB total score) and ED symptomatology and cognitive reppraisal, were mediated by metacognitions. A total of six mediation analyses were conducted, which included bootstrapped confidence intervals (CIs) for assessing the significance of the indirect paths. Such bootstrapped confidence intervals are considered less biased than Sobel's test (Preacher & Hayes, 2004). When lower-level and upper-level confidence intervals (CI) do not overlap zero, the mediation is significant.

The mediational model tests the indirect effect of the independent variable (Irrational beliefs: ABS-2

IB total score) on the consequent dependent variables of EDI-3, EAT-40, ERQ scores through the mediators metacognitions about uncontrollability and danger and metacognitions about need to control thoughts. Path c prime (c^{I}) represents the indirect effect of IV on DV once the mediator is considered. In all the analyses, the level of significance was set at $p < 0.05$ (two-sided). The Statistical Package for Social Sciences Version 23 (SPSS) was used for all calculations.

Results

Correlational Analyses

Bivariate correlational analyses showed that all ABS-2 subscales and MCQ subscales are moderately, positively and significantly correlated with each other. See Table II for all correlational coefficients.

Mediation Analyses

Mediation analyses revealed that both MCQ-negative beliefs about uncontrollability and danger ($F_{(2,69)} = 49.052$, $p < 0.0001$, $R^2 = 0.587$) and MCQ-need to control thoughts ($F_{(2,69)} = 39.827$ $p < 0.0001$, $R^2 = 0.536$) significantly mediate the relationship between IBs (ABS-2-total score) and EDI-3-general psychological maladjustment. However, the ABS-2 IB total score remains a significant predictor in the mediation model, indicating only partial mediation.

Scores in MCQ-negative beliefs about uncontrollability and danger mediate significantly and partially the relationship between IBs (ABS-2 IB total scores) and EAT-40 total scores ($F_{(2,70)} = 13.353$, $p < 0.0001$, $R^2 = 0.276$). Instead, scores in MCQ-need to control thoughts mediate the same relationship ($F_{(2,70)} = 14.716$, $p < 0.0001$, $R^2 = 0.296$) however completely, with ABS-2 IB total score losing significance as a predictor.

To a lesser extent, MCQ-negative beliefs about uncontrollability and danger ($F_{(2,70)} = 7.873$, $p < 0.008$, $R^2 = 0.1836$) mediated the relationship between IBs (ABS-2 IB total score) and ERQ-cognitive reappraisal, while MCQ-need to control thoughts did not ($F_{(2,70)} = 6.087$, $p = 0.0037$, $R^2 = 0.1481$). However, confidence intervals revealed that such mediations are not statistically significant. Please see Table III for all coefficients and confidence intervals and Figure 1 for mediation models with significant partial and complete mediations.

Discussion

The current study is the first, to our knowledge, to investigate the relationship between IBs and metacognitions, as a potential additional contributing factor in predicting ED symptom severity and ED-related psychopathology as well as in predicting the capacity to apply cognitive reappraisal. Overall, IBs and metacognitions seem to be related constructs. While IBs are associated with all outcomes, including ED symptom severity, ED-related psychopathology and cognitive reappraisal, metacognitions were found to contribute, albeit not completely, to the relationship between IBs and ED-related psychopathology, but not to the relationship between IBs and cognitive reappraisal. Instead, the metacognition need to control thoughts contributed significantly to explaining ED severity, where IBs' contribution is lost.

Concerning correlational analyses, IBs and metacognitions were moderately and positively correlated with each other, with the exception of the metacognition of cognitive confidence, in line with the partial overlap that different conceptualizations of maladaptive cognitions within the cognitive framework may conceptually have (DiGiuseppe et al., 2017). For

Table II. Correlational Analyses between ABS-2 Irrational beliefs and MCQ-Metacognitions ($n = 77$).

	MCQ Positive Beliefs about Worry	MCQ Negative Beliefs about Worry	MCQ Cognitive Confidence	MCQ Need to Control Thoughts	MCQ Cognitive Self-Consciousness
ABS-2 Irrational Awfulizing	0.441	0.461	0.165	0.641	0.306
	$p < 0.0001$	$p < 0.0001$	$p=0.160$	$p < 0.0001$	$p=0.008$
ABS-2 Irrational Demandingness	0.423	0.388	0.186	0.579	0.354
	$p < 0.001$	$p=0.001$	$p=0.112$	$p < 0.0001$	$p=0.002$
ABS-2 Irrational Negative global evaluations	0.532	0.497	0.216	0.624	0.362
	$p < 0.0001$	$p < 0.0001$	$p=0.065$	$p < 0.0001$	$p=0.002$
ABS-2 Irrational Low Frustration Tolerance	0.469	0.457	0.114	0.586	0.337
	$p < 0.0001$	$p < 0.0001$	$p=0.334$	$p < 0.0001$	$p=0.003$
ABS-2 Total Irrational Beliefs Score	0.518	0.501	0.193	0.672	0.374
	$p < 0.0001$	$p < 0.0001$	$p=0.100$	$p < 0.0001$	$p=0.001$

Table III. Mediation Analyses Examining the Role of Irrational Beliefs as Predictor and MCQ-Metacognitions as Mediators on ED Symptomatology and Cognitive Reappraisal ($N = 72$).

(a) MCQ-Negative Beliefs about Uncontrollability and Danger as Mediator

	EDI-3 General Psychological Maladjustment		**EAT TOT**		**ERQ Cognitive Reappraisal**	
	β	SE	β	SE	β	SE
Path c (IV-DV)	0.8501**	0.1158	0.3991**	0.0867	−0.0862+	0.0271
Path a (IV-Med)	0.1675**	0.0344	0.1606**	0.0333	0.1672**	0.0340
Path b (Med-DV)	1.7474**	0.3466	0.6379+	0.3018	−0.2060+	0.0920
Path c[1] (Direct IV-DV)	0.5575**	0.1154	0.2966+	0.3018	−0.0518	0.0305
Indirect effect	**Path ab 95% Bootstrapped Confidence Interval**					
	Lower	Upper	Lower	Upper	Lower	Upper
	0.1475	0.4503	0.0000	0.2029	−0.0778	0.0003

(b) MCQ-Beliefs about Need to Control Thoughts as Mediator

Path c (IV-DV)	0.8501**	0.1158	0.3991**	0.0867	−0.0862+	0.0271
Path a (IV-Med)	0.1876**	0.0245	0.1819**	0.0239	0.1873**	0.0242
Path b (Med-DV)	1.9985*	0.5162	1.0613+	0.4141	−0.1816	0.1319
Path c[1] (Direct IV-DV)	0.4752+	0.1434	0.2060	0.1124	−0.0522	0.0365
Indirect effect	**Path ab 95% Bootstrapped Confidence Interval**					
	Lower	Upper	Lower	Upper	Lower	Upper
	0.1559	0.6128	0.0396	0.3574	−0.0983	0.0279

Note: ABS, Attitudes and Beliefs Scale; AN, Anorexia Nervosa; BED, Binge Eating Disorder; BMI, Body Mass Index; BN, Bulimia Nervosa; DV, dependent variable; EAT, Eating Attitudes Test; ED, Eating Disorders; EDI, Eating Disorder Inventory; ERQ, Emotion Regulation Questionnaire; IV, independent variable; MCQ, Meta-cognitions Questionnaire; OSFED, Other Specified Feeding or Eating Disorders; p, statistical significance

Note: 95% CI = bias corrected confidence intervals based on 5000 bootstrapped samples.

$^{+}p = .01$; $^{*}p < .001$; $^{**}p < .0001$.

example, overlap in constructs of cognitions were found in studies on anxiety and depression, where Beck's CBT concepts of maladaptive cognitions overlapped partially with Ellis' irrational beliefs processes (Sava, 2009; Szentagotai & Freeman, 2007; Tecuta et al., 2019; Wong, 2008). In the current study, ED patients who reported greater levels of negative self-beliefs and/or of awfulizing thinking endorse more strongly metacognitions about uncontrollability and danger of thoughts. Both IBs and metacognitions have been found to be associated with higher psychopathology and with negative emotions (Tajrishi et al., 2011; Vîslă et al., 2016).

Considering the mediational relationships explored among the examined constructs, the contribution of metacognitions varied depending on the type of considered metacognition and the type of outcome. Concerning ED symptom severity, the relationship between IBs and ED symptom severity including bulimia symptoms, dietary restraint, bulimic and food preoccupations, was found to be completely mediated by the metacognition of need to control thoughts and partially mediated by uncontrollability and danger of thoughts (See Figure 1). Thus, irrational belief processes contribute to increased ED severity, however the relationship is entirely explained by the patient's tendency of controlling such rigid and negative thought patterns. Integrating in CBT models of EDs the metacognitive tendency to control/suppress thoughts might offer incremental and unique information which is not captured by irrational belief processes, since they do not include elements of control. While the IB of demandingness or "must statements", included in the total IB score used in mediation analyses may be conceptually extendable to rigid expectations of control (e.g. I *must* control my thoughts), the predictive value of this IB has been found to be weaker compared to other IBs in the literature (Tecuta et al., 2019; Vîslă et al., 2016). Similarly to our study, metacognitions concerning the need to control thoughts were found to predict drive for thinness in AN patients (Davenport et al., 2015). A sense of control seems to have an important role in ED etiology (Surgenor et al., 2002) due to a sense of loss of control in other aspects of one's life (Fairburn et al., 1999), as hypothesized by clinical researchers for quite some time (Bruch, 1973; Crisp, 1980; Garfinkel & Garner, 1982). Moreover, higher endorsement of negative beliefs concerning the self were found to

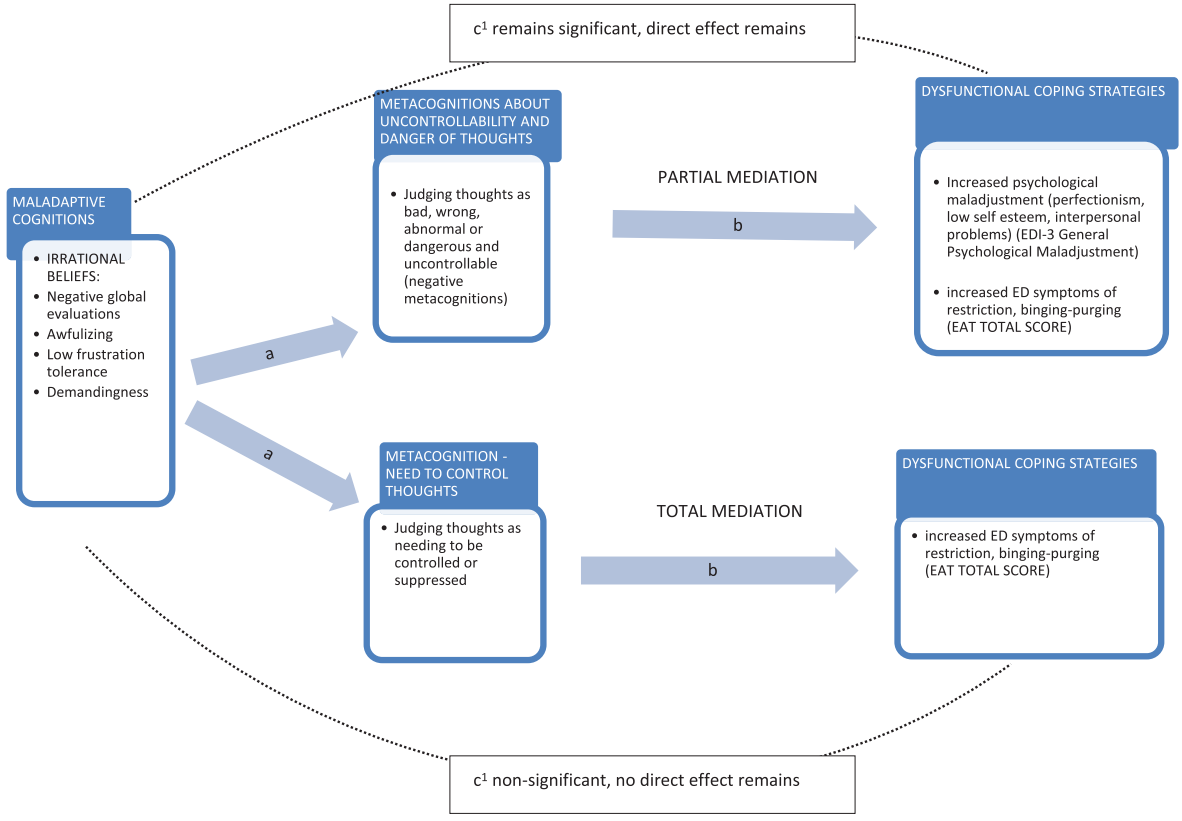

Figure 1. Mediation models.

lead to greater thoughts on loss of control, which predicted binge eating and craving in a sample of BN and BED patients more so than other types of thoughts concerning dietary restraint (Legenbauer et al., 2018). However, the current study findings where IBs lose predictive value on ED symptom severity may be due to not differentiating between the four specific IBs which might have revealed different associations.

With regards to ED-related psychopathology, both metacognitions concerning the need to control thoughts and uncontrollability and danger partially mediated the relationship between IBs and this outcome. IBs retain their predictive role on ED-related psychopathology despite the significant contribution of metacognitions. While a causal relationship between IBs and metacognitions has not yet been investigated, theoretical metacognitive models (Vann et al., 2013) would posit that ED patients in response to negative thought contents may judge such negative thinking negatively as uncontrollable, dangerous or needing to be controlled which in turn might contribute to an increased use of dysfunctional coping strategies encompassed in ED-related psychopathology (See Figure 1). However, considering a REBT theoretical perspective, metacognitions concerning a need to control thoughts and uncontrollability and danger of thoughts, might represent a manifestation of the IB of awfulizing, demandingness or negative global evaluation (e.g. "worrying/having negative thoughts is terrible", "I must control my thoughts").

Concerning cognitive reappraisal, no support was instead found for a possible mediation role of either metacognition considered in the current study. While metacognitions were found to be associated with other cognitive processes in EDs such as worry (Sapuppo et al., 2018) and craving/desire thinking (Spada et al., 2016), metacognitions did not contribute to reduced use of cognitive reappraisal due to irrational belief processes in our ED sample. However, a lack of significant results could be due to the relatively small sample size.

Several important clinical and theoretical implications for ED cognitive models and ED treatment emerge. In particular, in present CBT models and treatment approaches for EDs, irrational belief processes might be sufficient to explain difficulties in cognitive reappraisal as well as in explaining ED-related psychopathology, which may be targeted with cognitive restructuring or cognitive disputation, the primary mechanism of cognitive change in traditional second-wave CBT (Beck & Haigh, 2014; Ellis, 1994; Kazantzis et al., 2018). Such results

might be clinically important in supporting the notion promoted by clinicians of working towards an increasngly optimal transtheoretical approach in CBT rather than persuing a fragmentation of CBT approaches (Ellard et al., 2010).

While metacognitions may not warrant integration in CBT models of EDs in directly predicting cognitive reappraisal and ED-related psychopathology above and beyond the contribution of IBs, on the other hand, metacognitions pertaining to attempts to control and suppress thoughts may offer incremental validity to CBT models of EDs given their important contribution to ED symptom severity. For example, within the CBT-E model (Fairburn et al., 2003), which introduces in the traditional CBT model for EDs four crucial maintenance mechanisms of core low self-esteem, clinical perfectionism, mood intolerance and interpersonal difficulties, metacognitions about the need to control thoughts might be integrated as an additional maintenance mechanism, to be considered as a transdiagnostic feature (Vann et al., 2014). Interventions on metacognitions may include cognitive restructuring, a technique of traditional CBT approaches, of such metacognitions (Wells, 2009). Especially in EDs, the metacognitions that should be targeted concern the need to control thoughts, independently of the content of such thoughts. Additional interventions for RNT through metacognitive therapy (MT) techniques (Wells, 2009) or through rumination-focused CBT techniques (Watkins, 2016) may be warranted to further enhance ED symptom reduction. Thus far, an integration of CBT with MT has been proposed for bulimia nervosa (Cooper et al., 2009), however a transdiagnostic MT model for EDs has not yet been formulated or tested in an randomized controlled trial (Vann et al., 2014).

Limitations of the current study include a small sample size and not considering ED diagnostic differences. The findings may also be due to the ABS-2 instrument's focus on contextual areas of life regarding achievement, approval and comfort rather than focusing on specific ED themes of food, body weight and shape as well as the MCQ-65 measuring general metacognitions rather than specific ED-related metacognitions. Future research should further explore irrational beliefs pertaining to ED themes in relation to metacognitions over time, as well as retest the relationship in predicting cognitive reappraisal with a larger sample.

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Effectiveness of a selective alcohol prevention program targeting personality risk factors: Results of interaction analyses☆

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ABSTRACT

Aim: To explore whether specific groups of adolescents (i.e., scoring high on personality risk traits, having a lower education level, or being male) benefit more from the Preventure intervention with regard to curbing their drinking behaviour.
Design: A clustered randomized controlled trial, with participants randomly assigned to a 2-session coping skills intervention or a control no-intervention condition.
Setting: Fifteen secondary schools throughout The Netherlands; 7 schools in the intervention and 8 schools in the control condition.
Participants: 699 adolescents aged 13–15; 343 allocated to the intervention and 356 to the control condition; with drinking experience and elevated scores in either negative thinking, anxiety sensitivity, impulsivity or sensation seeking.
Measurements: Differential effectiveness of the Preventure program was examined for the personality traits group, education level and gender on past-month binge drinking (main outcome), binge frequency, alcohol use, alcohol frequency and problem drinking, at 12 months post-intervention.
Intervention and comparator: Preventure is a selective school-based alcohol prevention programme targeting personality risk factors. The comparator was a no-intervention control.
Findings: Intervention effects were moderated by the personality traits group and by education level. More specifically, significant intervention effects were found on reducing alcohol use within the anxiety sensitivity group (OR = 2.14, CI = 1.40, 3.29) and reducing binge drinking (OR = 1.76, CI = 1.38, 2.24) and binge drinking frequency ($\beta = 0.24$, $p = 0.04$) within the sensation seeking group at 12 months post-intervention. Also, lower educated young adolescents reduced binge drinking (OR = 1.47, CI = 1.14, 1.88), binge drinking frequency ($\beta = 0.25$, $p = 0.04$), alcohol use (OR = 1.32, CI = 1.06, 1.65) and alcohol use frequency ($\beta = 0.47$, $p = 0.01$), but not those in the higher education group. Post hoc latent-growth analyses revealed significant effects on the development of binge drinking ($\beta = -0.19$, $p = 0.02$) and binge drinking frequency ($\beta = -0.10$, $p = 0.03$) within the SS personality trait.
Conclusions: The alcohol selective prevention program Preventure appears to have effect on the prevalence of binge drinking and alcohol use among specific groups in young adolescents in the Netherlands, particularly the SS personality trait and lower educated adolescents.

1. Introduction

Preventure is a selective prevention programme with a personality-targeted approach. It targets young adolescents with two risk factors for heavy alcohol consumption: early-onset alcohol use (Grant & Dawson, 1997; Hawkins et al., 1997) and personality risk for alcohol abuse (e.g. (Rutledge & Sher, 2001)). Preventure has proven to be effective in Canadian, British and Australian studies when offered to high-school students (Conrod, Stewart, Comea, & Maclean, 2006; Conrod, Castellanos, & Mackie, 2008; Conrod, Castellanos-Ryan, & Mackie, 2011). In a recent

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study on the effectiveness of Preventure in The Netherlands, no program effects were found when looking at the incidence of alcohol use at the follow-up points separately (Lammers et al., 2015). By modelling the development of alcohol use over time using latent growth modelling, positive program effects were found. The exposure to the intervention resulted in significantly less growth in binge drinking and binge drinking frequency over the whole group of young adolescents (Lammers et al., 2015). In the current post hoc analyses of the Dutch Preventure study, we explored whether certain theory-based high risk groups would benefit more from the Preventure intervention than others.

Specific characteristics of study participants may moderate the relationship between the Preventure intervention and substance use behaviours (Conrod et al., 2008; Conrod et al., 2011; Kreamer, Wilson, Fairburn, & Agras, 2002). The risk moderation hypothesis suggests that prevention programs should be more effective in high-risk groups compared to lower risk groups. On the basis of previously reported moderators in the literature (Conrod et al., 2008; Kuntsche, Knibbe, Gmel, & Engels, 2006; Verdurmen, Koning, Vollebergh, van den Eijnden, & Engels, 2011), we specifically examined participants' personality traits, educational level and gender as possible moderators of intervention effects.

Two personality dimensions were previously found to be predictive of heavy alcohol use and alcohol use disorders, namely (1) an impulsive sensation seeking dimension, and (2) a behavioural inhibition dimension (Conrod et al., 2006). These two broad personality dimensions are either more proximal to alcohol use and misuse or they map onto specific motivational processes underlying alcohol use or misuse (Conrod et al., 2006). The impulsive sensation seeking dimension is related to drinking problems through negative affect coping motives. In contrast, the inhibition dimension is associated with positive affect related drinking, which is in turn associated with heavier drinking and drinking problems (Conrod et al., 2006). Within these two dimensions, Conrod and colleagues (Comeau, Stewart, & Loba, 2001; Sher, Bartholow, & Wood, 2000) distinguished four personality profiles at higher risk of developing alcohol problems: sensation seeking (SS), impulsivity (IMP), anxiety sensitivity (AS) and negative thinking (NT). Both anxiety sensitive and hopeless individuals showed higher levels of alcohol use and drinking problems (Sher et al., 2000; Conrod, Pihl, & Vassileva, 1998; Stewart, Peterson, & Pihl, 1995; Krank et al., 2011). Sensation seekers were found to drink earlier, at greater frequency, and they were at risk of heavy alcohol use (binge drinking) (Sher et al., 2000; Castellanos-Ryan, Rubia, & Conrod, 2011; Krank et al., 2011). Impulsive individuals showed an increased risk of early alcohol and drug use (Krank et al., 2011; Shin, Hong, & Jeon, 2012; Walther, Morgenstern, & Hanewinkel, 2012). Consistent with the Canadian, British and Australian studies (Conrod et al., 2006; Conrod et al., 2008; Conrod et al., 2011), we hypothesised that Preventure would be effective in reducing binge drinking rates among the sensation seekers' trait, and reducing drinking rates and problem drinking among the anxiety sensitivity and negative thinking personality traits (Conrod et al., 2006).

A unique feature of the education system in the Netherlands is that the population of secondary school pupils is divided into different education levels and there are important differences in substance use behaviours between adolescents from lower and higher educational backgrounds (Sallona et al., 2008; Spijkerman, Van den Eijnden, & Huiberts, 2008; Verdurmen et al., 2012). For example, a great proportion of pupils from lower education levels report binge drinking; 75% of pupils aged 13–15 with preparatory vocational training (lower educational level) engage in binge drinking, compared to 56% of students with pre-university education (higher educational level) (Verdurmen et al., 2012). In other Dutch prevention trials, (Verdurmen et al., 2011; Koning et al., 2009; Verdurmen, Koning, Vollebergh, van den Eijnden, & Engels, 2014), education level was found to moderate intervention effects. Because binge drinking is more common among pupils from lower educated levels, and previous trials indicated that lower educated students might benefit more from alcohol prevention programmes (Koning et al., 2009), we hypothesised that Preventure would be more effective in reducing binge drinking in the group of lower educated students at follow-up compared to students with a higher education level.

Finally, boys and girls have different drinking patterns. For instance, boys tend to drink more frequently and are more engaged in binge drinking compared to girls (Verdurmen et al., 2012), at least at the time this trial was conducted. In general, externalizing risk factors, such as low self-regulatory capacities, are more common among boys (Chassin, Pitts, & Prost, 2002; Hill, White, Chung, Hawkins, & Catalano, 2000) and internalizing factors, like low self-esteem, are more present among girls (Chassin et al., 2002; Colder, Campbell, Ruel, Richardson, & Flay, 2000). Furthermore, girls are more likely to use substances as a way to cope with stress, while boys are more likely to use out of enhancement motives (Kuntsche et al., 2006). Because the intervention matches those differences expected for the personality types, we expected boys and girls to benefit both from the Preventure program.

With the exploration of these certain theory-based high risk groups, the Preventure programme can possibly be implemented more effective and more tailored into the Dutch school setting.

2. Method

2.1. Study sample

A total of 100 schools were selected randomly from all public secondary schools in The Netherlands (N = 405). Sixty schools fulfilled the inclusion criteria: 1) at least 600 students, 2) <25% of students from migrant populations, and 3) no special education. Fifteen schools (25%) were willing to participate. A screening survey was carried out among all students attending grade 8 and grade 9 in the participating schools. The students who reported to have drunk at least one glass of alcohol, and scored more than one standard deviation above the sample mean on one of the four personality risk scales were classified as belonging to a risk group (Woicik, Stewart, Pihl, & Conrod, 2009). In total, 4844 students participated in the screening, and 699 students participated in the study (see Fig. 1). Analyses revealed no significant differences in prevalence or demographic characteristics between consenting and non-consenting students. Randomization occurred at school level to avoid contamination between conditions. Parents and students provided active informed consent to participate in the intervention part of the study. The study was approved by the Medical Ethical Commission for Mental Health (METIGG). The design, including the power analyses, is described in more detail in earlier reports (Lammers et al., 2011; Lammers et al., 2015). The trial is registered in The Netherlands Trial Register (NTR1920).

A total of 581 students (83%) completed follow-up measures after 2 months, 552 students (79%) after 6 months and 530 students (76%) at the 12-month follow-up. The students who only completed the screening questionnaire (7% of all respondents) were more likely to have a lower level of education than those who completed at least one of the three follow-up questionnaires (53% vs. 34%, $\chi^2(1) = 8.20$, $\rho < 0.004$).

2.2. Intervention

Preventure is a brief intervention using motivational interviewing strategies and cognitive behavioural skills training, that is tailored to one of the four personality profiles (Conrod et al., 2011; Conrod et al., 2013). It focuses on changing coping strategies rather than substance use specifically. The intervention involved two 90-minute group sessions, carried out at the participants' schools, during school hours. Group-sessions were supported by student manuals, in which thoughts and exercises could be logged. In the first group session, psycho-educational strategies were used to educate students about the target

personality variable, and the associated problematic coping behaviours, such as risky behaviour, and substance misuse. Students were motivated to explore ways of coping with their personality through a goal-setting exercise. In the second session, participants were encouraged to identify and challenge personality-specific cognitive thoughts that lead to problematic behaviours. Students assigned to the control group received no further intervention.

2.3. Treatment integrity

The intervention was provided by three qualified counsellors and two co-facilitators. The counsellors were observed by a supervisor at their first two group sessions at each school, and were provided with feedback through four peer reviewing meetings during the implementation. Eighty percent (80%) of participants were present for the first intervention session and 71% for the second session. In total, 71% of the students followed both group sessions. Students who did not attend both group sessions (29%) were more likely to have recently been binge drinking (59% vs. 45%) ($\chi^2(1) = 5.12, \rho < 0.024$) and were more likely to skip one or more of the follow-up measurements ($\chi^2(1) = 25.87, \rho < 0.0001$) than students who attended both group sessions.

2.4. Outcome measures

2.4.1. Baseline assessment

The baseline questionnaire included demographic variables: age, sex, year of level, ethnicity and level of education. For baseline screening, the Substance Use Risk Profile Scale (SURPS; (Woicik et al., 2009)) was used, which distinguishes four personality profiles. Each profile is assessed using five to seven items that can be answered on a 4-point scale. Studies in both adolescent and adult samples in several countries have shown that this scale has good internal reliability, convergent and discriminant validity, and adequate test–retest reliability (Krank et al., 2011; Woicik et al., 2009; Malmberg et al., 2012). All four subscales demonstrated good internal consistency in the current sample (Cronbach's $\alpha = 0.84$ for NT, 0.72 for AS, 0.69 for IMP and 0.66 for SS). These reliability estimates converge with those from previous research (e.g. (Malmberg et al., 2012; Jaffee & D'Zurilla, 2009)) and are satisfactory for short scales (Loewenthal, 1996).

2.4.2. Primary outcome measure

The primary outcome was binge drinking at 12 months follow-up measurement, assessed with the question 'How many times have you had five or more drinks on one occasion, during the past four weeks?', with the answer categories 'none', '1', '2', '3–4', '5–6', '7–8' and '9 or more'. Because the binge drinking variable was skewed to the low end, the item was recoded into a binominal variable (0 = 'none'; 1 = '1 or more').

2.4.3. Secondary outcome measures

Alcohol use was assessed by 1-month prevalence (Engels, Knibbe, & Drop, 1999) at 12 months follow up measurement by asking: 'In the past four weeks, did you drink any alcoholic beverage(s)?' Alcohol use was recoded into a binominal variable (0 = 'none'; 1 = '1 or

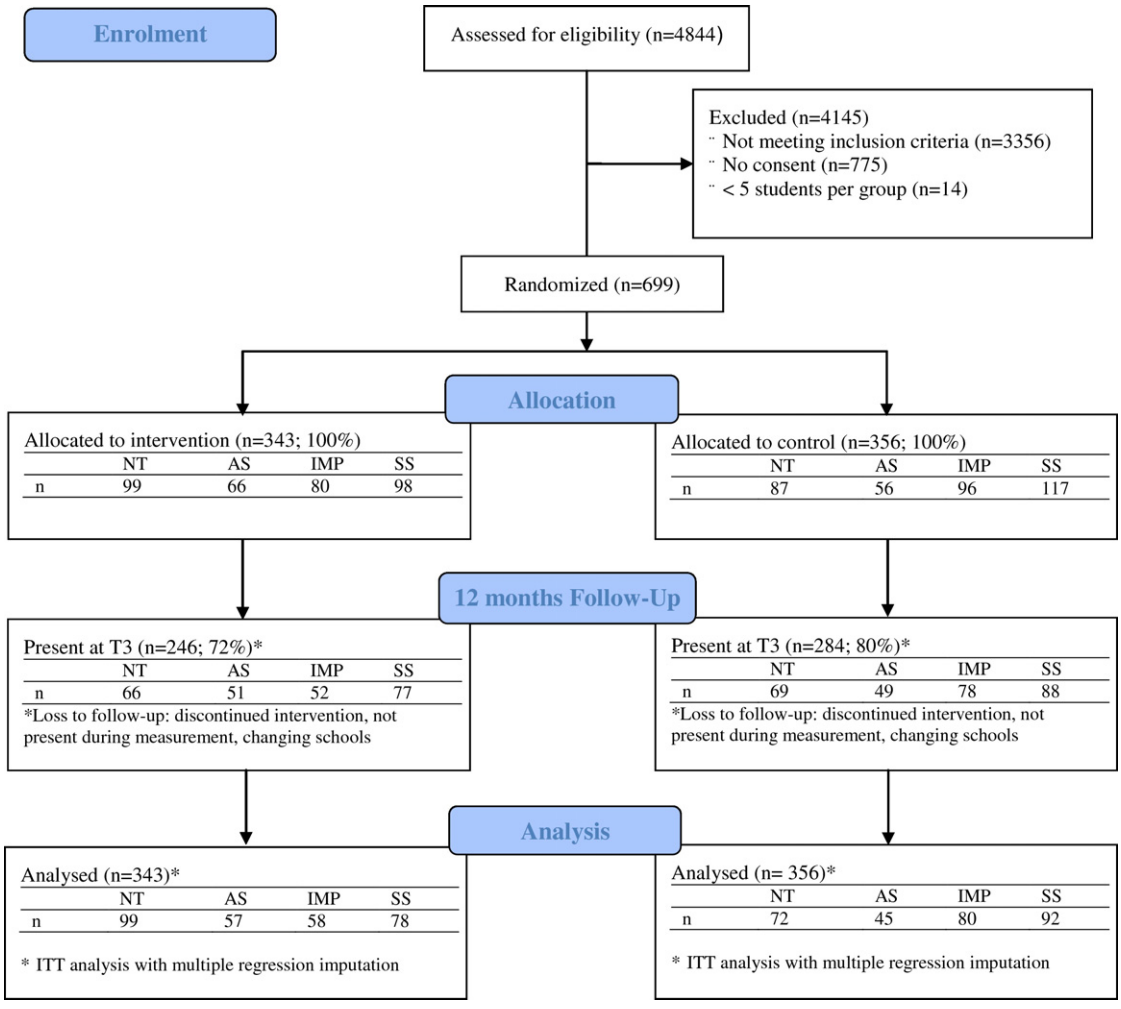

Fig. 1. Flow diagram of recruitment and progress throughout the study.

more'). Binge drinking frequency was assessed with the same question as binge drinking. Frequency of alcohol use was assessed with the question 'In the past four weeks, how often did you drink one or more alcoholic beverage(s)?', ranging from 0 to 40 or more times. The binge drinking frequency and alcohol frequency items were log-transformed to approximate a normal distribution. To assess drinking problems, the abbreviated Rutgers Alcohol Problems Index (RAPI) (White & Labouvie, 1989) was used. Participants could indicate on a scale ranging from 0 (never) to 5 (>6 times) how often they experienced each of 18 alcohol-related problems during their life. Item scores were summed. Because the variable was skewed, the item was recoded into a binominal variable (0 = 'absence'; 1 = 'presence'). The original RAPI has been well validated for use with both clinical and community adolescent samples (White & Labouvie, 1989; Wiers, 2008).

2.5. Statistical analyses

Descriptive analyses were conducted to examine whether randomization resulted in a balanced distribution of demographic and outcome variables over the two conditions. The randomization resulted in an uneven distribution in terms of age, sex and level of education. Hence, these variables were included as covariates in all subsequent analyses. As the intervention condition showed higher binge drinking at baseline than the control condition, binge drinking was also used as covariate. To correct for the potential non-independence (complexity) as well as clustering of the data, the TYPE = COMPLEX procedure in Mplus was used [cf (Malmberg et al., 2012)]. Next, to determine the effect of the intervention on the alcohol use outcomes we made use of the intention to treat principle (ITT) [cf (Verdurmen et al., 2011; Malmberg et al., 2010)]. Missing data were imputed using multiple regression imputation in Mplus 6.11 (Muthén & Muthén, 1998). To examine moderation effects of different high-risk groups, intervention interaction analyses were conducted with the variables sex, level of education and the four personality traits AS, NT, IMP and SS, for all the primary and secondary outcome measurements. To test for interaction effects, we computed product terms of study condition with the variables sex, level of education and the four personality traits AS, NT, IMP and SS, respectively. Interaction effects were included separately in the regression analyses [cf (Conrod et al., 2006)]. The level of statistical significance was set at p-value < 0.05. We chose not to correct for multiple testing seeing that this is the first time the Preventure Programme was tested in the Netherlands and the interaction analyses are therefore of a more exploratory nature. Valuable information on potential subgroups for which the program could be more effective would be lost if we correct for multiple testing. The effects of the intervention condition were compared to the effects of the control condition using multivariate regression analyses in Mplus 6.11. For the dichotomous variables we used logistic regression analyses, with ML and the CATEGORICAL ARE option (reported in OR). For the continuous variables regression analyses were used, with the MLR estimator (reported in β). The main effects of the variables involved in interaction analyses were also included in the models assessing interactions, as were all covariates. Furthermore, post hoc latent growth analyses were conducted to examine the effect of Preventure on the linear increase in alcohol use. A latent-growth model approaches the analysis of repeated measures from the perspective of an individual growth curve for each subject; each growth curve has a certain initial level (intercept) and a certain rate of change over time (slope) (Duncan, Duncan, Strycker, Li, & Alpert, 1999). In this latent growth model, the alcohol outcome slope was regressed on the Preventure intervention condition variable, controlled for the other outcome measures and the covariates age, sex and education. The fit of the models was reported by χ^2 and, because with large sample sizes the χ^2 is often significant, we also reported the CFI, TLI and the RMSEA.

3. Results

3.1. Descriptive analyses

Descriptive analyses revealed significant differences between the experimental conditions with regard to sex ($\chi^2(1) = 5.96$, $\rho = 0.015$), age (t (697) = 2.98, $\rho < 0.003$) and level of education ($\chi^2(1) = 24.77$, $\rho < 0.001$). The intervention condition included more girls, slightly younger students and more students with a low education level. Furthermore, the students in the intervention condition were more likely to engage in binge drinking at baseline ($\chi^2(1) = 10.43$, $\rho < 0.001$) than the students in the control condition (see Table 1).

3.2. Moderators

Interaction analyses examined if adolescents' personality traits, level of education or gender moderated the relationship between the intervention condition and substance use. Significant Intervention x Personality Group interactions were found for anxiety sensitivity (AS) and sensation seeking (SS) for binge drinking, binge drinking frequency and alcohol use at 12 months post-intervention (see Table 2). For NT and IMP, the intervention effects were not significant. Intervention × education level analyses indicated significant interaction effects on binge drinking, binge drinking frequency and alcohol frequency. Young adolescents with lower education were less engaged in binge drinking, and used alcohol less frequent than adolescents with higher level of education, after receiving the intervention (see Table 3).

No significant interaction effects were found for the outcome variable problem drinking, and no significant interaction effects were found for boys and girls.

3.3. Intervention effects on growth over time

Analyses were conducted to examine the effect of Preventure on the linear increase in alcohol use among subgroups, by means of a latent-growth curve approach. The intercept and slope for binge drinking (intercept = 1.22, $p < 0.001$ and slope = 0.50, $p < 0.001$) and binge drinking frequency (intercept = 1.05, $p < 0.000$ and slope = 0.58, $p < 0.000$) were significant, indicating that levels of binge drinking and binge drinking frequency increased over time. The fit between the model and the data was excellent for both binge drinking (χ^2 [N = 699] = 403.691, $p < 0.001$; RMSEA = 0.024 (0.000–0.068), CFI = 0.996, TLI = 0.994) and binge drinking frequency (χ^2 [N = 699] = 14.048, $p < 0.02$; RMSEA = 0.060 (SD = 0.005), CFI = 0.986, TLI = 0.979).

For sensation seekers, there was a significant effect of the intervention on the binge drinking slope ($\beta = -0.07$, $p = 0.02$), and binge

Table 1
Baseline demographic characteristics of intervention and control condition.

Outcome	Measure	Intervention	Control	
n = 699		Mean (SD)/%	Mean (SD)/%	p-Value
Demographics	Male	47%	57%	<0.015
	Age	13.9 (0.98)	14.1 (0.77)	<0.003
	Dutch	87%	87%	n.s.
	Low level of education	43%	26%	<0.001
Alcohol use	Total group	60%	59%	n.s.
	NT	55%	59%	n.s.
	AS	52%	49%	n.s.
	IMP	70%	60%	n.s.
	SS	62%	62%	n.s.
Binge drinking	Total group	49%	37%	<0.001
	NT	47%	36%	n.s.
	AS	46%	35%	n.s.
	IMP	51%	42%	n.s.
	SS	52%	34%	<0.01

Note. NT = negative thinking; AS = anxiety sensitivity; IMP = impulsivity, SS = sensation seeking.

Table 2
Interaction effects personality traits on alcohol outcomes at 12-month follow-up (T3) among alcohol users at baseline.

		Binge drinking		Alcohol use		Problem drinking		Binge drinking frequency		Alcohol frequency	
		OR (95% CI)	*p*	OR (95% CI)	*p*	OR (95% CI)	*p*	*β* (*SE β*)	*p*	*β* (*SE β*)	*p*
AS	Sex	0.96 (0.69, 1.33)	0.81	0.55 (0.38, 0.79)	0.00	0.89 (0.60, 1.32)	0.56	0.03 (0.03)	0.40	−0.06 (0.04)	0.11
	Age	1.40 (1.07, 1.83)	0.01	1.60 (1.14, 2.25)	0.01	1.53 (1.18, 1.99)	0.00	0.14 (0.05)	0.00	0.18 (0.05)	0.00
	Edu	0.90 (0.75, 1.09)	0.28	1.04 (0.72, 1.50)	0.74	1.17 (0.97, 1.41)	0.10	−0.09 (0.04)	0.04	−0.03 (0.05)	0.53
	Cond	0.95 (0.60, 1.50)	0.81	0.80 (0.44, 1.44)	0.45	1.00 (0.65, 1.54)	0.99	−0.01 (0.05)	0.78	−0.02 (0.05)	0.68
	AS	0.64 (0.38, 1.10)	0.09	0.47 (0.28, 0.78)	0.00	0.95 (0.54, 1.68)	0.86	−0.09 (0.05)	0.05	−0.12 (0.04)	0.00
	CxAS	0.98 (0.44, 2.18)	0.96	2.14 (1.40, 3.29)	0.03	0.81 (0.37, 1.78)	0.59	0.03 (0.05)	0.52	0.08 (0.04)	0.04
NT	Sex	1.01 (0.94, 1.09)	0.76	0.61 (0.42, 0.88)	0.01	0.92 (0.61, 1.38)	0.68	0.04 (0.03)	0.18	−0.04 (0.04)	0.32
	Age	1.16 (1.03, 1.31)	0.01	1.57 (1.13, 2.19)	0.01	1.55 (1.18, 2.02)	0.00	0.14 (0.05)	0.00	0.17 (0.05)	0.00
	Edu	0.95 (0.85, 1,06)	0.32	1.03 (0.81, 1.30)	0.80	1.17 (0.97, 1.41)	0.09	−0.09 (0.05)	0.05	−0.02 (0.05)	0.69
	Cond	0.97 (0.86, 1.09)	0.64	0.88 (0.47, 1.65)	0.69	1.03 (0.65, 1.64)	0.90	−0.02 (0.05)	0.78	−0.01 (0.06)	0.82
	NT	0.99 (0.90, 1.09)	0.87	1.13 (0.68, 1.87)	0.64	1.10 (0.75, 1.61)	0.62	−0.03 (0.04)	0.46	0.01 (0.04)	0.85
	CxNT	1.03 (0.89, 1.20)	0.66	1.02 (0.89, 1.18)	0.76	0.96 (0.84, 1.09)	0.52	0.02 (0.06)	0.69	0.03 (0.05)	0.56
IMP	Sex	1.02 (0.76, 1.37)	0.91	0.58 (0.41, 0.83)	0.00	0.91 (0.61, 1.34)	0.63	0.04 (0.03)	0.20	−0.04 (0.04)	0.23
	Age	1.41 (0.91, 2.18)	0.01	1.60 (1.14, 2.23)	0.01	1.54 (1.19, 1.99)	0.00	0.09 (0.03)	0.00	0.17 (0.05)	0.00
	Edu	0.90 (0.75, 1.09)	0.29	1.03 (0.82, 1.30)	0.80	1.17 (0.98, 1.40)	0.09	−0.05 (0.02)	0.04	−0.02 (0.05)	0.65
	Cond	0.87 (0.53, 1.43)	0.59	0.98 (0.51, 1.87)	0.95	0.87 (0.58, 1.29)	0.48	−0.03 (0.06)	0.64	0.00 (0.06)	0.99
	IMP	1.14 (0.74, 1.75)	0.55	1.34 (0.74, 2.44)	0.33	0.92 (0.47, 1.81)	0.81	0.04 (0.05)	0.47	0.02 (0.05)	0.65
	CxIMP	1.05 (0.93, 1.20)	0.42	0.96 (0.82, 1.13)	0.61	1.07 (0.92, 1.25)	0.36	0.05 (0.06)	0.33	−0.00 (0.06)	0.95
SS	Sex	1.04 (0.77, 1.41)	0.80	0.58 (0.39, 0.86)	0.01	0.91 (0.57, 1.44)	0.69	0.04 (0.03)	0.20	−0.04 (0.04)	0.26
	Age	1.41 (1.06, 1.86)	0.02	1.59 (1.14, 2.20)	0.01	1.54 (1.18, 2.01)	0.00	0.14 (0.05)	0.00	0.17 (0.05)	0.00
	Edu	0.91 (0.67, 1.24)	0.34	1.03 (0.82, 1.30)	0.79	1.17 (0.97, 1.41)	0.09	−0.09 (0.05)	0.06	−0.02 (0.05)	0.70
	Cond	1.06 (0.72, 1.57)	0.77	1.03 (0.55, 1.96)	0.92	0.96 (0.64, 1.44)	0.85	0.03 (0.04)	0.41	0.03 (0.05)	0.54
	SS	1.21 (0.77, 1.90)	0.42	1.14 (0.68, 1.94)	0.61	1.02 (0.62, 1.69)	0.93	0.06 (0.04)	0.10	0.06 (0.04)	0.15
	CxSS	1.76 (1.38, 2.24)	0.04	0.68 (0.31, 1.46)	0.32	1.01 (0.53, 1.92)	0.98	0.24 (0.05)	0.04	−0.08 (0.05)	0.06

Note. Adjusted for cluster effects. AS = anxiety sensitivity, NT = negative thinking, IMP = impulsivity, SS = sensation seeking. OR = odds ratio, CI = confidence interval, *β* = standardized logistic regression coefficient, Edu = education, C = condition.

drinking frequency slope ($\beta = -0.10, p = 0.03$). This indicates that adolescents with the personality trait SS who received the intervention increased their binge drinking behaviour less than those adolescents with the same personality trait in the control condition. The fit between model and data was good for both binge drinking (χ^2 [N = 699] = 29.095, $p < 0.03$; RMSEA = 0.033 (0.000–0.091), CFI = 0.981, TLI = 0.964) and binge drinking frequency (χ^2 [N = 699] = 33.571, $p < 0.01$; RMSEA = 0.039 (SD = 0.016), CFI = 0.982, TLI = 0.967). No significant effects were found on the intercepts and slopes for the outcome measures alcohol use and drinking problems, nor for the other personality traits IMP, NT and AS.

4. Discussion

In a previous study on the effectiveness of Preventure in the Dutch setting, no program effects were found when looking at the incidence of alcohol use at the follow-up points separately (Lammers et al., 2015). By taking the development of alcohol use over time into account, significant program effects were found over the whole group of young adolescents (Lammers et al., 2015). In the current secondary analyses of the Preventure programme, we explored whether certain theory-based subgroups would benefit more from the Preventure intervention than others. The interaction analyses revealed that the Dutch Preventure intervention had beneficial effects for young adolescents with the personality traits anxiety sensitivity and sensation seeking. Adolescents scoring high on SS seemed to benefit most from Preventure when it comes to binge drinking and binge drinking frequency outcomes. Adolescents scoring high on AS benefit most from Preventure with regard to the outcome alcohol use at 12 months post-intervention. Post hoc latent growth analyses revealed that the intervention resulted in significantly less growth in binge drinking and binge drinking frequency over 12 months' time within adolescents scoring high on SS. In our study we used both regression analyses and latent growth analyses. Combining these two approaches increased the reliability of the outcome measurements and provided a more complete picture of the intervention effects of the Preventure programme. In order to meet the CONSORT statement we used regression analyses as the primary analyses, and the latent growth analyses as post hoc analyses.

The findings of the current study are in line with previous studies of Conrod and colleagues. According to trials among Canadian and British young adolescents (Conrod et al., 2006; Conrod et al., 2008), Preventure was particularly effective in preventing the incidence of binge drinking in those students with an sensation seeking personality, and preventing alcohol use among students with an anxiety sensitivity personality, after four and six months post-intervention. Consistent with the British trial (Conrod et al., 2011), the Preventure programme had an impact in reducing the relationship between SS and the growth in binge drinking

Table 3
Interaction effects education on alcohol use outcomes at 12-month follow-up (T3) among alcohol users at baseline.

	Binge drinking		Alcohol use		Problem drinking		Binge drinking frequency		Alcohol frequency	
	OR (95% CI)	*p*	OR (95% CI)	*p*	OR (95% CI)	*p*	*β* (*SE β*)	*p*	*β* (*SE β*)	*p*
Sex	1.01 (0.93, 1.09)	0.83	0.58 (0.40, 0.84)	0.00	0.91 (0.61, 1.37)	0.66	0.04 (0.03)	0.18	−0.04 (0.04)	0.25
Age	1.44 (1.11, 1,88)	0.01	1.65 (1.21, 2.26)	0.00	1.55 (1.19, 2.03)	0.00	0.15 (0.05)	0.00	0.18 (0.05)	0.00
Condition	0.88 (0.70, 1.11)	0.28	0.47 (0.12, 1.88)	0.28	0.83 (0.30, 2.37)	0.74	−0.14 (0.09)	0.11	−0.15 (0.13)	0.25
Education	0.90 (0.76, 1.06)	0.20	0.89 (0.67, 1.18)	0.43	1.14 (0.89, 1.46)	0.30	−0.16 (0.06)	0.01	−0.09 (0.06)	0.15
Cond × Edu	1.47 (1.14, 1.88)	0.04	1.32 (1.06, 1.65)	0.05	1.06 (0.075, 1.51)	0.74	0.25 (0.09)	0.04	0.47 (0.11)	0.01

Note. Adjusted for cluster effects. OR = odds ratio, CI = confidence interval, *β* = standardized logistic regression coefficient, Cond = condition, Edu = education.

after 12 months. No significant effects were found for the personality traits impulsivity (IMP) and negative thinking (NT) at the different follow-up points, nor did the intervention significantly impact the relationship between the personality traits IMP, NT and AS, and the growth in binge drinking, which is in line with the findings of Conrod et al. (Conrod et al., 2006; Conrod et al., 2008; Conrod et al., 2011).

So, consistent with the Canadian and British trials, there was some evidence that intervention effects for AS were stronger in relation to alcohol onset measures, and intervention effects for SS were more consistently revealed for binge drinking outcomes. The personality-specific intervention was effective in reducing the drinking behaviour that is most problematic for each personality type. These findings provide further support for the necessity of personality targeting interventions for preventing alcohol misuse among young adolescents.

No significant effects were revealed on problem drinking for the personality traits. We expected these to be present particularly among the AS and NT personality traits. Conrod and colleagues only found effects in reducing problem drinking at the longer term, after 24 months post-intervention (Conrod et al., 2011; Conrod et al., 2013). This may implicate that curbing the growth of drinking in early onset drinkers may delay the onset of problem drinking over the longer term. Future research is needed to examine outcomes beyond 12 months post-intervention to see whether the intervention is effective for alcohol-related problems at later ages for AS and NT.

Because of the different education levels within the Dutch school system, we tested the differences between students receiving education at a 'high level' (e.g. pre-university education) and students receiving education at a 'lower level' (e.g. vocational training). Conrod et al. (Conrod et al., 2006; Conrod et al., 2008; Conrod et al., 2011; Conrod et al., 2013) did not distinguish between different levels of education, because of the different school systems in Canada and England. In our study, the significant effects were found mainly among students with lower-level education. It seems that students in this education category benefit more from the intervention than students with higher education, perhaps because they are more engaged in alcohol drinking and binge drinking than students with higher level of education (Verdurmen et al., 2012). These findings are consistent with findings from a previously tested Dutch alcohol parent and student prevention program. In this study moderation effects were found for educational level on heavy weekly alcohol use, indicating that lower educated adolescents profited more from the alcohol intervention than students with a higher education level (Verdurmen et al., 2011; Koning et al., 2009). Our results can be interpreted as indicating that Preventure is most effective among young adolescents at a lower level of education, and is best suited for this type of education. Consistent with previous studies of Conrod and colleagues (Conrod et al., 2006; Conrod et al., 2008; Conrod et al., 2011; Conrod et al., 2013), and as expected, no significant moderation effects were found for gender.

4.1. Limitations

The current study has some limitations. First, our study was confined to students who voluntarily participated in the intervention and for whom parental consent was obtained. Fifty-two percent of the potential participants did not consent or failed to obtain parental consent. For the group of students who were identified as high risk based on the screening, no differences were found on demographic variables or the prevalence of alcohol use between those who participated in the study and those who did not provide consent. However, the group of students who participated can be a selective group, because they can differ on other characteristics which were not measured. The results may therefore not be generalizable to the whole group of students who are screened positive for one of the personality traits. Second, the use of self-reports might have led to measurement errors, due to situational and cognitive influences (Brener, Billy, & Grady, 2003). To overcome situational influences (e.g. social desirability) and to optimize measurement validity, we guaranteed full confidentiality (anonymity) to our participants (e.g. (Koning et al., 2009; Del Boca & Darkes, 2003)). Third, the intervention and control conditions differed at baseline on sex, age, level of education and binge drinking status. The intervention condition included more girls, slightly younger students and more students with a low education level, and the students were more likely to engage in binge drinking. Randomization at school level is probably responsible for this unequal distribution. Therefore, cluster level effects were accounted for in the analyses. A possible solution for future trials might be to randomize within schools, although one should be careful to avoid contamination effects.

Preventure has been evaluated in different countries (Conrod et al., 2006; Lammers et al., 2015; Conrod et al., 2013), and the results on alcohol misuse appear to be fairly robust. Our results show that the personality targeted Preventure is a promising intervention in the Dutch setting, especially for secondary schools with a lower level of education (vocational schools). Preventure is complementary to universal alcohol prevention programmes. Whereas universal alcohol prevention is most effective in increasing knowledge and changing attitudes among young adolescents in general, selective prevention seems to be more effective in changing alcohol misuse behaviour among high risk young adolescents more specifically. Future research could be focused on populations with a higher proportion of high-risk adolescents, such as the setting of special education or youth with mild mentally disabilities.

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Authors' contributions

JL and FG were responsible for data collection and data analysis. JL and MK were responsible for reporting the study results. PC, the principal investigator of the Preventure trials in the UK and Canada, trained the Dutch therapists and contributed to writing this report. MK, RE and RW were supervisors. All authors read and approved the final manuscript.

Declarations of interest

J.L., F.G., M.K. and R.E. declare that they have no conflicts of interest. P.C. is the developer and licensee of Preventure. In 2012 P.C. wrote a chapter for an ERAB (the European Foundation for Alcohol Research) book, 'Underage Drinking', for which she received an honorarium, and also received reimbursement of the travelling costs for a meeting in Brussels. In 2008, P.C. received a research grant from ERAB for a project on social networks and drinking behaviour of adolescents. P.C.'s salary was supported by a research fellowship from Action on Addiction when this trial commenced and is currently supported by a Senior Scientist Award (Chercheur Boursier-Senior) from the Fondation de Recherche du Quebec-Sante (FRQ-S). R.W.'s research is paid primarily by national grant agencies (N.W.O., National Science Foundation, Netherlands; ZON-MW, Medical Research Council, the Netherlands) and university money. In addition, R.W. had EU funding (FP7 Alice Rap). His research is not sponsored by tobacco companies. R.W. gave a paid talk for Lundbeck pharmaceutical company, was co-applicant in two awarded grants from ERAB and was also involved in the ERAB/ABMRF Underage Drinking Report (2012). ERAB is an independent foundation paid by the alcohol-industry that awards alcohol-related research after an independent scientific evaluation (peer-reviewed), with guarantee of completely independent scientific expression (in accordance with the Dublin principles), http://www.api.or.at/sp/alcoholpolicy%20dokumente/dublinpriciples.pdf.

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Chapter IX

HUMOR AND MENTAL HEALTH

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ABSTRACT

The idea that humor can be associated with mental well-being has been spreading in recent years; therefore, a discrete body of research has investigated the potential benefits of humor for mental health and psychological well-being. Some evidence has emerged that humor produces positive short-term emotional changes and may attenuate negative emotions as a result of cognitive distraction. Nevertheless, cross-sectional studies have found no single correlations between sense of humor and the ability to regulate negative emotions. Different humor styles have been found to mediate the relationship between positive personality qualities and well-being, although the mediator models used to explain this relationship are still far from producing conclusive results. Research findings make clear that humor is a multidimensional construct, consisting of components that can affect mental health and well-being either positively or negatively. Consequently, various humor styles may have different effects on social interactions as well as mental health. Therefore, in examining the potential role of humor in improving mental health processes and psychological well-being we should take into consideration various humor styles, contexts and circumstances.

INTRODUCTION

In contemporary Western culture, a sense of humor is widely viewed as a highly desirable personality characteristic. Individuals with a greater sense of humor are thought to cope better with stress, to get along well with others and enjoy better mental and even physical health [1] . The idea that humor is associated with mental well-being has spread in recent years. In this regard, we can recall a work of Carol Ryff [2], which was intended to verify whether the six criteria of psychological well-being she proposed were similar to those shown by ordinary people. This study found that the best indicators associated with positive functioning identified by middle-aged and older adults also included a sense of humor.

During the late 1990s, humor was included in the list of the core strengths of character or enduring positive human traits identified by Positive Psychology [3]. The Values in Action (VIA) Classification of Strengths identifies 24 components of good character that contribute to optimal human development and organizes them under six broad virtues. Virtues are the core characteristics valued by moral philosophers and religious thinkers: wisdom, courage, humanity, justice, temperance, and transcendence. The last one (i.e. transcendence) includes strengths that build connections to the larger

universe and provide meanings: appreciation of beauty and excellence, gratitude, hope, humor, and spirituality. Humor in the VIA is conceptualized as a unipolar and unidimensional strength, which scope is restricted to those forms that serve some moral good. However, humor is a multidimensional concept and the VIA classification does not cover all of the virtues-related humorous behaviors; hence, further research is required to investigate the role of virtue in humor [4]. Unfortunately, the strength of humor has not received much attention from Positive Psychology researchers, although it has much to offer for the promotion of well-being.

Components of humor have been seen as effects of psychological and physical states of a person. Psychological conditions that have been claimed to be related to humor in that way include depression, autism, borderline personality disorder, hysteria, schizophrenia, mood disturbance, psychological repression, aggression, and anxiety [5]. A recent review reported scientific evidence of the influence of depression on the ability to laugh, which suggests that reduction of laughter frequency is a symptom of depression and that its increase may be used as a marker of clinical improvement [6].

On the other hand, aspects of humor could also be determinants of physical and mental conditions. I tried to summarize the research on humor's effects on physical health in the previous chapter. The aim of this chapter is to review the relevant, recent research on the effects of humor on psychological conditions.

First to address this issue, I briefly describe the mechanisms that have been hypothesized to explain the influence of humor and laughter on mental health and well-being.

An important mechanism through which a sense of humor may be beneficial to mental health is by contributing to one's ability to regulate emotions, which is an essential aspect of mental health [7]. Sense of humor might produce "habitual amusement-related positive emotions or moods" [8]; in other words, it might directly affect psychological well-being by making people feel better emotionally. This conceptualization of sense of humor asserts that it should be positively related to measures of positive affect (including happiness) and negatively related to measures of negative affect (including depression).

An indirect contribution of sense of humor to mental health is to enhance the performance on tasks that demand directed attention by inclining a person toward positive affect. This indirect contribution was demonstrated experimentally in the late eighties by Isen and her colleagues [9]. The positive mood and flexible thinking induced by several methods, including exposure to humorous material, was found to contribute to the effective functioning in attention-demanding situations.

Another mechanism states that humor might indirectly benefit health and mental well-being through an interpersonal mechanism, by increasing one's level of social support. Individuals who use humor in an affiliative and non-hostile manner are able to reduce effectively interpersonal conflicts and tensions and enhance positive feelings in others. As a result, they may enjoy more numerous and satisfying social relationships [10]. In fact, it may be easier for individuals with a great sense of humor to establish and maintain friendships, to develop a rich network and thus, to get the mental and physical health benefits that derive from social support. This hypothesized mechanism focuses on interpersonal aspects of humor and the social competence with which individuals express humor in their relationships, rather than the frequency with which they engage in laughter. This model emphasizes the distinction between styles of humor that facilitate relationships and enhance social support, and other forms that are potentially maladaptive.

Finally, Can and colleagues [11] provided a model to understand the actual processes through which effective and ineffective styles of humor may be relevant to psychological well-being. The proposed model assumes that humor promotes well-being through positive personality qualities that serve as mediators in the relationship between humor styles and perceptions of stress. Using humor effectively, through higher levels of self-enhancing humor and lower levels of self-demeaning humor, can help to

maintain a more positive personal style, characterized by higher positive affectivity and positive qualities like optimism, happiness, and hope.

In conclusion, implications of humor for positive mental health were proposed to be related to the abilities to regulate negative emotions and enjoy positive emotions, to establish meaningful relationships with others, and possess a set of positive personality characteristics and resources.

A review published in 1999 [5] indicated that, in general, humor as a response (e.g. laughter) may contribute to a reduction of existing mental health problems, whereas a great sense of humor can beneficially influence mental health by moderating the perceived intensity of negative life events. A more recent review [10] described research investigating the potential benefits of humor in regulating negative emotions, coping with stressful events, and establishing meaningful social relationships. Crucial points emerge from this review. Experimental laboratory research confirmed a short-term beneficial effect of humor and laughter, but provided little evidence for longer-term psychological benefits. Correlational studies found weak or inconsistent evidence for mental benefits of a sense of humor. Research on humor styles found that positive and negative styles of humor are differentially correlated with the individuals' experiences of close relationships, emotional well-being and healthy functioning.

DOES HUMOR PREDICT POSITIVE AFFECT?

Positive affect can be defined as a state of pleasurable engagement with the environment eliciting feelings, such as happiness, joy, excitement, enthusiasm, and contentment [12]. Positive affect is part of the concept of subjective well-being that includes life satisfaction, absence of negative emotions, optimism, and positive emotions [13]. It is also part of the concept of psychological well-being that encompasses trait-like dispositions, such as optimism and cheerfulness [14]. The literature on the relationship between affectivity and health is consistent. The strongest link with health was found with trait affective styles, which reflects a person's typical emotional experience, rather than state affect. The presence of positive affect, as a dispositional state was found to be associated with positive health experiences, such as a stronger immune response, fewer illness symptoms and pain reported, a better health in general and longevity [13,15–17]. Positive affect was also associated with protective psychosocial and behavioral factors, such as strong social connectedness, perceived social support, preference for adaptive coping responses, and performing health behaviors [13].

To the extent that humor produces a positive emotional state [18], we can safely say that it has a direct effect on psychological well-being of individuals.

Investigations of humor and emotions have demonstrated, in a number of laboratory experiments, the effects of humor on mood. In particular, smiling and laughter are expressions of the positive emotion of mirth that is induced by the perception of humor; the act of smiling and laughing by itself, even when done artificially, may induce feelings of amusement and mirth, at least temporarily [19–22]. These experiments provided fairly consistent evidence of short-term effects of humor on positive mood and feelings of well-being in the laboratory.

A more recent cross-sectional study [23] confirmed that a good sense of humor predicted well-being of the people who use it. Results indicated that only humor appreciation was an effective predictor of emotional well-being and personal development, whereas another dimension evaluated in this study (i.e., contact with nature) was a predictor of psychological functioning.

However, in the literature there are also studies that did not confirm the hypothesis that humor has positive effects on mental well-being. Among them, we recall the study of Kuiper and Martin [24] indicating that individuals with a greater tendency to laugh at everyday life did not show higher levels of positive affect.

In conclusion, findings for the role of laughter and sense of humor as predictors of psychological well-being are to date consistent, although less than those on the relationship between stable differences in affectivity and health.

CAN HUMOR ATTENUATE NEGATIVE EMOTIONS?

Chronic negative affect has been shown to be related to poorer health experiences [25], and recent levels of negative affect have proven to be a reliable predictor of physical health [26]. For example, negative emotions can intensify a variety of health threats and contribute to prolonged infection and delayed wound healing. Accordingly, Kiecolt-Glaser and colleagues [27] argued that distress-related immune deregulation may be one core mechanism behind the health risks associated with negative emotions.

Besides increasing positive moods, there is experimental evidence that humor can reduce negative moods, thus bringing benefits to health. Laboratory experiments found that exposure to a humorous video led to a significant reduction in reported levels of anxiety [28,29]. There is also some evidence that humor can reduce the effects of experimentally induced depressed moods [30].

A recent study of medical education explored the effectiveness of humor when used as intervention in a large group teaching over negative emotions amongst students [31]. Humor was found to be truly effective in relieving students on their negative emotions of depression, anxiety and stress.

Taken together, these findings suggest that humor produces positive short-term emotional changes. Cross-sectional studies have found the presence of at least moderate negative correlations between some humorous aspects and measures of neuroticism, anxiety, and depression [32]. Nevertheless, other experimental studies have not confirmed an inverse relationship between humor and levels of anxiety and depression [10]. Furthermore, some other cross-sectional studies found no single correlations between sense of humor and anxiety [33].

A recent study aimed to demonstrate that the cognitive demands involved in humor processing can attenuate negative emotions [34]. The authors hypothesized that humorous stimuli attenuate negative emotion to a greater extent than do equally positive non-humorous stimuli. Participants reported less negative feelings in both mild and strongly negative trials with humorous, positive stimuli than with non-humorous positive stimuli, whereas humor did not differentially affect emotions in the neutral trials. Cognitive demanding stimuli were more effective in regulating negative emotions than those that were less demanding. These findings supported the idea that humor may attenuate negative emotions as a result of cognitive distraction.

HUMOR STYLES AND PSYCHOLOGICAL WELLBEING

Martin and colleagues [35] have recently proposed a new approach to the study of individual differences in the use of humor that takes into account the multidimensionality of this construct. They identified four different styles of humor, or ways in which people use humor in their daily lives: two potentially detrimental styles (aggressive and self-defeating humor) and two potentially beneficial styles (affiliative and self-enhancing humor). Benevolent humor is used to be accepted socially (affiliative) or to deal with stressful situations (self-reinforcement), whereas non-benevolent humor is used to tease others (aggressive) or self-mock (worthlessness). Different humor styles were found to be associated with health and psychological well-being in different ways [35]. The self-reinforcing and the affiliative styles correlated negatively with anxiety and depression and positively with self-esteem and a global score of psychological well-being. On the other hand, higher scores on the worthlessness humor style were associated with increased anxiety, depression, psychiatric symptoms, and lower self-

esteem and well-being. The aggressive style was related to hostility and aggression. These results were confirmed by other studies. In one of these [36], the benevolent humor styles were associated with higher self-esteem, lower levels of depression and anxiety, and multiple self-competencies associated with better coping. The non-benevolent humor styles were instead associated with a lower self-esteem, higher levels of anxiety and depression, and lower perceptions of empowerment and self-competencies. In another study [37], self-enhancing humor was negatively related, and self-defeating was positively related to both evaluations of past stressors and anticipated future stressors. The two self-directed styles of humor were reliably related to well-being outcomes, although they were not shown to be both adaptive: self-defeating humor style was associated with poorer adjustment and lower well-being than self-enhancing humor style [37,38].

In a cross-cultural study, Kazarian and Martin [39] investigated the differences in the use of humor styles, by gender and culture, among Lebanese, Canadian and Belgian students. Lebanese students showed a lower use of adaptive humor, compared to the Canadians and less use of affiliative and aggressive humor styles than the Belgians. Canadian and Belgian males used aggressive humor more than the female of their own country. In this study, the association between humor styles and mental health was only partly supported by empirical evidence. These results confirm the hypothesis that only some types of humor are associated with mental well-being, while others may even have a harmful effect [35].

Taken together, these studies support the idea that sense of humor is a multidimensional construct, consisting of components that can affect mental health and well-being either positively or negatively.

HUMOR AND OTHER PERSONAL RESOURCES

People who are high on positive personality qualities, such as optimism, autonomy, and personal growth tend to report a higher level of positive functioning, including experiencing higher levels of positive affect, greater life satisfaction, increased level of self-esteem, in addition, to the absence of negative affect. These positive personality qualities are also associated with more positive approaches to coping with stressful situations and to a better overall health. Research supports the health benefits of greater optimism [40], higher levels of hope as a stable trait [41], and stable differences in happiness [42]. Effective use of humor may be one way that people with more positive personality qualities use to maintain their positive outlooks. Indirect support to this idea came from research indicating that a good sense of humor was associated with higher levels of cheerfulness [35]. Another positive quality that was associated with humor was hopefulness. In fact, a study found that participants who watched a comedy video, as compared to those who viewed a non-humorous video, reported a greater increase in feelings of hopefulness [43]. Some research has also shown that people with a greater sense of humor have a better vision of themselves. For example, employees engaged in a guided program of non-humor dependent laughter demonstrated a significant increase in several different aspects of self-efficacy in the workplace, including self-regulation, optimism, positive emotions, and social identification, and they maintained these gains at follow-up [44].

Several studies on humor styles explored the relation between adaptive and maladaptive humor and positive personality characteristics. Looking at different humor styles affiliative and self-enhancing humor were found to be positively correlated with indicators of positive mental health, such as psychological well-being, self-esteem, and optimism [35,45], and negatively correlated with depression [46,47], anxiety [48], loneliness [49], and global distress [38]. On the other hand, aggressive and self-defeating humor showed negative associations with indicators of positive mental health, and positive correlations with various negative emotions and impaired psychosocial functioning (for a review see Martin [10]). In a recent study [37], initial evidence was found to support a mediator model in which

the role of humor styles in explaining perceptions of stress was mediated through a composite of positive personality styles, including optimism, hope, and happiness (i.e., humor styles → positive personality → perception of stress). A different mediator model was tested in another recent study [50] involving a sample of Serbian young adults. A mediating role of humor styles in the relationship between personality traits and psychological well-being was partially shown. Self-enhancing humor style mediated the relationship between extraversion, neuroticism and satisfaction with life, whereas affiliative humor style partially mediated the relationship between neuroticism and affective well-being (i.e., personality → humor styles → affective well-being).

A recent study [51] investigated humor styles in the context of explicit (i.e., conscious, deliberate) and implicit (i.e., automatic, habitual) self-esteem. Results showed that participants with a self-defeating humor style had damaged self-esteem, defined as a combination of low explicit and high implicit self-esteem. A possible mechanism behind these results could be that the frequent use of self-defeating humor might result in a downward spiral of social rejection, resulting in low explicit social self-esteem. Nevertheless, the correlational design of this study did not allow making causal inferences. Other recent studies found that humor styles mediated the relationships between positive and negative self-evaluation standards and psychological well-being. For example, Dozois and colleagues [52] found that self-enhancing and self-defeating humor styles mediated the relationship between early maladaptive schemas and depressed mood. Early maladaptive schemas influenced information processing, emotional reactions to life situations, self-control, and interpersonal relationships. Furthermore, the relationship between the primary evaluative component of the self-schema and psychological well-being (rated in terms of social self-esteem and lower depression) was mediated by a more affiliative humor, whereas a more self-defeating humor, induced by negative self-evaluative standards, led to a decrease in social self-esteem [53].

Taken together, these findings show that a good sense of humor or humor styles might be reliable predictors of a better mental health, even if their predictive power is less than that of other positive personality qualities. Nevertheless, the mechanisms linking these variables and the mediator models used to explain them are still far from exhaustive and conclusive.

DOES HUMOR IMPROVE INTERPERSONAL PROCESSES?

Research has only recently been directed to investigate the potential effect of humor on interpersonal relationships, since humor was supposed to improve interpersonal processes and facilitate social relationships [1].

Studies of dating and married couples have consistently shown that greater satisfaction with the relationship is associated with a good sense of humor of the partner and the amount of humor and laughter shared between the spouses [10]. A more recent study [54] found that partners tended to resemble each other with regard to the sense of humor. However, couple similarity on sense of humor was unrelated to the relationship quality, in contrast with what was expected. On the contrary, another recent study found little similarity within couples on humor styles, but it found that the best predictors of satisfaction were perceptions of a partner's humor style [55].

In a qualitative study of dating relationships, Amy Bippus [56] drew a distinction between humor that serves a bonding function and more negative types, such as cruel, inappropriate, and overbearing humor that may be injurious to the relationship. Humor styles, together with conflict styles, were found to serve as a mediator between the attachment style and relationship satisfaction in the context of romantic relationships [57]. Specifically, humor styles reflecting attitudes about others were related to the avoidance attachment style, while those reflecting attitudes about the self were related to the anxiety attachment dimension.

Another study on humor in close relationships underlined the necessity to evaluate separately positive, negative, and instrumental uses of humor by each partner, since they were differentially associated with marriage satisfaction [58].

A few recent studies have examined associations between potentially healthy and unhealthy humor styles and variables having to do with close relationships. The distinction between positive and negative uses of humor appeared to be critical, since affiliative and aggressive styles had opposed relationships with the couples' satisfaction [59]. Moreover, a recent study showed that the two other-directed humor styles explained much more variance of the relationship satisfaction than the self-directed styles. Thus, they were potentially crucial to consider as personal qualities, but their relevance likely was greater when the uses of humor were directed toward interpersonal, rather than intrapersonal, goals [55].

Overall, correlational studies examining associations between trait humor and several variables relevant to personal relationships found a positive correlation of humor with intimacy, empathy, social assertiveness, and interpersonal trust [10].

Studies on general social relationships confirmed the role of humor styles in facilitating social interactions. A recent study [60] found that labeling social comments as humorous had positive effects on recipients' reactions to these comments. Furthermore, when the acquaintance was described as feeling depressed, affiliative comments made in a humorous fashion led to more positive reactions than did non-humorous affiliative comments. A correlational study on the relation between shyness and humor styles found a significant negative correlation between shyness and affiliative humor and a positive correlation between shyness and self-defeating humor, indicating that shy people, who have difficulties in social situations, tend to use less adaptive humor styles [61]. Finally, coping humor was found to be positively associated with pleasure and self-confidence people attributed to their interactions and with time they spent with others although the strength of this relation was moderated by depression [62].

Studies on peer-relations in childhood and adolescence also seem to provide initial empirical support to the relationship between humor styles and peer acceptance. One of these studies investigated how different humor styles may bear on peer relationships and bullying during middle childhood. Results indicated that adaptive humor styles helped the child's status within the peer group, whereas maladaptive humor styles hindered it [63]. Another study showed that positive humor styles and trait cheerfulness were positively correlated with various domains of social competence in undergraduate students, whereas negative humor styles and trait lousy mood were negatively correlated with social competence [64].

However, there is also some evidence that humor may play a negative role in interpersonal relationship. For example, one study on close relationships found that for men higher coping humor was associated with lower marital satisfaction and greater negative affect and verbal negativity during marital discussions [65]. Another study indicated that greater humor expression by husbands during a problem discussion predicted a greater likelihood of separation in newly married couples, in the context of serious life stress [66]. A qualitative study on the role of humor among Finnish school boys found that violent humor was used as a resource and strategy for boys to construct masculinity and gain social status [67]. The effect of such a negative humor strategy might have serious consequences on students' lives.

This emerging body of research makes clear that humor styles, as expressions of a sense of humor, cannot be regarded as uniformly positive in relation with social interaction. Findings demonstrate the usefulness of treating humor as a multidimensional variable to understand better the roles it might play across relationships. Therefore, in examining the potential role of humor in improving interpersonal processes we should take into consideration various humor styles, gender differences, and specific

interpersonal contexts and circumstances.

THE USE OF HUMOR IN MENTAL ILLNESS

Probably due to what seems to be the potential benefit of humor and laughter, in the last 30 years we have seen an increase in the use of humor with individuals with mental illness.

A recent review [6] reported some evidence supporting the hypothesis of the therapeutic action of laughter on depression. Empirical findings seem to demonstrate that laughter may improve mood directly, moderate negative consequences of stressful events on psychological well-being and mediate the normalization of the hypothalamic, pituitary, adrenocortical system dysfunctions involved in the depression pathogenesis. Through these mechanisms, laughter can counteract depressive symptoms. Furthermore, the favorable effects of laughter on social relationships and physical health may have a role in influencing the ability of depressed patients to face the disease.

Results of empirical studies on the therapeutic use of humor in depressed patients showed that humor proved to be helpful. This was the case with the use of humor in the group therapy of geriatric patients with depression and Alzheimer's [68]. A recent pilot study found significant short-term mood improvement after training addressing humor skills in patients with major depression, although there was no significant long-term improvement of depressive symptoms [69]. In a study of hospitalized adolescent psychiatric patients, higher coping humor was associated with lower levels of depression and higher self-esteem, although it was unrelated to feelings of hopelessness [70]. A study of hospitalized adult psychiatric patients found that higher sense of humor tended to be associated with lower depression and higher self-esteem and positive moods among clinically depressed patients [71].

Overall, these findings give some support to a general protective role of humor in mood disturbance.

Studies on the effect of humor styles on mental health specify that only the benevolent styles of humor have a protective role. Recently, Düşünceli [72] investigated the effect of humor styles on psychopathology among university students in Turkey. Results of a structural equation model indicated that the self-enhancing humor style decreased symptoms of a variety of psychological disturbances, such as somatization, obsessive compulsive disorder, anxiety and phobic anxiety, interpersonal sensitivity, depression, anger-hostility, and psychotic disorder. The affiliative humor style also decreased the symptoms of mood disorders. The self-defeating humor style, in contrast, increased the symptoms of mood and anxiety disorders. These findings support the result of previous studies [35] showing that self-enhancing humor style predicted anxiety disorders negatively, whereas self-defeating humor style predicted anxiety disorders positively.

Despite the presence of studies that have not confirmed an inverse relationship between humor and levels of anxiety and depression [73], other studies supported this view. For example, in a study on personality-vulnerability dimensions and positive and negative styles of humor, undergraduates with higher levels of depressed mood reported less use of self-reinforcing and affiliative humor, and an increased use of self-depreciating humor [74]. This study took into account two personality traits, autonomy and social dependency (i.e., tendency to base their self-esteem on the opinions of others). It suggested that self-reinforcing style, being inversely correlated with social dependency, could protect people from depression in response to situations of social rejection.

Olson and colleagues [75] found that among individuals with high rumination, those with higher adaptive humor styles (especially self-reinforcing humor style) had significantly lower levels of dysphoria than individuals with high rumination and lower adaptive humor. Rumination is a negative, anxious repetitive thought that is highly correlated with depression. Based on these results, humor was hypothesized to act as a distracter from ruminative thoughts, also to mitigate the negative effects of rumination, thus indirectly helping prevent depressive episodes [76]. However, an experimental study

did not confirm the role of humor in either effectively distracting for rumination or reducing the amount of rumination [76].

In a community sample of Israeli adults, affiliative and self-enhancing humor styles on one hand, and aggressive and self-defeating humor styles on the other mediated the relationship between self-criticism, a trait that confers vulnerability to depression, and neediness, which is related to levels of depressive symptoms [77].

Pietrantoni and Dionigi [78] found that Italian people who had experienced a number of events perceived as negative and used more aggressive and worthlessness styles of humor were more prone to develop anxiety and depression than those using more adaptive humor styles. Hugelshofer and colleagues [79] found that higher levels of affiliative and self-enhancing humor and lower levels of self-defeating humor were each associated with fewer depressive symptoms in a large sample of students. Additionally, higher levels of affiliative humor provided a buffer against the deleterious effects of a negative attributional style, even though this relation varied between women and men. Chen and Martin [38] reported a similar pattern of relationships when looking at mental health based on self-reported symptoms.

Although a greater sense of humor seems to be related to lower severity of disturbance in clinically depressed individuals and to fewer depressive symptoms in healthy people, this does not seem to be the case among patients with schizophrenia. In one study, hospitalized patients with chronic schizophrenia were shown 70 comedy movies over a three-month period, while those in a control group were shown an equal number of non-humorous dramatic movies [80]. After these interventions, patients who had watched the comedy movies were rated by the staff as having significantly lower levels of verbal hostility, anxiety/depression and tension than those in the control group. The patients themselves reported greater perceived social support from the staff. The authors of the study acknowledged that these findings may have had more to do with the effects of the movies on the perceptions of the hospital staff than on the actual functioning of the patients. Another study of humor in hospitalized schizophrenic patients similarly found no relation between coping humor and self-report and psychiatrist-rated hostility, aggression, and anger [81]. Overall, the rather limited research on this topic provides little evidence that schizophrenic patients with high humor have a better psychological adjustment than are those with less of a sense of humor.

In a recent review of the literature, Marc Gelkopf [82] stated that empirical studies on the use of humor and laughter in people with serious mental illness have not produced consistent results, because of serious methodological shortcomings. In particular, most studies lack control groups, use non-standardized assessment tools, involve extremely small samples, and do not administer an adequate control stimulus for distinguishing between the effects of humor and those of positive emotions in general. Therefore, this field needs further investigation.

CONCLUSION

A discrete body of research has investigated the potential benefits of humor for mental health and psychological well-being. Findings for the role of laughter and sense of humor as predictors of psychological well-being are consistent, although less than those on the relationship between stable differences in affectivity and health. Some evidence has emerged that humor produces positive short-term emotional changes and may attenuate negative emotions as a result of cognitive distraction. Nevertheless, cross-sectional studies have found no clear correlations between sense of humor and the ability to regulate negative emotions. A good sense of humor or humor styles might mediate the relationship between positive personality qualities and well-being, although the mediator models used to explain this relationship are still far from exhaustive and conclusive. Research findings make clear

that humor is a multidimensional construct, consisting of components that can affect mental health and well-being either positively or negatively. Consequently, humor styles cannot be regarded as uniformly positive in relation with social interaction or with severity of disturbance in clinically depressed individuals and other mentally ill patients. Therefore, in examining the potential role of humor in improving mental health processes and psychological well-being we should take into consideration various humor styles, contexts and circumstances.

An area of research that has been understudied is related to the connection between humor and quality of life (QoL) outcomes in chronic disease. The few studies in the literature show conflicting results. In patients with head and neck squamous cell carcinoma, sense of humor, but not depression or anxiety levels, at diagnosis predicted QoL and depression level at 6 years follow-up [83]. In patients with systemic sclerosis, a progressive rheumatic disease that can be fatal in severe cases, humor coping did not significantly predict any of the disease-related outcomes, either cross-sectionally or longitudinally [84]. More recently, a sense of humor among patients with chronic obstructive pulmonary disease has proven to be associated with positive psychological functioning and enhanced quality of life, but laughing aloud was shown to cause acute deterioration in pulmonary function secondary to worsen hyperinflation [85]. Overall, these results indicate that humor may not be directly beneficial to QoL in chronic disease.

We can speculate that conflicting results in research on humor and mental health may be related to difficulties in conceptualization and measurement of the sense of humor. The various pieces of this process have been identified, as much progress has been made in defining the key aspects of humor; however, what is still missing is the full view of the complex connection between them.

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ORIGINAL RESEARCH

An innovative approach for the assessment of mood disturbances in patients with eating disorders

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Objective. Assessment of mood in eating disorders (EDs) has important clinical implications, but the current standard psychiatric classification (DSM-5) has limitations. The aim of the current study is to broaden the evaluation of depressive symptomatology by providing a comprehensive and innovative assessment approach in EDs through instruments that capture clinical phenomena of demoralization, subclinical distress, and psychological well-being.

Methods. Seventy-nine patients who met diagnostic criteria for EDs of the *Diagnostic and Statistical Manual of Mental Disorders – Fifth edition* (DSM-5) were evaluated for depressive symptoms through Paykel's Clinical Interview for Depression, the Structured Clinical Interview for DSM-5 for major depressive episode and persistent depressive disorder, and the Diagnostic Criteria for Psychosomatic Research (DCPR) interview for demoralization. Further, self-report inventories encompassing psychological well-being and distress were used.

Results. Guilt, abnormal reactivity to social environment, and depressed mood were the most common depressive symptoms in the sample. DSM-defined depressive disorders were found in 55.7% of patients. The DCPR-demoralization criteria identified an additional 20.3% of the sample that would have been undetected with DSM criteria. Both DSM and DCPR diagnostic categories were associated with compromised psychological well-being and distress. Demoralization, unlike depression, was not associated with the severity of ED symptomatology.

Conclusion. The findings indicate that a standard psychiatric approach, DSM-5-based, captures only a narrow part of the spectrum of mood disturbances affecting patients with EDs. A broadened clinimetric assessment unravels the presence of demoralization and yields clinical distinctions that may entail prognostic and therapeutic differences among patients who would be otherwise simply labeled as depressed.

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Introduction

Depression is a frequent complication of eating disorders (EDs) and eating disturbances are common manifestations of depressive illness. The nature of the relationship, however, has been a source of controversy. A shared etiology postulates a common set of risk factors leading to the development of both EDs and depression.[1] Mood disorder onset might precede, follow, or develop simultaneously to the ED,[2] suggesting the need of specifically evaluating the individual case.

Diagnosis of depression in EDs constitutes a difficult task. Not surprisingly, comorbidity rates of major depressive disorder (MDD) display wide fluctuations from 40% to 80%[2,3] and lack predictive value as to response to antidepressant therapy.[4] Overlapping symptomatology, such as excessive weight loss, over-eating, sleep disturbance, fatigue, irritability, concentrating difficulties, and poor memory,[5,6] may account for inflated depression diagnoses in this clinical population.[7,8]

It has been suggested that exclusive reliance on conventional diagnostic classification systems may not

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provide sufficient clinical information, and assessment may benefit from additional sources of information.[9] One source derives from expanding collection of symptoms to clinical manifestations that frequently occur in the longitudinal development of mood disorder.[10] The Clinical Interview for Depression[11,12] is uniquely suited for capturing such manifestations. Another important element of the clinical process comes from the concept of demoralization,[13,14] a feeling state characterized by the perception of being unable to cope with some pressing problems and/or of lack of adequate support from others.[15] Demoralization, seldom investigated in EDs,[16] may co-occur with major depression or be independent[15] and is associated with adverse health outcomes and poor quality of life. Finally, a neglected area in assessment is psychological well-being, despite the availability of validated instruments and its growing importance in establishing resilience. Dimensions of positive functioning were found to affect the complex balance between positive and negative affects both in mood[17] and eating[18,19] disorders.

The aim of the current study was to broaden the evaluation of depressive symptomatology in EDs with instruments that capture clinical phenomena such as demoralization and subclinical distress and to examine their associations with dimensional measures of psychological well-being. More specifically, the study aimed to provide a comprehensive and innovative assessment of mood in EDs, capturing not only traditional psychiatric disturbances such as depression but also subclinical manifestations and psychological states such as demoralization. We hypothesize that a subset of ED patients exhibits demoralization syndrome in the absence of major depression and vice versa. In addition, we hypothesize that demoralization is associated with significant distress and impaired positive functioning.

Methods

Participants

Consecutively recruited patients ($n = 81$) who met Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5) criteria for EDs,[20] anorexia nervosa (AN), bulimia nervosa (BN), binge-eating disorder (BED), and other specified feeding or eating disorder (OSFED) were recruited from specialized ED treatment centers, Centro Gruber and Residenza Gruber (Bologna, Italy), before commencing treatment. ED diagnoses were established at intake by the consensus of a psychiatrist and a clinical psychologist independently using the Structured Clinical Interview for DSM-5 (SCID).[20] With the exception of two patients who refused to participate, all invited patients took part in the study ($n = 79$).

Ethical review committees of the Centro Gruber and Residenza Gruber in Bologna, Italy, approved the study and all patients provided written informed consent after the procedures were explained to them.

Measures and clinical variables

The evaluation was performed during routine assessment visits. Participants underwent detailed clinical interviews by a trained clinical psychologist and completed several self-rating questionnaires for the assessment of distress and psychological well-being. Data were collected between April 2016 and October 2017.

(1) Depressive disorder diagnoses were obtained using the SCID[20] for depressive disorders. For a diagnosis of major depression, patients had to exhibit five out of eight symptoms one of which was depressed mood or loss of interest or pleasure. The criterion of significant weight gain or loss or change in appetite was excluded as ED patients exhibit changes in weight and appetite in accordance with ED disorder diagnosis. For a diagnosis of persistent depressive disorder, in addition to depressed mood for most of the day, for more days than not for 2 years, the patients had to exhibit at least two additional symptoms, with the exception of poor appetite or overeating.

(2) Depressive symptoms were assessed with the change version of the Clinical Interview for Depression 20-item interview,[11,12] a dimensional observer-rated assessment instrument which consists of an expanded version of the Hamilton Rating Scale for Depression.[21] The interview covers 20 symptom areas. In this modified version, two items concerning appetite and weight gain/loss (items 12 and 13) were omitted due to the potentially confounding aspects of ED-related symptomatology. Each item is rated on a 1–7 point scale, with 1 indicating the absence of symptoms and 7 severe incapacitating manifestations. A score of 3 or above in the individual items was considered the cut-off for the presence of the symptom. The scale encompasses a wide range of symptoms (such as irritability and phobic anxiety) compared to other scales and is particularly suitable to assess subclinical symptoms of mood disorders.[10,12,22] One item concerning reactivity to social environment, selected from the full version of the CID, was added to the 18 items.

(3) Demoralization diagnosis was obtained using The revised Structured Interview for the Diagnostic Criteria for Psychosomatic Research (DCPR)-Demoralization Criteria.[14] Diagnoses were formulated independently of DSM diagnostic findings. Items of the interview for DCPR are scored through a yes/no response format. The structured interview has demonstrated high inter-rater reliability, and Cohen's kappa for demoralization was found to be 0.90.[23] The revised DCPR criteria[14] allow differentiation of two expressions of demoralization: helplessness (the individual maintains the capacity to react, but lacks adequate support) and hopelessness (when the individual feels he/she alone is responsible

TABLE 1. Socio-demographic characteristics of ED patient sample ($n = 79$)

Variable	Total ED sample (n = 79)	Outpatients (n = 42)	Inpatients (n = 37)	*p*
Age	28.83 ± 11.25	28.64 ± 12.38	29.06 ± 9.943	0.873+
Education (years)	14.44 ± 3.15	14.40 ± 3.03	14.48 ± 3.355	0.912+
Marital status (% single)	74.7	84.6	74.3	0.087*
Occupation (% employed or student)	75.3	92.3	51.35	0.001*
BMI (kg/m^2)				
AN (*n*)	(42): 15.26 ± 1.76	(17): 15.63 ± 1.69	(25): 15.00 ± 1.79	0.260+
BN (*n*)	(13): 22.60 ± 5.29	(7): 24.05 ± 6.91	(6): 20.90 ± 1.87	0.350+
BED (*n*)	(13): 35.53 ± 9.95	(10): 32.73 ± 9.77	(3): 43.92 ± 4.69	0.092+
OSFED (*n*)	(11): 21.26 ± 8.61	(8): 18.30 ± 3.65	(3): 33.11 ± 14.93	0.392+
Illness duration (years)	9.45 ± 9.17	7.49 ± 8.96	11.69 ± 9.021	0.04+
Antidepressant use within group (%)	27.8	22.2	38.9	0.125*

Note. AN, anorexia nervosa; BED, binge-eating disorders; BN, bulimia nervosa; and OSFED, Other-specified feeding or eating disorder.
*Pearson Chi-squared.
+T-test for independent samples.

for the situation and there is nothing he /she or anyone else can do to overcome the problem).

(4) Self-report depressive symptoms were assessed with the Beck Depression Inventory II (BDI-II)[24] a 21-item questionnaire. A total score ranging 0–63 indicates depression severity with higher total scores indicate more severe depressive symptoms. Composite scales of cognitive and somatic-affective symptoms were calculated.[25]

(5) Positive functioning was evaluated with the Psychological Well-being Scales – PWB,[26,27] an 84-item self-rated questionnaire that covers six inter-related areas of psychological well-being which allow the development of optimal functioning: autonomy, environmental mastery, personal growth, positive relations with others, purpose in life, and self-acceptance. Items are constructed on a six-point 1–6 Likert scale, yielding six subscale scores ranging from 14 to 84. Subscale scores range from 0 to 98 with higher scores indicate greater psychological well-being in specific dimensions.

(6) ED symptomatology was assessed with the Eating Attitudes Test-40,[28,29] a 40-item screening measure identifying behaviors and cognitive patterns of EDs. Items are constructed on a 0–3 four-point Likert scale, yielding three subscale scores for dimensions of dieting, body, and food preoccupation, oral control, and a total score ranging from 0 to 120. Higher scores indicate greater ED psychopathology.

In addition to administering these clinical scales, Body mass index (BMI), illness duration in months, and type of antidepressant therapy were collected from the medical records.

Data analysis

Descriptive analyses were run for frequency of CID-rated specific depression symptoms and frequencies of demoralization and depressive illness (persistent depressive disorder and MDD) in the total sample. Univariate analyses of variance using the general linear model were performed to test for associations between DSM-5 Depressive Disorders and the DCPR-based classification of demoralization and average scores on dimensional psychological measures after controlling for illness duration. DSM-5 and DCPR-based diagnoses were examined separately. For all tests performed, the significance level was set at 0.05, two-tailed. In view of the exploratory nature of the investigation, adjustment for multiple testing was not performed. Age, educational level, and BMI were not significantly correlated with any outcome variable and were therefore excluded from analyses.[30]

Results

ED patients characteristics

The patient response rate was high with 97.53% ($n = 79$) of ED outpatients out of 81 agreeing to participate (see Table 1 for descriptive socio-demographic and clinical data). Data on specific depression symptoms through CID interview were available for 72 patients. The 79 ED patients were all female with mean age 28.83 ± 11.25 years, range 15–58 years, and mean educational years 14.44 ± 3.15. About half, 53.2% ($n = 42$), were outpatients and the remaining 46.8% were inpatients ($n = 37$). Outpatients and inpatients did not differ significantly in main socio-demographic characteristics, that is age, education, or in BMI. They differed significantly in illness duration ($p = 0.04$) with inpatients reporting longer length of illness (11.69 ± 9.02 years) compared to outpatients (7.49 ± 8.96 years). Almost a third ($n = 22$, 27.8%) of patients were currently on antidepressants, the most common being selective serotonin-reuptake

TABLE 2. Frequency of depression symptoms (CID items) in ED patients ($n = 72$)

CID ITEM	Symptom frequency (*n*)	Symptom frequency (%)
Guilt	57	79.2
Environmental reactivity	56	77.8
Depressed mood	55	76.4
Energy and fatigue	51	70.8
Generalized anxiety	46	63.9
Work and interests	42	58.3
Somatic anxiety	41	56.9
Pessimism	38	52.8
Delayed insomnia	33	45.8
Phobic anxiety	29	40.3
Suicidal tendencies	25	34.7
Phobic avoidance	23	31.9
Irritability	23	31.9
Early insomnia	22	30.6
Depressed appearance	22	30.6
Panic attacks	14	19.4
Psychomotor retardation	14	19.4
Agitation	7	9.7
Hostility	4	5.6

Note. CID, Clinical Interview for Depression.

inhibitors ($n = 18$). Inpatient and outpatient groups did not differ significantly in severity (BDI and CID total scores) of depression. Diagnostic subgroups (AN, BN, BED, and OSFED) also did not differ in severity of depression. See Table 1.

Frequency of depressive symptoms in ED patients

The most common CID depressive symptoms in the ED sample ($n = 72$) were feelings of guilt, environmental reactivity, depressed mood, and low energy or fatigue, which were present in about two-thirds of the sample. Please see Table 2 for frequencies of these and of other depressive symptoms.

Relationship of DSM depression diagnoses and DCPR demoralization

Diagnoses are displayed in Figure 1. Nineteen patients (24.0%) were without any mood-related comorbidity (i.e., unaffected). A fifth of patients reported only demoralization (20.3%), 12 with helpless demoralization, and 4 cases of hopeless demoralization. In terms of DSM-defined diagnoses, comorbid persistent depressive disorder was reported by 16.5% of the patients, while MDD was the most prevalent (39.2%). Demoralization overlapped partially with both persistent depressive disorder and MDD. None of the unaffected ED patients and about half ($n = 16$) of the comorbid MDD group were on antidepressant medications. Three demoralized and four ED patients with persistent depressive disorder were also on antidepressants.

Associations between DSM 5 Depressive Disorders and dimensional psychological variables

According to univariate analyses of variance comparisons, comorbid depressive disorder (MDD or persistent depressive disorder) was associated with significantly greater distress in terms of depressive symptoms in BDI-II as well as in EAT-eating-related pathology, including oral control, food and bulimic worry, and dietary restraint. In terms of psychological well-being, presence of a depressive illness was associated with significantly worse functioning in PWB dimensions of environmental mastery, positive relations with others, purpose in life, and self-acceptance. Table 3 displays the comparisons between ED patients with and without comorbid DSM depressive illness.

Associations between DCPR demoralization and dimensional psychological variables

Univariate analyses of variance yielded some significant associations between diagnoses formulated according to the DCPR-based demoralization and dimensional psychological variables. Demoralization diagnosis in ED patients was also associated with significantly greater distress in terms of BDI-II scores but not in terms of EAT-eating-related pathology, in which no significant differences between demoralized and non-demoralized ED patients emerged. Nonetheless, in PWB dimensions of psychological well-being, occurrence of demoralization was associated with significantly worse functioning in environmental mastery, positive relations with others, purpose in life, and self-acceptance. Table 3 illustrates the comparisons between demoralized and non-demoralized ED patients.

Discussion

Despite some limitations of the current study, namely the small sample size and cross-sectional design, the joint use of a comprehensive clinical interview for depression[11,12] with the DSM diagnostic criteria[20] and demoralization and psychological well-being assessment has yielded important clinical insights into mood disturbances in EDs.

First, diagnostic criteria place particular emphasis on a specific set of symptoms within a certain symptomatology. Such priority, however, does not necessarily apply to a setting of comorbidity, where other symptoms may be prominent and characteristic. The innovativeness of the applied assessment approach resides in the use of the clinimetric approach. Clinimetrics refers to clinically

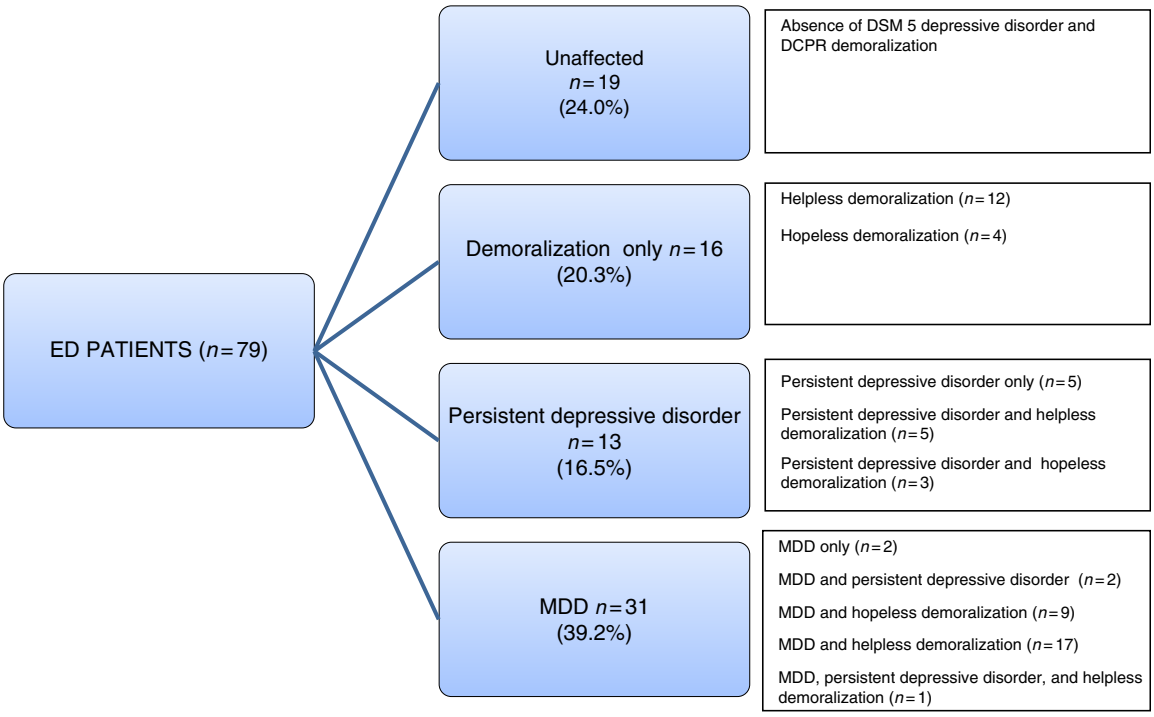

FIGURE 1. Prevalence of demoralization subtypes, persistent depressive disorder, and major depression in ED patients.
Notes: DCPR, Diagnostic Criteria for Psychosomatic Research; ED, eating disorder; MDD, major depressive disorder.

relevant information frequently ignored by traditional psychiatric approaches such as patterns of symptoms, severity of illness, effects of comorbid conditions, timing of phenomena, rate of progression of illness, functional capacity, and other aspects such as positive functioning. The use of a macro-analytic evaluation using clinician-rated scales such as the CID and DCPR, followed by the use of a micro-analysis of specific symptoms through self-rating scales, allows to capture subclinical symptoms, which would have been otherwise undetected.[9] Using the CID, the most common depression symptoms in EDs were depressed mood, feelings of guilt, and abnormal reactivity to social environment. Guilt has been found to be exceedingly common in ED patients, not globally, but in particular, in relation to eating and eating behaviors[31,32] and in relation to body shame.[33] Moreover, it has been found to persist throughout the recovery process from the disorder.[31] Reactivity to social environment refers to the changes in mood and symptomatology, as a result of environmental circumstances, either improvement or worsening. It has been found to characterize cyclothymia[34] and to be prevalent in the prodromal phase of BN compared to unaffected controls.[35] Recent studies on emotional reactivity in EDs[36] suggest that such reactivity in AN and BN might be related to social situations in which patients are pressured to consume high-calorie food, evoking states of anxiety, and depression.[37]

Anxiety, whether generalized, somatic or phobic, was also found to be very common. Studies have shown that anxiety symptomatology is often comorbid and may precede EDs.[38] More specifically, EDs have been found to be associated with body anxiety, eating and food preoccupations, pre-meal anxiety,[39] and avoidance behaviors relating to food, body, and interpersonal situations.[40,41] Indeed, recent research explores the efficacy of exposure therapy and response prevention in the treatment of AN.[42]

Figure 1 illustrates the complexity of mood assessment in EDs. Using DCPR criteria, 20% of patients met the criteria for demoralization. Such patients would not be identified using DSM criteria only. The percentage of demoralization cases is in line with varying prevalence rates in the medical and psychiatric setting.[15] In EDs, a previous study which had not taken into account a possible overlap with major depression and dysthymic disorder had reported higher rates.[16] Interestingly, cases of demoralization in the absence of depressive disorder were mostly of the helpless subtype.

Associations of DCPR demoralization with dimensional psychological measures provide further support to its validity and utility. Consistent with previous studies,[15,43] demoralization was found to be associated with lower psychological well-being and greater distress. Moreover, the same number of significant associations was found between demoralization and depressive illness and psychological variables, with the exception of ED-related symptoms, which were not associated with demoralization. Findings lend support to the hypothesis

TABLE 3. Associations of DSM-5 depressive disorders and DCPR-based demoralization with dimensional psychological measures ($n = 79$)

VARIABLE	Depressive disorder (+) $n = 44$	Depressive disorder (–) $n = 35$				Demoralization (+) $n = 51$	Demoralization (–) $n = 28$			
	Estimated marginal mean (S.E.)	Estimated marginal mean (S.E.)	F (1.72)	p	Partial eta squared	Estimated marginal mean (S.E.)	Estimated marginal mean (S.E.)	F (1.72)	p	Partial eta squared
BDI-II Cognitive subscale	17.667 (1.092)	9.764 (1.124)	25.122	<0.0001	0.273	11.641 (.808)	5.234 (1.044)	22.062	<0.0001	0.253
BDI-II Somatic-affective subscale	12.297 (.856)	6.086 (.856)	26.145	<0.0001	0.287	17.272 (1.018)	8.345 (1.309)	26.883	<0.0001	0.286
EAT oral control	12.493 (1.326)	7.071 (1.520)	7.211	0.009	0.092	10.533 (1.333)	9.439 (1.848)	0.217	0.643	0.003
EAT food -bulimic worry	12.232 (.938)	6.383 (1.075)	16.777	<0.0001	0.191	10.648 (.984)	7.957 (1.364)	2.409	0.125	0.033
EAT dietary restraint	27.497 (2.281)	13.347 (2.614)	16.597	<0.0001	0.189	23.717 (2.388)	17.061 (3.312)	2.499	0.118	0.034
PWB autonomy	47.035 (2.356)	54.367 (2.499)	4.557	0.037	0.066	46.595(2.095)	58.097 (3.005)	9.230	0.003	0.124
PWB environmental mastery	55.965 (1.772)	64.767 (1.772)	12.318	0.001	0.161	42.342 (1.612)	56.549 (2.312)	23.779	<0.0001	0.268
PWB personal growth	57.388 (1.888)	64.063 (2.002)	5.880	0.018	0.083	58.228 (1.750)	65.033 (2.510)	4.631	0.035	0.067
PWB positive relations	50.666 (2.184)	63.564 (2.317)	16.398	<0.0001	0.201	51.021(1.924)	67.915 (2.758)	23.625	<0.0001	0.267
PWB purpose in life	47.537 (1.779)	55.614 (1.887)	9.694	0.003	0.130	47.425 (1.562)	58.994 (2.240)	16.799	<0.0001	0.205
PWB self-acceptance	46.150 (2.356)	35.227 (2.221)	11.375	0.001	0.149	34.705 (1.890)	51.447 (2.711)	24.025	<0.0001	0.270

Note. (+) Disorder or syndrome present; (–) Disorder or syndrome absent; BDI-II, Beck Depression Inventory II; EAT, Eating Attitudes Test; PWB, Psychological Well-Being scales.

that DCPR demoralization might be suitable for classifying psychological distress in EDs that is not confounded by the ED symptoms themselves. Indeed, demoralization does not seem to depend on illness type or severity, affecting a wide range of psychiatric and medical illnesses alike.[15]

Subjective incompetence (a feeling of being trapped or blocked because of a sense of inability to plan or start actions toward goals) is a major component of demoralization.[44,45] Such feelings of inadequacy and low self-efficacy have been previously documented in EDs.[46,47] Individuals, who perceive themselves as incompetent are uncertain and indecisive as to their directions, display high reactivity to environmental stimuli and low psychological well-being. Not surprisingly, patients with EDs were found to present with very high rates of dropout.[48]

In both standard assessment and treatment approaches, most studies focus on pathological symptomatology and its reduction, as well as modifications of physical and behavioral aspects, ignoring gains in positive aspects such as quality of life and psychological well-being.[18,19,49] The pursuit of euthymia, defined as how the individual adjusts the psychological dimensions of well-being to changing needs, may thus become one of the targets of treatment. Such positive functioning characteristics have been found to be persistently compromised in various psychiatric illnesses including EDs[18] and their impairments are correlated with increased vulnerability to future adversity and may thus be a viable psychotherapeutic target.[50-53]

The high comorbidity rates found in the current study between EDs and depression are in line with those in the literature, ranging from 40% to 80%, as well as high comorbidity rates with dysthymic disorder which surpass those found in the general population.[2-4] In the current study, depressive disorders were associated with worse overall functioning in terms of both psychological distress and well-being, a result that is in line with the literature. Depressed ED patients exhibit greater dietary restriction, body dissatisfaction, and worse quality of life,[54] social[55]and global functioning compared to unaffected ED patients.[56-58] Moreover, it is well-documented that ED severity is significantly associated with severity of the depression.[59]

As expected, an overlap between the demoralization and depressive illness was found, as in other medical psychiatric populations.[15]

Clinical guidelines for the screening of depression in EDs recommend the Beck Depression Inventory-II and the Hamilton Depression Rating Scale.[60,61] However, such standardized screening measures mainly based on DSM criteria might not be sufficient in such a complex clinical population with frequent medical complications.

Conclusion

The presence of demoralization syndrome in EDs is undoubtedly relevant to treatment and recovery from

EDs. Hopelessness and helplessness[62] and poor self-efficacy[63,64] have been identified by ED patients themselves as barriers to change and recovery in qualitative studies. In chronic AN patients, the recovery process may be hindered by feelings of hopelessness and "feeling stuck."[65] Indeed, demoralization has been found to affect response to psychotherapy.[66,67]

Moreover, the clinical utility of depression diagnoses in ED populations is called into question by treatment trials. Depression comorbidity in EDs has an unclear role in treatment response with inconsistent results across ED categories.[68,69] For instance, inconclusive or mixed findings have been reported for FDA-approved fluoxetine in BN[70-72] with lack of improvement in AN.[73] Antidepressants in ED patients were devoid of impact on likelihood and persistence of recovery from MDD in a longitudinal study.[4]

Fava, Rafanelli, and Tomba[9] have advocated that exclusive reliance on diagnostic criteria has impoverished the clinical process in psychiatry. Customary clinical taxonomy in psychiatry does not include clinical distinctions that demarcate major prognostic and therapeutic differences among patients who otherwise seem to be deceptively similar since they share the same psychiatric diagnosis.[9] This investigation has illustrated how a broader perspective in evaluation of mood disturbances in EDs may lead to an individualized assessment of the complex balance between euthymia, dysthymia, and eating behavior which may entail important treatment implications. Further studies, using a comprehensive clinimetric approach,[74] with larger samples and a longitudinal design, are needed.

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MINI REVIEW
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Recent Progress in Sleep Quality Monitoring and Non-drug Sleep Improvement

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Insomnia is one of the most common health risk factors in the population as well as in clinical practice, which is associated with genes, neuron, environment, behavior, and physiology, etc. This review summarizes the recent progress in sleep quality monitoring and non-drug sleep improvement. The innovation of wearable and effective invention suggests a new approach and have deep implications toward sleep improvement and yet, the health care innovation system is also facing the challenge to foster the progress.

Keywords: insomnia, sleep disorders, sleep quality, sleep monitoring, polysomnography, light pollution

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INTRODUCTION

Insomnia is one of the most common health risk factors in the population as well as in clinical practice, which is associated with genes, neurons, environment, behavior, physiology, etc. (Buysse, 2013; Harvey et al., 2014). Insomnia is defined as the subjective perception of difficulty with sleep initiation (over 30 min of sleep latency), duration, and consolidation, resulting in dissatisfied sleep quality despite adequate opportunity for sleep (Schutte-Rodin et al., 2008). The understanding of the whole dynamics of the sleep–wake cycle could lead us to a better solution on insomnia, which is controlled by interactive neurochemical processes among multiple neural structures (Espana and Scammell, 2004; Brown et al., 2012).

Insomnia has gradually become a prevalent phenomenon in fast-paced urban life. Insomnia occurs among individuals of different ages (Johnson et al., 2006; Kryger, 2006), and symptoms occur in approximately 33–50% of the adult population (Ancoli-Israel and Roth, 1999). Insomnia is the most prevalent and accounts for almost half of all sleep disorders (15% of the whole population) (Cao et al., 2017). Due to the complexity of the neural system that controls sleep, it is a great challenge to accurately diagnose and treat insomnia.

During the past few years, a wide range of hardware including wearable devices has enabled us to access more personal health performance via mobile applications and help improved our health. However, the reliability and validation vary among different applications (Peake et al., 2018). For insomnia management and improvement, it is critical to develop a set of comprehensive sleep valuation as well as following therapies (Kapur et al., 2017).

This review summarizes the recent progress in sleep quality monitoring and non-drug sleep improvement, with a comprehensive analysis on the related advantages and limitations, trying to conclude effective suggestions for sleep problems improvement in general.

SLEEP QUALITY MONITORING

Insomnia should be properly diagnosed before treatment. Subjective sleep quality assessment is mainly through subtly developed questionnaires. The most commonly used forms are the *Morning Evening Questionnaire (MEQ)*, *Pittsburgh Sleep Quality Index (PSQI)*, *the Hamilton scale*, etc. (Schwab et al., 1967; Horne and Ostberg, 1976; Buysse et al., 1989). PSQI sleep quality assessment was invented by the University of Pittsburgh and was most frequently used. It contains nine questions with each answer scoring between 0 and 3. The PSQI index is calculated as the sum of all the scores. The lower the score is, the better the sleep quality. Clinical studies have shown that the PSQI demonstrates high reliability and validity to analyze sleep problems under many circumstances, but just like other self-report inventories, its scores can be easily affected by the testee (Grandner et al., 2006; Mollayeva et al., 2016).

Sleep doctors routinely use a device called polysomnography recorder (PSG) for sleep quality monitoring (Jafari and Mohsenin, 2010). The PSG records electroencephalogram (EEG), electromyogram (EMG), electrocardiogram (ECG), respiration, and body movements along with other vital signs. Polysomnography is commonly used for sleep quality assessment, therapy, and sleep disorders (Gregorio et al., 2011). There are several limitations to obtain high quality of PSG data, including the first night effect in decreased sleep efficiency due to the unfamiliar environment and lack of comfort brought by the test, the difference in PSG variables by sex and different age groups, the control subjects, research angles and environments of different lab groups, and so on, thus making PSG hard for normalization (Newell et al., 2012; Boulos et al., 2019).

Presently, new technologies and innovations on *wearables* have made sleep monitoring easy to use and enable us to access sleep data in a real-world environment, compared to PSG (Kelly et al., 2012). Recent systematic reviews on the sleep monitoring methods have been introduced to value sleep quality, emphasizing the powerful innovation of wearables and the application on athletes, which allows complementary access with respect to classical sleep quality valuation and diagnose insomnia and its severity level (Peake et al., 2018; Claudino et al., 2019). Comparison on the result between PSG and wearables has shown consistency but needs further refinement for reliability (Lee et al., 2019).

The new Apple watch not only has a sleep monitoring function but also achieved CFDA approval for early warning of atrial fibrillation. A small electrocardiographic device developed by Harvard University infers sleep quality by cardiopulmonary coupling (CPC) monitoring (Thomas et al., 2005). These products are relatively simple in structure when compared to the PSG and are much more comfortable to wear. Most sleep monitoring devices in the consumer market refer to actigraph (body movement), heart rate, and heart rate variability (HRV) to predict sleep structure, to evaluate the quality of sleep (Kosmadopoulos et al., 2014). Other products with comparable functions include wrist bands, sleep monitoring belts, and radar beam trackers. One of such examples is the sleep monitoring belt based on piezoelectric sensing technology developed by an Israeli company named EarlySense and a Finlandizei company called Beddit recently acquired by Apple.

The accuracy of these consumable products, however, has been challenged by medical doctors, and whether they could replace the PSG device for clinical use is yet to be determined. However, a recent trend on the cooperation between the pharmaceutical and wearable companies has been shaping. For instance, Eli Lily and Apple have started large-scale clinical trials on Alzheimer's disease, with the help of iPhones, watches, and sleep monitor belt.

NON-DRUG THERAPY AND SLEEP IMPROVEMENT TECHNIQUES FOR INSOMNIA

Currently, most insomnia patients take hypnotic drugs for treatment. However, a large percentage of the population feel reluctant to take sleeping pills, and this led to the development of non-drug insomnia therapeutics. Non-drug treatment of insomnia is divided into two major categories: cognitive behavioral therapy for insomnia (CBT-I), which is performed in the absence of auxiliary devices (Morin, 2004), and physiotherapy through repetitive transcranial magnetic resonance (rTMS), white noise and music, aromatherapy, and light therapy devices.

Cognitive behavioral therapy (CBT) is a fairly simple and easy way to treat insomnia. It can relieve insomnia through such behavioral interventions as sleep restriction, stimulus control, and paradoxical intervention. For example, sleep restriction allows a subject to stay in bed only when he or she feels sleepy and this gradually improves sleep quality by increasing sleep efficiency (Miller et al., 2014). Stimulus control improves sleep quality by limiting non-sleep behaviors in the bed and establishing good bed-sleep conditioned reflexes (Hood et al., 2014). No auxiliary devices are needed for CBT-I, but the drawback of this tool is its low compliance rate.

Repetitive transcranial magnetic stimulation (rTMS) relieves insomnia by lowering the level of arousal for the targeted cerebral cortex (Jiang et al., 2013). Low-frequency (<1 Hz) repetitive transcranial stimulation inhibits the excitement of the cerebral cortex and can induce slow waves, a brain wave that mostly appears as a subject enters deep sleep. Although this method is effective, the equipment is too large for consumable commercialization.

White noise refers to the combination of sound of multiple frequencies. White noise diminishes the excessive concentration of attention to relax the mood and alleviate insomnia (Messineo et al., 2017). Most natural sounds such as wind, rain, water flow, and other natural sounds all belong to the white noise family. White noise is often used in conjunction with soothing music to regulate mood and help with sleep.

Aromatherapy and *meditation* are commonly used together. Both methods are considered to be effective in reducing psychological stress. The fragrance of natural flowers and plants has been accompanying human beings into dreams throughout the 2 million years of evolution. We used to

live in the jungle, mountains, or grasslands. It is thought that the awakened memories in ancient times help us fall into sleep faster. Meditation helps people relax and rapidly fall asleep by distracting attention and reducing anxiety (Martires and Zeidler, 2015).

Light therapy is gaining increasing attention from doctors and hospitals. The principle of light therapy is to adjust the phase and amplitude of biological clock oscillation through specific light stimulation, so as to establish and consolidate a regular sleep–wake cycle and improve the quality of sleep (van Maanen et al., 2016). Light therapy products have been developed in the form of large light boards and small desktop lightboxes. Recently, head-mounted light therapy glasses have been invented to improve portability and ease of use. The innovation has dramatically increased the patients' compliance with light therapy.

DISCUSSION AND CONCLUSION

Having a better knowledge on sleep physiology and insomnia is important for both health and medical reasons. Although we lack further understanding of the nerve system controlling the sleep–wake cycle, it doesn't stop us from seeking better monitoring and treatment on insomnia.

The pre-programmed passive wearables provide us a new angle to understand sleep, together with the classical evaluation form and PSG, shaping a comprehensive monitoring ecosphere and potential synergistic effect for clinical, post-hospital, and daily needs.

On the other hand, we need a better solution to improve sleep disorder, and there has been progress showing that, besides sleep medications, we do have more effective choices owing to the development of non-drug insomnia therapeutic.

The availability of digitized data in clinical and daily scenarios, combined with the arrival of powerful artificial intelligence (AI) algorithms, could bring deeper implications for health and medicine industry. New medicine or non-drug equipment like light therapy will speed up the upgrade.

The health innovation system should promote such progress by working closely with hospitals, pharmaceutical companies, and academic institutes. Proper guidance should be given to educate the public on the limitations along with the promotion of health technologies.

AUTHOR CONTRIBUTIONS

WC and JC: first draft. WC: literature. YG: modified. JC: proofreading.

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Sequential Combination of Cognitive-Behavioral Treatment and Well-Being Therapy in Depressed Patients with Acute Coronary Syndromes: A Randomized Controlled Trial (TREATED-ACS Study)

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Keywords
Acute coronary syndrome · Cognitive-behavioral therapy · Depression · Sequential treatment · Well-being therapy

Abstract
Introduction: Randomized controlled trials (RCT) of psychotherapeutic interventions have addressed depression and demoralization associated with acute coronary syndromes (ACS). The present trial introduces psychological well-being, an increasingly recognized factor in cardiovascular health, as a therapeutic target. ***Objective:*** This study was designed to determine whether the sequential combination of cognitive-behavioral therapy (CBT) and well-being therapy (WBT) may yield more favorable outcomes than an active control group (clinical management; CM) and to identify subgroups of patients at greater risk for cardiac negative outcomes. ***Methods:*** This multicenter RCT compared CBT/WBT sequential combination versus CM, with up to 30 months of follow-up. One hundred consecutive depressed and/or demoralized patients (out of 740 initially screened by cardiologists after a first episode of ACS) were randomized to CBT/WBT associated with lifestyle suggestions ($n = 50$) and CM ($n = 50$). The main outcome measures included: severity of depressive symptoms according to the Clinical Interview for Depression, changes in subclinical psychological distress, well-being, and biomarkers, and medical complications and events. ***Results:*** CBT/WBT sequential combination was associated with a significant improvement in depressive symptoms compared to CM. In both groups, the benefits persisted at follow-up, even though the differences faded. Treatment was also related to a significant amelioration of biomarkers (platelet count, HDL, and D-dimer), whereas the 2 groups showed similar frequencies of adverse cardiac events. ***Con-***

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clusions: Addressing psychological well-being in the psychotherapeutic approach to ACS patients with depressive symptoms was found to entail important clinical benefits. It is argued that lifestyle changes geared toward cardiovascular health may be facilitated by a personalized approach that targets well-being.

Introduction

There is extensive evidence that the presence of depressive symptoms in acute coronary syndromes (ACS) is associated with poor therapeutic adherence, a higher frequency of relapses, and increased mortality [1]. Mood disturbances may consist of major or minor depressive episodes, chronic depression, and demoralization [1–3], which is characterized by a sense of subjective incompetence [4].

The relationship of depression to ACS has generated the hypothesis that treatment of mood disturbances may yield improved medical and psychological outcomes. A number of randomized controlled trials (RCT) have indicated the effectiveness of antidepressant drugs compared to placebo in relieving depression, yet a favorable effect on cardiovascular events was not detected [1] or could not be generalized [5]. Similar findings have been reported for the application of cognitive-behavioral therapy (CBT) to ACS [6], pioneered by the ENRICHD trial [7].

Psychotherapeutic approaches, however, have been mainly shifted to the side of psychological dysfunction and have neglected psychological well-being. There is increasing evidence of the role of positive psychological assets on lifestyle and cardiovascular health [8].

In this trial, the sequential use of distress and well-being psychotherapeutic strategies was selected. The first phase of treatment (CBT) was concerned with distress associated with hospitalization and medical events. In the second phase, well-being therapy (WBT), a specific psychotherapeutic approach for modulating psychological well-being [9], was introduced and suggestions for lifestyle modifications geared to cardiovascular health were provided [10]. The sequential combination of CBT and WBT has been found to yield enduring clinical benefits in the setting of psychiatric disorders [9, 10], with particular reference to recurrent depression [11].

The aim of the trial was to evaluate the efficacy of the sequential combination of CBT and WBT, compared to clinical management (CM), in terms of depressive symptoms (primary outcome), psychological distress, and well-being, as well as cardiovascular events, biomarkers, and mortality (secondary outcomes), both after treatment and up to a 30-month follow-up. The identification of subgroups of patients at greater risk for cardiac negative outcomes was included.

Materials and Methods

Sample

Participants were patients hospitalized for a first episode of acute myocardial infarction or unstable angina at the Cardiology Divisions of Maggiore Hospital (Bologna, Italy) and Molinette Hospital (Torino, Italy). Myocardial infarction was documented based on cardiac symptoms (presence of acute chest, epigastric, neck, jaw, or arm pain or discomfort or pressure without an apparent noncardiac source) and signs (acute congestive heart failure or cardiogenic shock in the absence of non-CHD causes) associated with ECG findings (characteristic evolutionary ST-T changes or new Q waves) and/or cardiac biomarkers (blood measures of myocardial necrosis, specifically CK, CK-MB, CK-MBm, or troponin, and cTn). Instable angina was documented based on cardiac symptoms (chest pain lasting less than 20 min) with likely ECG findings (ST-segment depression and an abnormal T-wave) in absence of myocardial necrosis biomarkers.

Medically eligible patients underwent a psychological evaluation by 2 clinical psychologists with expertise in the field of psychosomatic aspects of cardiovascular diseases about 30 days after ACS. The inclusion criteria were: a current diagnosis of major/minor depression or dysthymia according to DSM-IV-TR [12] and/or demoralization according to Diagnostic Criteria for Psychosomatic Research (DCPR) criteria [13]. The exclusion criteria included a positive history of bipolar disorder (DSM-IV-TR), major depression with psychotic features, a positive history of substance abuse/dependence during the previous 12 months, suicide risk, and current use of antidepressants and/or psychotherapy.

A psychological evaluation was performed in 288 patients with a first episode of ACS, and the first 100 depressed and/or demoralized consecutive patients were enrolled (Fig. 1).

Assessment

Medical Variables

Data on ACS, traditional cardiac risk factors (smoking habit, hypertension, dyslipidemia, a family history of cardiovascular disease, diabetes mellitus, and left ventricular ejection fraction <40), medications, and comorbidities were collected from medical records. The cardiologists involved in this study evaluated the patients at intake and once every 6 months to monitor changes in the clinical course of cardiac disease. Data from electrocardiograms, echocardiograms, X-rays, blood pressure and blood samples (cholesterol levels, creatinine, glycosylated hemoglobin, C-reactive protein, and coagulation/fibrinolysis biomarkers) were provided at intake. The Global Registry of Acute Coronary Events (GRACE) risk index [14] was calculated during hospital admission for ACS to determine the risk of morbidity and mortality both in hospital and 6 months after discharge. From the beginning of the psychological treatment and up to a 30-month follow-up after the end of the intervention, information about cardiac negative outcomes,

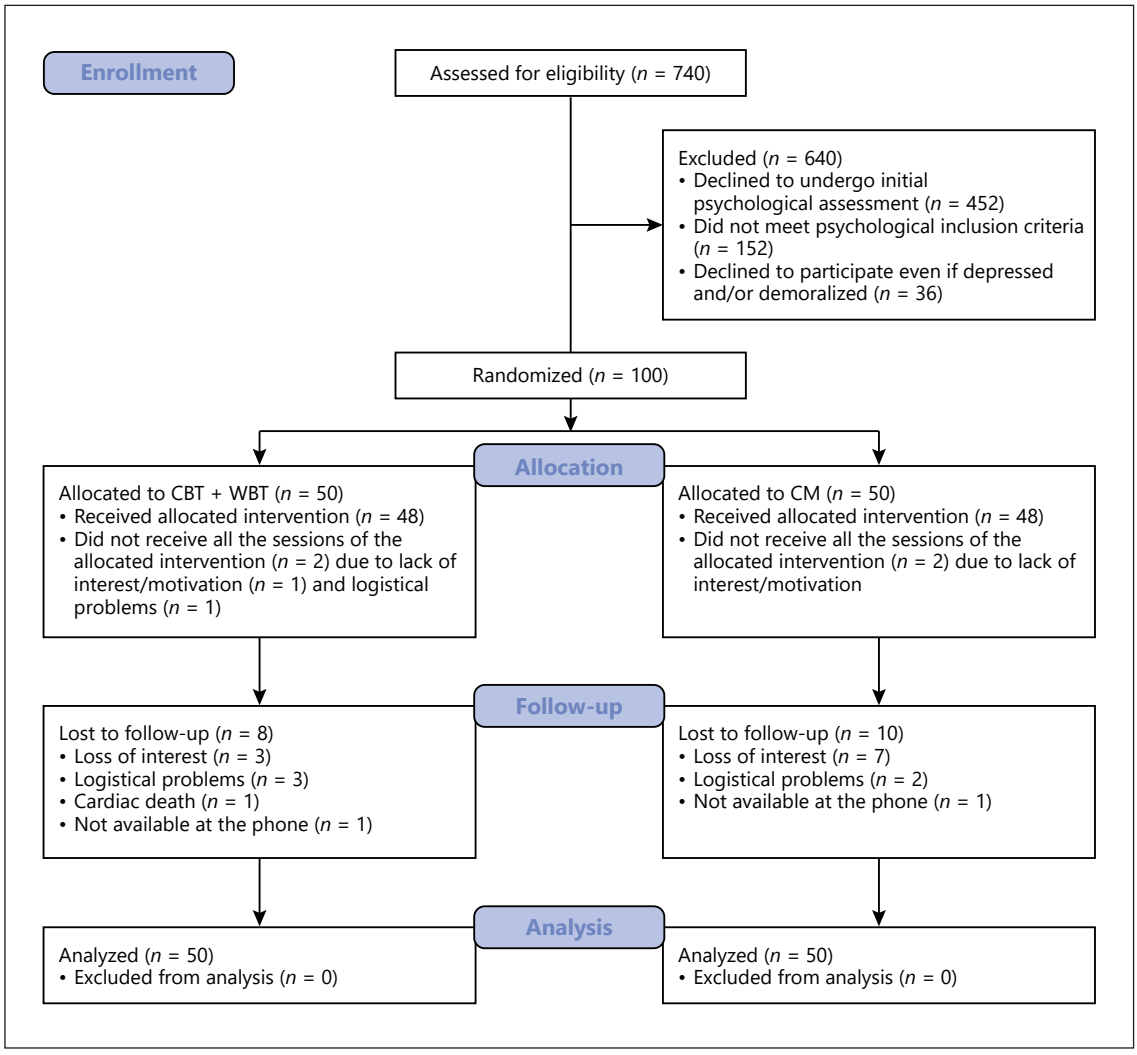

Fig. 1. CONSORT flow diagram of this study.

such as rehospitalizations due to cardiac complications, acute myocardial infarction, unstable angina, angioplasty, cardiac surgery, and cardiac mortality after the first ACS, was collected.

Psychological Variables

Psychological assessment included both observer-rated and self-reported measures before the beginning of the interventions (baseline, pretreatment), at the end (posttreatment), and 3, 6, 12, and 30 months after the end of treatment. The Structured Clinical Interview for DSM-IV-TR, Axis I Disorders [15], was used to investigate the presence of major/minor depression and dysthymia. The Semi-Structured Interview based on the DCPR (SSI-DCPR) [16] was administered to assess the presence of demoralization [17]. This interview has shown excellent interrater reliability, with κ values ranging from 0.69 to 0.97 [18]. The 20-item change version of the Clinical Interview for Depression (CID) [19, 20], a modified version of the Hamilton Rating Scale for Depression [21, 22], was used to perform a comprehensive assessment of affective symptoms. It contains 20 items rated on a 7-point Likert scale, with specification of each anchor point based on the severity, frequency, and/or quality of the symptoms. The higher the score, the worse the psychological condition. The CID has been shown to be a sensitive assessment tool in clinical trials [20]. The Symptom Questionnaire (SQ) [23, 24] is a 92-item self-report questionnaire that yields 4 main scales, i.e., depression, anxiety, hostility-irritability, and somatization. The higher the score, the higher the psychological distress. The Psychological Well-Being scales (PWB) [25–26], an 84-item questionnaire, was used to evaluate 6 psychological well-being dimensions (autonomy, environmental mastery, personal growth, positive relations, purpose in life, and self-acceptance). Higher scores correspond to greater psychological well-being.

Study Design

This study is a 2-center RCT with a longitudinal and prospective design. The enrolled patients were randomly assigned to either CBT/WBT or CM and assessed at the beginning and the end of the CBT/WBT or CM sessions, and at subsequent follow-ups up to 30 months after the conclusion of the interventions. Treatment allo-

cation was accomplished through random computerized assignment that allocated 50% of the patients to each treatment group, with assignments concealed until the time of group assignment. Patients were assessed by 2 clinical psychologists, who were blind to treatment assignment, at pretreatment and posttreatment, and 3, 6, 12, and 30 months after the end of treatment. Both the sequential combination of CBT/WBT and the CM were performed by psychotherapists who had received specific training. Both interventions consisted of 12 weekly, 45-min sessions. The sequential administration of CBT (8 sessions) and WBT (4 sessions) was based on a written protocol [9–10]. The WBT techniques were used to improve or balance one or more of the 6 dimensions of psychological well-being (environmental mastery, purpose in life, personal growth, autonomy, self-acceptance, and positive relations with others), and they were supplemented with suggestions for lifestyle modifications geared toward cardiovascular health, including treatment adherence.

CM entails the same amount of time and attention from a professional figure than the experimental group, but specific interventions (such as exposure strategies, diary work, and cognitive restructuring) were proscribed [27]. Such a form of active control – unlike in previous trials that have used treatment as usual [6] – allows discrimination of specific and nonspecific ingredients of the psychotherapeutic approach. It consists of empathic listening, review of the patient's clinical status and providing opportunities for disclosure of distress and worries, and encouragement of treatment adherence.

Statistical Analyses

Data were analyzed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA). The quality of data collection was monitored regularly to assure accuracy and completeness. For all tests performed, significance level was set at 0.05 (two-tailed). The sample size was estimated using Piface software, which identified a minimum of 16 participants per arm to detect the expected superiority of CBT/WBT on CM [11], with a power of 80% and a significance level of 5%. Thus, with 50 patients per group we expected a "large" effect size (Cohen's $d = 0.8$) [28].

A multivariate ANOVA was used to examine differences in dimensional psychological variables (i.e., CID-20 total score and PWB and SQ scale scores) between patients assigned to CBT/WBT and CM at preintervention.

A mixed-model ANOVA (repeated measures) was performed to test differences between groups (CBT/WBT or CM) on the CID-20 total score, PWB scales, and SQ scales scores at different follow-up evaluations. All analyses were performed by using intention-to-treat analysis, where missing values were managed by means of a multiple-imputations procedure. Greenhouse-Geisser correction was applied when appropriate. All analyses were adjusted for cardiac illness severity (i.e., GRACE index for the 6-month probability of cardiac mortality) [14].

Each biomarker was dichotomized around the baseline median of the sample in order to identify subgroups of patients at a higher cardiovascular risk. The McNemar test (applied to contingency tables) was used to identify significant changes over time in the frequencies of DSM, DCPR diagnoses, and subgroups of patients at a higher cardiovascular risk.

Survival analyses (Cox Regression and Kaplan-Meier) to identify cardiac events and mortality that occurred between pretreatment and the 30-month follow-up were performed.

Results

Baseline Profile of the Sample

The first 100 consecutive depressed and/or demoralized patients 1 month after ACS were enrolled, yielding 50 patients in each treatment group. The mean age of the sample was 58.8 years (SD = 10.5, range 40–84). The participants were mainly men (69%), married (69%), employed (58%), and graduated from high school (44%). No significant differences based on group allocation were found (Table 1).

As for the cardiac profile of the sample, ST-elevation myocardial infarction (STEMI) was the most frequent form of ACS (66%) and almost all of the patients (94%) underwent percutaneous transluminal coronary angioplasty – 77% with the application of a single stent and 17% with 2 or more stents. The most frequent cardiovascular risk factors registered at hospital admission were dyslipidemia (58%) and hypertension (52%). No differences concerning ACS-related aspects or GRACE risk scores were found when comparing CBT/WBT versus CM (Table 1).

Among the medications prescribed at discharge, the most frequent were statins (96%), β-blockers (96%), and platelet aggregation inhibitors (96%). Patients allocated to CM were prescribed significantly more frequently β-blockers, calcium antagonists, and α-adrenergic receptor inhibitors compared to the CBT/WBT group (Table 1). The sample presented with a number of medical comorbidities; the most frequent were gastrointestinal (43%) and endocrine diseases (14%). As for comorbid medical diagnoses and levels of biomarkers assessed at baseline, the 2 groups did not show any significant difference (Table 1). From the psychological point of view, the most frequent diagnosis was demoralization (91%), followed by minor depression (56%). The 2 groups did not show any statistical difference, except for PWB "personal growth" scores ($F = 4.45$; df = 1, 98; $p = 0.038$) and frequency of depression/demoralization comorbidity ($\chi^2 = 4.86$; df = 1; $p = 0.028$), which were significantly higher among the CBT/WBT patients (Table 1).

Pre-/Postintervention Modifications

Psychological Variables

Forty-eight patients completed the CBT/WBT treatment, and 48 patients attended CM sessions. Two patients in each group dropped out early, mainly due to a lack of interest or motivation. Forty and 38 patients, respectively, completed follow-up evaluations (Fig. 1).

Table 1. Baseline sociodemographic, medical, and psychological profile of the sample

Variable	CBT/WBT group (n = 50)	CM group (n = 50)
Mean age (SD), years	57.64 (9.99)	60.02 (10.94)
Sex, *n* (%)		
Males	31 (62)	38 (76)
Females	19 (38)	12 (24)
Marital status, *n* (%)		
Single	4 (8)	7 (14)
Married	33 (66)	36 (72)
Separated	5 (10)	4 (8)
Divorced	2 (4)	1 (2)
Widow/widower	6 (12)	2 (4)
Occupation, *n* (%)		
Employed	34 (68)	24 (48)
Unemployed	1 (2)	4 (8)
Retired	13 (26)	19 (38)
Homemaker	2 (4)	3 (6)
Education, *n* (%)		
Primary school	5 (10)	5 (10)
Middle school	16 (32)	18 (36)
High school	19 (38)	25 (50)
University	8 (16)	1 (2)
Postgraduate education	2 (4)	1 (2)
Type of ACS, *n* (%)		
STEMI acute myocardial infarction	33 (66)	33 (66)
NSTEMI acute myocardial infarction	14 (28)	13 (26)
Unstable angina	3 (6)	4 (8)
Medical procedure for ACS, *n* (%)		
Single PTCA	38 (76)	39 (78)
PTCA with 2 or more stents	9 (18)	8 (16)
None	3 (6)	3 (6)
Drug-eluting stent	24 (51.1)	18 (38.3)
Cardiovascular risk factors, *n* (%)		
Dyslipidemia	31 (62)	27 (54)
Hypertension	27 (54)	25 (50)
Smoker (current)	22 (44)	20 (40)
Familiarity	17 (34)	11 (22)
Diabetes	10 (20)	9 (18)
LVEF <40	4 (8)	3 (6)
Mean GRACE risk index at admission (mortality) (SD)		
In-hospital risk, %	3.51 (8.58)	4.56 (7.90)
6-month risk, %	6.60 (11.60)	8.69 (10.57)
Mean GRACE risk index at admission (mortality + AMI) (SD)		
In-hospital risk, %	15.50 (9.85)	16.56 (10.49)
6-month risk, %	25.30 (12.73)	27.50 (15.00)
Medications, *n* (%)		
Cholesterol reducers	49 (98)	47 (94)
β-blockers*	46 (92)	50 (100)
Platelet aggregation inhibitors	48 (96)	48 (96)
Cardioaspirin	47 (94)	48 (96)
Vasodilators	36 (72)	35 (70)
Angiotensin-converting enzyme inhibitors	31 (62)	35 (70)
Polyunsaturated fatty acids – omega-3	11 (22)	10 (20)
Antihyperglycemics	6 (12)	8 (16)
Diuretics	6 (12)	5 (10)
Angiotensin receptor blockers	5 (10)	4 (8)
Calcium antagonists*	1 (2)	6 (12)

Table 1 (continued)

Variable	CBT/WBT group (n = 50)	CM group (n = 50)
α-adrenergic receptor inhibitors*	0 (0)	4 (8)
Antihyperuricemics	0 (0)	2 (4)
Antiarrhythmic	1 (2)	0 (0)
Heart rate reducers	0 (0)	1 (2)
7 or more medications*	11 (22)	23 (46)
Medical comorbidities, n (%)		
Digestive system diseases	18 (36)	25 (50)
Endocrine diseases	9 (18)	5 (10)
Circulatory/cardiac comorbidities	2 (4)	4 (8)
Prostatic and male reproductive system diseases	3 (6)	2 (4)
Urinary system diseases	2 (4)	2 (4)
Orthopedic diseases	1 (2)	3 (6)
Asthma	3 (6)	1 (2)
Chronic obstructive pulmonary disease	2 (4)	1 (2)
Stroke/aneurysm	2 (4)	1 (2)
Heteroplasia/neoplasia	2 (4)	1 (2)
Hyperuricemia	0 (0)	3 (6)
Glaucoma	1 (2)	0 (0)
Multiple sclerosis	1 (2)	0 (0)
Cluster headache	1 (2)	0 (0)
Cushing disease	1 (2)	0 (0)
Sarcoidosis	1 (2)	0 (0)
Thalassemia	0 (0)	1 (2)
Rheumatoid arthritis	0 (0)	1 (2)
2 or more medical comorbidities	12 (24)	13 (26)
Mean biomarkers (SD)		
Hemoglobin, g/dL	13.91 (1.21)	13.93 (1.33)
Platelets, $n \times 10^3$/mm^3	235.42 (57.64)	232.96 (50.20)
Creatinine, mg/dL	0.94 (1.78)	0.95 (0.20)
Triglycerides, mg/dL	115.96 (52.91)	121.69 (58.68)
HDL cholesterol, mg/dL	51.98 (16.59)	46.51 (12.01)
LDL cholesterol, mg/dL	87.40 (25.48)	93.96 (29.25)
Total cholesterol, mg/dL	156.44 (31.07)	160.90 (37.45)
Glycated hemoglobin, mmol/mol	41.20 (8.36)	42.97 (10.21)
Fibrinogen, mg/dL	347.84 (66.04)	356.49 (68.28)
D-dimer, mg/L FEU	0.68 (1.39)	0.45 (0.39)
HRV[a], ms	51.10 (27.66)	41.50 (12.29)
C-reactive protein		
BO, mg/dL	0.19 (0.21)	0.39 (0.69)
TO, mg/L	0.28 (0.39)	0.64 (1.16)
Mean SQ (SD)		
Anxiety	8.60 (4.73)	7.24 (4.67)
Depression	7.92 (4.77)	6.90 (4.87)
Somatization	9.82 (5.65)	7.82 (5.12)
Hostility	4.70 (4.00)	5.34 (4.36)
Mean PWB (SD)		
Autonomy	62.20 (9.18)	61.80 (9.25)
Environmental mastery	55.28 (11.52)	55.32 (10.65)
Personal growth*	60.48 (9.88)	56.18 (10.50)
Positive relations with others	61.26 (13.26)	60.20 (10.68)
Purpose in life	56.80 (11.51)	56.22 (11.59)
Self-acceptance	54.48 (11.63)	55.80 (13.68)
Mean CID-20 (SD)		
CID-20 total score	38.18 (8.48)	36.20 (8.57)
Depression (DSM), n (%)	35 (70)	27 (54)

Table 1 (continued)

Variable	CBT/WBT group (n = 50)	CM group (n = 50)
Major depression	2 (4)	3 (6)
Minor depression	32 (64)	24 (48)
Dysthymia	1 (2)	0 (0)
History of depression (DSM), n (%)	34 (68)	26 (52)
Demoralization (DCPR), n (%)	47 (94)	44 (88)
History of demoralization (DCPR), n (%)	36 (72)	32 (64)
Comorbidities, n (%)		
Depression + demoralization*	32 (64)	21 (42)
Chronicity of depression/demoralization, n (%)		
Current + previous episode of depression	26 (52)	19 (38)
Current + previous episode of demoralization	35 (70)	31 (62)

ACS, acute coronary syndrome; AMI, acute myocardial infarction; CBT, Cognitive-Behavioral Therapy; CID-20, 20-item Clinical Interview for Depression; CM, clinical management; DCPR, diagnostic criteria for psychosomatic research; GRACE, Global Registry of Acute Coronary Events; HRV, heart rate variability; LVEF, left ventricular ejection fraction; NSTEMI, non-ST-segment elevation myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty; PWB, Psychological Well-Being scales; SQ, Symptom Questionnaire; STEMI, ST-segment elevation myocardial infarction; WBT, Well-Being Therapy; BO, Bologna; TO, Torino. * $p \leq 0.05$.
[a] Assessed only in Torino.

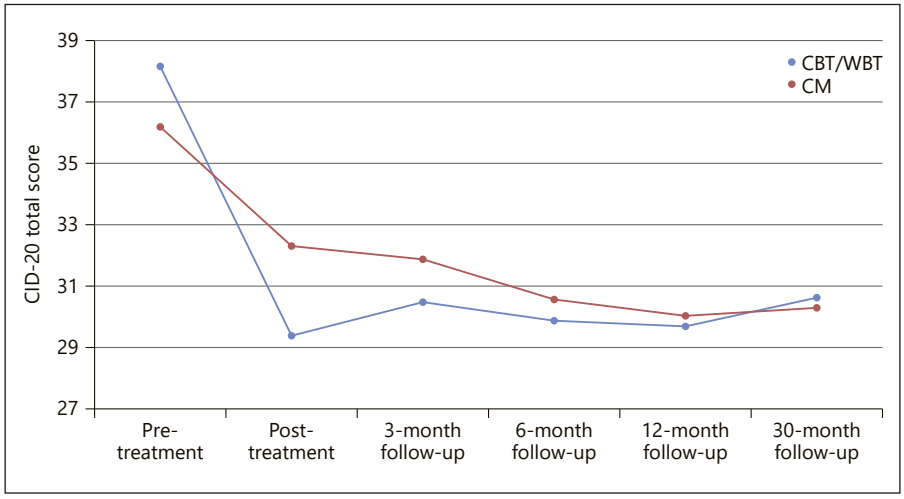

Fig. 2. CID-20 total scores at different time points (intention-to-treat analysis).

As for the CID-20 total score, a significant interaction between group allocation and time was found (F = 2.75; df = 3.85; $p < 0.05$; Fig. 2). Significant decreases in symptom scores from pre- to posttreatment were found in both the CBT/WBT ($p < 0.001$) and CM ($p < 0.01$) groups. However, the effect sizes for score modifications were strong in the CBT/WBT treatment group (Cohen's d = 1.161 and 1.393, respectively) and weak/medium among CM patients (Cohen's d = 0.492 and 0.589, respectively) (Table 2). Patients allocated to CBT/WBT reported significant lower scores posttreatment (p = 0.040) compared to those assigned to CM. Starting from the 3-month follow-up, the CID-20 score differences between the 2 groups were no longer significant. The benefits, however, tended to persist in both groups.

No significant interactions were found between time and group allocation in relation to SQ and PWB mean scores, except for hostility as assessed by the SQ (F = 3.12;

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Table 2. Effects of treatment groups on psychological characteristics

Variable	Pretreatment	Posttreatment	3-month follow-up	6-month follow-up	12-month follow-up	30-month follow-up	Time × group			Cohen's *d**	Within-group score change*, [a]
							F	df	*p* value		
Intention-to-treat analysis											
CBT/WBT group (*n* = 50), mean (SD)											
PWB autonomy	62.20 (9.18)	64.58 (9.42)	64.54 (9.24)	64.40 (9.12)	65.50 (8.53)	64.93 (9.67)	0.173	3.846	0.948	–0.26	–2.38 (–5.51 to 0.76)
PWB environmental mastery	55.28 (11.52)	57.33 (12.93)	59.48 (11.32)	58.02 (11.83)	58.36 (12.15)	58.69 (10.97)	0.309	4.353	0.886	–0.17	–2.09 (–5.61 to 1.43)
PWB personal growth	60.48 (9.88)	61.46 (9.92)	61.95 (9.91)	60.79 (9.58)	60.55 (9.54)	59.94 (9.34)	0.982	4.253	0.420	–0.10	–0.93 (–3.91 to 2.06)
PWB positive relations	61.26 (13.26)	61.82 (13.50)	61.88 (12.86)	60.60 (13.08)	61.27 (12.08)	60.48 (11.60)	0.709	4.183	0.592	–0.04	–0.57 (–3.33 to 2.19)
PWB purpose in life	56.80 (11.51)	57.31 (11.21)	58.35 (10.09)	57.88 (10.85)	57.42 (9.81)	57.63 (9.70)	1.104	3.803	0.353	–0.04	–0.49 (–4.14 to 3.17)
PWB self-acceptance	54.48 (11.63)	55.70 (14.36)	57.59 (13.51)	55.83 (14.19)	56.66 (11.92)	56.15 (13.90)	1.593	4.325	0.170	–0.09	1.30 (–4.48 to 1.89)
SQ anxiety	8.60 (4.73)	7.04 (5.23)	6.60 (4.87)	6.67 (4.19)	6.62 (4.51)	6.00 (4.35)	1.008	4.180	0.405	0.31	1.54 (–0.10 to 3.19)
SQ depression	7.92 (4.77)	7.21 (5.42)	6.38 (5.03)	7.06 (5.22)	6.91 (5.08)	5.99 (4.64)	0.605	4.180	0.667	0.14	0.70 (–0.98 to 2.37)
SQ somatization	9.82 (5.65)	8.80 (5.73)	8.67 (5.42)	8.96 (5.02)	9.49 (5.19)	8.17 (5.00)	0.787	3.981	0.534	0.18	1.04 (–0.75 to 2.84)
SQ hostility	4.70 (4.00)	5.19 (4.96)	5.18 (4.46)	4.41 (3.71)	5.32 (4.71)	3.81 (3.37)	3.121	4.288	0.013	–0.11	–0.51 (–1.91 to 0.89)
CID-20 total score	38.18 (8.48)	29.39 (6.55)	30.48 (5.81)	29.89 (5.88)	29.70 (6.51)	30.64 (7.02)	2.748	3.853	0.030	1.16	8.73 (5.39 to 12.07)
CM group (*n* = 50), mean (SD)											
PWB autonomy	61.80 (9.25)	62.82 (8.77)	63.20 (8.51)	63.21 (9.00)	64.57 (9.34)	63.71 (9.26)				–0.11	–1.02 (–4.16 to 2.11)
PWB environmental mastery	55.32 (10.65)	56.69 (8.81)	57.81 (10.15)	57.51 (8.78)	58.03 (11.19)	58.81 (8.10)				–0.14	–1.33 (–4.85 to 2.19)
PWB personal growth	56.18 (10.50)	56.54 (8.70)	56.67 (9.65)	57.10 (8.90)	57.64 (10.24)	57.00 (8.85)				–0.04	–0.41 (–3.40 to 2.57)
PWB positive relations	60.20 (10.68)	59.90 (10.93)	59.93 (12.13)	58.78 (10.82)	58.95 (11.54)	60.56 (10.78)				0.03	0.31 (–2.45 to 3.07)
PWB purpose in life	56.22 (11.59)	54.97 (9.41)	55.47 (10.32)	55.96 (10.12)	55.63 (10.82)	57.76 (8.16)				0.12	1.23 (–2.42 to 4.89)
PWB self-acceptance	55.80 (13.68)	56.03 (11.52)	57.86 (12.84)	58.32 (12.39)	59.69 (13.38)	59.94 (10.52)				–0.02	–0.15 (–3.34 to 3.04)
SQ anxiety	7.24 (4.67)	6.39 (4.41)	6.13 (4.21)	7.10 (5.14)	6.33 (5.09)	5.69 (4.07)				0.19	0.87 (–0.78 to 2.51)
SQ depression	6.90 (4.87)	5.94 (4.22)	5.83 (4.75)	6.80 (5.45)	6.22 (5.09)	5.83 (4.18)				0.21	0.98 (–0.69 to 2.66)
SQ somatization	7.82 (5.12)	8.24 (4.90)	7.87 (4.58)	8.15 (5.64)	7.90 (5.38)	7.61 (4.72)				–0.08	–0.44 (–2.23 to 1.36)
SQ hostility	5.34 (4.36)	4.12 (3.78)	4.71 (3.92)	6.01 (4.73)	5.17 (4.14)	4.56 (4.11)				0.30	1.24 (–0.16 to 2.64)
CID-20 total score	36.20 (8.57)	32.30 (7.26)	31.89 (7.11)	30.59 (7.28)	30.03 (7.05)	30.30 (6.82)				0.49	3.97 (0.63 to 7.31)

All analyses were adjusted for the GRACE index (6-month probability of cardiac mortality). CID-20, 20-item Clinical Interview for Depression; CBT, Cognitive-Behavioral Therapy; CM, clinical management; PWB, Psychological Well-Being scales; SQ, Symptom Questionnaire; WBT, Well-Being Therapy. * Pre-/posttreatment scores change. [a] Values are expressed as mean differences (95% CI).

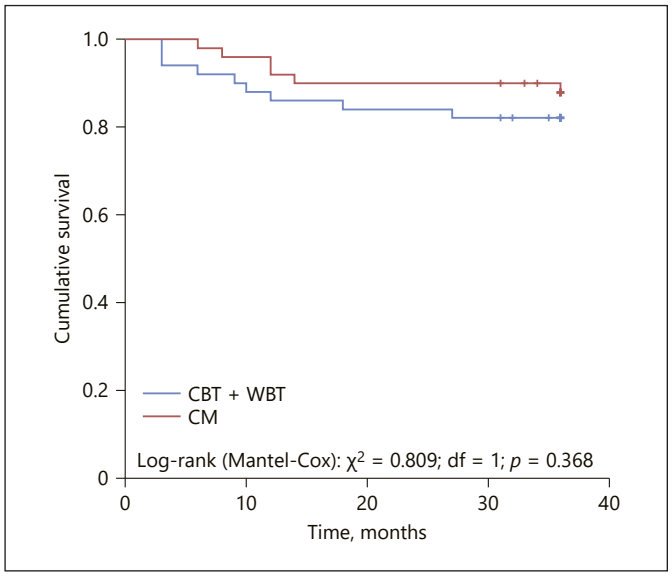

Fig. 3. Survival curves of the CBT/WBT and CM groups.

Color version available online

df = 4.29; $p < 0.05$), with CM group showing significantly higher scores at the 6-month follow-up than CBT/WBT ($p = 0.039$; Table 2).

Biomarkers

At the 3-month post-intervention follow-up, we observed a significant reduction of the frequencies of patients with biomarker levels considered to be at risk (below or above the median) only among patients allocated to the CBT/WBT group. In particular, we found a significant decrease in cases with a high platelet count (from 52 to 36%; $p < 0.05$; median = $226 \times 10^3/mm^3$), lower HDL cholesterol (from 52 to 34%; $p < 0.05$; median = 47 mg/dL), and a higher D-dimer level (from 56 to 40%; $p < 0.05$; median = 0.31 mg/L FEU) in patients assigned to CBT/WBT compared to those receiving CM. No significant decrease in patients with risky levels of biomarkers was observed in the CM group.

Survival Analyses

Within 36 months from baseline, 15% of the total sample had an adverse cardiac outcome. As for cardiac morbidity and mortality, we did not find any significant difference between the CBT/WBT and CM groups in terms of survival. Indeed, among the patients allocated to CBT/WBT 16% ($n = 8$) had nonfatal cardiac events and 1 patient (2%) had a cardiac death (occurring after 18 months from baseline), whereas among the CM patients 10% ($n = 5$) had nonfatal events and 1 patient (2%) had a cardiac death (after 36 months from baseline). Nonetheless, the CBT/WBT patients displayed most of the negative cardiac outcomes within the first 9 months, with almost half of them (4 out of 9) relapsing during treatment sessions. On the contrary, CM participants were more likely to relapse after a longer period (starting after 8 months from baseline) (Fig. 3).

Stratifying the sample by group allocation, among CBT/WBT patients the probabilities of cardiac death, both in hospital (Wald = 4.235; df = 1; HR = 1.040; 95% CI 1.002–1.079; $p = 0.040$) and at 6 months postdischarge (Wald = 4.594; df = 1; HR = 1.031; 95% CI 1.003–1.060; $p = 0.032$) as calculated with GRACE indices, were found to predict a worse cardiac prognosis. On the contrary, in the CM group adverse cardiac outcomes were predicted by baseline scores of depression, as assessed by CID (Wald = 5.540; df = 1; HR = 1.204; 95% CI 1.031–1.404; $p = 0.019$).

Discussion

To our knowledge, this is the first RCT demonstrating a significant improvement in depressive symptoms and biomarkers in patients with ACS following sequential CBT/WBT when compared with CM. This study provides new important clinical insights regarding the treatment of depression in the setting of ACS. The sequential combination of CBT/WBT was effective in significantly decreasing depressive symptoms compared to CM. In both groups the benefits persisted at follow-up, even though the differences between them faded (Fig. 2). It is noteworthy the different trend observed in the 2 groups concerning hostility, since it represents a key variable in the literature on the psychological issues embedded in depressive states [29] and it has been found to have a negative effect on the cardiac prognosis [30].

Medical outcomes did not differ between the 2 groups, yet among the CBT/WBT patients a negative cardiac prognosis was associated with a greater severity of the cardiac illness (as indicated by the GRACE indexes and the timing of relapses), whereas in the CM group it was associated with the severity of baseline depressive symptomatology. Moreover, patients who were assigned to the treatment group displayed significant decreases in placement according to normative values of platelet counts, HDL cholesterol, and D-dimer. There is evidence that these biomarkers may indicate a prognostic significance of the occurrence of cardiovascular events [31–33].

The findings are important in view of the methodology that was used. The patients were not assessed during hospitalization but rather after 1 month, when stress linked to hospitalization and the impact of acute illness are likely to subside and the evaluation of depressive symptoms is likely to be more reliable [34]. The impact of the CBT/WBT sequential combination was not compared to treatment as usual, as occurred in other studies [6], but rather to CM, where patients received the nonspecific elements of psychotherapy [27, 35]. Indeed, also CM yielded significant improvement in affective symptoms. This indicates that nonspecific support after ACS may be important, but specific psychotherapeutic strategies are associated with greater benefits and it underlines the need to schedule booster sessions (i.e., WBT or brief CBT) in order to reinforce progress or address potential obstacles to the continuance of the positive changes made during the therapy.

WBT is a short-term psychotherapeutic strategy that emphasizes self-observation of psychological well-being via the use of a structured diary, cognitive restructuring of interfering thoughts and/or behaviors, and homework assignments [9, 10]. The working hypothesis was that lifestyle changes could only be achieved with a personalized approach that targets psychological well-being [9]. Based on examples taken from post-ACS everyday life, the patients allocated to CBT/WBT were instructed on how to overcome specific obstacles concerning lifestyle (i.e., specific strategies for medication adherence, scheduling of gradual physical exercises, and dietary modification according to specific prescriptions following hospital guidelines). In the phase that immediately follows ACS, interventions that bring the person out of negative functioning and distress may be important, and this was the target of the first phase of psychotherapy (CBT). However, facilitating progression toward restoration of the positive ("there is life after ACS") and appreciation of healthy lifestyle is another target that requires specific interventions (WBT). The results of this investigation confirm previous studies on the role of psychotherapeutic strategies in the setting of ACS [6] and provide a valid alternative/integration to pharmacological strategies, which carry the disadvantages of side effects of antidepressant drugs [36–37], with particular reference to cardiovascular safety [38]. The sequential psychotherapeutic strategy that was used may also be applied after pharmacological treatment of depression, if appropriate, and may have potential in extending therapeutic benefits beyond the time of medication administration, as it has been found to be the case in psychiatric settings [39].

This therapeutic approach may be potentially extended to cardiovascular rehabilitation in view of the suitability of WBT for the rehabilitation process [40] and the adverse prognostic role of an unhealthy lifestyle and depressive symptoms in these settings [41–43]. A number of clinical situations (delayed recovery after treatment, discrepancy between cardiovascular status/functioning, presence of a psychological comorbidity, problems with lifestyle and risky behavior, and presence of stressful circumstances) may be addressed by the sequential strategy we have outlined.

The findings of this investigation targeting psychological well-being in ACS should be seen as preliminary and await proper replication studies. It should also be noted that more than a quarter of the ACS patients diagnosed with depression and/or demoralization (36 out of 136; 26.5%) refused to join the RCT. This percentage, however, is lower than the refusal rates found in the literature on secondary prevention programs, which range from 31.4 [44] to 72.2% [45] among depressed patients. Moreover, about half of the 740 patients initially screened by the cardiologists refused to undergo psychological assessment and almost half of those who agreed refused to join the trial or revoked the initial consent. The results are thus likely to reflect a self-selected population. Nonetheless, they indicate a road to the practice of lifestyle medicine [46] that is worth perusing.

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Statement of Ethics

This study was approved by the institutional review board of the ethics committees of both centers (identifier: Studio CE 09058). Written informed consent was secured from all of the patients for both the initial psychological evaluation and trial participation, after the procedures had been fully explained to them. The participants did not receive any compensation. The authors assert that all of the 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.

Conflict of Interest Statement

The authors have no conflict of interests to declare.

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Author Contributions

C.R., G.A.-D., and G.A.F. conceptualized and designed this study. C.R., S.G., G.A.-D., and G.A.F. collected, analyzed, and interpreted the data. C.R., S.G., and G.A.F. wrote the first draft of this paper. S.G. performed the statistical analyses. All of the authors critically revised this work for important intellectual content and provided administrative, technical, or material support. C.R., G.A.-D. and G.A.F. supervised the whole process.

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Use of Social Desirability Scales in Clinical Psychology: A Systematic Review

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Objective: There is still an open debate about the utility of social desirability indicators. This report systematically reviewed the use of social desirability scales in studies addressing social desirability in clinical psychology. **Method:** A systematic review (January 2010–March 2015) was conducted, including 35 studies meeting the inclusion criteria of being published in peer-reviewed journals and describing quantitative findings about an association of social desirability with clinical psychology variables using a cross-sectional or longitudinal design. **Results:** Social desirability was associated with self-reports of various clinical-psychological dimensions. Most of the included studies treated social desirability as a 1-dimensional variable and only 10 of 35 disentangled the impression management and self-deception components. Although theoretical literature does not consider social desirability a mere response bias, only 4 of the reviewed articles controlled for the possible suppressor effect of personality variables on social desirability, while the majority focused upon the stylistic (response bias) rather than the substantive (personality) nature of this construct. **Conclusion:** The present review highlighted some limitations in the use of social desirability scales in recent clinical psychology research and tried to offer a few suggestions for handling this issue. J. Clin. Psychol. 72:534–551, 2016.

Keywords: social desirability; impression management; self-deception; response bias; systematic review

Social desirability (SD), or socially desirable responding, is "the tendency to give answers that make the respondent good" (Paulhus, 1991, p. 17) with respect to current social norms and standards. SD may affect several psychological variables, especially when they are measured through self-reports, which facilitate the respondents manipulating their answers. For example, respondents to sensitive surveys asking about taboo topics such as racism, sexual activities, and illegal behavior may underreport socially undesirable activities (Krumpal, 2013). This is because self-report items include both a *description content* (e.g., introverted vs. extraverted) and an *evaluative content* (e.g., good vs. bad; Bäckström & Björklund, 2014; Saucier, 1994). When a self-report is *evaluated* as highly desirable or undesirable, the subject's self *description* could be biased (Bäckström, Björklund, & Larsson, 2012; Saucier, 1994). Therefore, SD scales could be useful for detecting the evaluative content in a self-report measure (see Bäckström & Björklund, 2014). However, the nature, the measurement, and whether and how to deal with SD are still matters for debate (Ziegler, MacCann, & Roberts, 2012).

In the first half of the 20th century, several articles discussed the threats that can occur during the administration of self-reports (e.g., Cronbach, 1946; Hartshorne & May, 1928). However, in 1957 Edwards made the first attempt to measure SD by using some items from the Minnesota Multiphasic Personality Inventory (MMPI). Later, Crowne and Marlowe (1960) developed the 33-item Marlowe Crowne Social Desirability Scale (MCSDS) to measure SD without any reference to psychopathology. Over the years, several short versions of this scale have been developed (e.g., Ballard, 1992; Reynolds, 1982; Strahan & Gerbasi, 1972).

The abovementioned measures consider SD as a one-dimensional variable. Nevertheless, a major contribution in clarifying the concept of SD was offered by Paulhus (1984, 1991), who

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identified two components of SD: impression management (IM) and self-deception (SDE). IM is intended as a conscious inclination to offer unrealistic positive responses designedly to deceive others, while SDE is an unconscious tendency in which the respondent actually believes his or her positive self-reports. IM and SDE were then further partitioned: IM into agentic management and communal management (Blasberg, Rogers, & Paulhus, 2014) and SDE into self-deceptive enhancement and self-deceptive denial (Paulhus, 2002; Paulhus & John, 1998; Paulhus & Reid, 1991; Vecchione & Alessandri, 2013).

Agentic bias involves exaggerating one's social or intellectual status, whereas communal bias involves denying socially deviant impulses and claiming pious attributes (Blasberg et al., 2014). The Balanced Inventory of Desirable Responding (BIDR; Paulhus, 1988, 1991, 1998) allows disentangling IM and SDE, with the possibility of further partitioning SDE into self-deceptive enhancement and self-deceptive denial. The BIDR originally used a 7-type Likert scale, but psychometric studies have confirmed that it fits better within a dichotomous coding system (e.g., Gignac, 2013; Helmes & Holden, 2003). More recently has been developed the Bidimensional Impression Management Index (BIMI; Blasberg et al., 2014), which allows to disentangle IM into agentic management and communal management. Overall, several studies confirmed a multifactorial structure of SD (Gignac, 2013; Ventimiglia & MacDonald, 2012).

Until the 80s, SD tools were mainly considered measures of faking. Participants who scored high in SD scales were regarded as tending to fake, and self-reports that correlated significantly with SD scales were considered as lacking of validity (Nederhof, 1985). A turning point occurred when McCrae and Costa (1983) found very little differences between self- and partner-rating scores of SD, while testing whether neuroticism–extraversion–openness scales were affected by SD. Therefore, they attributed the correlations of SD with personality to the substantive nature of SD, concluding that individuals who obtained high scores on SD scales "were in fact better adjusted, friendlier, and more open to experience than those who scored low" (McCrae & Costa, 1983, p. 886).

From that time to the present day, many studies have been dedicated to discussing the substantive (personality trait) or stylistic (faking or bias) nature of SD, with controversial results. Indeed, some findings attested to the personality characteristics of SD (Ones, Viswesvaran, & Reiss, 1996; Pauls & Stemmler, 2003; Smith & Ellingson, 2002; Uziel, 2010) and other studies found that SD may contain both substantive and stylistic features (Connelly & Chang, in press; Lönnqvist, Paunonen, Tuulio-Henriksson, Lönnqvist, & Verkasalo, 2007; Vecchione & Alessandri, 2013). Some authors, however, argued that SD contains neither substance nor style but could instead be a form of method variance (Holden & Passey, 2010).

In conclusion, the substance versus style nature of SD does not seem to be an either/or question (Schwartz, Verkasalo, Antonovsky, & Sagiv, 1997); however, within this controversial body of research, indication of not taking the SD scales as measures of faking seems to prevail (MacCann, Ziegler, & Roberts, 2012). Related to this issue is the need of taking into account the role of personality variables when dealing with SD scales. Indeed, as Bäckström et al. (2012) suggest, the influences of SD on other variables could be because of its strict relationship with personality variables, in particular with the Big Five traits, and thus a good approach to SD would require checking the possible overlapped variance between SD and personality variables.

There is still an open debate about the utility of bias indicators like SD scales, with some authors viewing them as useless (McGrath, Mitchell, Kim, & Hough, 2010) and others deeming such scales worthwhile to be administered (Podsakoff, MacKenzie, Lee, & Podsakoff, 2003; Rohling et al., 2011); therefore, we believe this issue deserves further investigation.

The relevance of SD has been largely investigated in psychological areas such as personality psychology, organizational psychology, and neuropsychology (e.g., Ones et al., 1996; Rogers, 2008; Ziegler et al., 2012). In the literature, there are also studies that attest to the relevance of SD in clinical psychology (Huang, Liao, & Chang, 1998; Merckelbach, Jelicic, & Pieters, 2011). However, the only available review on the use of SD in clinical psychology dates back more than 30 years ago (Evans, 1982), highlighting that SD is actually an underestimated topic within this psychological area. A more recent review explored the use of SD scales in nursing contexts within the 2-year period of 2004–2005 (van de Mortel, 2008). However, findings were too specific to the nursing context to draw conclusions on the relevance of SD in clinical psychology.

The Present Study

This study aimed to review how SD has been recently addressed in clinical psychology, establishing the following objectives: (a) to investigate the association of SD with other variables in the contexts of clinical psychology; (b) to ascertain whether SD was measured as a mono- or multidimensional variable; and (c) to find out whether personality traits were controlled for when testing the effect of SD on other variables. The last issue is related to whether SD was considered a stylistic or bias or a substantive variable. We also offered suggestions for addressing the SD issue, based on the literature related to other psychological fields.

Method

We followed the PRISMA statement (Moher, Liberati, Tetzlaff, Altman, & The PRISMA Group, 2009) to conduct this review. PRISMA statement is an evidence-based protocol developed by an international group of researchers to help authors improve the reporting of systematic reviews and meta-analyses.

Eligibility Criteria

Eligibility criteria included (a) only empirical studies (involving adolescent or adult participants) that explored the association of SD with other psychological variables within topics that are pertinent to clinical psychology and (b) were published in peer-reviewed journals. The imposed restrictions included English language, publication date from January 2010 to March 2015, and published or ahead of print publication status. The publication date restriction was used to discuss the most recent trends in the management of SD while reducing the cost of retrieving a large number of articles.

Search Strategy and Selection Criteria

We identified studies by searching two electronic databases, PsycINFO and Google Scholar and the last search was run on March 31, 2015. We also scanned the reference lists of the retrieved articles. We used the following search terms in the titles: social desirability, socially desirable responding, impression management, self-deception, response bias, and faking. We searched for these terms in the titles to ensure that SD was not a marginal topic in the study. We excluded books, dissertations, and conference proceedings.

We independently performed eligibility assessment and disagreements were resolved by consensus. The inclusion criteria used to select articles from abstract and full text were as follows: SD was (a) one of the main variables of interest, (b) investigated in relation to other variables that were relevant to clinical psychology, (c) measured with a quantitative tool. Studies concerning areas other than clinical psychology, such as economics, personality, organizational psychology, neuropsychology, validation studies, and those involving only children, were excluded.

We reviewed abstracts, retrieved eligible full-text articles, and re-reviewed them. We extracted data from the included studies using a data extraction form, with consensus resolution of decisions. Information extracted from each included article is as follows: author(s), year of publication, and country; characteristics of participants (sample type and size, gender, and age); clinical psychology topics that were associated with SD; SD measures; personality traits that were controlled for when investigating the association between SD and other variables; and key findings related to the association of SD with clinical psychology variables (see Table 1).

Results

A total of 35 studies were identified for inclusion in the review. The search of databases provided 391 citations from PsycINFO and 1,190 citations from Google Scholar for a total of 1,581 citations. Based on examination of the publication type and abstract and after adjusting for duplicates, 108 remained. Of these, 73 studies were discarded because, after reviewing the full text, they did not meet the inclusion criteria. The full text of the remaining 35 citations was then

Table 1
Summary of the 35 Reviewed Studies' Characteristics

Study (country)	Participants	Main topic	SD measure[a]	Personality traits controlled for	Key results[b]
			Attitude, knowledge, and health behavior		
Ambwani & Chmielewski, 2013 (United States)	155 adults aged 18–23 years (69% female)	Body weight	PAI-PIM	None	SD significantly predicted weight-reporting discrepancies for women but not for men.
Boyer et al., 2012 (Canada)	41 women aged 18–27 years; 20 with provoked vestibulodynia (PVD) and 21 controls	Sexual arousal	BIDR-7	None	IM was not a moderator between genital and subjective arousal. In the PVD group, IM was significantly negatively correlated with subjective sexual arousal.
Crutzen et al., 2010 (The Netherlands)	7,077 adults (mean age = 43.3, *SD* = 13.1, 56.6% female)	Health risk behaviors (e.g., alcohol use, drug use, smoking)	MCSDS BIDR-6 SDS-17	None	Three longitudinal studies did not find any significant influence of SD on self-reported health risk behaviors in web-based research.
Crutzen et al., 2011 (The Netherlands)	5,495 adults (mean age = 47.1, *SD* = 16, 54% female)	Physical activity	MCSDS	None	SD did not influence self-reported physical activity in web research.
Davenport et al., 2012 (United Kingdom)	134 women aged 18–54 years	Excessive eating and compulsive buying	SDS-17	Self-esteem, impulsivity, reward sensitivity, anxiety	SD was negatively correlated with excessive eating and compulsive buying, but after controlling for personality traits, SD weakly influenced only compulsive buying.
Davis et al., 2010 (Canada)	568 adults (mean age = 19.74, *SD* = 2.29, 70.5% female)	Drinking	BIDR-6	None	IM was significantly negatively correlated with consumption and risky drinking, while SDE was not correlated.
Foster, 2013 (United States)	676 college students (mean age = 22.92, *SD* = 5.43, 82.44% female)	Drinking	MCSDS	None	SD negatively predicted drinking regardless of gender effect.

(*Continued*)

Table 1
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Study (country)	Participants	Main topic	SD measure[a]	Personality traits controlled for	Key results[b]
Gucciardi, Jalleh, & Donovan, 2010 (Australia)	224 athletes aged14-62 years (61.16% male)	Doping attitude and susceptibility	SDS-17	None	SD moderated and did not mediate the relationship between attitudes to doping and doping susceptibility.
Henderson, Evans-Lacko, Flach, & Thornicroft, 2012 (United Kingdom)	392 adults aged 25–45 years (46.65% male)	Mental health knowledge and willingness for social contact in face-to-face vs. online interview	MCSDS-short form	None	SD was positively correlated with willingness for social contact only in the face-to-face group, while it was not correlated with mental health knowledge in both groups.
Huberman, Suschinsky, Lalumière, & Chivers, 2013 (Canada)	79 women aged 18–39 years	Sexual arousal in different condition (erotic audio vs. erotic films)	BIDR-6	None	IM was significantly negatively correlated with sexual arousal self-reports in both auditory and audiovisual erotic stimuli groups.
Petróczi & Nepusz, 2011 (United Kingdom)	278 athletes (mean age = 20.1, $SD = 1.9$,71.6% male)	Doping	MCSDS	None	SD predicted doping opinion together with control, deterrence, and attitude to doping.
Poínhos, Oliveira, & Correia, 2015 (Portugal)	266 higher education students aged 18–27 years (62.8% female)	Eating behavior	MCSDS	None	SD was significantly negatively correlated with emotional, external and binge eating, and positively with eating self-efficacy. It also weakened the correlations among eating behavior variables.
Schoch & Raynor, 2012 (United States)	38 normal weight women (mean age = 20.3, $SD =$ 6.9)	Dietary intake	MCSDS-short form	None	Higher SD was associated with more accurately reporting of energy intake.
Vu, Pham, Tran, & Ahmed, 2013 (Ethiopia)	114 young aged 15–24 years (51.8% female)	Sexual behavior	MCSDS	None	SD was positively associated with self-reported sexual abstinence.

(*Continued*)

Table 1
Continued

Study (country)	Participants	Main topic	SD measure[a]	Personality traits controlled for	Key results[b]
		Physical and mental symptoms and quality of life and well-being			
Aavik, Aavik, & Punab, 2014 (Estonia)	112 males (mean age = 52.78, *SD* = 8.69) with chronic prostatitis/chronic pelvic pain syndrome	Chronic pain and urinary symptoms	BIDR-6	None	IM (positively) and SDE (negatively) were significantly correlated with pain; only SDE was negatively correlated with urinary symptoms.
Ambwani, Boeka et al., 2013 (United States)	359 bariatric surgery candidates aged 18–68 years (82% female)	Anxiety and depression	PAI-PIM MCSDS	None	Both measures of SD were negatively correlated with anxiety and depression.
Arab et al., 2014 (Iran)	123 patients with addiction disorders (mean age = 34.8, *SD* = 9.3, 82% males)	Quality of life	MCSDS	None	SD was not correlated with quality of life.
Brajša-Žganec, Ivanović, & Lipovčan, 2011 (Croatia)	392 students aged 19–26 years (50% females)	Subjective well-being	MCSDS-short form	Big Five	SD showed a significant influence on subjective well-being, which disappeared after controlling for personality traits.
Dawes, Palmer, Allison, Ganiats, & Jeste, 2011 (United States)	1,860 females aged 57–91 years	Physical health, well-being and attitude toward aging	MCSDS-short form	None	SD significantly predicted physical health, well-being and attitude toward aging, but this influence disappeared after controlling for age, income, education, and ethnicity.
DeVylder & Hilimire, 2015 (United States)	686 college students (mean age = 18.75, *SD* = 1.41, 57% female)	Psychotic experience	MCSDS	None	SD negatively predicted self-reported psychotic experiences.

(*Continued*)

Table 1
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Study (country)	Participants	Main topic	SD measure[a]	Personality traits controlled for	Key results[b]
Di Milia & Muller, 2012 (Australia)	191 adults (mean age = 36.28, *SD* = 12.94, 53% males)	Sleepiness	BIDR-6	None	IM was not associated with sleepiness.
Fastame & Penna, 2012 (Italy)	201 adults aged 19–99 years (45.52% female)	Depression and well-being	MCSDS	None	Age and SD significantly predicted depression (negatively) and well-being (positively). The group aged 75–99 years scored higher on SD than the other age groups (20–30 years and 65–74 years).
Heintzelman Trent, & King, 2015 (United States)	176 adults aged 18–69 years (39.7% female)	Well being in three experimental conditions: Fake bad, fake good and honest	BIDR-6	None	The total BIDR score was significantly positively correlated with four scales of well-being, with the higher values in the fake good condition.
Ishida & Okada, 2011 (Japan)	23 adults (mean age = 23.04, *SD* = 8.29, 61% females)	Anxiety	MAS (lie scale)	None	SD was not correlated with anxiety. SD influenced granulocyte count (positively) and lymphocyte count (negatively).
Messina, Fogliani, & Paradiso, 2010 (Italy)	111 graduate students aged 24–58 years (69% female)	Alexithymia	EPQ-R (lie scale)	Neuroticism, extraversion, psychoticism	SD showed a significantly negative correlation with alexithymia, which disappeared after controlling for neuroticism.

(*Continued*)

Table 1
Continued

Study (country)	Participants	Main topic	SD measure[a]	Personality traits controlled for	Key results[b]
Pompili et al., 2011 (Italy)	200 participants (mean age = 39.45, *SD* = 13.72, 54% female) 58 with psychiatric disorders and 142 controls	Hopelessness	BIDR-6	None	In both groups hopelessness was significantly negatively associated with SDE but not with IM.
Soubelet & Salthouse, 2011 (United States)	1175 adults aged 18–93 years (63% female)	Mood and well-being	MCSDS	None	SD was significantly positively correlated with age, positive affects, life satisfaction, and negatively with depression, negative affects, and trait anxiety. Correlations of age with both personality and mood self-reports decreased after controlling for SD.
Surbey, 2011 (Australia)	80 undergraduate students aged 17–47 years (66% female)	Depression, optimism, and cooperation	SDQ BIDR-7	Dispositional optimism	SDE, but not IM, was significantly negatively correlated with depression and positively with optimism. Only optimism predicted cooperation.
		Treatment variables and outcomes			
Bradshaw Donohue, Cross, Urgelles, & Allen, 2011 (United States)	82 mothers aged 18–49 years in treatment for substance abuse and child neglect	Parental satisfaction	CAPI Lie scale	None	SD responders (Lie scale score ≥ 8) scored significantly higher on parental happiness with children than valid responders (Lie scale score < 8)
Davis Doherty, & Moser, 2014 (Canada)	1,747 males (mean age = 34.35, *SD* = 9.15) in substance abuse treatment (82% moderate vs. 18% high intensity treatment)	Substance abuse related outcomes	BIDR 7	None	Both IM and SDE increased significantly from pre- to post-treatment and affected changes on self-reported drug- and alcohol-related attitudes/beliefs/locus of control and self-efficacy.

(*Continued*)

Table 1
Continued

Study (country)	Participants	Main topic	SD measure[a]	Personality traits controlled for	Key results[b]
Freeman, Schumacher, & Coffey, 2015 (United States)	54 males (mean age = 35.54, *SD* = 9.28) in substance abuse treatment and their partners (mean age = 34.89, *SD* = 9.26)	Intimate partner violence	BIDR-7	None	SDE and IM were significantly positively correlated with negotiating tactics with partner. Only IM was negatively correlated with psychological aggression. No correlations were found with physical and sexual aggression and injurious behavior.
Mathie & Wakeling, 2011 (United Kingdom)	1,730 males (mean age = 43.65, *SD* = 12.6) with a sexual offense sentence	Sexual antisocial behaviors	BIDR-6	None	Both IM and SDE significantly increased from pre- to post-treatment and were negatively correlated with offence-specific measures.
Nolte, Elsworth, & Osborne, 2013 (Australia)	331 patients (mean age = 62.2, *SD* = 13.2) (74.2% female) with chronic health problems in a self-management program	Self-management of chronic disease	MCSDS	None	SD was not a mediator between pre- and post-health education intervention outcomes
Reese et al., 2013 (United States)	102 clients of counseling centers aged 18–51 years (79.4% female)	Therapeutic alliance in three experimental conditions	MCSDS-short form	None	SD was not correlated with a measure of therapeutic alliance in none of the experimental conditions.
Zemore, 2012 (United States)	200 patients aged 18–60 years (70% male) in substance abuse treatment	Drug use and readiness to change	MCSDS-short form	None	SD significantly negatively affected psychiatric severity, drug use, and self-reported change readiness. These variables positively influenced the treatment attendance.

Note. *SD* = standard deviation.
[a]PAI-PIM = Personality Assessment Inventory-Positive Impression Management; BIDR = Balanced Inventory of Desirable Responding; MCSDS = Marlowe Crowne Social Desirability Scale; CAPI = Child Abuse Potential Inventory; SDS-17 = Social Desisrability Scale-17; MAS = Manifest Anxiety Scale; EPQ-R = Eysenck Personality Questionnaire-Revised; SDQ = Self Deception Questionnaire.
[b]SD = social desirability; IM = impression management; SDE = self deception.

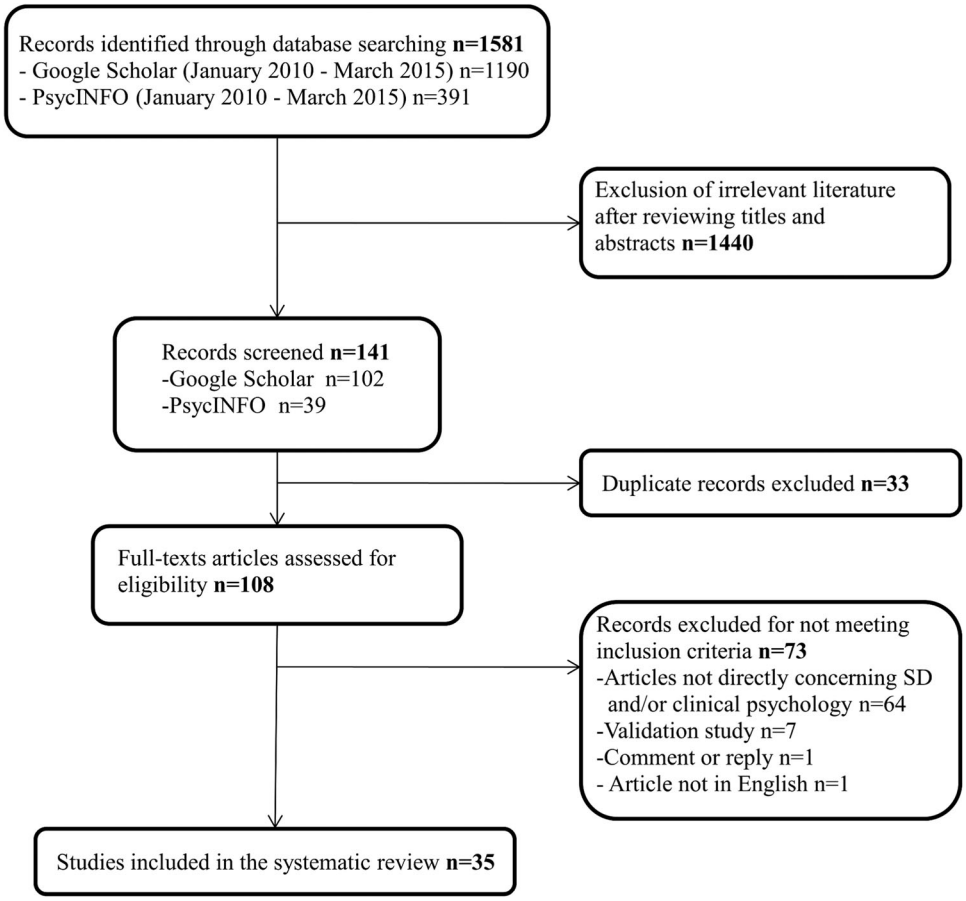

Figure 1. Flow diagram of literature search and study selection.

examined in greater detail. All these studies met the inclusion criteria and were thus included in the systematic review. No additional relevant studies were obtained by checking the references of located papers (see the flow diagram in Figure 1). Table 1 presents a summary of information on the 35 reviewed studies that met the inclusion criteria.

The retrieved studies involved samples ranging from 23 to 5,612 participants and were conducted mainly in North America ($n = 16$) and Europe ($n = 12$). The most frequently used SD measures were the MCSDS ($n = 18$; Ballard, 1992; Crowne & Marlowe, 1960; Reynolds, 1982; Strahan & Gerbasi, 1972), and the BIDR ($n = 12$; Paulhus, 1988, 1991, 1998). The Social Desirability Scale–17 (Stöber, 1999, 2001) was administered in three studies, while the Self-Deception Questionnaire (Sackeim & Gur, 1978) was used only in one study. Five studies administered a lie scale to detect more or less conscious lying within personality questionnaires, such as the Eysenck Personality Questionnaire (Eysenck, Eysenck, & Barrett, 1985), the Personality Assessment Inventory (Morey, 2007), the Manifest Anxiety Scale (Tayler, 1953), and the Child Abuse Potential Inventory (Milner, 1986). Although lie scales are developed to measure distortion in a specific self-report, we included these five studies in the review as the authors used them purposely to measure SD. Among the 35 included studies, only four (11.43%) controlled for the effect of various personality variables on SD.

To summarize the main results, we grouped the included studies based on three areas of interest: self-reports of attitude, knowledge, and health behavior; physical and/or mental symptoms and quality of life and well-being; and treatment variables and outcomes.

Self-Reports of Attitude and Health Behavior

Fourteen studies addressed SD in relation to self-reports of attitude, knowledge, and health behavior. Taken together, SD correlated negatively with certain undesirable self-reports, such as drinking behavior, doping use, and external or binge eating, and correlated positively with desirable characteristics, such as eating self-efficacy or willingness for social contacts, attesting that SD is a relevant issue in this area. Only two studies (Crutzen & Göritz, 2010, 2011) found no effect of SD on health self-reports (e.g., alcohol use and smoking) in web-based research. Results of these studies seem to indicate an influence of the administration mode on SD score; however, evidence from a recent meta-analysis (Dodou & de Winter, 2014) indicates that there is no difference in social desirability between paper-and-pencil surveys and computer surveys.

Most studies (11 of 14) treated SD as a one-dimensional variable and only three disentangled IM and SDE. Two of them found significantly negative correlations between IM and measures of sexual arousal in normal (Huberman, Suschinsky, Lalumière, & Chivers, 2013) and clinical samples (Boyer, Pukall, & Holden, 2012). A third study (Davis, Thake, & Vilhena, 2010) found that, in normal adults, IM was negatively correlated with consumption and risky drinking, while SDE did not show any significant correlations with such behaviors. The only study that controlled for personality variables indicated that the significantly negative influence of SD on excessive eating disappeared after controlling for self-esteem and impulsivity (Davenport, Houston, & Griffiths, 2012).

Physical and/or Mental Symptoms and Quality of Life and Well-Being

Fourteen studies addressed SD in relation to physical and/or mental symptoms and quality of life and well-being. Here, too, there were several positive and negative correlations with desirable and undesirable characteristics, respectively, attesting the relevant role of SD. Among the studies that investigated SD and quality of life in individuals with addiction disorders only one study failed to report significant correlations (Arab et al., 2014).

Again, most studies (10 of 14) treated SD as a one-dimensional variable with only four studies disentangling the effects of IM and SDE. SDE (but not IM) was negatively associated with depression and hopelessness in two samples from the general population (Pompili et al., 2011; Surbey, 2011); therefore, it was hypothesized that SDE could be a protective factor for depression and suicide risk. In another study, IM was positively correlated with pain scores and not associated with urinary symptoms, whereas SDE was negatively correlated with both pain and urinary symptoms in a sample of men with chronic prostatitis or chronic pelvic pain syndrome (Aavik, Aavik, & Pukal, 2013). One study did not find any association between IM and self-reported sleepiness in a sample of 191 normal adults (Di Milia & Muller, 2012). Overall, three of the four studies that addressed IM and SDE highlighted the importance of disentangling these components of SD.

Three studies controlled for personality variables when investigating the relationship between SD and the target or outcome variables and found that in all cases the effect of SD was suppressed. In fact, SD had no influence on subjective well-being in a sample of students after controlling for the Big Five dimensions (Brajša-Žganec, Ivanović, & Lipovčan, 2011); the correlation between SD and alexithymia was not any more significant after controlling for neuroticism in a sample of graduate students (Messina, Fogliani, & Paradiso, 2010); and the positive association of IM and SDE with intentions to cooperate in patients with depression became negligible after controlling for dispositional optimism (Surbey, 2011).

Treatment Variables and Outcomes

Seven studies examined the effect of SD in self-reports of treatment variables and outcomes, and in most of them SD correlated negatively with certain undesirable self-reports such as psychiatric symptoms or drug addiction severity and correlated positively with desirable characteristics such as parental happiness or treatment attendance. On the contrary, two studies found a negligible effect of SD on clinical outcomes such as therapeutic alliance (Reese et al., 2013) and self-management of chronic disease (Nolte, Elsworth, & Osborne, 2013).

Only three of seven studies disentangled the effects of IM and SDE, and in two of them these components had the same effect on the outcomes, while a third study highlighted some differences between them. Both components of SD, with no differences, increased from pre- to posttreatment in a large sample of male offenders in substance abuse treatment (Davis, Doherty, & Moser, 2014), and in a sample of adult males sentenced as sexual offenders, they showed similar correlations with offence-specific measures (Mathie & Wakeling, 2011). In a third study, involving a sample of males in substance abuse treatment and their partners, IM was more negatively related than SDE to an undesirable behavior such as intimate partner violence (Freeman, Schumacher, & Coffey, 2015). None of the seven studies included in this section controlled for personality variables.

Discussion

This systematic review was conducted to investigate how SD has been treated in the recent clinical psychology literature, with the intention to stimulate the attention of researchers and clinicians to a variable that has been instead widely faced in many other fields of psychology (Ziegler et al., 2012). We included only studies in which SD was quantitatively addressed. Attention was paid to the SD multidimensionality (Gignac, 2013) and its possible nature as a trait (McCrae & Costa, 1983), because some authors recommend not using SD scales as measures of faking (MacCann et al., 2012).

Results of the 35 reviewed articles provide some evidence that SD is associated with several self-report variables in clinical psychology, such as attitude, knowledge and health behaviors, physical and mental symptoms, quality of life and well-being, and treatment variables and outcomes. These findings seem to indicate that evaluative aspects may overwhelm the descriptive purposes of the examined self-reports (Saucier, 1994), suggesting that SD should be taken into account when addressing self-reports in clinical psychology.

Within the examined studies, the most administered SD scale was the MCSDS, which operationalized SD as a one-dimensional variable. However, key results from a few studies that operationalized SD as a multifactorial construct showed that, consistent with studies in other psychological fields (Blasberg et al., 2014; Gignac, 2013; Paulhus, 2002), disentangling IM and SDE is useful because these two components could lead to different conclusions. For instance, IM but not SDE was significantly related to self-reports of undesirable behaviors such as alcohol use (Davis et al., 2010) and partner violence (Freeman et al., 2015), whereas only SDE was a protective factor against depression, hopelessness, and suicide risk (Pompili et al., 2011; Surbey, 2011).

Another important issue was the use of lie scales as measures of SD in five of the included studies. We deem that lie scales are instruments developed to detect potential distortions that a *specific* self-report could elicit. Therefore, in our opinion, they could be useful to detect convergent validity of SD scales, with which they had high correlations (e.g., Stöber, 2001), but we discourage their use as a direct measure of SD. However, further studies are needed to ascertain what lie scales are and are not sharing with SD scales.

With regards to the effect of personality variables on the relationship between SD and other self-reported variables, although only four of the 35 reviewed studies took into account this issue, consistent with other studies (McCrae & Costa, 1983; Ziegler et al., 2012), they attested to the suppressor role of personality variables on SD. Indeed, after controlling for personality variables such as neuroticism, impulsivity, self-esteem, dispositional optimism, or the Big Five dimensions, the association or influence of SD on clinical variables such as excessive eating (Davenport et al., 2012), alexithymia (Messina et al., 2010), subjective well-being (Brajša-Žganec et al., 2011), or intentions to cooperate (Surbey, 2011) disappeared. Therefore, controlling for personality variables seems to be relevant to clarify the role of SD in self-reports, which might otherwise be overestimated.

Limitations

The present review has several limitations. The first one is related to the restrictive eligibility criteria that could have lead to the exclusion of several studies. Such criteria were the narrow

time range of the included studies (2010-2015) and choices such as entering only keywords strictly related to SD, running the search only in the article title, and excluding dissertations and unpublished work. The choice of including only articles concerning topics of clinical psychology could have led to bias in the study selection; however, we matched our independent choices and resolved a few negligible discrepancies by consensus.

Another aspect is the interpretation of the results of the retrieved studies. Although we followed the key methodological recommendations for conducting systematic reviews, the findings of the present review were presented in a narrative way instead of through statistical analyses (e.g., as in a meta-analysis). This was mainly because of the lack of a general consensus framework to organize the results, and thus we used a subjective framework, extrapolated from personality studies by Paulhus (1991, 1998, 2002) and McCrae and Costa (1983).

It is important to acknowledge that most of the included studies relied on a sample of convenience, such as university or undergraduate college students; therefore, results should be interpreted with caution. Other reasons for such caution are the cross-sectional design of most studies, the recruitment of nonclinical participants, and the exclusive use of self-reports without verifying them by using other sources. Despite these limitations, results from the 35 examined studies can help to draw attention to aspects of SD that warrant further examination within clinical psychology research.

Directions for Future Research

We suggest administering the SD scales in future research, which will help to disentangle these construct components, IM and SDE. The BIDR (Paulhus, 1991, 1998) has followed a course of successive improvements over 35 years (Blasberg et al., 2014; Paulhus, 1984, 2002; Sackeim & Gur, 1978), so that it currently seems to be the best choice to measure the two main subfacets of SD, namely, IM and SDE. Recently, the BIMI (Blasberg et al., 2014) has also been made available to further disentangle communal and agentic forms of IM.

We also recommend that future research investigates the possible suppressive role of personality variables on SD by administering personality scales together with SD scales. The Big Five personality dimensions have a particularly relevant effect on SD (Ones et al., 1996; Paulhus, 2002), which has to do with the possible interpretation of SD as a personality trait more than a faking intention, that is, a more substantive than stylistic issue (Connelly & Chang, in press; Ziegler et al., 2012). Indeed, a reason why the effect of SD on self-reports variables is suppressed by introducing personality variables might be because of the overlapping variance between SD and other personality traits. Notably, a very brief version of the Big Five is available, which can be used when the length of the questionnaire is a concern (Gosling, Rentfrow, & Swann, 2003).

MacCann et al. (2012) recommend not to use SD scales as strictly faking scales, because it may lead to misinterpretation of the effect of SD on self-reports of other variables. Hall and Hall (2012) propose alternative strategies to address suspected cases of faking. For example, in place of using SD measures to assess effort or response bias, they suggest administering other tests such as the Test of Memory Malingering, the MMPI-2 F-K ratio, the MMPI FBS, the Rey 15-item test, or the California Verbal Learning Test. However, Hall and Hall (2012) also pointed out that the diagnosis of malingering cannot be made with 100% certainty from just a test, and thus they recommend using a nonconfrontational approach that integrates psychometric test results with clinical information.

Conclusion

In this review, we encourage clinical psychologists to take SD into consideration when investigating self-reports of various target behaviors. We also suggest clinical psychologists address this issue more effectively by using adequate SD scales that disentangle the different aspects of this construct and take into account personality variables to avoid interpreting SD merely as a measure of faking.

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Values, acceptance, and belongingess in graduate school: Perspectives from underrepresented minority students

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ABSTRACT

Background: Although the enrollment rate of students who come from racial and ethnic backgrounds traditionally underrepresented (URM) in higher education settings is steadily increasing in United States graduate programs, URM students are still considerably underrepresented. Systemic racial and ethnic discrimination, microaggressions, and low belongingness may negatively impact psychological functioning and interfere with academic success. Objective: This study explored the relationship between racial and ethnic stressors, belongingness, acceptance, and valued living on the psychological functioning of URM graduate students. Method: Participants (N = 436) were URM students pursuing their doctoral degree in the United States who completed the *Schedule of Racist Events, Racial and Ethnic Microaggressions Scale, Campus Connectedness Scale, Valued Living Questionnaire*, *Philadelphia Mindfulness Scale*, and the *Depression, Anxiety, and Stress Scales*. Results: Racial and ethnic microaggressions and stressors were positively associated with psychological distress and belongingness was negatively associated with psychological distress (*r's* = .21-0.33). However, three hierarchical regression analyses demonstrated that both acceptance of internal experiences and values-based living predicted psychological functioning (depression, anxiety, and stress) over and above the negative effects of racial and ethnic stressors and low perceived belongingness. Conclusions: Although systemic changes are needed to address the inequities that URM graduate students face, helping students to cultivate an accepting stance and live consistently with personal values could buffer against the effects of these stressors on psychological functioning.

Several communities are underrepresented in higher education in the United States relative to their numbers in the general population, Athough the enrollment rate of racially and ethnically diverse students at doctoral programs within the United States has increased over the past decade (de Brey et al., 2019), the percentage of diverse students in graduate school remains disproportionately low (Okahana & Zhou, 2018).[1] Specifically, according to the yearly Survey of Earned Doctorates, the proportion of U.S. citizens and permanent residents who identify as African American or Black, Hispanic or Latinx, American Indian, and Alaska Natives; Native Hawaiians or Other Pacific Islander and who earn their doctoral degree is lower than expected given the racial-ethnic make-up of adults living in the United States (NSF, NCSES, 2018). For example, although approximately 12.8% of the U.S. adult population identifies as Black (U.S. Census Bureau, 2017) only 6.7% of U.S. citizens and permanent residents who earned doctoral degrees in 2017 identified as Black (NSF, NCSES, 2018). Similarly, whereas 16% of the total U.S. adult population identifies as Hispanic or Latino (U.S. Census Bureau, 2017), only 7.1% of those who earned doctoral degrees in 2017 identified with this group (NSF, NCSES, 2018). Representation of doctoral completers who identify as White (70%; NSF, NCSES, 2018) is relatively close to the representation of this racial and ethnic group in the U.S. (77%; U.S. Census Bureau, 2017) whereas the proportion of U.S. citizens and permanent residents receiving doctorates who identify as Asian (9.8%; NSF, NCSES, 2018) is larger than the proportion of the U.S. population identifying with this racial/ethnic category (5.9%; U.S. Census Bureau, 2017). Although these patterns of representation are

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[1] There is not one universally accepted definition of underrepresentation in education (Page et al., 2013) and some schools and universities do not operationally define this term. The definition we use here has been explicitly adopted by several educational and research organizations including the American Association of Medical Colleges (AAMC Executive Committee, 2004) and the National Science Foundation (National Science Foundation, 2018, National Center for Science and Engineering Statistics, 2019). The National Institutes of Health uses a broader definition of URM which includes those captured in the NSF definition as well as individuals from disadvantaged backgrounds and, some educators define URM as groups that are a numerical minority within their field of study (Lundy-Wagner, Vultaggio, & Gasman, 2013). See the discussion section for limitations associated with using the definition we chose.

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relatively stable across major field of study, there are some exceptions. For example, individuals identifying as Black are not underrepresented among those who earned doctorates in education, whereas those who identify as Asian are underrepresented among those earning doctorates in Humanities and the Arts (4.2%; NSF, NCSES, 2018).

Although inequities in access to educational opportunities likely prevent some racially and ethnically diverse students from pursuing doctoral study, there are also obstacles that can arise during the course of doctoral study that increase URM students' time to completion and attrition. The PhD Completion Project found that the ten-year completion rates among U.S. citizens and permanent residents were 51% for Hispanic/Latino students and 47% for Black/African American students as compared to 55% for White students (Sowell, Zhang, Bell, & Redd, 2008). Although multiple factors likely contribute to racial and ethnic differences in rates of completion in doctoral programs, psychological risk and resiliency factors merit consideration.

The transition to graduate school is a time of dramatic change for most students in that the structure, responsibilities and expectations of success in doctoral programs are quite different from those that characterize the undergraduate experience (A PhD State of Mind, 2018). Beginning a doctoral program often requires students to successfully negotiate a host of academic, social and financial challenges (e.g., (Ali, Kohun, & Levy, 2007)). Although the nature of the challenges and stressors students face may vary across fields of study, personal characteristics, and program environments, one likely universal stressor is the increased academic responsibilities associated with doctoral study (e.g., El-Ghoroury, Galper, Sawaqdeh, & Bufka, 2012; Wyatt & Oswalt, 2013). Doctoral students are more likely than master's level students to describe feeling inadequately prepared for the work they are expected to complete (e.g., UC Berkeley Graduate Assembly, 2014). Doctoral students also report stress related to finances/debt, inadequate work-life balance (e.g., El-Ghoroury et al., 2012; Wyatt & Oswalt, 2013), and the time management demands of graduate school (e.g., Schramm-Possinger & Powers, 2015). These contextual stressors may be contributing to the "mental health crisis" in graduate education noted by concerned educators (e.g., Evans, Bira, Gastelum, Weiss, & Vanderford, 2018; Tsai & Muindi, 2016). Recent studies suggest that between one third (Evans et al., 2018; Garcia-Williams, Moffitt, & Kaslow, 2014; Levecque, Anseel, De Beuckelaer, Van der Heyden, & Gisle, 2017) and one half (UC Berkeley Graduate Assembly, 2014) of graduate students meet criteria for depression.

Graduate students of color, including those underrepresented in doctoral programs, along with members of other groups with cultural identities that are often marginalized and oppressed, exist in an even more stressful environment. URM students are often exposed to a range of racial stressors (Alexander & Hermann, 2016; Clark, Mercer, Zeigler-Hill, & Dufrene, 2012; Keels, Durkee, & Hope, 2017; Maton et al., 2011; Proctor, Kyle, Fefer, & Lau, 2017; Ramirez, 2014; Sowell, Allum, & Okahana, 2015). These include both microaggressions, defined as "brief and commonplace daily verbal, behavioral and environmental indignities, whether intentional or unintentional, that communicate hostile, derogatory or negative slights and insults to the target person or group" (Sue, Capodilupo, et al., 2007, p. 273) and discrimination, or "… differential treatment of members of [minority] groups by both individuals and social institutions" Williams & Mohammed, 2009, p. 21). URM students can encounter these racial stressors in the context of their interactions with their faculty advisors (Noy & Ray, 2012), during supervision (e.g., Constantine & Sue, 2007), and in their roles as teaching assistants (e.g., Gomez, Khurshid, Freitag, & Lachuk, 2011). One recent study found that virtually all of the minority graduate students in their sample (98.8%) reported having recently experienced a microaggressions (Lilly et al., 2018).

URM students, who primarily pursue their doctoral degrees in predominately white institutions (PWIs), may also experience a low perceived sense of belongingness in their programs. Belongingness is theoretically and operationally defined in the literature in a myriad of ways (e.g., Ashida & Heaney, 2008; Baumeister & Leary, 1995; Osterman, 2000) but it is primarily characterized by the feeling that one is valued, needed, accepted, and that one "fits" in a particular system or environment (Hagerty & Patusky, 1995). Belongingness is impacted by a range of factors, including the cultural relevance and responsiveness of one's educational environment (e.g., Museus, Yi, & Saelua, 2017), and is a key contributor to student success. A higher sense of belonging has shown to be associated with stronger intentions to persist among Black undergraduate students (e.g., Hausmann, Schofield, & Woods, 2007), higher grades among international students (Glass & Westmont, 2014), and stronger academic engagement and lower emotional distress among graduate students (Clark et al., 2012).

Given that URM and other graduate students of color face the added burden of exposure to racial stressors and threats to belongingness during their doctoral training, they are potentially at an even higher risk for developing psychological difficulties. Previous studies (not focusing solely on graduate students) have established a strong association between exposure to discrimination and microaggressions and negative psychological functioning (i.e. depression and anxiety; Blume, Lovato, Thyken, & Denny, 2012; Graham, West, & Roemer, 2015; Hwang & Goto, 2008; Lambert, Herman, Bynum, & Ialongo, 2009; Smith, Allen, & Danley, 2007; Williams, Neighbors, & Jackson, 2003). A low sense of belongingness is also related to poorer psychosocial functioning, including a lower sense of self-adequacy and self-integrity (e.g., Layous et al., 2017), greater perceived stress, and more symptoms of depression (Torres, Driscoll, & Burrow, 2010). Thus, it is not surprising that 65% of URM doctoral students in a large-scale national study reported occasionally or frequently worrying about their physical or mental health (Sowell et al., 2015).

Although systemic changes that reduce inequities in educational access and create more inclusive program environments are essential to improving URM graduate student psychosocial functioning, there may be ways to complement these efforts by providing URM doctoral students with personal coping strategies aimed at enhancing their resilience and success (Tsai & Muindi, 2016). In particular, helping URM doctoral students cultivate an accepting stance toward challenging internal experiences and increase their engagement in personally valued activities during graduate school may improve their psychosocial well-being. There is a large literature documenting the psychosocial benefits of helping people to cultivate an acceptance stance using mindfulness practices and other clinical strategies (e.g., Dimidjian et al., 2016; Keng, Smoski, & Robins, 2011) and to integrate these practices with strategies that encourage engagement in valued actions (e.g., A-Tjak et al., 2015; Hayes, Orsillo, & Roemer, 2010; Hayes-Skelton, Roemer, & Orsillo, 2013; Roemer, Orsillo, & Salters-Pedneault, 2008). There is some evidence that such mindfulness- and acceptance-based behavioral approaches to treatment are acceptable to (Fuchs, West, Graham, Kalill, & Morgan, 2016) and effective with (e.g., Fuchs, Lee, Roemer, & Orsillo, 2013), clients from nondominant cultural and/or marginalized backgrounds. Moreover, a series of studies have demonstrated that providing *undergraduate* students with workshops that teach students how to cultivate an acceptance stance and promote valued living improve psychosocial functioning (e.g., Danitz & Orsillo, 2014; Danitz, Suvak, & Orsillo, 2016; Eustis, Hayes-Skelton, Orsillo, & Roemer, 2018; Firestone et al., 2019; Levin, Haeger, Pierce, & Twohig, 2017; Sagon, Danitz, Suvak, & Orsillo, 2018).

These interventions are all informed by theory (e.g., Hayes, Luoma, Bond, Masuda, & Lillis, 2006; Hayes, Wilson, Gifford, Follette, & Strosahl, 1996; Roemer & Orsillo, 2002) and research (e.g., Aldao, Nolen-Hoeksema, & Schweizer, 2010; Baer, Smith, & Allen, 2004; Chawla & Ostafin, 2007; Ford, Lam, John, & Mauss, 2017; Levin, Hildebrandt, Lillis, & Hayes, 2012; Schwartz & Sortheix, 2018) highlighting the roles of *experiential avoidance*, or an unwillingness to remain in contact with internal experiences such as emotions, thoughts, and physiological sensations and *values inaction*, or a lack of sustained engagement in personally meaningful actions, in causing and

maintaining psychological distress and functional impairment. Similarly, they are informed by theories linking mindfulness, defined as paying attention in the present moment with an accepting, allowing, non-judgmental stance (e.g., Kabat-Zinn, 1994, pp. 78–80) and psychological well-being (Tomlinson, Yousaf, Vittersø, & Jones, 2018).

These broad, transdiagnostic theories of clinical problems have also been used to explain psychological distress and well-being among racial and ethnic minorities encountering racial stress. Graham, West, and Roemer (2013) proposed that when individuals encounter racial stressors, they may be prompted to engage in efforts to avoid the painful thoughts, emotions, and physical sensations elicited by those experiences, and to avoid situations and activities that could bring them in contact with additional racial stress. To restrict. Moreover, Graham and colleagues hypothesized that these attempts at experiential and behavioral avoidance heighten distress and reduce quality of life by restricting engagement in valued actions. Preliminary support for their theory comes from two studies of Black individuals showing that mindfulness moderated the relationship between exposure to racist events and anxious arousal (Graham et al., 2013) and living consistently with ones' values moderated the relationship between exposure to racial stressors and depression and anxiety (Graham et al., 2015). This preliminary work suggests that URM students who encounter racial stressors and face threats to belongingness might similarly engage in experiential and behavioral avoidance as a means of coping with these challenging program factors. If experiential avoidance and values inaction are associated with psychological distress among URM doctoral students, over and above the effects of program factors (racial stressors and microaggressions, low belongingness), targeting these constructs with workshops aimed at cultivating acceptance and encouraging values action may have positive benefits.

The goal of the current study was to explore the potential role that psychological acceptance and self-reported engagement in personally valued activity may play in predicting the psychological functioning of URM doctoral students over and above the effects of program variables including exposure to racist events, microaggressions, and sense of belongingness in one's graduate program. We hypothesized that URM doctoral students who had been exposed to higher rates of racial stressors and microaggressions in their graduate programs and those who experienced a lower sense of personal belonging, would report higher rates of depression, anxiety, and stress. Second, we predicted that valued living and acceptance would positively impact psychosocial functioning over and above the effects of exposure of racial stressors, microaggressions, and low belongingness for URM doctoral students.

1. Materials and method

1.1. Recruitment

Consistent with similar studies in this area, emails with the survey link were sent to department chairs at universities with graduate programs (with the request that they forward the research opportunity to their student community), diversity offices, and graduate student organizations. In total, 344 universities and groups were contacted via email. We also used snowball sampling to increase participation; respondents were encouraged to send the survey to other students who may be eligible for, and interested in, the study. Finally, a Facebook study page was created and using this page we "liked" URM graduate student groups in the hope that this might raise awareness about our study and recruit additional participants. To preserve anonymity, we did not ask participants how they learned about the study.

1.2. Participants

Participants were 436 graduate students who identified as members of racial and ethnic groups underrepresented in doctoral programs in the United States: Black or African American, Hispanic or Latinx, American Indian or Alaska Native, Native Hawaiian and other Pacific Islander.[2] To be included in the study, participants also had to be currently enrolled in years one to three of their programs. Participants were excluded if they did not meet the inclusion criteria or if they were enrolled in a doctoral program at the same university as the research team.

The flow of participants through the study is displayed in Fig. 1. Of the 830 potential participants who clicked on the survey, 717 completed the eligibility screening. A total of 277 individuals were excluded and 4 did not consent, leaving a final sample of 436. The demographic characteristics of the participants are displayed in Table 1. Participants ranged in age from 20 to 70 (M = 30.51, SD = 8.62) and 73.8% of the sample identified as cisgender female. Approximately ½ of the students were single and 74.4% self-identified as heterosexual. The racial/ethnic identities most commonly endorsed were Black (42.7%), Hispanic/Latinx (26.6%), and Multiracial (24.7%). The most frequently endorsed racial/ethnic identities of participants who identified as multiracial were White (56.3%), Black (33%), Hispanic/Latinx (35%), American Indian/Alaska Native (20.4%), and Asian (15.5%).

Characteristics of participants' doctoral program experience are displayed in Table 2. Several fields of study were represented including STEM programs (38.3%), Psychological and Social Sciences (22.6%), Education (22.6%), Humanities and Art (9.2%), and Business Management/Administration (1.1%). More than a third of participants were in the first year of their doctoral program.

1.3. Measures

Demographic measures. An adapted version of the *UMass Boston Comprehensive Demographic Questionnaire* (Suyemoto et al., 2016) was used to assess a wide range of demographic characteristics including sex, gender identity, sexual orientation, spiritual practices, socioeconomic status (current and family of origin), and racial and ethnic background.

Doctoral program variable measures. The *Schedule of Racist Events* (SRE; Landrine & Klonoff, 1996) is a widely used 18-item self-report measure assessing exposure to, and appraisal of, racist events. Although the measure is designed to capture recent racist events, lifetime racist events, and the appraised stressfulness of those events, in the current study we only assessed *current frequency* and adapted the question to only pertain to the time period during which the student had been enrolled in graduate school. Each of the first 17 items were rated on a 1 (*This never happened to me)* to 6 (*This happens to me almost all of the time/more than 70% of the time*). The final item, which asked participants to indicate how *different* their experiences in their graduate program would be without racism was rated on a 1 (*Same as now*) to 6 (*Totally different)* scale. A total score was derived that reflects the frequency of racist events. In the current sample, Cronbach's alpha was .93 suggesting strong internal consistency.

The *Revised 28-Item Racial and Ethnic Microaggressions Scale* (REMS28; Forrest-Bank, Jenson, & Trecartin, 2015) is a 28-item scale, adapted from the original 45 item version (Nadal, 2011) that captures the frequency of exposure to racial microaggressions. This measure yields a total score and six subscale scores can also be derived that assess the frequency of (1) second-class citizen and assumptions of criminality, (2) assumptions of inferiority, (3) assumptions of

[2] Given that there is no consistent definition of URM, we opted to use the NSF definition. Thus our study focused on students who identified as members of racial and ethnic groups underrepresented in the total pool of U.S. citizens and permanent residents earning doctorates in the United States on the basis of their ethnic/racial identity (e.g., Black or African-Americans, Hispanic or Latinxs, American Indian or Alaska Natives, Native Hawaiian and other Pacific Islanders) However, we recognize and acknowledge that discrimination negatively impacts a broad range of students, including members of racial groups that are not traditionally underrepresented in doctoral programs.

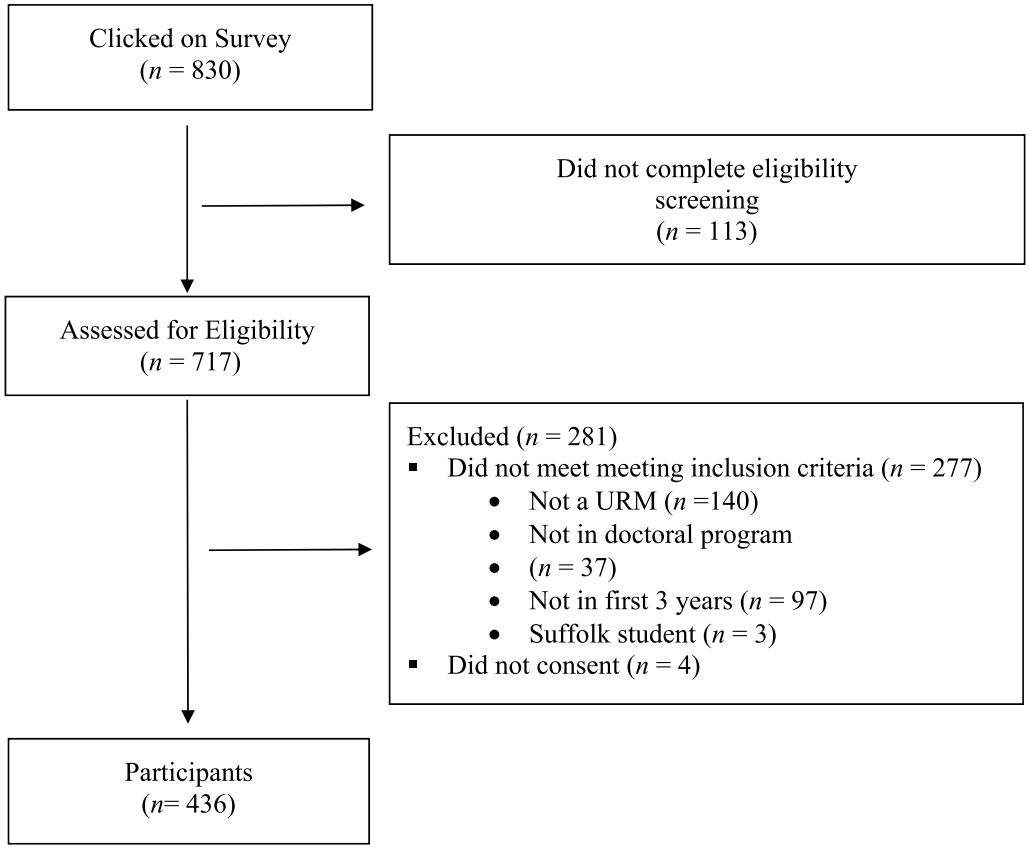

Fig. 1. Flowchart of participation with online survey. Clicked on Survey.

similarity, (4) microinvalidations, and (5) media microaggressions. Each statement is rated on a six-point Likert scale ranging from 0 *(I did not experience this event*) to 5 (*I experienced this event five or more times*). In the current study, students were asked to think about whether they had experienced each microaggression *during their time in graduate school.* In the current sample, Cronbach's alpha was .92 suggesting strong internal consistency.

The *Campus Connectedness Scale* (CCS; Lee & Davis, 2000) is a 14-item self-report measure designed to assess how connected or disconnected a student feels from the campus community. Each item is rated on a six-point Likert scale from 1 (*Strongly Disagree*) to 6 (*Strongly Agree*). In the current study, items were adapted to assess student's sense of belongingness in their doctoral program (e.g., "I don't feel I really belong with the people *in my doctoral program*"). The CCS has been used in many diverse student samples (Lee, 2003, 2005; Lee, Keough, & Sexton, 2002). Cronbach's alpha coefficient in the current study was 0.94.

Acceptance measure. The *Philadelphia Mindfulness Scale* (PHLMS; Cardaciotto, Herbert, Forman, Moitra, & Farrow, 2008) is a 20-item measure that assesses two components of mindfulness: present-moment awareness and acceptance. In the current study, only the acceptance scale was administered. Items, designed to capture an attitude of acceptance, openness, and compassion toward one's internal experience, are rated on a five-point scale from 1 (*Never*) to 5 (*Very Often*) where higher scores on the scale indicate higher levels of non-acceptance of those internal experiences.

The PHLMS-Acceptance subscale has been shown to negatively correlate with psychological distress (e.g., Danitz et al., 2016; Sagon et al., 2018), and has strong internal consistency in a diverse sample of first-year undergraduate students (Arauz, Danitz, Orsillo, & Coyne, 2017). In the current sample, internal consistency was 0.92.

Values measure. The *Valued Living Questionnaire* (VLQ; Wilson & Groom, 2002) is a 20-item, two-part self-report questionnaire that assessed participants' valued living and the extent to which a participant contacts their values in daily life. The first section identifies the values that the participant believes are important to their lives across 10 domains including family, work, and friendships that is rated on a 10-point Likert scale based on the corresponding values' level of importance. The second section asks how consistently they have lived a life that embodies those values on a 10-point Likert scale based on their level of consistency. An index of valued living is derived by multiplying the scores for importance and consistency.

This measure has shown good test-retest reliability and convergent validity with measures of psychosocial functioning (Wilson, Sandoz, Kitchens, & Roberts, 2010), including in Black American student samples (e.g., Graham, West, Martinez, & Roemer, 2016; VanBuskirk et al., 2012). Cronbach's alphas in the current sample were .82.

Psychosocial functioning measures. The *Depression, Anxiety, and Stress Scales* (DASS-21; Lovibond & Lovibond, 1995) is a well-established, commonly used 21-item measure that assesses depression, anxiety, and stress, producing a subscale score for each construct. Participants are asked to rate each statement on a four-point Likert scale from 0 (*did not apply at all*) to 3 (*applied to me very much*) depending on how much it applied during the past month.

The DASS has strong psychometric support, has been translated into a range of different languages and has been shown to have cross-cultural validity in community and student samples (e.g., Daza, Novy, Stanley, & Averill, 2002; Fawzy & Hamed, 2017; Jafari, Nozari, Ahrari, & Bagheri, 2017a; Jafari, Nozari, Ahrari, & Bagheri, 2017b; Singh, Junnarkar, & Sharma, 2015; Wang et al., 2016). The DASS-21 has shown internal consistency and convergent validity in samples of Black undergraduate and graduate students (e.g., Donovan & West, 2015; Graham et al., 2016; Lee, Corneille, Hall, Yancu, & Myers, 2016; VanBuskirk et al., 2012; West, Donovan, & Roemer, 2010), Latinx students (e.g., Cabriales, Cooper, & Taylor, 2013; Flynn, Berkout, & Bordieri, 2016), American Indian students (e.g., Clark & Winterowd,

Table 1
Demographic characteristics of participants.

Characteristic	*N* (%)
Race	
Black	178 (42.7)
Hispanic/Latinx	111 (26.6)
Multiracial*	103 (24.7)
White	58 (56.3)
Black	34 (33.0)
Hispanic/Latinx	36 (35)
American Indian/Alaska Natives	21 (20.4)
Asian	16 (15.5)
Not Listed	8 (7.8)
Middle Eastern/Northern African	6 (5.8)
Native Hawaiians/Pacific Islanders	6 (5.8)
American Indian/Alaska Natives	11 (2.6)
Native Hawaiians/Pacific Islanders	8 (1.9)
Middle Eastern	3 (.7)
Not Listed	2 (.5)
Gender	
Female Cisgender	319 (73.8)
Male Cisgender	97 (22.5)
Nonbinary/Fluid/queer/gender queer	9 (2.1)
Not listed	3 (.7)
Prefer not to say	4 (.9)
Sexual Orientation	
Heterosexual	323 (74.4)
Gay/Lesbian/Queer	43 (9.9)
Bisexual/Pansexual	49 (11.3)
Asexual	10 (2.5)
Not listed	3 (.7)
Prefer not to say	6 (1.4)
Relationship Status	
Single	223 (51.4)
Married/Civil Union	110 (25.4)
Cohabitating	54 (12.4)
Separated/Divorced	15 (3.4)
Not Listed	31 (7.1)

Note. *Ns do not add up to 103 because participants could choose multiple options.

Table 2
Characteristics of Participants' Doctoral Program Experience.

Characteristic	*N* (%)
Field of Study	
STEM	142 (38.3)
Psychology/Social Sciences	84 (22.6)
Education	84 (22.6)
Humanities/Art	34 (9.2)
Business Management/Administration	4 (1.1)
Not Listed	23 (6.2)
Year in Program	
Year 1	156 (35.9)
Year 2	129 (29.7)
Year 3	150 (34.5)

2012), and sample of Pacific Islanders (Ran et al., 2016). In the current sample, Cronbach's alphas were Depression (0.92), Anxiety (0.84), and Stress (0.85).

1.4. Procedures

The institutional review board approved all study procedures. Recruitment materials, with a link directly to the survey, were sent via email to department chairs at universities with graduate programs and graduate student organizations and were posted on listservs and social media sites. Interested participants were invited to click on the link to learn more about the study and determine their eligibility, and if appropriate, provide their consent. After providing consent, students received access to the packet of measures described above, which they completed anonymously. If students wanted to be entered into a raffle to win one of six $50 Visa gift cards as a compensation for their time, they were redirected away from the survey to a second survey independent from their responses where they provided their contact information.

1.5. Data analysis plan

Descriptive statistics were calculated to allow us to characterize our sample. Zero order correlations were conducted to explore the potential relationships between program variables (i.e., exposure to racial microaggressions and racist experiences and perceived belongingness in doctoral program), acceptance, self-reported engagement in valued actions, and current psychological functioning (depression, anxiety, and stress). A series of hierarchical multiple regressions were conducted to assess the combined contribution of engagement in valued activities and acceptance in predicting psychological distress after controlling for the influence of program variables. For each equation, program variables (i.e., exposure to racist experiences and microaggressions and students' sense of belonging) were entered at Step 1, and acceptance and engagement in valued actions were entered on Step 2.

2. Results

2.1. Descriptive statistics

Descriptive statistics for all study variables are displayed in Table 3. On the Schedule of Racist Events (SRE), a considerable proportion of students endorsed being treated unfairly because of their identity as a person of color by their coworkers, fellow students, or colleagues (45.5%) or by professors and staff members (39.8%). Additionally, 64.4% of students reported that they had been really angry about something racist that was done to them and 42.6% of students believed that their experience in graduate school would be different if they had not been treated in a racist or unfair way. On the Racial and Ethnic Microaggressions Scale (REMS), approximately one-third of the participants reported that they had been ignored at school or work (34.6%) or assumed to be not intelligent (31.8%) because of their race. 32% of the students reported that someone acted surprised at their scholastic or professional success because of their race.

In this sample, 39.25% of the students met the cutoff for moderate to severe depression, 49.5% for moderate to severe anxiety, and 38% for moderate to severe stress. The mean score on the PHLMS in the current study suggested a level of psychological acceptance similar to those reported by college students ($M = 32.30$, $SD = 8.95$) (e.g., Danitz et al., 2016; Flynn et al., 2016; Sagon et al., 2018). The personal values of education ($M = 8.97$, $SD = 1.50$), family ($M = 8.51$, $SD = 2.9$), and employment ($M = 8.49$, $SD = 1.88$) were rated as most important by participants.

Table 3
Descriptive Statistics.

Constructs	*M*	*SD*	Possible Range of Scores
Exposure to Racist Events	37.74	14.94	18–108
Exposure to Racial and Ethnic Microaggressions	1.33	1.00	0–5
Belongingness	55.31	15.71	14–84
Non-Acceptance of Internal experiences	31.27	8.91	10–50
Valued Living	4311.12	1693.52	0-10,000
DASS_Depression	12.30	10.76	0–21
DASS_Anxiety	10.79	9.45	0–21
DASS_Stress	16.71	9.94	0–21

2.2. The relationship between program experiences and psychological functioning

Correlations were conducted to examine the relationships between measures of program variables, psychological flexibility, and psychological functioning[3]). As shown in Table 4, the frequency of exposure to racist experiences and microaggressions were positively and significantly correlated with stress, anxiety and depression; as the levels of these racial stressors increased, the levels of self-reported psychological distress also increased. In contrast, sense of belonging was negatively and significantly correlated with the DASS subscales such that higher perceived belonging was associated with lower depression, anxiety, and stress. There were also strong negative correlations between engagement in valued living and all three indices of psychological distress such that greater self-reported engagement in valued actions was associated with lower levels of stress, depression, and anxiety. Finally, there was a strong, significant, and positive association between all three psychological symptom measures and non-acceptance; as the level of non-acceptance increased, the level of psychological distress also increased (see Table 4).

Table 4
Relationships Between Measures of Doctoral Program Variables, Psychological Flexibility, and Psychological Functioning.

	DASS_Depression	DASS_Anxiety	DASS_Stress
Racist Experiences	.21**	.29**	.28**
Microaggressions	.18**	.22**	.25**
Belongingness	-.33**	-.23**	-.29**
Non-Acceptance of Internal Experiences	.53**	.46**	.56**
Valued Living	-.19**	-.19**	-.25**

Note. $^{**}p < .01$.

2.3. Impact of engagement in valued living and non-acceptance on psychological functioning over the effects of contextual program factors

Hierarchical multiple regressions were used to assess the combined contribution of engagement in valued living and psychological non-acceptance in predicting psychological distress after controlling for the influence of program variables. For each equation, exposure to racist experiences and microaggressions and students' sense of belonging variables were entered at Step 1, and valued living and non-acceptance were entered on Step 2. The results are displayed in Table 5

In the equation predicting depression, at Step 1, program variables significantly contributed to the regression model and accounted for 12% of the variation in depression. The addition of acceptance and values variables in Step 2 explained an additional 23% of the variation in depression and this change in R^2 was significant and produced a large effect size. In this final step, when all predictors were in the equation only belongingness, non-acceptance and valued living exerted unique significant effects on depression.

In the regression equation predicting anxiety at Step 1, program variables similarly significantly contributed to the regression model accounting for 11% of the variation in anxiety. The acceptance and values variables in step two explained an additional 16% of the variation in anxiety and this change in R^2 was significant and produced a medium effect size. On the final step, racist events, non-acceptance, and valued living each contributed a significant proportion of unique variance to the prediction of anxiety.

Finally, at Step 1 of the equation predicting stress, program variables significantly contributed to the regression model and accounted for 12% of the variation in stress. The acceptance and valued living variables in Step 2 explained an additional 25% of the variation in stress and this change in R^2 was significant, and produced a large effect size. When all variables were in the equation, belongingness, non-acceptance, and valued living, each significantly predicted unique variance in stress.

3. Discussion

Although the enrollment rate of URM graduate students is increasing, URM students are still underrepresented in doctoral programs, their time to completion is longer, and they are at a higher risk for attrition (e.g., Sowell et al., 2015). Although many graduate students face challenges during their transition to graduate school, students with marginalized identities carry the additional burden of racial and ethnic discrimination, exposure to microaggressions, and threats to belongingness. This context, and the psychological distress it elicits, likely impact academic performance, and ultimately, attrition in doctoral programs.

This study explored the role that engagement in valued living activities and non-acceptance could play in predicting the psychological functioning of URM graduate students. Not surprisingly, we found that URM doctoral students who had been exposed to higher rates of racial stressors and microaggressions in their graduate programs reported higher rates of depression, anxiety, and stress although it was weak in magnitude. Our finding is consistent with previous studies demonstrating this association in graduate and undergraduate student samples (e.g., Clark & Winterowd, 2012; Graham et al., 2015; Proctor et al., 2017; Torres et al., 2010). For example, Clark and Winterowd (2012) found that school psychology graduate students experienced significantly higher racial/ethnic microaggressions than their white peers and that higher levels of microaggressions were associated with greater emotional distress. Additionally, Torres et al. (2010) found that racial/ethnic microaggressions decreased African-American graduate students' ability to cope and contributed to perceived stress, which, in turn, increased their likelihood of depressive symptoms.

We also found that a lower sense of personal belonging in one's doctoral program was associated with higher rates of depression, anxiety, and stress, another finding consistent with previous research (e.g., Lee, 2005; Lee et al., 2002; Torres et al., 2010). Moreover, a lower sense of belonging contributed to both depression and stress over and above the effects of racial stressors, values, and non-acceptance. Thus, this study adds to the growing evidence that a thwarted sense of belongingness negatively impacts student success (O'Meara, Griffin, Kuvaeva, Nyunt, & Robinson, 2017) and dampens career aspirations (Ostrove, Stewart, & Curtin, 2011).

Both engagement in valued living and a self-reported stance of acceptance toward challenging internal experiences, uniquely contributed to all three aspects of psychosocial functioning (depression, anxiety, and stress) over and above the effects of exposure of racial stressors, microaggressions, and belongingness. The salience of these constructs to psychological functioning is not surprising given previous research documenting their benefits (e.g., Danitz et al., 2016; Danitz & Orsillo, 2014; Graham et al., 2015; Sagon et al., 2018). These findings suggest that programs aimed at helping URM graduate students cultivate an accepting stance and maintain engagement in a broad array of valued activities during their graduate study may be one potential method of enhancing psychological well-being and student success, even in the face of program stressors.

Although programs aimed at building resilience among students with URM deserve consideration, systemic changes are essential to address pervasive inequities that URM students face in the higher education system in the United States. Graduate departments must provide a more inclusive environment, support students of color, and dismantle barriers to academic success and persistence (Figueroa, 2015) and institutions and federal agencies need to provide resources

[3] To correct for a positive skew on the DASS subscales of depression and anxiety we created log transformed variables which were used in all analyses.

Table 5
The Impact of Values and Acceptance on Psychology Functioning Over and Above the Effects of Program Variables.

	Depression				Anxiety				Stress			
Predictors	$_{\Delta}R2$	β	$_{\Delta}F$	*p*	$_{\Delta}R2$	β	$_{\Delta}F$	*p*	$_{\Delta}R2$	β	$_{\Delta}F$	*p*
Step 1	.12		24.29	.001	.11		17.18	.001	.12		16.36	.001
Racist Experiences		.09		.173		.20		.003		.14		.033
Microaggressions		.06		.375		.07		.324		.12		.070
Belongingness		-.29		.001		-.15		.009		-.21		.001
Step 2	.23		47.98	.001	.16		34.83	.001	.25		41.24	.001
Racist Experiences		.04		.489		.13		.038		.08		.176
Microaggressions		.02		.792		.06		.361		.08		.152
Belongingness		-.23		.001		-.09		.078		-.12		.008
Non-Acceptance of Internal Experiences		.47		.001		.38		.001		.48		.001
Valued Living		-.09		.040		-.11		.040		-.12		.006

that address financial disparities. There is evidence that such changes have a measurable impact. For example, the *Opportunities in Genomics Research Group* showed significant increases in the Ph.D. matriculation of URM students over eight years of National Institutes of Health funding (Whittington, Wallace, & Shadding, 2017). URM students who participated in a *Bridges to the Doctorate* program through the University of Illinois at Chicago were successful in gaining admission to the doctoral programs and demonstrated a high rate of research productivity (Kim et al., 2009). Black students in the *Meyerhoff Scholars Program* at the University of Maryland, Baltimore County have been shown to be 4.8 times more likely to complete doctoral programs in STEM areas than those not in the program (Maton et al., 2016). The outcomes of these programs are encouraging, but much more change is needed.

3.1. Limitations

Although this study offers some promising suggestions for how URM student psychological functioning may be enhanced by acceptance and engagement in valued actions, there are limitations to this study that are important to consider. First, this study relied on self-report of experiences. Self-report measures can be problematic because people may respond in a biased way in order that their responses seem socially acceptable (e.g., Paulhus, 1991). It is possible that the students underreported their experiences of racist events, microaggressions, or psychological distress because of these reasons. Notably, the cross-sectional nature of this research does not allow for us to make causal claims about the relationships we examined. It may be that experiencing less psychological distress is what helps students to be more accepting of their internal experiences and to engage more consistently in valued action. Longitudinal studies are needed to determine if acceptance and valued action predict psychosocial functioning across the course of students' program of study.

Also, the measures used to assess racial and ethnic stress and microaggressions may not have been generalizable to the wide range of ethnic groups sampled here. Some of the items on these scales (e.g., *Someone asked me to teach them words in my "native language"*) may not be applicable to all URM students. Moreover, previous research has supported that people with different intersectional identities (i.e., Black woman versus Hispanic woman) will experience different types and frequencies of microaggressions (Keels et al., 2017; Proctor et al., 2017). Thus, the measures we used to assess exposure to discrimination and microaggressions could have been insufficient. Finally, the measures used in the current study to assess program climate were adapted to specifically capture experiences during graduate school. These adaptations may have reduced the validity or reliability of the measures.

The use of a sample of convenience may have reduced the external validity of the findings because of sampling bias. Students who volunteered may have been different in some fundamental way from the larger population of doctoral students. In other words, graduate program experiences (positive or negative) and their current functioning (psychologically distressed or not) may have been related to their willingness to participate. There is some evidence that this sample reported lower levels of microaggressions and racist events as compared to other samples and similar levels of psychological distress (e.g., Clark et al., 2012; Evans et al., 2018; Proctor et al., 2017; Torres et al., 2010).

A major limitation of our study was our exclusion of students whose racial identity was exclusively Asian. Although we adopted a commonly used definition of URM students for our inclusion criteria, there is clear evidence that students with a broad range of cultural identities encounter stigmatizing experiences in academic contexts including Asian Americans (e.g., Cheryan & Bodenhausen, 2000; Hwang & Goto, 2008), women (e.g., Barthelemy, McCormick, & Henderson, 2016), men (e.g., Isacco, Hammer, & Shen-Miller, 2016), those who identify as transgender (e.g., Goldberg & Kuvalanka, 2019). Individuals with disabilities (e.g., Callahan et al., 2018), those from low socioeconomic backgrounds (e.g., Lee, 2017), members of the LGBTQ community (e.g., Turner, Pelts, & Thompson, 2018), and international students (e.g., Laufer & Gorup, 2019). We also failed to assess whether participants were domestic or international students. Considering the different experience of international and domestic students in doctoral programs in the United States (e.g., Curtin, Stewart, & Ostrove, 2013), future research should assess and explore the influence of this aspect of identity on the relationship between acceptance, engagement in values actions and psychological functioning. Future studies should consider broader definitions of underrepresentation, including the potentially unique stressors associated with intersectionality.

Also, this sample was too small for us to compare experiences and functioning across racial and ethnic groups and we did not include a sample of White students as a comparison group.

Finally, our study was limited in that we only explored the impact of microagressions, racial stressors, belongingness, acceptance and valued action on psychosocial functioning. Moreover, the relationships we found among study variables were modest. Future studies may want to explore the potential contribution of other constructs such as cognitive defusion or self as context.

3.2. Future directions

Despite these limitations, the current study provides data that supports the future exploration of the potential benefits of offering values and acceptance-based programs to doctoral students transition into graduate programs. However, it is essential that the development of such programs be done in concert with, not instead of, changes aimed at addressing the overarching systemic factors that significantly reduce URM graduate students' overall psychological health and success in graduate programs (see Wilson, DePass, & Bean, 2018).

4. Conclusions

URM doctoral students who are exposed to higher rates of racial stressors and microaggressions report higher rates of depression,

anxiety, and stress. Additionally, URM doctoral students who have a lower sense of belonging within their programs reported higher rates of depression, anxiety, and stress. This sense of belonging, in addition to acceptance of painful internal experiences and engagement in valued living, contributed to psychosocial functioning over and above the effects of exposure to racial stressors, microaggressions, and belongingness.

Declaration of competing interest

None.

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