State and Trait Loneliness In Patients With Somatic Symptom Disorder

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Based on the above described overview, the question arises which role the experience of loneliness in daily life can play in developing and maintaining somatic symptoms and maladaptive responses as typically seen in somatic symptom disorder. Until...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Somatic symptom and related disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46267

Source
ToetsingOnline

Brief title
State and Trait Loneliness In Patients With Somatic Symptom Disorder

Condition

- Somatic symptom and related disorders

Synonym
"somatic symptom disorder" and "somatoform disorder"

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Loneliness, Somatic Symptom Disorder, State, Trait

Outcome measures

Primary outcome

Phase 1

Trait-loneliness: The de Jong Gierveld lonelinessscale

Social support evaluation: The Social Support List * Interactions and Social

Support List - Discrepancies

Phase 2

Questions of the ESM

Secondary outcome

Questionnaires about complaints:

HADS-NL

SCL-90

Study description

Background summary

The Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV) described somatoform disorders as a mental illness that is characterized by physical complaints for which no somatic cause has been found. These complaints are not imagined and are not imitated or simulated. Previous research has shown that this group of patients is quite prevalent in healthcare: in primary healthcare one in three somatic symptoms are medically unexplained, and in

secondary healthcare these numbers are even higher (Khan, Khan, Harezlak, Tu, & Kroenke, 2003; Kroenke, 2003; Nimnuan, Hotopf, & Wessely, 2001). Patients who experience medically unexplained somatic symptoms tend to persist in searching for an explanation or treatment of their symptoms by visiting different medical doctors. This group of patients thereby causes an expensive burden on health care resources. The medical and social costs are approximately 7000 euro per patient a year (Zonneveld,
Sprangers, Kooiman, Van *t Spijker, & Busschbach, 2013).

Since the publication of the Diagnostic and Statistical Manual of Mental Disorders 5th Edition (DSM-5) in 2013, the classification of somatoform disorders has changed. The classification of somatoform disorders in DSM-IV is controversial. There is no consistent statement about dealing with comorbidity. Also the use of the criterion for unexplained somatic symptoms, raises a lot of questions. As a result, the somatoform disorders as classified by the DSM-IV have been, only partly, replaced in the DSM-V by somatic symptom and related disorders. Contrary to the somatoform disorders of DSM-IV, in which one or more somatic symptoms have to be unexplained, symptoms can either be medically explained or unexplained to set the diagnosis of a somatic symptom disorder (SSD) (Van der Feltz* Cornelis, & Van Houdenhove, 2014). Most relevant are the maladaptive responses these patients have when confronted with their somatic symptoms. As described in DSM-V this might involve excessive thoughts, emotions and behavior coherent with the somatic symptoms. Another criterion is the persistence of somatic symptoms, typically more than six months. At this moment little is known about the prevalence and costs of SSD, and therefore we will rely on the literature on somatoform disorders as classified by the DSM-IV. In addition to implications and consequences, also causal and sustaining factors of SSD are currently unknown.

People with somatoform disorders often feel misunderstood and socially rejected. They also experience loneliness. Research has found that the number of chronic illnesses can be a predictor of loneliness (Van Dam, 2012; Dirkzwager, & Verhaak, 2007; Kara, & Mirici, 2004; Kool, Middendorp, Boeije, & Geenen, 2009; Theeke, 2009). Loneliness can be defined as an unpleasant feeling when experiencing a discrepancy between the desired and the actual social network of a person (Perlman, & Peplau, 1981). The quantity or the quality of one*s social relationships are not conform to someone*s needs (Hawkey, & Cacioppo, 2010; Van Roekel, 2014). Loneliness tends to be a large problem in current society. In The Netherlands there is a high prevalence of loneliness. In total 43% of the adult population (19 years and older) indicates to be lonely, based on a questionnaire filled in by 457.153 Dutch citizens (Gezondheidsmonitor Volwassenen GGD-en, CBS en RIVM, 2016).

There are clear links between loneliness, social support and health. Whereas social support has been associated with better health, loneliness has been associated with poorer health. Additionally, social support can minimize loneliness (Segrin, & Domschke, 2011; Segrin, & Passalacqua, 2010). The Social

Support Theory of Cohen (1985) explains the relation between social support and well-being. First, being part of a social network provides positive experiences and stable, socially rewarding roles. Second, a social network enables resources to respond to the needs of a person during stressful events. Research has shown that loneliness is related to several medical issues. Social epidemiology has shown that, among others, the absence of positive social relationships is a significant risk factor for broad-based morbidity and mortality. People who feel lonely have a greater probability to develop heart diseases in comparison to people who feel socially connected. Loneliness has also found to be a risk factor for the development of pain, depression, and fatigue, which are common symptoms in SSD (Cacioppo, & Cacioppo, 2014; Jaremka et al., 2014; Jaremka, Fagundes, Glaser, Bennett, Malarkey, & Kiecolt-Glaser, 2013; Mushtag, Shoib, Shah, & Mushtag, 2014; Stadler, Snyder, Horn, Shrout, & Bolger, 2012) .

In most studies examining the negative health effects of loneliness, loneliness was measured as a trait (Hawkey, &*Cacioppo, 2010).*In the last years, research has started to shift focus to measuring variability and fluctuations in feelings of loneliness, also referred to as state levels of loneliness. In many of these studies, fluctuations have been investigated using Experience Sampling Method (ESM). ESM is a procedure to assess participants in their daily environment, providing repeated moment-to-moment measurements. The most interesting aspect of ESM is that it relies on an app instead of paper diaries (Myin-Germeys, Oorschot, Collip, Lataster, Delespaul, & van Os, 2009). ESM has several advantages compared to questionnaires or diaries. First, ecological validity is higher, because measurement can take place during participant*s normal daily life environment. Second, it minimizes recall bias, because participants evaluate their experiences in the moment. By using paper diaries it is more difficult to measure at several moments of the day and these diaries are often filled in at the end of the day which increases a recall bias. This is an important limitation in the current population as research has shown that people who suffer from somatic complaints tend to overestimate symptoms as time passes by (Houtveen, & Oei, 2006). Finally, using ESM allows measurement and investigation of possible influences of the context people are in (Brown, Strauman, Barrantes-Vidal, Silvia, & Kwapil, 2011). Studies on state levels of loneliness in the daily life of adolescents, have shown that loneliness is affected by temporal characteristics and social contexts (Doane, & Adam, 2010; Van Roekel, 2014). Measuring in daily life provides insights into moment to moment effects (Roekel, Scholte, Engels, Goossens, & Verhagen, 2014). For example, in depression, moment to moment differences in loneliness have been investigated by using ESM, elucidating the causal mechanisms of depression. The results have shown that state loneliness was followed by an increase of negative evaluations of social company and being more alone. Trait loneliness predicted symptoms of depression (van Winkel, Wichers, Collip, Jacobs, Derom, Thiery, Myin-Germeys, & Peeters, 2017).

Study objective

Based on the above described overview, the question arises which role the experience of loneliness in daily life can play in developing and maintaining somatic symptoms and maladaptive responses as typically seen in somatic symptom disorder. Until now, research cannot make solid conclusions on the causal relationship between loneliness and somatic symptoms. On the one hand somatic symptoms and chronic illness can function as risk factors for loneliness. On the other hand loneliness itself can act as a risk factor for several somatic symptoms. Knowledge about the relation between loneliness and somatic symptom disorder may help in the development of more tailored interventions in this group of patients.

The current research will consist of two phases, each representing one study. In the first phase possible differences in trait loneliness and evaluation of social support between patients with SSD and healthy controls will be investigated using standardized questionnaires. Assuming that patients with SSD will report more loneliness, the second study will investigate the role of loneliness in a more detailed way by fluctuations of loneliness during the day, also referred to as the state levels of loneliness, using ESM. More specifically, the relation between fluctuations in loneliness and fluctuations in the experience of somatic symptoms will be examined. One of the most powerful characteristics of ESM research is that it can provide insights not only in the relation between variables, but also in the causal direction of that relation. The current study will investigate the direction of the relation between loneliness and somatic symptoms.

Study design

Phase 1
In a between group design, patients with SSD and healthy controls will be compared concerning their average level of loneliness (i.e. trait loneliness) and their evaluation of the current social support they experience.

Phase 2
An observational design using the Experience Sampling Method (ESM) will be used to measure loneliness and somatic symptoms at multiple moments in daily lives of the participants. Individuals will be asked to fill in the same questions on different, quasi-random (random beeps with fixed intervals) time points during the day. A *beep* on their smartphone signals to answer the questions directly or at least within 10 minutes.

Study burden and risks

There are no risks or adverse consequences associated with participation in the

study. Participants can stop their participation at any time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Somatic symptom disorder
18 years and older
Sufficient understanding of the spoken and written Dutch language

Exclusion criteria

History of psychosis or bipolar disorder

Substance abuse
Cognitive impairment that hampers understanding of the questionnaires.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2018
Enrollment:	176
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2018
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	06-07-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	23-11-2020
Application type:	Amendment

Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL65769.096.18

Study results

Date completed:	24-01-2023
Actual enrolment:	176