



Universitat
de les Illes Balears

**DOCTORAL THESIS
2018**

**Doctoral Programme of Human Cognition and
Evolution**

**PERSON-CENTERED APPROXIMATION TO
PSYCHOSES: EFFECTIVENESS AND OUTCOMES**

Emilio Ramón López Navarro

Thesis Supervisor: Prof. Enric Munar Roca

Thesis Supervisor: Dr. Antoni Mayol Pou

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Thesis Tutor: Prof. Enric Munar Roca

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The force of mind is only as great as its expression; its depth only as deep as its power to expand and close itself.

Georg Wilhelm Friedrich Hegel. *Phenomenology of Mind* (1910)

Welcome or not, change is unavoidable. Life itself is change. Each moment is different from every other. Nothing remains static for an instant, from a planetary to a molecular level.

Prochaska, Norcross, & DiClemente. *Changing for good* (1994)

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I am very grateful to my grandfathers who helped to build the person that I have become, wherever you are I hope you can see this work and feel proud of your grandson. My sincere gratitude to my grandmothers, without their kindness this thesis could not be possible. There is something beauty and transcendent in the fact that through time and space your kindness and support were given to me.

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Foreword

This Ph.D. dissertation follows the regulation of University of Balearic Islands for Ph.D. thesis formed by a compendium of publications.

The three publications that conform the Ph.D. thesis are listed below:

López-Navarro, E., Del Canto, C., Belber, M., Mayol, A., Fernández-Alonso, O., Lluís, J., ... Chadwick, P. (2015). Mindfulness improves psychological quality of life in community-based patients with severe mental health problems: A pilot randomized clinical trial. *Schizophrenia Research*, 168(1–2), 530–536. <https://doi.org/10.1016/j.schres.2015.08.016> (Impact Factor 2015: 4.453; Quartile: 1; Position 17 of 139)

López-Navarro, E., Del Canto, C., Fish, J., Mayol, A., Munar, E., & Chadwick, P. (2018). Does mindfulness improve executive functions and theory of mind in schizophrenia-related disorders? A randomized pilot clinical trial. *Schizophrenia Research*, manuscript in preparation. (Impact Factor 2017: 3.958; Quartile: 1; Position 23 of 139)

López-Navarro, E., Del Canto, C., Mayol, A., Fernández-Alonso, O., & Munar, E. (2018). Psychotic symptoms and quality of life: A mediation analysis of daily-life coping. *Psychiatry Research*, 262, 505–509. <https://doi.org/10.1016/j.psychres.2017.09.034> (Impact Factor 2017: 2.223; Quartile: 2; Position 61 of 142)

Abstract

The overarching aim of this PhD dissertation is to analyze the feasibility of the person-based conceptualization of psychoses in the frame of a public rehabilitation center for people experiencing persistent psychotic symptoms. Treatment of psychoses has been constrained by the biological conceptualization of the psychotic phenomena: people experience psychotic symptoms due a malfunction in the brain (which gives little space for a psychological or contextual formulation). However, given the poor outcomes of the biological-driven treatment of psychoses, there is an increasing interest in how person-centered approach to psychosis can help to understand the psychotic phenomena and improve the treatment delivered in the public health system. To face this challenge, the thesis sets up around two particular aims: 1) assess the feasibility and effectiveness of mindfulness applied to psychotic symptoms, and 2) analyze the impact over well-established scientific knowledge that the use of subjective measures could have.

In the paper *Mindfulness improves psychological quality of life in community-based patients with severe mental health problems: A pilot randomized clinical trial* we assess the feasibility of mindfulness training when added to standard treatment, as well its effects over psychotic symptoms and well-being of people experiencing persistent psychotic symptoms. Heartened by the findings of the first paper as well by the literature attesting the cognitive benefits of mindfulness, in *Does mindfulness improve executive functions and theory of mind in schizophrenia-related disorders? A randomized pilot clinical trial* we explore if the same mindfulness intervention can have positive impact over executive functions and theory of mind skills of people experiencing persistent psychotic symptoms. Finally, in *Psychotic symptoms and quality of life: A mediation analysis of daily-life coping*, we analyze how the person-centered

approach applied to assessment can bring new insights about the relationship between persistent psychotic symptoms, quality of life, and daily-life coping.

The relevance of the results from the three publications are commented in the discussion section of this thesis, as well their fitness with prior research and the implications for future studies. Additionally we discuss the importance of adopt a person-centered approach in the study of persistent psychotic symptoms, and the promising theoretical framework of the phenomenology applied to psychoses.

Resumen

El objetivo general de esta tesis doctoral es analizar la viabilidad de una formulación de la psicosis centrada en la persona dentro del marco terapéutico de un centro de rehabilitación público para personas que sufren síntomas psicóticos persistentes. El tratamiento de las psicosis se ha visto limitado por la concepción biologicista del fenómeno psicótico: las personas lo experimentan debido a un funcionamiento anómalo de su cerebro (lo que deja poco espacio para una formulación psicológica o contextual del mismo). Sin embargo, dado los pobres resultados del tratamiento biologicista en la psicosis, hay un creciente interés en cómo el enfoque centrado en la persona que sufre síntomas psicóticos puede ayudar al entendimiento del fenómeno y a mejorar el tratamiento proporcionado en el sistema público de salud. Para afrontar este desafío, la tesis se articula en torno a dos objetivos más detallados: 1) evaluar la viabilidad y resultados de una intervención de Mindfulness aplicada a síntomas psicóticos persistentes, y 2) analizar el impacto que sobre hechos científicos considerados sólidos pueda tener el utilizar medidas subjetivas de evaluación.

En *Mindfulness improves psychological quality of life in community-based patients with severe mental health problems: A pilot randomized clinical trial* analizamos la viabilidad del entrenamiento en mindfulness cuando es añadido al tratamiento habitual, así como sus efectos sobre los síntomas psicóticos y la calidad de vida de personas que experimentan síntomas psicóticos persistentes. Alentados por los resultados del primer artículo y por la literatura que relaciona la práctica del Mindfulness con beneficios cognitivos, en *Does mindfulness improve executive functions and theory of mind in schizophrenia-related disorders? A randomized pilot clinical trial* exploramos si la misma intervención del primer artículo puede tener un efecto positivo sobre las funciones ejecutivas y la teoría de la mente de personas que experimentan síntomas

psicóticos persistentes. Finalmente, en *Psychotic symptoms and quality of life: A mediation analysis of daily-life*, analizamos como la aproximación a la psicosis centrada en la persona aplicada al proceso de evaluación puede ofrecer nuevos conocimientos sobre la relación entre los síntomas psicóticos persistentes, la calidad de vida, y el afrontamiento llevado a cabo en el día a día.

La relevancia de los resultados de los tres artículos es comentada en la sección de discusión, así como su encuadre dentro de la evidencia previa y sus implicaciones de cara a futuros estudios. Además, se analiza la importancia de asumir un enfoque centrado en la persona en el estudio de los síntomas psicóticos persistentes, y el uso de la fenomenología como marco teórico en el que desenvolver el estudio de las psicosis.

Resum

L'objectiu general d'aquesta tesi doctoral és analitzar la viabilitat d'una formulació de la psicosis centrada en la persona dins el marc terapèutic d'un centre de rehabilitació públic per a persones que pateixen símptomes psicòtics persistents. El tractament de les psicosis s'ha vist limitat per la concepció biologicista del fenomen psicòtic: les persones ho experimenten a causa d'un funcionament anòmal del seu cervell (el que deixa poc espai per a formulació psicològica o contextual del mateix). No obstant això, donat els pobres resultats del tractament biologicista a la psicosis, hi ha un creixent interès en com l'enfoc centrat en la persona que pateix símptomes psicòtics pot ajudar a l'enteniment del fenomen i a millorar el tractament proporcionat en el sistema públic de salut. Per afrontar aquest repte, la tesi s'articula entorn a dos objectius més detallats: 1) avaluar la viabilitat i resultats d'una intervenció de Mindfulness aplicada a símptomes psicòtics persistents, i 2) analitzar el impacte que sobre fets científics considerats sòlids pugui tenir el utilitzar mesures subjectives d'avaluació.

A Mindfulness improves psychological quality of life in community-based patients with severe mental health problems: A pilot randomized clinical trial analitzem la viabilitat de l'entrenament en mindfulness quan es afegit al tractament habitual, així com els seus efectes sobre els símptomes psicòtics i la qualitat de vida de persones que experimenten símptomes psicòtics persistents. Encoratjats per els resultats del primer article i per la literatura que relaciona la pràctica del mindfulness amb beneficis cognitius, a *Does mindfulness improve executive functions and theory of mind in schizophrenia-related disorders? A randomized pilot clinical trial* vam explorar si la mateixa intervenció del primer article pot tenir un efecte positiu sobre les funcions executives i la teoria de la ment de persones que experimenten símptomes psicòtics persistents. Finalment, a *Psychotic symptoms and quality of life: A mediation analysis of daily-life*, analitzem

com l'aproximació a la psicosis centrada en la persona aplicada al procés d'avaluació pot oferir nous coneixements sobre la relació entre els símptomes psicòtics persistents, la qualitat de vida, i l'afrontament dut a terme en el dia a dia. La rellevància dels resultats dels tres articles es comentada a la secció de discussió, així com el seu enquadrament dins de l'evidència prèvia i les seves implicacions de cara a futurs estudis. A més, s'analitza la importància d'assumir l'enfoc centrat en la persona en el estudi dels símptomes psicòtics persistents, i l'ús de la fenomenologia com a marc teòric en què desenvolupar el estudi de les psicosis.

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1. Introduction

Severe Mental Illness (SMI) is a disorder that affects 4.2% of people in developed countries (NIHM, 2018). There is no consensus about the specific clinical criteria followed for its diagnosis. Kessler, Wai, Demler, & Walters (2005) include as SMI all those mental disorders that fulfill any of the following criteria: a diagnosis of non-affective psychosis, a Bipolar I or II diagnosis according to DSM-IV-TR criteria, a serious suicide attempt during the last twelve months, inability to develop any work activity, a substance abuse that compromised daily life activities, impulse control disorder with repeated serious violence; or any disorder that resulted in 30 or more days out of role in the year. Parabiaghi, Bonetto, Ruggeri, Lasalvia, & Leese (2006) focus on the psychotic experience rather than specific clinical diagnoses, thus the criteria proposed are the presence of persistent psychotic symptoms, chronic course, and social disfunction. On this line, the public Spanish Ministry of Health Social Services & Equality defines SMI as a disorder where persistent psychotic symptoms (both positive and negative) have been present for at least 2 years, and social functioning has been compromised for a minimum of six months (Spanish Ministry of Health, Social Services & Equality, 2009). Notwithstanding the different definitions, there are two core features: persistent psychotic symptoms that are distressing, and low quality of life as a consequence of poor social functioning.

Treatment in SMI has focused on pharmacological interventions aiming to reduce the frequency and intensity of psychotic symptoms, and psychological interventions as contributing treatment. The rationale behind pharmacological interventions consist in that syndromes are associated with specific neurochemical patterns. Through drugs administration these patterns can be changed to reduce the

symptoms that conform the syndrome. Although pharmacological interventions (mainly neuroleptics) are effective controlling the symptoms during acute phases, their effectiveness as a stand-alone prolonged treatment for SMI is currently challenged. Pharmacological interventions have a major problem with adherence to treatment as well as unwanted side effects. Furthermore, there is an increasing controversy about the effectiveness of sustained pharmacological treatment delivered to people experiencing persistent psychotic symptoms. Several studies have pointed to a better functioning and quality of life on those patients not taking antipsychotic drugs (Morrison et al., 2014; Murray et al., 2016; Wils et al., 2017; Wunderink, Nieboer, Wiersma, Sytema, & Nienhuis, 2013). Moreover, recent studies suggest that cognitive impairment in psychotic disorders are associated to sustained administration of antipsychotic drugs (Harrow & Jobe, 2018), and might be interacting with a premorbid cognitive function (Bentall, 2003). Additionally, the treatment delivered from this perspective has showed poor results when aiming at recovery. It is important to point out that in developed countries the 16% of the cases reach complete recovery, while in non-developed countries the rate reaches 61%. (Hopper, Harrison, Janca y Sartorius, 2007). Two conclusions can be driven from this: 1) if the origins are biological the recovery rate should be the same across cultures, and 2) the treatment delivered in developed countries (focused on biological processes) seems less effective achieving recovery than treatment delivered in non-developed countries (which relies on community processes).

Regarding psychological interventions, the recommended psychotherapy is Cognitive Behavior Therapy (CBT) for Psychosis (National Institute for Health and Care Excellence, 2018; Spanish Ministry of Health, Social Services & Equality, 2009), which has shown small to medium effect reducing psychotic symptoms and improving

the well-being of people suffering SMI (Kråkvik, Gråwe, Hagen, & Stiles, 2013; Mehl, Werner, & Lincoln, 2015; Wykes, Steel, Everitt, & Tarrrier, 2008). The prominent position of pharmacological interventions and their biological explanation of psychotic symptoms have constrained how psychological interventions are delivered to people experiencing persistent psychotic symptoms (Pérez-Álvarez, García-Montes, Vallina-Fernández, & Perona-Garcelán, 2016). Adoption of a biological explanation of psychotic symptoms leaves little space for an SMI case formulation articulated around personal history, contextual features, personality, or personal values and goals; and its reliability as a diagnostic tool is not so accurate as supposed (Bentall, 2003). Therefore, some authors suggested that a more useful approach should entail a case formulation that goes from syndromes to symptoms (Chadwick, 2006), as it establishes a cognitive continuum between psychotic experiences and the rest of mental events and helps to center the intervention over the person and not over his brain. Keeping in mind that biological conceptualization has not been revealed as a powerful treatment option to improve quality of life or social functioning of people experiencing psychosis, it is necessary to develop psychological interventions that – at least – satisfy two goals: 1) be enough independent to formulate cases in a personal way but that do not challenge the dominant paradigm in clinical settings, and 2) improve well-being of people experiencing symptoms despite treatment. In this regard, mindfulness has been proposed as a suitable person-based intervention that can address both requisites.

Mindfulness is a technique incorporated by third-wave CBT – mainly Acceptance and Commitment Therapy (ACT) (Hayes, Strosahl, & Wilson, 1999) – from Eastern meditation that alludes to a nonreactive awareness and concentration of oneself. There are several Western definitions of mindfulness that emphasize different

aspects of the experience to being mindful. However, the most inclusive and therapeutically useful conceptualization of Western tradition, defines mindfulness as “self-regulation of attention so that it is maintained on immediate experience, thereby allowing for increased recognition of mental events in the present moment” and “adopting a particular orientation toward one’s experience that is characterized by curiosity, openness, and acceptance” (Bishop et al., 2004). While there is an increasing number of adaptations for mindfulness teaching – i.e. Mindfulness in children uses shorter but more frequent periods of meditation –, all of them share the same core concepts: cognitive defusion, decentering awareness, and acceptance. Cognitive defusion and decentered awareness refer to experience thoughts and emotion as mere mental events that occur, not as true reflections of the world or about one-self (Greeson, Garland, & Black, 2014). The difference with acceptance relies on that decentering and defusion refer to noticing the event rather react to it. In this regard, acceptance is defined as the capacity to be available for present experience without trying to terminate it if distressing or extend it if pleasant. In a more behavioral perspective has been defined by Butler and Ciarrochi (2007) as “a willingness to experience psychological events (thoughts, feelings, memories) without having to avoid them or let them unduly influence behavior”. Thus, acceptance alludes to accept the experience without any link to goal-directed actions. In Appendix I can be consulted a transcription of a standard protocol for mindfulness teaching extracted from Eifert and Forsyth (2005).

As can be concluded, the main difference of mindfulness with other treatment approaches is that its aim is to redirect the person’s relationship with his symptoms – and other mental events as well– instead try to reduce or remove them. In other words: the core concept is to live in spite of the symptoms and not around them, which can be

very useful when symptoms persist despite standard treatment. Mindfulness has demonstrated to be effective increasing well-being in cancer (Shaw, Sekelja, Frasca, Dhillon, & Price, 2018), Generalized Anxiety Disorder (Hoge et al., 2013), resistant major depressive disorder (MacKenzie & Kocovski, 2016), borderline personality disorder (Wupperman, Neumann, Whitman, & Axelrod, 2009), and chronic pain (Ball, Nur Shafina, Sharizan, Franklin, & Rogozińska, 2017). Taking into account that the main instruction in mindfulness is orienting attention, research about the cognitive effects of this practice soon appeared in the scientific literature. Mindfulness practice has been related to improvement in attention (Chiesa, Calati, & Serretti, 2011; Mak, Whittingham, Cunnington, & Boyd, 2018), working memory (Lao, Kissane, & Meadows, 2016; Zeidan, Johnson, Diamond, David, & Goolkasian, 2010), Executive Functions (EF) – specially cognitive inhibition – (Gallant, 2016; Teper & Inzlicht, 2013) and Theory of Mind (ToM) (Ridderinkhof, de Bruin, Brummelman, & Bögels, 2017; Tan, Lo, & Macrae, 2014) in healthy people and clinical populations as well (Marciniak et al., 2014; Paller et al., 2015).

The suggestive findings of the effects of mindfulness over well-being and cognition invite to consider it as a good candidate for the treatment of people suffering persistent psychotic symptoms. However, mindfulness in psychosis has been slow to develop due initial concerns about its effects over the psychotic symptoms. Deatherage (1975) reported a set of cases where meditation is not recommended, as it may be a trigger for symptom exacerbation. Yorston (2001) reported a case of a middle-aged woman diagnosed with bipolar disorder that experienced a maniac episode after meditation. These studies suggest that mindfulness is not suitable for people with SMI, however, there are several methodological limitations that merit mention. In the case of

Deatherage (1975) the meditation was not delivered by a specialist in mental health, also there is no mention to other treatments implemented as well as their interaction of these with meditation. Regarding Yorston (2001), the meditation consisted of lessons taught in a Buddhist center by a non-clinical specialist. In spite of the poor quality of evidence regarding the application of mindfulness to psychotic symptoms, the idea of being potentially harmful for people experiencing psychotic symptoms was generalized (Dobkin, Irving, & Amar, 2012; Kuijpers, van der Heijden, Tuinier, & Verhoeven, 2007).

In 2005, Chadwick, Taylor, and Abba (2005) conducted a pilot study in a clinical setting using a wait-list design to assess the outcomes of mindfulness applied to persistent psychotic symptoms. Twelve patients were recruited and randomly allocated to group mindfulness or a wait-list. Authors found that after completion there is an improvement in CORE scores (a combined measure of symptoms, social functioning, distress, and risk feelings). It is important to point out that this is the first study where psychotic symptoms did not increase due to mindfulness practice. The major difference with prior research assessing consists of the modifications done to the mindfulness protocol. As proposed by Chadwick (2006), mindfulness applied to persistent psychotic symptoms must be adapted as follows:

- Sessions should be run in a therapeutic context, this means that an educational or informal group context is not adequate for running sessions targeting persistent psychotic symptoms. Also, it is important that professionals involved in the sessions have experience managing people suffering psychotic symptoms.
- Use of a body sensation easy to detect (i.e. Breathing sensation on the nose) is crucial as it provides an anchor to the present moment. If the attention drives to

the content of psychotic symptoms, an easily detectable sensation helps to move the attention back to the moment.

- Although standard Mindfulness sessions last for 20 to 45 minutes, when applied to persistent psychotic symptoms they should last for a maximum of 10 minutes. This lapse of time is the optimal interval to facilitate a fully aware decentered perception of the symptoms. As this will lessen the impact of the content of the symptoms, sessions will be reinforced and more likely to be followed.
- Prolonged silence should be avoided as they can trigger that clients get lost in their symptoms. Thus, it is recommended to provide continuous instructions that guide the meditation.
- The instructions given during the sessions should emphasize three aspects in a strict order. The first instruction is related to how to react when a symptom arises to the mind, people are encouraged to adopt an attitude of “let go” instead react to the content. The aim of this instruction is to reduce distress and prepare the person for the next instruction: focus the attention towards the symptom without avoidance. At this point, both instructions will show to the client that voices are not so powerful. The third instruction consists in to observe the symptom without judge its contents or without judge oneself by experiencing it. For this instruction, the participant is taught to decompose the experience in sensorial properties that allow separate oneself from them. For example, an insulting voice can be decomposed in tone, volume, genre etc.
- Clients are provided with an audio tape for home practice, which is recommended but not mandatory to stay in the mindfulness intervention program. Also, clients are encouraged to apply mindfulness during short periods

in daily life – while waiting for the bus for example – to promote generalization of mindfulness as a coping strategy with persistent psychotic symptoms.

Following this adaptation, Chadwick, Hughes, Russell, Russell, & Dagnan (2009) assessed the feasibility and outcomes of group mindfulness therapy for 22 people experiencing persistent psychotic symptoms using a waiting list design. Participants were randomly allocated to group mindfulness or wait list and were assessed before and after treatment completion. Analysis showed that group mindfulness compliers reduced significantly their CORE scores and increased their ability to respond mindfully to distressing thoughts and images assessed with the Southampton Mindfulness Questionnaire (SMQ). These results extended the previous findings of mindfulness as a safe therapeutic tool using a more robust design (Chadwick, Taylor, & Abba, 2005). Langer, Cangas, Salcedo, and Fuentes (2012) used the same mindfulness adaptation using a control group design and a total sample of 18 SMI participants. There were no differences between groups in the Clinical Global Impression-Schizophrenia Scale but there was in the SMQ scale. Therefore, Langer et al. (2012) conclude that mindfulness is a safe tool as it did not increase symptoms in the experimental group when compared with the control group. The growing literature about the effects of mindfulness led Khoury, Lecomte, Gaudiano, & Paquin (2013) to conduct a metaanalysis including studies with “any mindfulness pre-post or controlled effects of a clinical intervention using any mindfulness protocol for any psychotic disorders” (Khoury et al., 2013). Authors found that mindfulness was associated with a medium effect size over well-being, affective symptoms, and negative psychotic symptoms, which is comparable to those findings reported for CBT for psychosis (Wykes et al., 2008). Moreover, results pointed to a small effect reducing positive

symptoms, which suggests that change the relationship of the person with the symptoms may reduce the frequency and intensity of the later. These results were reproduced by Louise, Fitzpatrick, Strauss, Rossell, and Thomas (2018) who updated incorporating new research clinical trials published since the prior metaanalysis.

Based on the literature reviewed above, there is enough evidence to support the interest of research and the feasibility and outcomes of the inclusion of mindfulness in recommended treatment delivered to people diagnosed with SMI.

2. Aims

The overarching aim of this PhD thesis is to study the feasibility of include a person-based approach on the treatment and formulation of persistent psychotic symptoms instead the mainstream brain-based treatment delivered in the public health system. To face this challenge, the thesis assesses if inclusion of a person-based intervention, namely mindfulness, is feasible and effective when combined with standard treatment delivered to people experiencing psychotic symptoms in a public health rehabilitation setting. Also, the thesis links up its overarching aim through the assessment of subjective measures to generate new insights into the relationship of clinical constructs used in clinical settings.

In the paper entitled “Mindfulness improves psychological quality of life in community-based patients with severe mental health problems: a pilot randomized clinical trial” we assess the feasibility and impact of mindfulness over psychotic symptoms and quality of life in users from a community rehabilitation center. The results obtained led us to research in two ways that are addressed in the other papers: effects of mindfulness over cognition, and the relevance of subjective measures in well-being research of people suffering persistent psychotic symptoms.

The improvement of quality of life registered, as well the literature reviewed about the effects of mindfulness over cognition, drove us to assess if the same results could be registered when applied to people suffering from persistent psychotic symptoms. This chance was fostered by the fact that both executive functions and theory of mind are the best predictors of well-being and social functioning in psychotic disorders. The results of this study are reported in the paper entitled “Does mindfulness

improve executive functions and theory of mind in schizophrenia-related disorders? A randomized pilot clinical trial”.

Finally, as mindfulness is grounded on subjective concepts (like relationship with own thoughts) and research up to now has focused on objective measures that overlook people’s opinion, we studied how well-established facts may change if instead asking the clinician we ask to the person who suffers the symptoms. The results of this apparently simple point of view shift are reported in the paper entitled “Psychotic symptoms and quality of life: A mediation analysis of daily-life coping”.

In summary, the general aim of the dissertation sets two goals: first, it assesses the feasibility and outcomes of an intervention based on how person connects with its mental contents; and second, it generates new knowledge about daily-life factors that influence well-being in people experiencing psychosis.

3. Publications

- a. **López-Navarro, E.**, Del Canto, C., Belber, M., Mayol, A., Fernández-Alonso, O., Lluís, J., ... Chadwick, P. (2015). Mindfulness improves psychological quality of life in community-based patients with severe mental health problems: A pilot randomized clinical trial. *Schizophrenia Research*, 168(1–2), 530–536. <https://doi.org/10.1016/j.schres.2015.08.016> (Impact Factor: 4.453; Quartile: 1; Position 17 of 139)



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Mindfulness improves psychological quality of life in community-based patients with severe mental health problems: A pilot randomized clinical trial



Emilio López-Navarro^{a,*}, Cristina Del Canto^b, Miriam Belber^b, Antoni Mayol^c, Ovidio Fernández-Alonso^c, Josep Lluís^d, Enric Munar^d, Paul Chadwick^e

^a Institut Universitari d'Investigació en Ciències de la Salut (IUNICS), University of Balearic Islands, Ctra Valldemossa km 7,5, Balearic Islands, Spain

^b Department of Clinical Psychology, Son Espases Hospital, Balearic Health Service, Ctra Valldemossa, 79, Palma de Mallorca, Balearic Islands, Spain

^c UCR Serralta Community Rehabilitation Center, Balearic Health Service, Balearic Islands, Spain

^d EvoCog, UIB-IFISC, Associated Unit to CSIC, Spain

^e Department of Psychology, Institute of Psychiatry, Psychology & Neuroscience, King's College London, United Kingdom

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ABSTRACT

Objective: To examine the effectiveness of group mindfulness-based intervention (MBI) in patients diagnosed with severe mental illness. The primary outcome was health-related psychological quality of life. Secondary measures were environmental, social and physical health related quality of life, frequency and intensity of psychotic symptoms and daily-life mindfulness.

Method: Forty-four patients from a public community rehabilitation center for people with severe mental illness were recruited, and randomly allocated to Integrated Rehabilitation Treatment (IRT) or IRT plus MBI. Measures included PANSS interview, WHOQOL-BREF, and Mindfulness Attention Awareness Scale. MBI comprised 26 one-hour weekly sessions. Intention-to-treat analysis was used.

Results: One patient did not complete IRT + MBI and two did not complete IRT. At baseline there were no statistical group differences in demographic characteristics or primary and secondary outcomes. At post-treatment interaction between treatment and time in health-related psychological quality of life was statistically significant, and simple effect analysis showed significant differences for between and within subject factor in favor of MBI. Interaction was also significant in PANSS negative symptoms, simple effects showed a statistical trend in within subject factor. Time factor was significant in environmental and physical quality of life.

Conclusions: Data suggest mindfulness added to IRT may enhance psychological quality of life in people with severe mental illness from a public community center. Results also suggest that mindfulness may impact frequency and intensity of negative symptoms.

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1. Introduction

Severe mental illness (SMI) affects 5.8% of the population in developed countries (Kessler et al., 2005). According to Parabiaghi et al. (2006) people with SMI mainly suffer persistent psychotic symptoms, chronic course and significant impairment of social functioning, thus a wide range of disorders can be included within this category (i.e. schizophrenia, bipolar disorder etc.). Furthermore, the American Psychological Association (APA) states that SMI involves impairment in psychological functioning of such severity that a person's ability to perform routine demands of daily life is significantly compromised, and its consequences for a person's social functioning are severe and persistent (American

Psychological Association, 2009). All definitions of SMI (e.g. Kessler et al., 2005) have a common consequence for the person who suffers it: high psychological distress and poor quality of life (QoL).

Treatment in SMI patients mainly consists in reducing or controlling core symptoms, so pharmacotherapy (i.e. antipsychotics or mood stabilizers) is accepted as the base of the treatment plan (Gardner and Bostwick, 2012; Malhi et al., 2012). Nevertheless pharmacotherapy has several limitations: unwanted side effects (i.e. weight gain, abnormal movements etc.), low impact on negative symptoms, positive symptoms persist in spite of treatment in around a third of cases, and a major problem of non-adherence to treatment, relapse and rehospitalization. To address these issues, pharmacotherapy has been combined with psychosocial rehabilitation programs drawing from psychotherapy, family intervention, and training in social skills and illness management (American Psychological Association, 2009). In recent years, there is increasing interest in how such programs might best improve QoL of

* Corresponding author.

E-mail address: Emilio.lopez@uib.es (E. López-Navarro).

people with SMI. In this regard, mindfulness would be a suitable addition to psychosocial rehabilitation due to its effectiveness in improving QoL in disorders characterized by treatment-resistant symptoms (Lauche et al., 2013; Reiner et al., 2013; Zainal et al., 2013).

Mindfulness has been operationalized as the self-regulation of attention to focus on the present-moment experience with openness and acceptance (Bishop et al., 2004). Thus mindfulness-based interventions (MBI) are assumed to decrease distress through a set of interrelated processes facilitating a mode of present-centered awareness wherein the individual relates to experience with acceptance instead of avoidance or control (Williams, 2010). Outcome research on mindfulness for psychosis has been slow to develop, perhaps because of concerns based on isolated case reports of traditional meditation sometimes being either too difficult or even harmful to this client group (Chadwick, 2014). For example, Deatherage and Lethbridge (1975) argue that traditional meditation may require too much motivation and “rationality” for some persons with psychosis, at least in the early stages of the therapy. Again, Yorston (2001) reports how traditional meditation triggered onset of mania in two cases. However, contemporary mindfulness for psychosis has been developed specifically for people with psychotic symptoms, and has shown promise and no negative effects (Chadwick, 2014). Three pilot studies offered preliminary evidence that group MBI for people with psychosis has beneficial effects and increases mindfulness skills (Chadwick et al., 2005, 2009; Langer et al., 2012). Furthermore, a qualitative study of 16 people who completed mindfulness for psychosis groups (Abba et al., 2008) described a psychological process whereby patients began to reclaim power previously invested in distressing voices and paranoid beliefs, and to feel greater self-control and self-acceptance.

A recent meta-analysis estimates that interventions that include mindfulness have a medium effect on QoL in patients with psychotic symptoms (Khoury et al., 2013), though analysis does not separate interventions that are primarily mindfulness-based from those where mindfulness practice is part of a broader therapy. The present study uses a randomized controlled trial to compare the effect of group MBI plus rehabilitation versus rehabilitation alone on health-related psychological quality of life in 44 patients with SMI attending a public community rehabilitation center. Secondary measures assessed if mindfulness-based intervention affects other dimensions of health-related quality of life (environmental and physical), psychotic symptomatology, and mindfulness skills.

2. Materials and methods

2.1. Design

A single center, randomized clinical trial with pre- and post-treatment measures was designed. There were two treatment arms: Integrated Rehabilitation Treatment (IRT) and IRT enhanced with group MBI.

The study complied with the Declaration of Helsinki and ethical approval was granted by the Research Ethics Committee of the University of Balearic Islands. Intention-to-treat analysis was used to avoid overestimation of the efficacy resulting from removal of non-compliers. Multiple stochastic imputation was selected to deal with missing data – an appropriate and robust method (Baraldi and Enders, 2010), and recommended to deal with data missing at random (Fielding et al., 2012). This pilot trial follows the JARS group recommendations (Cooper, 2008) for randomized clinical trial reporting standards.

2.2. Study sample

51 patients from a public community rehabilitation center for people with SMI were asked to participate. Inclusion criteria were 1) age between 18–65, 2) clinical record of schizophrenia, schizoaffective or bipolar disorder, 3) being in a stable post-acute phase of illness defined as having experienced no changes in psychiatric medication or

hospitalization in the last month, 4) previous history of psychotic symptoms, 5) no prior experience of mindfulness or yoga-based interventions, 6) be able to understand and read Spanish language, and 7) gave written informed consent. Exclusion criteria were 1) significant cognitive impairment, 2) inability to attend mindfulness sessions, and 3) posed a risk of violence to the researchers. No payment was made for participation in the study. Recruitment took place between December 2012 and February 2013 for the first group and between July 2013 and August 2013 for the second group.

2.3. Measures

The primary outcome measure was health-related psychological quality of life, assessed using the 26-item World Health Organization Quality of Life-BREF (WHOQOL-BREF) (Harper et al., 1998). Secondary measures included three further dimensions of quality of life, also assessed by WHOQOL-BREF: physical health, social relationships, and environment. The Spanish validation of WHOQOL-BREF (Lucas Carrasco, 1998) has shown satisfactory internal consistency and adequate test–retest reliability (Mas-Expósito et al., 2011).

Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987) was included as a secondary measure to detect any changes in psychotic symptomatology. The PANSS is a semi-structured interview used for measuring symptom severity of patients with SMI. Each of the 30 items is scored from 1 to 7, higher scores reflecting greater psychopathology. For the purposes of this study, four PANSS scores were used: PANSS total, PANSS general psychopathology cluster, PANSS negative cluster, and PANSS positive cluster. Spanish adaptation is considered equivalent to original English form (Kay et al., 1990).

In order to detect changes in mindful awareness in everyday life the Mindfulness Attention Awareness Scale (MAAS) (Brown and Ryan, 2003) was used as a secondary outcome. This 15-item scale focuses on attention/awareness component of mindfulness construct. The instrument can be independently used to assess individuals either with or without meditation experience and has been widely used in mindfulness research. The Spanish version of MAAS has good reliability indexes and good temporal stability (Soler et al., 2012).

2.4. Assessment

Patients were contacted by their regular psychiatrist to perform a personal interview. At interview each patient was informed about mindfulness and what participation in the trial would involve. At the end of the interview each patient, or his legal guardian, was invited to participate and to sign informed consent.

After informed consent for trial participation was signed, randomization identification was assigned to each patient and recorded in the clinical record form. A master randomization list was created to record randomization identifications and corresponding treatment assignment, access to master randomization list was restricted to psychologist and psychiatrist who led mindfulness sessions. Patients were randomly allocated by software to IRT or IRT + MBI group, with a group size for MBI of 10–12 (12 being the maximum size for groups with this client group). Each of the two cohorts was randomized once numbers were sufficient to begin a mindfulness group. Once allocated, patients were assessed by a psychologist specifically trained to manage SMI patients and coordinate clinical trials who was blind to patient allocation. Psychological assessment consists in a videotaped PANSS interview followed by WHOQOL-BREF and MAAS questionnaires. PANSS interview was evaluated at the end of the study by two clinical psychologists from the local hospital service; both had no contact with patients and were blind to allocation. Access to master randomization list was restricted during the study to keep blinding.

2.5. Intervention

IRT consisted in pharmacotherapy combined with 26 one hour weekly sessions of cognitive behavior therapy techniques for symptom management (e.g. sharing the cognitive ABC model, monitoring thoughts, feelings and behaviors), social skills training focussed on assertiveness, and psychoeducation about SMI management as well as strategies for preventing relapse and conflict management. IRT contained no mindfulness training or family intervention.

MBI groups ran throughout the 26 week rehabilitation treatment program (Carmody and Baer, 2009). Mindfulness group therapy sessions lasted 60 min and were carried out in venue ceded for free by city council. To help clients to ground every session began with a habituation period to the room with relaxing music as background followed by 10-minute body awareness exercises led by a trained psychologist.

Then, 15 min of guided meditation was led by a psychiatrist and a clinical psychologist trained in mindfulness and experienced in working with SMI patients. Frequent guidance was imparted in every mindfulness session encouraging awareness and acceptance of bodily sensations, sensations of breathing, and thoughts, images and voices that might arise. Guidance also encouraged participants to notice and let go of worry and engagement with the content of thoughts, voices or other psychotic symptoms that might arise, and of criticism or judgment. Finally, sessions included 15 min of reflective group discussion aimed at facilitating patients' understanding and insights drawn from the mindfulness practice. Guidance and reflection followed Chadwick et al. (2005, 2009). Home practice was encouraged between mindfulness sessions and participants were given an audio tape for home practice with the guidance instructions used during group sessions.

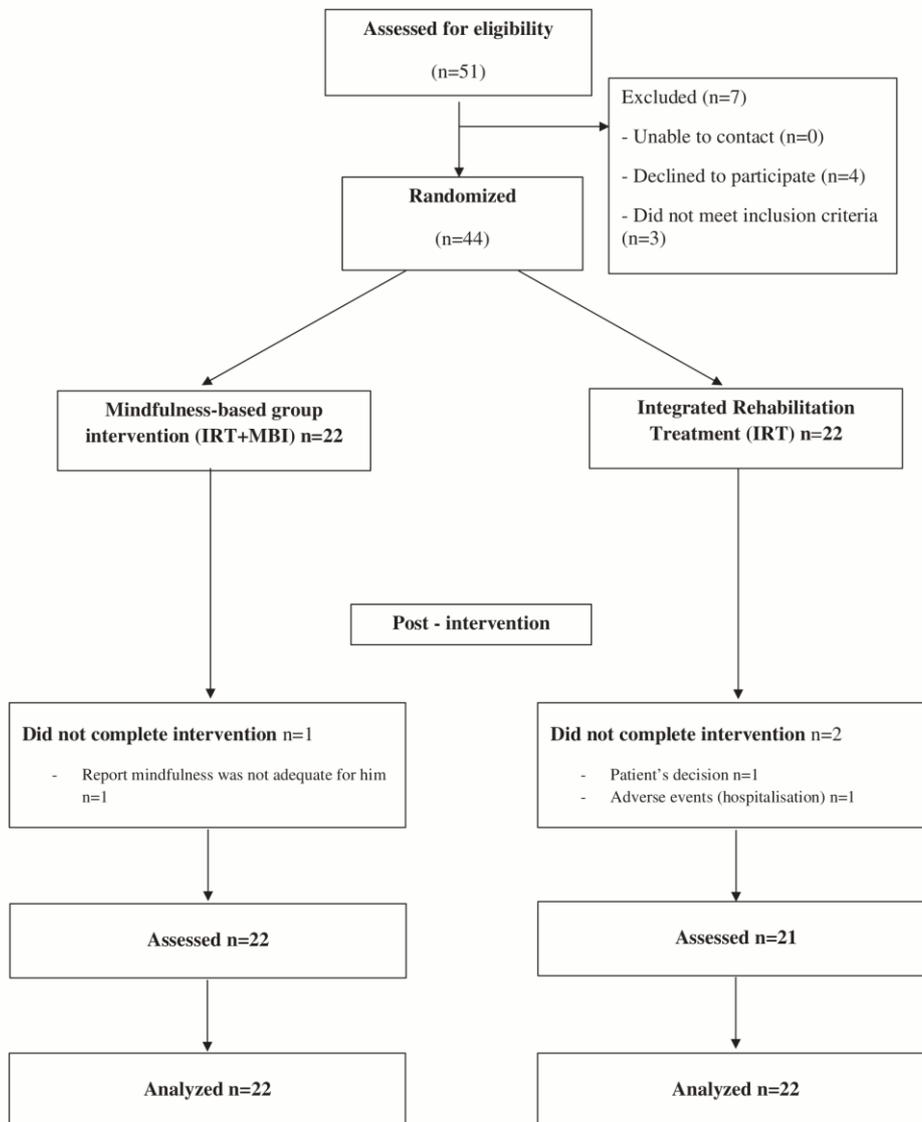


Fig. 1. CONSORT flowchart.

2.6. Statistical analyses

Before proceeding to conduct any analysis over the outcome variables, the assumption of multivariate normality and homogeneity of variances was tested. Both groups of participants were compared on baseline variables using Chi square and independent sample t tests.

As a manipulation check, analyses were conducted using repeated-measures analyses of variance (ANOVA) for different dependent variables (WHOQOL-BREF dimensions and MAAS) with Treatment condition (IRT, IRT + MBI) as between-participants factor and Time (baseline and post-treatment) as within-participants variable. In order to examine any significant difference in interaction between factors Bonferroni contrast was used. The level of statistical significance was set at 5%.

3. Results

Fifty one patients were assessed against inclusion criteria (Fig. 1). Seven participants were excluded, 4 declined to participate and 3 did not meet inclusion criteria. Twenty two patients were allocated to IRT + MBI group and twenty two to IRT group. One patient did not complete IRT + MBI treatment, reporting that mindfulness intervention was not adequate for him, but continued in IRT alone. In IRT condition two patients did not complete intervention, one due to patient's decision of not to come back to IRT and one due to adverse events (hospitalization) who was not followed-up. Final statistical analyses included 44 participants. The sample was predominantly male (81.8%), with a mean age of 38.44 (SD = 8.06), diagnosis of schizophrenia (89%), and mean duration of illness was 14.02 (7.01) years.

The first analyses checked the level of homogeneity between the mindfulness group and the waitlist group. Table 1 showed the results of these analyses. To check the assumption of normality, the Kolmogorov–Smirnov test was applied to: age ($Z(44) = 0.82, p = 0.51$), years since diagnosis ($Z(44) = 1.33, p = .06$), positive PANSS ($Z(44) = .64, p = .8$), negative PANSS ($Z(44) = .71, p = .7$), general PANSS ($Z(44) = .6, p = .86$), and total PANSS ($Z(44) = .69, p = .73$). Levene tests were applied to these same factors to check homoscedasticity: age ($F(1,43) = 1.88, p = .18$), years since diagnosis ($F(1,42) = .05, p = .83$), positive PANSS ($F(1,42) = .34, p = .56$), negative PANSS ($F(1,42) = .13, p = .72$), general PANSS ($F(1,42) = 1.81, p = .19$), and total PANSS ($F(1,42) = .02, p = .9$). As is shown in Table 1, there is no difference between IRT and IRT + MBI groups in age, years since diagnosis, gender, education level or diagnosis.

The assumption of normality was checked using Kolmogorov–Smirnov test in WHOQOL-BREF and MAAS: physical health (QoL), $Z(44) = .79, p = .55$; psychological health (QoL), $Z(44) = .77, p = .59$; social relationships (QoL), $Z(44) = .84, p = .49$; environment (QoL), $Z(44) = .83, p = .5$; and MAAS, $Z(44) = .56, p = .91$.

A 2×2 ANOVA (Treatment \times Time) for each measure was used. The WHOQOL-BREF results comparing IRT and IRT + MBI groups in primary and secondary outcomes are summarized in Table 2. For every dimension, there are seven lines of results: the four simple effects, the two main effects – Treatment and Time – and the interaction effect between these two factors. Our main hypothesis was based on the potential significance of this interaction.

On the primary outcome measure, psychological health-related quality of life, the interaction between Treatment and Time was clearly significant: $F(1,42) = 16.72; p < .001; \eta^2 = .285$. The analysis of simple effects of this interaction showed that there were significant differences between the Pre and Post assessments in the IRT + MBI group – $F(1,42) = 25.49; p < .001; \eta^2 = .378$, but not in the IRT group – $F(1,42) = .54; p = .467, \eta^2 = .013$. On the other hand, there were significant differences between the two groups in the Post assessment – $F(1,42) = 5.44; p = .025, \eta^2 = .115$, but not in the Pre assessment – $F(1,42) = .36; p = .55, \eta^2 = .009$.

Secondary measures of physical and environmental healths showed significant differences in the WHOQOL-BREF. Significant differences were found in Time factor on physical health ($F(1,42) = 7.23; p = .01; \eta^2 = .147$), simple effect analysis showed significant differences between Pre and Post in IRT + MBI group ($F(1,42) = 6.69; p = .013; \eta^2 = .137$). Time factor was found significant in environment dimension ($F(1,42) = 11.21; p = .002, \eta^2 = .211$) and simple effect analysis showed statistical differences between Pre and Post in IRT + MBI group: $F(1,42) = 11.21; p = .002; \eta^2 = .21$. There were no effects on social quality of life.

The same 2×2 ANOVA (Treatment \times Time) was applied to PANSS and MAAS data. There were no significant differences in PANSS positive scores. For PANSS negative scores, there was a significant Treatment–Time interaction – $F(1,42) = 4.44; p = .041, \eta^2 = .096$ –, and simple effect analysis showed a statistical trend between Pre and Post assessments in IRT + MBI ($p = .063, \eta^2 = .08$). PANSS general scores showed significant differences in Time factor – $F(1,42) = 5.54; p = .023, \eta^2 = .117$ –, when simple effects were analyzed statistical differences were found in IRT + MBI ($F(1,42) = 4.6; p = .038, \eta^2 = .099$) group, but not in IRT group ($F(1,42) = 1.4; p = .243, \eta^2 = .032$). For MAAS there were no differences in the interaction or the main effects (Table 2).

Table 1
Clinical and demographic characteristics.

	Total sample (n = 44)	IRT group (n = 22)	IRT + MBI group (n = 22)	Statistics
Age (mean, SD)	38.84 (8.06)	38.77 (8.93)	38.73 (7.46)	t = 0.018 p = 0.985
Sex (n, %)				
1. Man	36 (81.8)	17 (77.3)	19 (86.4)	$\chi^2 = .611$ p = .698
2. Woman	8 (17.2)	5 (22.7)	3 (13.6)	
Years since diagnosis (mean, SD)	14.02 (7.01)	14.05 (7.44)	14 (6.79)	t = 0.024 p = 0.981
Diagnosis (n, %)				
1. Paranoid schizophrenia	20 (45.4)	10 (45.5)	10 (45.5)	$\chi^2 = 1.111$ p = 0.953
2. Schizoaffective disorder	9 (20.4)	4 (18.2)	5 (22.7)	
3. Undifferentiated schizophrenia	6 (13.6)	4 (18.2)	2 (9.1)	
4. Disorganized schizophrenia	4 (9.1)	2 (9.1)	2 (9.1)	
5. Bipolar disorder	3 (6.8)	1 (4.5)	2 (9.1)	
6. Delusional disorder	2 (4.7)	1 (4.5)	1 (4.5)	
Age left education (n, %)				
1. 14 years old or less	20 (45.4)	11 (50)	9 (40.9)	$\chi^2 = 0.368$ p = 0.832
2. Between 15 and 17 years old	13 (29.5)	6 (27.3)	7 (31.8)	
3. 18 years old or more	11 (25.1)	5 (22.7)	6 (27.3)	

4. Discussion

The main finding of our study indicates that adding a mindfulness-based intervention (MBI) to an Integrated Rehabilitation Treatment (IRT) yielded improved psychological health-related quality of life (QoL) in people with severe mental illness, 89% of whom had a diagnosis of schizophrenia. Psychological QoL, as defined by the WHO, comprises self-esteem, positive feelings and bodily image, and reduced frequency of negative feelings (Harper et al., 1998). Data suggests that mindfulness intervention accounts for 38% of variance in health-related psychological QoL. Secondary measures indicated broader QoL benefits of the combination of IRT + MBI, with significant

improvement in scores for physical and environmental dimensions. Study retention rate was high (93%), with only one drop-out from IRT + MBI, and two from IRT, and there were no adverse events in the MBI participants.

Our results are convergent with previous findings about MBI in psychosis (Chadwick et al., 2009; Gaudiano et al., 2010; Langer et al., 2012), and go further assessing its effectiveness and feasibility as an add-on to IRT in a public community rehabilitation center. The improvement on psychological health-related QoL in people with SMI may be due in part to change in the relationship with their symptoms – a finding reported in a qualitative study of mindfulness for psychosis (Abba et al., 2008). According to Hayes, the more a person resists symptoms,

Table 2
ANOVA analysis.

SCALE mean (SD)		PRE	POST	F	p value	η^2
Physical QoL	IRT	21.5 (3.03)	22.23 (3.01)	1.48	.230	.034
	IRT + MBI	21.18 (3.3)	22.73 (3.41)	6.69	.013	.137
	PRE			.11	.741	.003
	POST			.27	.609	.006
	Treatment			0.01	.917	<.001
	Time			7.23	.010	.147
	Treatment × time interaction			.94	.338	.022
Psychological QoL	IRT	18.45 (4.17)	18.09 (4.17)	.54	.467	.013
	IRT + MBI	17.78 (3.28)	20.27 (2.64)	25.49	<.001	.378
	PRE			.36	.55	.009
	POST			5.44	.025	.115
	Treatment			.59	.447	.014
	Time			9.31	.004	.181
	Treatment × time interaction			16.72	<.001	.285
Social relationship QoL	IRT	7.91 (2.22)	8.5 (1.76)	1.48	.231	.034
	IRT + MBI	7.95 (2.19)	8.1 (2.67)	.09	.763	.002
	PRE			.01	.946	<.001
	POST			.28	.597	.007
	Treatment			.07	.79	.002
	Time			1.15	.289	.027
	Treatment × time interaction			.42	.523	.010
Environment QoL	IRT	23.95 (3.86)	25.09 (3.46)	1.94	.171	.044
	IRT + MBI	24.23 (4.51)	26.95 (3.95)	11.18	.002	.21
	PRE			.05	.831	.001
	POST			2.76	.104	.062
	Treatment			1.04	.314	.024
	Time			11.21	.002	.211
	Treatment × time interaction			1.9	.175	.043
MAAS	IRT	45.09 (14.22)	43.04 (12.51)	.61	.438	.014
	IRT + MBI	43.09 (14.39)	45.81 (14.33)	1.09	.303	.025
	PRE			.21	.645	.005
	POST			.47	.498	.011
	Treatment			.01	.919	<.001
	Time			.03	.855	.001
	Treatment × time interaction			1.67	.204	.038
PANSS positive	IRT	15.95 (6.22)	15.41 (6.99)	.43	.516	.01
	IRT + MBI	17.95 (6.58)	16.82 (6.24)	1.86	.179	.042
	PRE			1.07	.306	.025
	POST			.5	.484	.012
	Treatment			.83	.368	.019
	Time			2.04	.16	.046
	Treatment × time interaction			.25	.618	.006
PANSS negative	IRT	20.04 (6.23)	21.09 (5.91)	1.15	.29	.027
	IRT + MBI	21.72 (6.33)	19.86 (6.2)	3.65	.063	.080
	PRE			.79	.38	.018
	POST			.45	.505	.011
	Treatment			.02	.896	<.001
	Time			.56	.556	.008
	Treatment × time interaction			4.44	.041	.096
PANSS general	IRT	40.14 (11.06)	38.45 (11.59)	1.4	.243	.032
	IRT + MBI	41.45 (7.22)	38.41 (6.62)	4.6	.038	.099
	PRE			.22	.642	.005
	POST			.01	.987	<.001
	Treatment			.06	.811	.001
	Time			5.54	.023	.117
	Treatment × time interaction			.46	.501	.011

Bold values indicate significance at F tests ($p < .05$).

IRT and IRT + MBI rows reflect interaction analysis for Time factor (within subjects).

PRE and POST rows reflect interaction analysis for Treatment factor (between subjects).

the more likely functional impairment will result, as individuals forgo the pursuit of their goals due to avoidance of internal distress (Hayes et al., 1999). Mindfulness supports “cognitive defusion”, a metacognitive process aimed at undermining the literal quality of thoughts so that they are experienced more specifically as thoughts (I’m having the thought “I am going crazy”) rather than as their literal content (“I am going crazy”) (Gaudiano and Herbert, 2006). As patients learn to let go of struggle and reactivity, psychotic experiences come to be accepted as transient experiences that do not define the self and patients report reclaiming power from psychotic symptoms (Abba et al., 2008).

The frequency and intensity of positive psychotic symptoms did not change due to mindfulness intervention. This finding is congruent with previous studies on people with a diagnosis of schizophrenia (Chadwick et al., 2009; Langer et al., 2012), and indeed it has been argued that reduction in positive symptoms is not a target in mindfulness-based interventions (Bach and Hayes, 2002). There is, however, emerging evidence that MBIs affect negative symptoms, with a recent meta-analysis reporting small to medium effect sizes (Khoury et al., 2013). The present study found a statistical trend towards improvement in PANSS negative symptoms in IRT + MBI treatment; this exploratory finding is consistent with Khoury et al.’s conclusion that mindfulness affects this symptom cluster. Additionally, PANSS data suggest that mindfulness intervention may also reduce general psychopathology of this client group. Further research on outcomes, mediators and moderators, is needed.

There were no statistically significant differences in mindfulness scores, despite the effect size registered. This may reflect the small sample size, or the decision to use a measure of mindfulness in everyday life rather than a measure that targets mindfulness of difficult cognitions, such as the Southampton Mindfulness Questionnaire (Chadwick et al., 2008) which showed effects in earlier research on mindfulness for psychosis. Choice of outcomes and assessment tools in psychological therapies for psychosis remains an ongoing challenge.

The study has limitations that deserve mention. The sample size is small (though sufficient to test the primary outcome), with an uneven gender distribution of the sample, as 81% was male — though this gender imbalance is in line with the prevalence of SMI in the general population (NIMH, 2013). Also, in keeping with the initial aims of a pilot research clinical trial, the study aimed at exploring only immediate benefits of adding mindfulness to integrated rehabilitation care; future research could explore maintenance of gains. The main strengths are the randomized design with blind assessment; the first data on psychological quality of life following mindfulness in this client group; and the use of a well-defined active control treatment (because participants were drawn from the same community public healthcare service, integrated rehabilitation care was consistent across all participants and comprised medication, cognitive-behavior therapy, and education towards illness management).

The findings of our study are encouraging and warrant a full trial. Future research should include a follow-up phase and assess impact on service use (e.g. drug prescription), relapse and rehospitalization. Further research should also collect qualitative data to extend understanding of underlying processes triggered by mindfulness training (e.g. Abba et al., 2008). Nevertheless results showed that the inclusion of mindfulness within rehabilitation has potential to enhance quality of life, and perhaps even reduce negative symptoms. In summary, the study lends further support to the view that when adapted for people with SMI, mindfulness-based group interventions are acceptable, safe and therapeutic, and supports the call (Chadwick, 2014) for careful practice and research into the efficacy and effectiveness of mindfulness based interventions for people with psychosis and other severe mental health problems.

Contributors

All authors contributed to write the mindfulness intervention protocol. Enric Munar and Cristina del Canto wrote the informed consent. Emilio López-Navarro, Cristina del

Canto, and Miriam Belber conducted assessment. Emilio López-Navarro performed video-taped clinical interviews, which were evaluated by Cristina del Canto and Miriam Belber who were blind to patient’s allocation. Josep Lluís conducted body awareness exercise, while Antoni Mayol and Ovidio Fernández-Alonso led guided meditation. Emilio López-Navarro and Enric Munar performed the statistical analyses reported. First manuscript draft was written by Emilio López-Navarro, Cristina del Canto, Enric Munar and Paul Chadwick. All authors have approved the final manuscript.

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Conflict of interest

The authors report no potential conflicts of interest.

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Does mindfulness improve executive functions and theory of mind in schizophrenia-related disorders? A randomized pilot clinical trial

Emilio López-Navarro ^a, Cristina Del Canto ^b, Jessica Fish ^{c,d}, Antoni Mayol ^{a,e}, Enric Munar ^a, Paul Chadwick ^c

^a EvoCog Group, University of Balearic Islands, IFISC, Associated Unit to CSIC. Balearic Islands. Spain.

^b Department of Clinical Psychology. Son Llàtzer Hospital. Balearic Health Service. Balearic Islands. Spain.

^c Department of Psychology. Institute of Psychiatry, Psychology & Neuroscience, King's College London. United Kingdom.

^d The Oliver Zangwill Centre for Neuropsychological Rehabilitation, Cambridgeshire Community Services NHS Trust, United Kingdom.

^e UCR Serralta Community Rehabilitation Centre. Balearic Health Service. Balearic Islands. Spain.

Corresponding author: Emilio López-Navarro.

Abstract

Objective: to assess the effect over executive functions and theory of mind skills of a mindfulness-based intervention combined with integrated rehabilitation treatment in a sample of people diagnosed of schizophrenia-related disorders

Method: Fifty-six patients were recruited and randomly allocated either integrated rehabilitation treatment or integrated rehabilitation treatment enhanced with 26 mindfulness group sessions. Measures comprised PANSS interview, MAAS, Trail Making Test, Digit Span subtest from WAIS, Stroop Test, fluency and phonetic fluency tasks, Hinting Test and Reading the Mind in the eyes Test

Results: There were no differences between groups before start treatment. At post-treatment patients in mindfulness group increased their scores in MAAS, Trail Making Test Part B, non-congruent Stroop, and Reading the Mind in the Eyes Test. When groups were compared at post-treatment, participants attending mindfulness sessions scored higher than those at integrated rehabilitation treatment in MAAS.

Conclusions: Data suggest that mindfulness when added to integrated rehabilitation treatment improves cognitive performance of schizophrenia-related disorder patients, especially cognitive inhibition and theory of mind skills related to emotion recognition.

Keywords: mindfulness; schizophrenia; cognitive remediation; executive functions; theory of mind

1. Introduction

Deficits in critical cognitive domains have long been central to an understanding of schizophrenia and psychotic disorders. These domains comprise attention, processing speed, executive functions, episodic and working memory as well as social cognition (Cella, Huddy, Reeder, & Wykes, 2012). Executive Functions (EF) include a broad range of top-down processes such as decision making, problem-solving and concept formation (Ardila, 2008). There is general agreement about three core components of EF: Shifting, Inhibition, and Updating (Miyake et al., 2000). Shifting involves disengagement from an irrelevant task set and the subsequent engagement in a relevant task set. Updating comprises monitoring and coding relevant information and replacing outdated information with newer and more relevant information. Inhibition accounts for the operation of deliberately inhibiting prepotent responses and select less likely behavior in presence of a competing behavioral tendency. The three-component model of EF was updated by Fisk and Sharp (2004), who added a fourth factor, Access, that mediates the access to long-term memory representations and is involved in verbal fluency tasks. In sum, EF allows the flexible modification of behavior in response to environmental demands and underpins capacity for Theory of Mind (ToM) (Diamond, 2013). ToM is the ability to attribute mental states, such as intentions, beliefs, emotions, and so forth, to oneself and to others, thereby facilitating the understanding and prediction of behavior (Premack & Woodruff, 1978).

Deficits in EF and ToM have been targeted in psychological treatments for people with diagnoses of schizophrenia and other psychotic disorders. Cognitive remediation therapy seeks to establish durable and generalizable improvement in cognitive processing by using either compensatory methods (i.e. using residual

cognitive abilities to circumvent a specific deficit), or restorative interventions aimed at enhancing a target deficit. Wykes et al. (2011) meta-analysis showed that the effect size of cognitive remediation ranges from small to moderate and its effectiveness is increased when combined with psychiatric rehabilitation treatment. The effects of mindfulness-based interventions (MBI) on EF and ToM in the general population have been examined with broadly positive findings. For example, in nonclinical samples, dispositional mindfulness has been associated with better cognitive inhibition in adult (Chiesa, Calati, & Serretti, 2011; Teper & Inzlicht, 2013), as well working memory in children (Riggs, Black, & Ritt-Olson, 2014). Some authors have suggested that MBI could play a protective role against cognitive decline associated with aging (Gard, Hölzel, & Lazar, 2014). Although there is no study looking at impact of mindfulness on EF and ToM in schizophrenia, Tabak and Granholm (2014) reported benefits in processing speed and working memory in a sample of 5 veterans with psychotic features after six mindfulness sessions; and there is a growing literature attesting to the benefits of mindfulness for psychosis on distress and depression (Chadwick, Hughes, Russell, Russell, & Dagnan, 2009; Chadwick et al., 2016), psychological quality of life (López-Navarro et al., 2015), as well psychotic symptoms (Louise, Fitzpatrick, Strauss, Rossell, & Thomas, 2018).

The present pilot study used a randomized controlled design to compare the effects of 6 months of standard psychiatric rehabilitation versus 6 months of standard rehabilitation enhanced with weekly group mindfulness training on EF and ToM performance in participants diagnosed with psychotic disorders.

2. Methods

2.1. Design

A single center randomized controlled design pilot trial with pre and post-treatment measures was designed. 68 people diagnosed with psychotic disorder from a public community rehabilitation center were assessed for eligibility. Inclusion criteria were 1) age between 18-65; 2) one of the following DSM-IV-TR diagnosis: Schizophrenia (295.30; 295.10;295.90), Schizoaffective Disorder (295.70), Delusional Disorder (295.70), Bipolar Disorder (296.40; 296.4x; 296.5x; 296.5x); 3) no changes in psychiatric medication or hospitalization in last month; 4) have signed informed consent; and 5) be able to understand and read the Spanish language. Exclusion criteria were 1) significant cognitive impairment; 2) inability to attend mindfulness or rehabilitation treatment sessions; 3) posed a risk of violence to the researchers; and 4) refused to participate or to sign informed consent. No payment was made for participation in the study. Data collection was carried between August 2013 and July 2015 at the same community rehabilitation center. Intention-to-treat analysis was used. Multiple stochastic imputation was selected to deal with missing data (Baraldi & Enders, 2010). The study complied with the Declaration of Helsinki and was approved by the Research Ethics Committee of the University of Balearic Islands. Trial was registered in ISRCTN Registry: ISRCTN52873519.

Patients were contacted by their regular psychiatrist to perform a personal interview to be informed about mindfulness and what participation in the trial would involve and to assess eligibility. At the end of the interview eligible participants, or their legal guardians, were invited to participate and sign informed consent. After informed consent for trial participation was signed, randomization identification was assigned to each patient and recorded in the clinical record form. A master randomization list was

created to record randomization identifications and corresponding treatment assignment, access to master randomization list was restricted to psychologist and psychiatrist who led mindfulness sessions. Patients were assessed by a research psychologist specifically trained to manage patients with psychotic features and coordinate clinical trials who was blind to patient allocation. Once assessed, participants were randomly allocated by software to Integrated Rehabilitation Treatment (IRT) or IRT+MBI group, with a maximum group size for MBI of 12. Each of the three cohorts was randomized once numbers were sufficient to begin a mindfulness group.

2.2. Instruments

Demographic data and clinical features of participants were collected through a specifically designed clinical record form. Age, sex, education years, psychotic disorder diagnosed, age at onset and years of education were recorded. Diagnoses were obtained through clinical record. Primary outcomes were EF, ToM and general mindfulness awareness, participants were assessed before and after treatment completion.

Positive and Negative Syndrome Scale (PANSS) (Kay, Fiszbein, & Opler, 1987) was used to assess the frequency and intensity of psychotic symptoms. Interviews were videotaped for be scored at the end of the intervention by two clinical psychologists who were blinded to patient allocation. The Spanish adaptation is considered equivalent to the English form (Kay, Fiszbein, Vital-Herne, & Fuentes, 1990).

To detect changes in general mindfulness awareness in daily life as a consequence of treatment the Mindfulness Attention Awareness Scale (MAAS) (Brown & Ryan, 2003) was used. This 15-item scale focuses on attention/awareness component of mindfulness construct. The instrument can be independently used to assess

individuals either with or without meditation experience and has been widely used in mindfulness research. The Spanish version of MAAS has good reliability indexes and good temporal stability (Soler et al., 2012).

Cognitive assessment battery was designed to cover Miyake's model of executive functioning. Instruments were selected searching the best balance between feasibility and correlation with EF components as pointed by Aboulafia-Brakh et al. (2011).

-To assess Shifting, Trail Making Test (TMT) (Army Individual Test Battery, 1944) was used. This well-established test comprises two parts, A and B. Part B places over visuo-motor attention and information processing additional demands on attentional switching. Scores for completion time in seconds were used in the analysis.

-Digit Span (a subtest of the Wechsler Adult Intelligence Scale, 3rd edition, WAIS-III) 30 was used to assess Updating. Digit Span Backwards (DS-B) requires the participant to repeat the series in reverse sequence, and hence requires the manipulation and updating of information in working memory (Lezak, 1995). Raw scores for backwards trials were used in the analysis.

- Assessment of Inhibition was conducted using the non-congruent trial of Stroop Colour Word Test (SCWT) (Golden, 1978). This version of the Stroop paradigm consists of three 45-second trials. In the first trial the participant reads aloud a series of color names printed in black as fast as possible. In the second trial they name the color of a series of ink swatches. In the third, non-congruent, trial, the participant is shown lists of color names printed in ink of a conflicting color and asked to name the ink color rather than reading the color word. Non-congruent trial requires recruitment of

processes regarding Inhibition. Elements processed in 45 seconds were recorded as raw scores and used for statistical analyses.

- Access was assessed using the semantic trial from Phonemic and Semantic Verbal Fluency (Borkowski, Benton, & Spreen, 1967). The phonemic trials of this verbal fluency task require the participant to generate as many words as possible beginning with a given letter within 60 seconds, excluding proper nouns. A semantic trial in which participants were required to name as many animals as they could within 60 seconds was also administered (Ardila, Ostrosky-Solís, & Bernal, 2006). The total score semantic trial was used in the analysis.

Instruments used to assess ToM skills were:

- Reading the Mind in the Eyes Test (RMET) (Baron-Cohen, Wheelwright, Hill, Raste, & Plumb, 2001): This instrument is composed of 36 black and white photos of actors and actresses showing the eye region only. Participants are required to choose which adjective from a set of four (one target and three foils) best describes the mental state of the pictured person. Spanish adaptation has shown reliable and stable psychometric properties (Fernández-Abascal, Cabello, Fernández-Berrocal, & Baron-Cohen, 2013).

- Hinting Test (Corcoran, Mercer, & Frith, 1995). The test uses 10 short speeches in which a character drops a hint. The patients were asked what the character really meant. A correct answer was given 2 points. If a correct answer was not provided, a further hint was given and a correct answer at this stage was given 1 point. If the patient still did not give a correct answer a score of 0 was recorded. A summary total score was used in the analysis. The Spanish adaptation of The Hinting Test has good psychometric properties and discriminant validity (Gil, Fernández-Modamio, Bengochea, & Arrieta, 2013).

2.3. Intervention

There were two treatment arms: IRT and IRT enhanced with group MBI. IRT comprised pharmacotherapy combined with 26 one hour weekly sessions of cognitive behavior therapy techniques for symptom management as well as strategies for preventing relapse and conflict management. Both arms were delivered by routine clinical staff training in rehabilitation, and for IRT+MBI in mindfulness. IRT contained no mindfulness training or family intervention. IRT+MBI group ran throughout the 26-week rehabilitation treatment program. Mindfulness group therapy sessions lasted 60 minutes and began with relaxing music as background to help clients to ground. Then body awareness exercises along 10 minutes followed by 15 minutes of guided meditation developed by Chadwick (2005) for people with psychosis. Finally, sessions included 15 minutes of reflective group discussion. Details about IRT and MBI sessions can be found in López-Navarro et al. (2015). A trained psychiatrist was present during mindfulness sessions to check adherence to treatment protocol. First author attended 60% sessions to observe and confirm treatment fidelity.

2.4. Statistical Analyses

Descriptive statistics were generated for the sample and for each treatment arm. Statistical analyses were performed using raw scores. Before proceed to conduct any analysis the assumption of normality and homogeneity of variances was tested. Groups were compared at baseline on sociodemographic, clinical, cognitive, and ToM.

To test for group differences, a repeated-measures analysis of variance (ANOVA) was conducted for TMT Part B, STCW non-congruent trial, Semantic Verbal Fluency task and Digit Span Backwards scores, and MAAS. Treatment condition (IRT,

IRT+MBI) was set as between-participants factor and Time (baseline and post-treatment) as within-participants factor. So for every measure, there are seven lines of results: the four simple effects, the two main effects -Treatment and Time-, and the interaction effect between these two factors. Interaction was analyzed Bonferroni correction to control Type I error rate across comparisons. If parametric assumptions were not met a bootstrapped ANOVA was performed at 2000 iterations.

To check if ToM skills improved after mindfulness training a repeated-measures analysis of covariance (ANCOVA) was performed for Hinting Test and RMET scores with Treatment condition (IRT, IRT+MBI) as between-participants factor and Time (baseline and post-treatment) as within-participants factor. Keeping in mind that EF underlies ToM processes (López-Navarro, 2018) TMT Part B, STCW non-congruent trial, Semantic Verbal Fluency task and Digit Span Backwards scores were set as covariates. Before running the ANCOVA, the assumption of homogeneity of regression slopes was tested including interaction of main effects and covariates. Bonferroni correction was used to analyze interaction components.

In each ANOVA and ANCOVA eta squared was used as effect size estimator due it can be interpreted as explained variance. Confidence intervals for eta squared were calculated. Data were analyzed with IBM SPSS 21 for Windows. Statistical significance was set at .05.

3. Results

Sixty-eight patients were assessed against inclusion criteria, four declined to participate and twelve did not meet inclusion criteria. Fifty-two patients gave signed consent and were randomly allocated either IRT or IRT+MBI group. On average

participants attended 91.58% of the 26 mindfulness sessions (range 20 to 26). Table 1 shows the demographics and clinical features of the sample. Data from TMT, Digit Span, semantic verbal fluency (VF-animals), RMET, and Hinting Test were collected and analyzed for thirty-six patients only due materials did not reach on time to the research team.

Each outcome met normality and homoscedasticity assumptions except DS-B scores (see supplemental material A). Therefore further analyses including DS-B were bootstrapped. Comparison of demographic and clinical features showed no statistical difference between groups, detailed data are shown in Table 1. There were no differences between groups at baseline in EF, ToM, and MAAS scores (see supplemental material B).

3.1. Effects of mindfulness supplement on executive functioning

Repeated measures ANOVA on TMT-B scores indicated no main effects of group or interaction, but a statistical trend in time factor with a small effect size – $F(1,34)= 3.78$, $p= .059$, $\eta^2= .01$; CI: .001-.267–. Analysis of simple effects found a statistical difference for IRT+MBI group – $F(1,34)= 4.27$, $p= .046$ – associated to a medium effect size – $\eta^2= .112$; CI: .001-.281 –.

The equivalent ANOVA was performed for Inhibition component. Analysis of SCWT Non-congruent scores revealed a significant effect of time – $F(1,50)= 10.03$, $p= .003$ – and interaction – $F(1,50)= 8.68$, $p= .005$ – both associated to a large effect size – Time: $\eta^2= .167$, CI: .038-.314; Interaction: $\eta^2= .148$, CI: .028-.293–. Analysis of simple effects of the interaction revealed that performance of IRT+MBI group increased after treatment completion – $F(1,50)= 18.67$; $p<.001$; $\eta^2= .272$, CI: .108-.272 –.

Analyses of Access and Updating revealed no significant difference in any of the tasks. Table 2 shows detailed information of ANOVA results.

3.2. Effects of the mindfulness supplement on ToM skills

Assumption of homogeneity of regression slopes between covariates and each ToM measure was met. Analysis of main effects revealed differences in time – $F(1,26)= 8.4$; $p=.008$; $\eta^2= .244$, CI: .041-.435 – and interaction – $F(1,26)= 8.95$; $p=.006$; $\eta^2= .256$., CI: .047-.446 –. Analysis of simple effects showed IRT+MBI increased their performance in RMET after treatment completion – $F(1,26)= 11.34$; $p= .002$; $\eta^2= .304$, CI: .077-.487 –. There were a statistical trend when groups were compared after treatment completion – $F(1,26)= 3.68$; $p= .077$; $\eta^2= .115$, CI: .001-.306 –. ANCOVA performed over Hinting Test did not find statistical differences neither main effects nor interaction simple effects. Detailed information can be found on Table 2.

3.3. Effects of the mindfulness supplement on MAAS scores

The ANOVA on MAAS scores showed a significant main effect of Time – $F(1,50)= 15.64$; $p= .001$; $\eta^2= .238$; CI: .083-.385 –. The main effect of Group was not significant – $F(1,50)= 1.82$, $p= .184$; $\eta^2= .035$; CI: .001-.147. Interaction between Time and Group was significant ($F(1,50)= 10.69$; $p= .002$; $\eta^2= .176$; CI: .043-.323). Analyses of interaction components revealed significant differences between pre and post treatment in the IRT+MBI group – $F(1,50)= 26.09$; $p<.001$; $\eta^2= .343$, CI: .167-.48–, and between groups at post treatment – $F(1,50)= 5.3$; $p=.025$; $\eta^2= .144$; CI: .005-.229 – (see Table 2).

4. Discussion

This is the first trial assessing the effects in people with a psychotic disorder diagnosis of a prolonged mindfulness training on theory of mind (ToM) and executive functioning (EF: operationalized as shifting, access, inhibition, updating). Results showed that mindfulness added to standard rehabilitation had a moderate to large effect on inhibition (data from Stroop non-congruent task) and ToM assessed through attribution of mental states to others (RMET). There was also a significant pre-post improvement in attention shifting only for participants receiving mindfulness. Effect sizes on access and updating were in the expected direction, but small. Self-reported mindfulness skills increased in the mindfulness group only.

The finding on the non-congruent Stroop trial that mindfulness training added to rehabilitation has a large effect on the inhibition of prepotent responses is consistent with prior research assessing effects of mindfulness training on Stroop performance in other groups (Chiesa, Calati, & Serretti, 2011; Teper & Inzlicht, 2013). Allen et al. (2012) reported that members of the general population attending a 6-week mindfulness training increased their speed when completing a computerized version of the Stroop task. Another study with healthy people also found a positive relationship between completion of Mindfulness-Based Stress Reduction and fewer errors when completing the non-congruent Stroop trial (Jensen, Vangkilde, Frokjaer, & Hasselbalch, 2012). Again, Chesin et al. (2016) found that a 9-sessions program of mindfulness training reduced reaction time in non-congruent trials of Stroop in outpatients at high-suicide risk. The present study also found a pre-post improvement in attention shifting observed only in participants receiving mindfulness. The wider literature on the effects of mindfulness training on attention shifting suggests little or no benefit in working-age adults (Chambers, Lo, & Allen, 2008; Jensen et al., 2012) but findings in older adults

present a more mixed picture (Mallya & Fiocco, 2016; Moynihan et al., 2013). This pattern has led Gallant (2016) to propose that mindfulness training may improve attention shifting in people with cognitive impairment – this remediation perspective may help explain the present finding, given that people suffering persistent psychotic symptoms typically show significant impairment in attentional tasks (Gur, 2011). Whilst studies have found benefit of mindfulness training on updating, these were with healthy participants (Mrazek, Franklin, Phillips, Baird, & Schooler, 2013; Zeidan, Johnson, Diamond, David, & Goolkasian, 2010); and only one study has found impact of mindfulness training on access (assessed via semantic fluency) and this was in a sample of patients suffering from Alzheimer disease (Paller et al., 2015).

Our data suggests that mindfulness training increases the ability to attribute mental states to others. Two prior studies have assessed the effect of mindfulness on ToM skills, both in healthy adults only. Tan et al. (2014) reported that mindfulness training is related with better performance in RMET. However, Ridderinkhof et al. (2017) assessed the impact of mindfulness over a broad range of instruments related to empathy and found no significant relationship between mindfulness training and performance in RMET test. In addition to using nonclinical samples, both studies assessed the impact of a brief mindfulness training; the present study involved 26 weeks of mindfulness training in people diagnosed with psychotic disorders. A more helpful point of comparison is perhaps provided by a recent review of cognitive remediation therapy (Kurtz, Gagen, Rocha, Machado, & Penn, 2015) which reported a moderate effect over ToM deficits in people with schizophrenia spectrum diagnoses.

The current study is an initial small-scale trial to profile impact of long-term mindfulness training on executive function and theory of mind in psychotic disorders.

Replication is needed, with larger sample size. Future research also might assess home practice. Again, the choice of randomized design (rehabilitation alone versus rehabilitation plus mindfulness) has limitations - though it fits well with the finding that psychological therapy for psychosis can be more effective when combined with rehabilitation (Cella, Reeder, & Wykes, 2015). And future research might assess maintenance of effects over a follow-up period. Main strengths of the paper are: the randomized controlled design with blind assessment; the use of a well-defined active control treatment (participants were drawn from the same community healthcare service, so integrated rehabilitation was consistent across all participants); delivery of both interventions by suitably trained routine clinical staff; a very low drop-out rate; and the first data on impact of mindfulness training on EF and ToM in psychotic disorders.

In summary, the present study offers preliminary evidence of benefits in inhibition, attention shifting and attribution of mental states to others following long-term mindfulness training. These findings point to impact on cognitive processes related with orienting attention rather than memory or working memory, which are consistent with understanding of mechanisms in mindfulness-based intervention (Chiesa, Serretti, & Jakobsen, 2013), and may help to elucidate beneficial effects of mindfulness on psychological outcomes such as quality of life and wellbeing in people diagnosed with psychotic disorders (Chadwick et al., 2016; López-Navarro et al., 2015).

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Conflict of interest

The authors report no potential conflicts of interest.

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Table 1. Clinical and demographic features of the sample

	Total Sample (N= 52)	IRT Group (n=26)	IRT+MBI Group (n=26)	Statistics
Age (<i>mean, SD</i>)	39.71 (8.98)	40.15 (9.38)	39.42 (8.63)	$t= 0.292$ $p= 0.771$
Sex (<i>n, %</i>)				
1. Man	41 (78.8)	21 (80.8)	20 (76.9)	$\chi^2= 0.115$ $p= 0.734$
2. Woman	11 (21.2)	5 (19.2)	6 (23.1)	
Years since diagnosis (<i>mean, SD</i>)	14.13 (7.66)	14.58 (8.22)	13.69 (7.2)	$t= 0.413$ $p= 0.682$
Education years (<i>mean, SD</i>)	12.04 (2.08)	11.93 (1.89)	12.15 (2.25)	$t= -0.399$ $p= 0.691$
Diagnosis (<i>n, %</i>)				
1. Paranoid Schizophrenia	23 (44.2)	11 (42.3)	12 (46.2)	$\chi^2= 0.134$ $p= 0.999$
2. Undifferentiated Schizophrenia	8 (15.4)	4 (15.4)	8(15.4)	
3. Disorganized schizophrenia	4 (7.7)	2 (7.7)	2 (7.7)	
4. Schizoaffective Disorder	11 (21.2)	6 (23.1)	5 (19.2)	
5. Bipolar Disorder	4 (7.7)	2 (7.7)	2 (7.7)	
6. Delusional Disorder	2 (3.8)	1 (3.8)	1 (3.8)	
PANSS (<i>mean, SD</i>)				
1. Positive	14.9 (5.8)	14.69 (5.25)	15.11 (6.4)	$t= -0.261$ $p= 0.796$
2. Negative	19.08 (4.01)	19.16 (4.01)	19 (4.09)	$t= 0.137$ $p= 0.892$
3. General	36.11 (8.61)	36.5 (9.63)	35.74 (7.64)	$t= 0.319$ $p= 0.751$
4. Total	70.23 (15.46)	70.85 (15.25)	69.61 (15.94)	$t= 0.284$ $p= 0.777$

Table 2. Repeated Measures ANOVA over EF, ToM and Mindfulness outcomes.

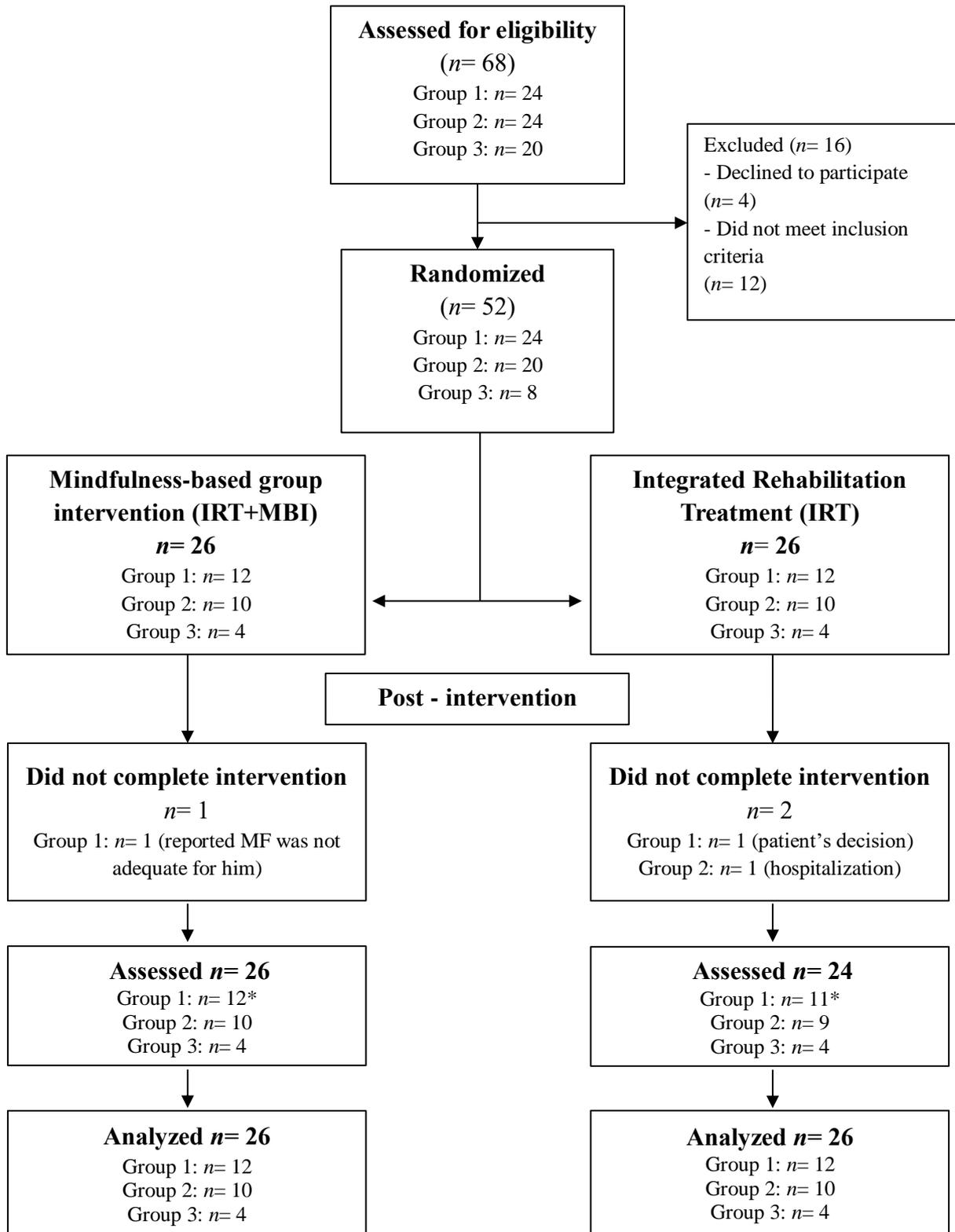
Outcome – mean (SD)		PRE	POST	F	p value	η ²
<i>Shifting</i>						
TMT-B	IRT	121 (71.32)	112.72 (47.93)	0.47	0.499	.014
	IRT+MBI	123.17 (79.38)	98.11 (47.83)	4.27	0.046	.112
	PRE			0.01	0.932	<.001
	POST			.84	0.366	.024
	Treatment			0.1	0.748	.003
	Time			3.78	0.059	.01
	Treatment x Time Interaction			0.96	0.335	.027
<i>Access</i>						
Digit Span – Backwards	IRT	16.2 (4.24)	16.18 (3.19)	<0.01	0.956	<0.001
	IRT+MBI	18.2 (5.17)	18.94 (3.89)	0.53	0.472	0.015
	PRE			1.64	0.209	0.046
	POST			3.51	0.07	0.094
	Treatment			1.21	0.28	0.034
	Time			<0.01	0.999	<0.001
	Treatment x Time Interaction			3.32	0.077	0.089
<i>Inhibition</i>						
Stroop Test – Non-congruent	IRT	30.69 (8.74)	30.81 (8.62)	0.02	0.876	0.001
	IRT+MBI	31.08 (9.67)	34.26 (8.57)	18.67	<0.001	0.272
	PRE			0.02	0.881	<0.001
	POST			2.11	0.153	0.040
	Treatment			0.63	0.430	0.013
	Time			10.03	0.003	0.167
	Treatment x Time Interaction			8.68	0.005	0.148
<i>Updating</i>						
Verbal Fluency – Semantic	IRT	3.83 (0.7)	3.61 (0.85)	1.65	0.209	0.045
	IRT+MBI	3.83 (0.71)	4.06 (0.54)	1.67	0.204	0.047
	PRE			<0.01	0.999	<0.001
	POST			3.52	0.07	0.094
	Treatment			1.21	0.28	0.034
	Time			<0.01	0.999	<0.001
	Treatment x Time Interaction			3.32	0.077	0.089
<i>Theory of Mind</i>						
RMET	IRT	17.65 (4.43)	17.53 (3.5)	1.54	0.225	0.056
	IRT+MBI	18.11 (4.65)	20.33 (3.54)	11.34	0.002	0.304
	PRE			1.16	0.291	0.043
	POST			3.68	0.077	0.115
	Treatment			0.06	0.803	0.002
	Time			8.40	0.008	0.244
	Treatment x Time Interaction			8.95	0.006	0.256
Hinting Test	IRT	14.67 (2.85)	15.11 (2.11)	0.57	0.457	0.021
	IRT+MBI	14.61 (2.55)	15.56 (3.62)	0.6	0.445	0.023
	PRE			1.28	0.268	0.047
	POST			1.47	0.236	0.054
	Treatment			2.1	0.159	0.075
	Time			0.78	0.384	0.029
	Treatment x Time Interaction			0.01	0.989	<0.001

Mindfulness

MAAS	IRT	43.88 (8.09)	44.5 (10.37)	0.23	0.631	0.005
	IRT+MBI	44.11 (8.53)	50.61 (9.18)	26.09	<0.001	0.343
	PRE			0.01	0.921	<0.001
	POST			5.3	0.025	0.144
	Treatment			1.82	0.184	0.035
	Time			15.64	0.001	0.238
	Treatment x Time Interaction			10.69	0.002	0.176

IRT and IRT+MBI rows reflect interaction analysis for Time factor (Within subjects)

PRE and POST rows reflect interaction analysis for Treatment factor (Between subjects)



* Only PANSS, MAAS and Stroop measures were collected

Figure 1: CONSORT flowchart

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Psychotic symptoms and quality of life: A mediation analysis of daily-life coping

Emilio López-Navarro^{a,*,1}, Cristina del Canto^b, Antoni Mayol^{a,c}, Ovidio Fernández-Alonso^c, Enric Munar^a

^a EvoCog Group – Associated Unit to CSIC, University of Balearic Islands, Balearic Islands, Spain

^b Department of Clinical Psychology – Son Espases Hospital, Balearic Health Service, Balearic Islands, Spain

^c UCR Serralta Community Rehabilitation Centre, Balearic Health Service, Balearic Islands, Spain



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ABSTRACT

Prior studies suggest the relationship between psychotic symptoms and Quality of Life (QoL) may be mediated by diverse constructs. QoL in schizophrenia-related disorders has been related with coping with daily stressors. Based on previous studies, our hypothesis was that coping mediates the relationship between psychotic symptoms and QoL. Therefore, the aim of the study was to test the hypothesis in a sample of people with schizophrenia-related disorders from a community rehabilitation center. Sixty-six patients were assessed using PANSS, WHOQOL-BREF questionnaire, and COPE Inventory. Regression analyses were performed for each WHOQOL-BREF dimension using PANSS and COPE factors as predictors. Mediation analysis was performed for each WHOQOL-BREF dimension using significant PANSS scales as predictors and significant COPE factors as mediators. Sobel test showed that Self-Sufficient (Problem-focused) coping mediates the relationship between PANSS Positive and WHOQOL-BREF Psychological and WHOQOL-BREF Environmental scores. Results suggest that coping style based on personal abilities and oriented to the stressors mediates the relationship between positive symptoms and QoL associated to well-being and environmental features. However, in our study no coping style mediated the relationship between negative symptoms and QoL. Depressive symptoms predicted each QoL dimension and were not mediated by any coping style.

1. Introduction

Schizophrenia-related disorders (SCHZ) are characterized by persistent psychotic symptoms, chronic course, and poor Quality of Life (QoL). The World Health Organization (WHO) defines QoL as a state of physical, mental, and social well-being that comprises objective indicators and subjective evaluations about personal development, emotional well-being, and meaningful life (WHO, 1995). Research of QoL in SCHZ has been constrained by the distinction between objective measurements (assessed by an expert) and subjective evaluation (self-reported measures), which are poorly correlated (Hayhurst et al., 2014). Some authors prefer to use SCHZ patients' self-reported measurements due congruency with WHO's definition of QoL (Hayhurst et al., 2014; Tomotake, 2011; Voruganti et al., 1998). Moreover, a subjective approach entails considerate QoL as a multidimensional construct that is affected by other constructs, like coping with daily stressors. The Distress/Protection Vulnerability Model (Ritsner, 2007) relates QoL with

coping strategies and provides a link between theoretical research and clinical practice. According to Ritsner (2007) QoL is the result of the interaction between stressors and protective factors against them, therefore QoL tends to diminish when stress exceeds protection factors.

QoL in people suffering from SCHZ is related with daily-life coping styles (Yanos and Moos, 2007). SCHZ patients are capable of identify which coping style they use and combine different coping strategies (Phillips et al., 2009), tend to use avoidance and less likely to apply task-oriented coping (Horan et al., 2007; Horan and Blanchard, 2003). Moreover, when coping and psychotic symptoms are taken into account, both explain more than 50% of variance of QoL (Holubova et al., 2015).

Based on the literature reviewed above we hypothesized that 1) intensity and frequency of psychotic symptoms will predict QoL, 2) coping style will mediate the relationship between QoL and psychotic symptoms. Thus, the aim of the present study was to assess coping style as a mediator between psychotic symptoms and QoL in a sample of

* Corresponding author.

E-mail address: Emilio.lopez@uib.es (E. López-Navarro).

¹ EvoCog Group, IFISC, Associated Unit to CSIC, Guillem Cifre Building, University of Balearic Islands, Ctra Valldemossa km 7,5. Balearic Islands, Spain.

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SCHZ patients from a public rehabilitation center.

2. Methods

2.1. Procedure and participants

A cross-sectional study was conducted between December 2014 and December 2015 in a public community rehabilitation center for people with SCHZ. Inclusion criteria were 1) age between 18–65; 2) a clinical record of paranoid schizophrenia, undifferentiated schizophrenia, or schizoaffective disorder; 3) being in a stable post-acute phase of illness; and 4) being able to understand and read Spanish language. Ethical approval was granted by the university research ethics committee.

Sixty-eight patients from a public community rehabilitation center for people with SCHZ were asked to participate. Patients and their legal guardians were contacted by their regular psychiatrist or psychologist to schedule an interview. During the meeting, the patient and his or her legal guardian were informed about the aim of the study as well that participation was not paid. At the end of the interview, they were invited to sign the informed consent and to schedule a date for the assessment with a psychologist specifically trained to manage SCHZ patients. Psychological assessment consisted of a videotaped Positive and Negative Syndrome Scale (PANSS) interview, followed by the World Health Organization Quality of Life-BREF (WHOQOL-BREF) and COPE Inventory questionnaire.

2.2. Instruments

Assessment instruments were:

- A case report form specifically designed for the study purposes. Age, sex, years of education, diagnostic according to clinical record and years since first diagnosis were collected.
- Frequency and intensity of psychotic symptoms were assessed with the Positive and Negative Syndrome Scale (PANSS). Spanish adaptation is considered equivalent to original English form (Kay et al., 1990). For the purposes of the study, PANSS scores were calculated according to the five factor model of Wallwork et al. (2012): Positive factor (P1, P3, P5, G9), Negative factor (N1, N2, N3, N4, N6, G7), Disorganized/concrete factor (P2, N5, G11), Excited factor (P4, P7, G8, G14) and Depressed factor (G2, G3, G6).
- The 26-item World Health Organization Quality of Life-Bref (WHOQOL-BREF) (Harper et al., 1998) was used to assess QoL through four dimensions: physical health, psychological health, social relationships, and environment. The Spanish validation (Lucas Carrasco, 1998) has shown satisfactory internal consistency and adequate test-retest reliability (Mas-Expósito et al., 2011), and has been used previously with SCHZ patients (López-Navarro et al., 2015; Mas-Expósito et al., 2011; Örsel et al., 2004).
- Coping style was assessed with COPE Inventory (Carver et al., 1989). It is a 60-item rating scale which assess coping with stressors through fifteen subscales: Positive reinterpretation and growth, Mental disengagement, Focus on and venting of emotions, Use of instrumental social support, Active coping, Denial, Religious coping, Humor, Behavioral disengagement, Restraint, Use of emotional social support, Substance use, Acceptance, and Planning. Having in mind the aim of our study we used the four coping factor solution proposed by Litman (2006): Self-Sufficient (Problem focused) factor that involves Planning, Active and Suppression of competing activities; Self-sufficient (Emotion focused) factor which comprises Restraint, Positive Reinterpretation, Acceptance, Humor and Religious coping; Avoidance coping factor which covers Behavioral disengagement, Denial, Substance use and Mental disengagement; and Socially supported factor that includes Emotional social support, Instrumental social support and venting emotions.

2.3. Data analysis

Descriptive measures were generated for every outcome and parametric assumptions were assessed. For those scores that not met parametric assumptions the remaining analyses were bootstrapped at 2000 iterations and bias-corrected. Then two ANOVA, one for sex and other for diagnostic, was performed to detect differences in demographic, symptoms, QoL, and coping variables.

To test our first hypothesis a backwards linear regression analysis was performed for each WHOQOL-BREF dimension using Wallwork's factors from PANSS scores as predictors. Second hypothesis was tested across two stages. First stage aimed to test if COPE factors can predict changes in WHOQOL-BREF dimensions. Thus regression analyses were carried for each QoL with COPE factors as predictor and backwards as entry method. Second stage consisted in a mediation analysis based in the linear general model for each WHOQOL-BREF dimension. Outcome variable was each of the WHOQOL-BREF dimensions, predictor variables were PANSS factors that significant predicted each WHOQOL-BREF dimension, and mediators were COPE factors that significantly predicted WHOQOL-BREF scores. If PANSS predictors were more than one, then mediation analysis was carried for each predictor setting the rest as covariates. Sobel Test was calculated to test significance of the mediation effect (Sobel, 1986).

Independent errors assumption was checked with Durbin-Watson statistic and multicollinearity assumption was tested through variance inflation factor (VIF). Data were analyzed using SPSS 21 for Windows with mediation analysis PROCESS plugin (Hayes, 2016). Statistical significance was set at 5%.

3. Results

Sixty-eight patients were assessed against inclusion criteria. Two were not interested in participate. The sample was mainly composed of paranoid schizophrenic patients (47%) with a mean age of 37.88 ($SD = 7.65$), primary education (31.8%), and mean duration of illness of 12.25 ($SD = 6.38$) years. PANSS, WHOQOL-BREF and COPE scores met parametric assumptions. There were no differences in any outcome when sex and diagnostic groups were compared. Table 1 shows detailed data of demographic and clinical features of the sample.

First regression analyses were performed over each WHOQOL-BREF dimension using PANSS scores as predictors. The regression model for WHOQOL-BREF Physical explained 46.2% of the total variance ($p < 0.001$) and only PANSS Depressed factor was significant predicting the outcome ($\beta = -0.647$, $p < 0.001$). Regression model for WHOQOL-BREF Psychological was found to be significant ($R^2 = 0.444$, $p < 0.001$) when including PANSS Positive ($\beta = 0.257$, $p = 0.044$), PANSS Negative ($\beta = 0.26$, $p = 0.039$), and PANSS Depressed factor ($\beta = -0.615$, $p < 0.001$). Only PANSS Depressed factor ($\beta = -0.377$, $p = 0.044$) was found to be significant in the model that best predicted the outcome of WHOQOL-BREF Social Relationship ($R^2 = 0.152$, $p = 0.019$). The best predicting model of WHOQOL-BREF Environmental ($R^2 = 0.347$, $p = 0.002$) included PANSS Positive ($\beta = 0.323$, $p = 0.022$), PANSS Negative ($\beta = -0.188$, $p = 0.037$), and PANSS Depressed factor ($\beta = -0.552$, $p = 0.001$). All regression models met multicollinearity and error independence assumptions. Detailed data about regression analyses are shown in Table 2.

Mediation analyses were performed for each WHOQOL-BREF dimension using each significant PANSS predictor extracted at stage two as independent variable and significant COPE factors predictors extracted at stage three as mediators. Detailed information about COPE factors as predictors of WHOQOL-BREF scores can be found in Table 2. Sobel test indicated that Self-Sufficient (Problem-focused) factor mediates between PANSS positive and WHOQOL-BREF Psychological ($t = 2.14$, $p = 0.032$) and WHOQOL-BREF Environmental scores ($t = 2.2$, $p = 0.027$). Bootstrapped effect sizes indicated that total effect model was significant and higher for the PANSS Depressed factor in each of

Table 1
Demographic and clinical features of the sample.

	N = 66
Sex (n, %)	
Men	49 (74.2)
Women	17 (25.8)
Age (mean, SD)	37.88 (7.65)
Education level (n, %)	
Primary education complete	21 (31.8)
Secondary education incomplete	19 (28.8)
Secondary complete	26 (39.4)
Diagnostic (n, %)	
Paranoid schizophrenia	31 (47)
Schizoaffective disorder	20 (30.3)
Undifferentiated schizophrenia	15 (22.7)
Years since diagnosis (mean, SD)	12.25 (6.38)
PANSS Interview (mean, SD)	
Positive	9.31 (4.35)
Negative	17.23 (5.86)
Disorganized/concrete	7.6 (2.99)
Excited	7.89 (3.75)
Depressed	7.83 (3.28)
WHOQOL-BREF (mean, SD)	
Physical	21.52 (3.1)
Psychological	18.48 (4.06)
Social Relationships	8.05 (1.94)
Environmental	24.63 (3.79)
COPE Inventory (mean, SD)	
Self-Sufficient (Problem focused)	27.36 (5.48)
– Planning	8.81 (2.62)
– Active coping	9.24 (2.44)
– Suppression of competing activities	9.32 (1.64)
Socially supported	28.09 (6.58)
– Use of emotional social support	9.81 (3.07)
– Use of instrumental social support	9.58 (2.51)
– Focus on and venting of emotions	8.69 (2.12)
Avoidance coping	30.38 (6.37)
– Behavioral disengagement	8.69 (2.43)
– Denial	7.28 (2.13)
– Substance use	5.3 (2.55)
– Mental disengagement	9.09 (2.57)
Self-Sufficient (Emotion focused)	44.51 (8.68)
– Restraint	9.17 (2.11)
– Religious coping	8.57 (3.15)
– Acceptance	9.28 (2.05)
– Humor	7.47 (2.44)
– Positive reinterpretation and growth	10 (2.53)

the assessed WHOQOL-BREF outcomes. Table 3 shows detailed data about effect size of the three different models (indirect, direct, and total) for each WHOQOL-BREF outcome and PANSS predictor with Self-Sufficient (Problem focused) as mediator.

4. Discussion

The main finding is that self-sufficient coping mediates between positive psychotic symptoms and QoL related to psychological well-being and environment. Also our data pointed that there is a strong relation between depressive symptoms and QoL which is not mediated by any dimension of daily-life coping.

The current study examined until what extent clinical symptoms can predict QoL in SCHZ patients. Our first hypothesis was partially supported by the data. Positive and negative psychotic symptoms predicted QoL linked to psychological well-being and environmental features, but not to social relationships and physical well-being. Convergent with prior work, intensity and frequency of negative psychotic symptoms predicted QoL (El Sheshtawy, 2011; Montemagni et al., 2014; Tsai et al., 2010). We found a direct relationship between positive psychotic symptoms and psychological well-being and environmental QoL. The divergence may be explained by the nature of the current study's instrument used to assess QoL. In contrast with previous studies mentioned above, we assessed QoL with a self-reported measure instrument which means that is not affected by the clinician's opinion.

In accordance with our second hypothesis, data partially support the role of coping style as a mediator. Our results showed that relationship between positive psychotic symptoms with Psychological and Environmental QoL is fully mediated by Self-sufficient coping. This is in line with Kommescher et al. (2016) who found that active and problem-focused coping style is related with improvement in psychotic symptoms in patients under rehabilitation treatment. Lim et al. (2015) also found that patients who rely in active coping strategies tend to report better QoL. Additionally, our data is convergent with Holubova et al. (2015) who also found a positive correlation between self-sufficient coping better QoL in SCHZ. According to Georgiades et al. (2015), self-sufficient coping may increase the perception of self-efficacy of SCHZ patients, and thus ameliorate the impact of positive symptoms in daily-life routines. However, our data do not show any mediation between negative symptoms and subjective QoL. This may be due overlapping features between negative symptoms and avoidance coping, which is

Table 2
Regression analyses results for each WHOQOL-BREF dimension.

Predictor	Physical QoL		Psychological QoL		Social Relationships QoL		Environmental QoL	
	Statistic	P value	Statistic	P value	Statistic	P value	Statistic	P value
<i>PANSS interview</i>								
Regression Model	$R^2 = 0.462$ $D-W = 2.05$ $VIF = 1$	< 0.001	$R^2 = 0.444$ $D-W = 2.28$ $VIF = 1.04$	< 0.001	$R^2 = 0.152$ $D-W = 2.36$ $VIF = 1$	0.019	$R^2 = 0.347$ $D-W = 1.67$ $VIF = 1.19$	0.002
Positive	$\beta = 0.01$	0.416	$\beta = 0.257$	0.044	$\beta = -0.032$	0.83	$\beta = 0.323$	0.022
Negative	$\beta = -0.07$	0.519	$\beta = -0.26$	0.039	$\beta = -0.098$	0.507	$\beta = -0.188$	0.037
Disorganized/concrete	$\beta = 0.21$	0.085	$\beta = -0.02$	0.857	$\beta = -0.076$	0.603	$\beta = 0.137$	0.098
Excited	$\beta = 0.04$	0.73	$\beta = 0.1$	0.475	$\beta = 0.002$	0.987	$\beta = -0.245$	0.353
Depressed	$\beta = -0.647$	< 0.001	$\beta = -0.615$	< 0.001	$\beta = -0.377$	0.013	$\beta = -0.552$	0.001
<i>COPE Inventory</i>								
Regression Model	$R^2 = 0.271$ $D-W = 1.81$ $VIF = 1.02$	0.002	$R^2 = 0.361$ $D-W = 1.66$ $VIF = 1.05$	< 0.001	$R^2 = 0.021$ $D-W = 1.93$ $VIF = 1$	0.385	$R^2 = 0.231$ $D-W = 1.59$ $VIF = 1.01$	0.003
Self-Sufficient (Problem focused)	$\beta = 0.403$	0.009	$\beta = 0.531$	< 0.001	$\beta = 0.092$	0.561	$\beta = 0.425$	0.005
Avoidance coping	$\beta = -0.291$	0.096	$\beta = -0.221$	0.101	$\beta = -0.15$	0.349	$\beta = -0.217$	0.151
Socially supported	$\beta = -0.077$	0.669	$\beta = 0.059$	0.710	$\beta = 0.081$	0.764	$\beta = -0.163$	0.377
Self-Sufficient (Emotion focused)	$\beta = -0.271$	0.226	$\beta = -0.124$	0.563	$\beta = 0.173$	0.321	$\beta = -0.037$	0.894

D-W: Durbin –Watson value. VIF: Variance Inflation Factor value.

Table 3
Standardized effect size of mediation analysis. Mediator Self-Sufficient (Problem focused) is present in each model. Bootstrapped confidence intervals are included.

OUTCOME	PREDICTOR	Total Effect			Direct Effect			Indirect Effect		
		β	Standard Error	CI 95%	β	Standard Error	CI 95%	β	Standard Error	CI 95%
WHOQOL Physical	PANSS Depression	-0.63 ^a	0.12	-0.86 ~ -0.39	0.61 ^a	0.11	-0.84 ~ -0.38	-0.16	0.05	-0.13 ~ 0.07
WHOQOL Psychological	PANSS Depression	-0.69 ^a	0.15	-0.99 ~ -0.39	-0.67 ^a	0.13	-0.93 ~ -0.4	-0.03	0.08	-0.21 ~ 0.1
	PANSS Positive	0.06	0.14	-0.23 ~ 0.36	-0.12	0.15	-0.42 ~ 0.17	0.18 ^b	0.09	0.05 ~ 0.44
	PANSS Negative	-0.12	0.11	-0.33 ~ 0.09	-0.8	0.1	-0.28 ~ 0.12	-0.04	0.05	-0.16 ~ 0.03
WHOQOL Environmental	PANSS Depression	-0.5 ^a	0.16	-0.82 ~ -0.17	-0.47 ^a	0.14	-0.76 ~ -0.18	-0.03	0.08	-0.21 ~ 0.11
	PANSS Positive	0.08	0.14	-0.21 ~ 0.37	-0.1	0.14	-0.38 ~ 0.19	0.18 ^b	0.09	0.05 ~ 0.42
	PANSS Negative	-0.14	0.1	-0.34 ~ 0.07	-0.1	0.95	-0.29 ~ 0.09	-0.04	0.05	-0.2 ~ 0.03

^a $p < 0.001$.
^b $p < 0.050$.

more likely to be applied by SCHZ patients (Horan and Blanchard, 2003).

Although not referred to psychotic symptoms, it is important to point out that Depression symptom factor was negatively associated with each QoL dimension. This finding gives further support to Alessandrini et al. (2016) and Rocca et al. (2016) data about the relevance of depression symptoms over SCHZ patients' QoL. Despite the evidence in healthy people about the effect of daily coping over depression symptoms (Folkman, 2010), we found that coping style does not mediate the effect of depression symptoms in any of the QoL dimensions of SCHZ patients.

The study has limitations and strengths that deserve mention. The main limitations are the small sample size that may affect to statistical procedures used to test the hypothesis, and gender distribution which may underrepresent female patients, although this gender imbalance is in line with the prevalence of SCHZ in the general population (NIMH, 2013). The main strengths are the statistical approach that goes beyond simple regression methods and the conceptualization of QoL of SCHZ patients as a multidimensional construct.

Future studies should include larger samples and methods based upon mediation analysis using self-reported measures. Evidence available (Fervaha et al., 2013) has shown that clinicians' concerns are focused on positive psychotic symptoms whereas patients were more concerned to depression. Further research should also entail a multidimensional approach to the study of QoL. This may allow research of emerging properties result from the interaction with other theoretical constructs, which is crucial to design treatment packages for SCHZ patients. In this regard, our results showed that interventions aiming to increase QoL of SCHZ patients should emphasize training of coping strategies based on dealing with daily stressors through personal capacities.

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Conflicts of interest

Authors report no potential conflict of interest.

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4. Discussion

The papers presented suggest that switching from a biological conceptualization to a person-centered formulation of the psychosis is feasible in the current public health system. This change in the therapeutic approach to the psychotic phenomena was conducted through a mindfulness-based intervention and the use of subjective assessment tools. The shift of focus from patients to persons showed that an intervention aiming at how patients relate with their symptoms is safe while improving their quality of life, executive functioning, and theory of mind. Also, focusing on the person provided a new understanding about how psychotic symptoms, coping and well-being are related in daily life functioning.

a. Effects of person-based consideration over clinical outcomes

The results show that mindfulness is a safe tool for people experiencing psychosis, as it does not increase the frequency of psychotic symptoms. The finding is convergent with previous studies where psychotic symptoms were assessed after mindfulness training (Chadwick et al., 2016, 2005; Langer et al., 2012; Newman Taylor, Harper, & Chadwick, 2009). However, it is important to point out that the research in this Ph.D. thesis is the first one that assessed psychotic symptoms using a videotaped interview scored by two clinical psychologists blinded to participants' allocation. Also, while prior research assessed psychotic symptoms globally, we used an interview that takes into account different aspects of the psychotic experience and computes them as a continuum. In other words, the instrument used to assess psychotic symptoms in our papers implies a more detailed assessment conducted in a robust way. The finding that mindfulness does not increase psychotic symptoms is explained by the

cognitive continuum between “normal” mental events and psychotic experiences: both are subjected to the same rules and principles. Although avoidance of unwanted thoughts and feelings seems desirable, research suggests that strategies to control or avoid one’s mental experience are ineffective, and often result in a rebound effect (Magee, Harden, & Teachman, 2012; Rassin, Merckelbach, & Muris, 2000; Wegner & Zanakos, 1994). Trying to avoid or suppress psychotic symptoms has the same paradoxical increasing effect (Gaudiano, Herbert, & Hayes, 2010). In contrast, mindfulness teaches to accept that psychotic experiences exist as other mental events, and thus psychotic symptoms they can be noticed or observed with no need to act upon their content. Therefore, if the person does not try to control or avoid the symptoms their frequency will not increase, although the attentional focus is directed to them. In Hayes’ words “seeing them [psychotic experiences] for what they are, and not what they say they are” (Hayes et al. 1999) does not increase the frequency or intensity of the symptoms.

Acceptance of the occurrence of the psychotic experience is also responsible for the other relevant finding of the dissertation: mindfulness practice combined with standard treatment improves well-being of the participants. This outcome is convergent with prior research suggesting the benefit of mindfulness for people experiencing psychosis (Chadwick et al., 2016, 2005; Newman Taylor, Harper, & Chadwick, 2009). As mentioned above, the cognitive continuum between thoughts and psychotic experiences permits to articulate them following a typical ABC schema in CBT (Craske, 2010). Hence, the distress is caused by how the person reacts to the psychotic symptom and not for its content (Freeman & Garety, 2014; Gaudiano et al., 2010; Goldstone, Farhall, & Ong, 2011). People experiencing persistent psychotic symptoms reacts to the

content of the voice with experiential avoidance. Experiential avoidance refers to the behavioral and cognitive efforts to avoid staying in contact with a sensation (i.e. suppression of thought, wear headphones, drink alcohol, ...). As discussed above, these strategies to cope with psychotic symptoms have the paradoxical effect of increase them. Reacting to the symptom struggling with it will also lead to worry and rumination about its content. Experiential avoidance, as well as worry and rumination, is grounded in the judgment of the content of the symptoms, which extends to the own self. As Chadwick et al. (2005) pointed out “Underpinning these reactions is an assumption that the “self” (which is reified) is defined by these experiences and how one reacts to them”.

In contrast, a mindful reaction notices the psychotic sensation but does not struggle with it. Instead of fighting or resisting the sensation, a mindful reaction implies acceptance of psychotic sensations as transient experiences that do not define the self, and not accurately reflect the reality (Chadwick, 2005). Thus, a mindful reaction encompasses observe the psychotic sensation and let it pass moving in and out of the awareness without getting caught in confrontation. Figure 1 shows a diagram adapted from Chadwick et al. (2005) opposing distressing reaction against mindful reaction.

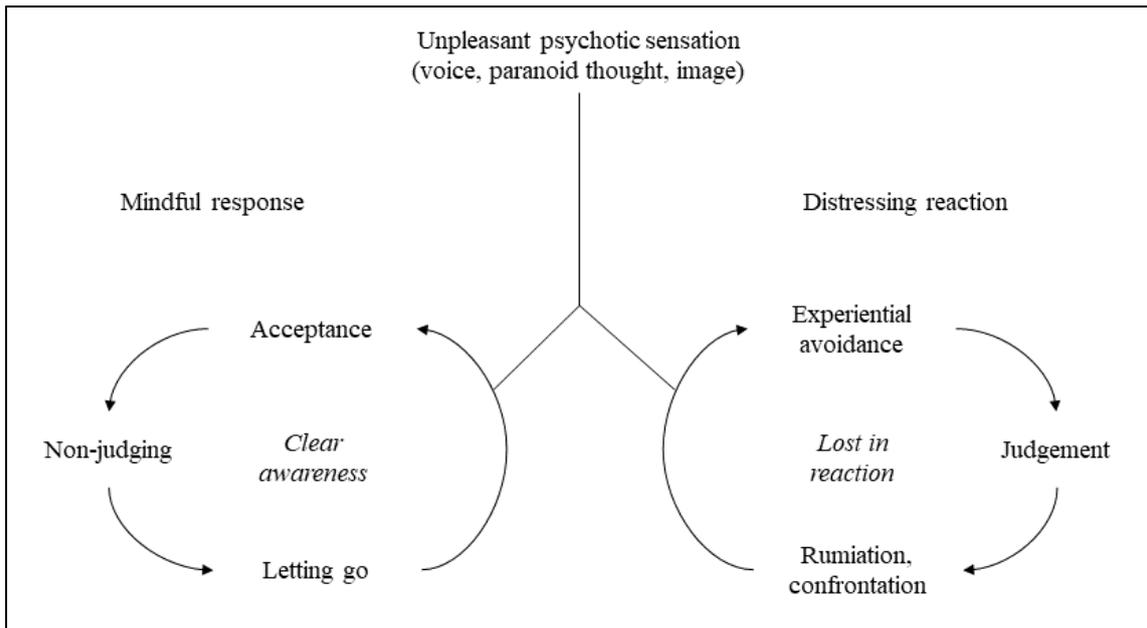


Figure 1. Comparison of the consequences of react with acceptance or experiential avoidance to the psychotic sensation. Adapted from Chadwick et al. (2005)

As proposed by Abba, Chadwick & Stevenson (2008), learning how to respond mindfully to persistent psychotic symptoms follows three stages. First, people learn to notice and center on the psychotic sensation in the present moment, the breath sensation works as an anchor to the present moment and prevents to get lost in the sensation. Second, participants learn to develop a moment-to-moment awareness that leads the person to be aware of their reactions to the happening of the psychotic sensation. This gives the chance to note the reaction, reconnect with the present through breath and body, and thus let go of the reaction. The third stage refers to the acceptance of voices, thoughts, and images as unpleasant, transient sensations that form part of the person's experience, but that do not define the self. Throughout the three stages, there is a continuous conscient attention performance to self-regulation of attention and non-reactivity to the experience no matter the emotional valence of it.

b. Effects of person-based consideration over cognitive skills

The second paper conforming this dissertation shows that mindfulness training, when combined with standard rehabilitation treatment, may improve cognitive performance. This improvement is based on the capacity to resist competing stimuli while focused on other stimulus, and the ability to perceive and recognize social emotions in other people. As mindfulness applied to psychotic symptoms taught to resist the automatic response of paying attention to the content, it seems reasonable that this ability is generalized to other aspects of the experience. Explanations of how mindfulness improves cognitive skills are numerous but still little theory links the psychological mechanisms of mindfulness with the broad variety of mindfulness-related outcomes. Although most theories are focused on biological arguments, *Monitoring and Acceptance Theory* (MAT) (Lindsay & Creswell, 2017) brings a chance to interpreting mindfulness' effects over cognition in terms of psychological processes. According to MAT, mindfulness-based interventions share the same core principles: attention monitoring and acceptance instructions that aim to increase awareness and nonreactivity to mental content. Monitoring practices are introduced first to train attention to observe the present-moment experience and are complemented with instructions fostering non-reactivity to the content of one's sensory experience, allowing to pass without further evaluation. The enhancement of attention monitoring is not the only responsible of cognitive performance improvement as it heightens affective experience and reactivity, as has been reported in people experiencing panic disorder (Ehlers & Breuer, 1996). Thereby, attention monitoring shall be complemented with acceptance of the experience to regulate reactivity to the affective dimension of the latter.

The data from the dissertation show that cognitive inhibition increases as a consequence of combine mindfulness with standard rehabilitation treatment. The relevance of this finding is highlighted by the strong association of executive functioning –mainly attention conflict monitoring– to well-being and social functioning of people experiencing persistent psychotic symptoms (Fett et al., 2011; Peña et al., 2018). Keeping in mind that the instrument used was emotionally neutral, it can be stated that according to MAT participants taking mindfulness sessions increased their attentional monitoring skills. Therefore, through training in neutral awareness of the psychotic sensation, the person learns to notice but not respond to it with distress or worry. In other words, the person trains his ability to resist the automatized response of paying attention to the content and confront the symptoms while focusing attention on sensation. On the other hand, the improvement in emotion recognition may be due to an increase in attention monitoring combined with acceptance, as suggested by MAT. When participants learned to notice the sensation and reacted accepting it instead of judging, they are practicing the ability to monitor their attention and decrease the affective reactivity to stimuli. Thereby their execution in Reading the Mind in the Eyes Test (Baron-Cohen, Wheelwright, Hill, Raste, & Plumb, 2001) enhances as the reactivity provoked by the gaze of each item is reduced, and the emotional connotations of the response choices are also reduced while the monitoring attention helps to a better choice of the target.

c. Effects of person-based consideration on contextual factors of well-being

Through the dissertation, it has been shown the clinical benefits of including a person-based intervention in the treatment package delivered to people suffering persistent psychotic symptoms, but this consideration was also extended to evaluate if it

can provide new insights and knowledge over factors contributing to the well-being of this clients.

Since its very beginning, research about psychotic symptoms and their effects over the person has been surrounded by an aureole that placed the psychotic phenomena beyond the scientific scrutiny of the social sciences (Bentall, 2003). The neurobiological consideration of psychoses places the person out of the category of “normal” human being. Thereby, the daily-life events that affect quality of life of a person without diagnostic are excluded from the life of a person experiencing psychosis, as the brain of the latter is supposed to work under other principles (Pérez-Álvarez et al., 2016). This has affected the instruments used to assess quality of life in psychosis, which have been named “objective measurements” that neglect the person’s opinion. These instruments consist of the evaluation of a person’s quality of life by a trained interviewer, usually a clinician from a medical context, according to social standards that dictate which is and which is not an adequate quality of life. As noted by Geekie & Read (2009), “only the ‘experts’ can make insightful observations about clients’ subjective experiences; a folly sadly found still in much of today’s research literature on mental health difficulties and clinical approaches to offering help to those who have such experiences”. Adoption of this approach is in its nature a contradiction when researching about quality of life as WHO defines it as “an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.” (World Health Organization, 2018).

Our study showed the relevance of adopting a person-centered perspective through self-reported measures when assessing quality of life of people experiencing psychotic symptoms. This perspective gave us the chance to register new ways of

relationship between psychotic symptoms and subjective quality of life. Surprisingly we found that experience positive persistent psychotic symptoms may be related to a positive quality of life. Moreover, data showed that daily-life coping, based on undertaking behaviors to actively engage with stressors, mediates this relationship increasing or decreasing its intensity. Also, we found that depression feelings are strongly associated with well-being and that coping cannot affect that relationship. Taken together, these findings point that the relevant agent for wellbeing of people suffering psychosis is not the symptoms, it is how the person conducts oneself during daily-life interactions. Hence, the importance granted to the presence of persistent psychotic experiences by the previous studies dilutes when the research instruments ask the person instead the clinician.

The relevance of this finding goes beyond basic research about psychosis to the clinical context. If treatment aims to increase wellbeing of people experiencing persistent psychotic symptoms, and coping can modify the relationship of the latter with quality of life, then the focus of the treatment must go beyond symptoms and target the whole person and how relates with their immediate context. On a broader interpretation, this finding aggregates to the evidence about the need of a holistic conceptualization of psychoses: it provides information of how the environment can ameliorate the effect of the core feature of psychosis, this is, psychotic experiences.

d. From syndromes to symptoms, from patients to persons

As proposed in the general aim of the dissertation, the benefits of incorporating a person-based approach in the treatment and formulation of persistent psychotic symptoms have been introduced, as well new insights about the daily-life determinants of well-being in this client. Mindfulness as a person-centered intervention has proven to

satisfy the two requisites mentioned previously at the introduction: 1) it can be carried together with neurobiological interventions while keeping its independence in case formulation, and 2) has shown clinical and cognitive benefits for people experiencing persistent psychotic symptoms. On the other hand, the use of subjective measures revealed that although the persistent psychotic symptoms influence quality of life, this relationship is modulated by how the person deals with daily stressors. Thereby a person-centered approach is not only desirable but also feasible to carry out in a public health setting.

A person-based approximation to the treatment of psychosis is based on changing the treatment focus from syndromes to symptoms, while a person-based approximation of research on well-being determinants adds the relationship with one self's context. Taken together, the conceptualization defended across the thesis entails how the person is on the world, which goes beyond the neurobiological determinants of the psychotic experience to a more phenomenological conceptualization (Pérez-Álvarez, 2018; Stanghellini & Rosfort, 2015). Phenomenology understands psychosis as a self-disturbance that affects being-in-the-world rather than a malfunction of biochemical or cognitive mechanisms (Sass, Borda, Madeira, Pienkos, & Nelson, 2018). According to this view, psychosis is a disturbance of "ipseity", an alteration of the pre-reflective bodily self-experience (Nelson, Parnas, & Sass, 2014). Alteration of ipseity in psychoses has three aspects: 1) *hyper-reflexivity*, a tendency for focal, objectifying, or alienating attention to be directed toward processes and phenomena that would normally be experienced as unnoticed or implicit; 2) *diminished self-affection*, refers to the absence of experience oneself as a unified subject of awareness or agent of action – a common feature in prodromal stages of psychoses –; and 3) *disturbed "grip" of the*

word, which refers to a loss of familiarity with the world and personal context as consequence of hyper-reflexivity and diminished self-affection. Both transformed the experience of the objects of the world and hence the person loss contact with it. From this point, psychotherapy is understood as a way of reconstructing the self and its relationship with the world.

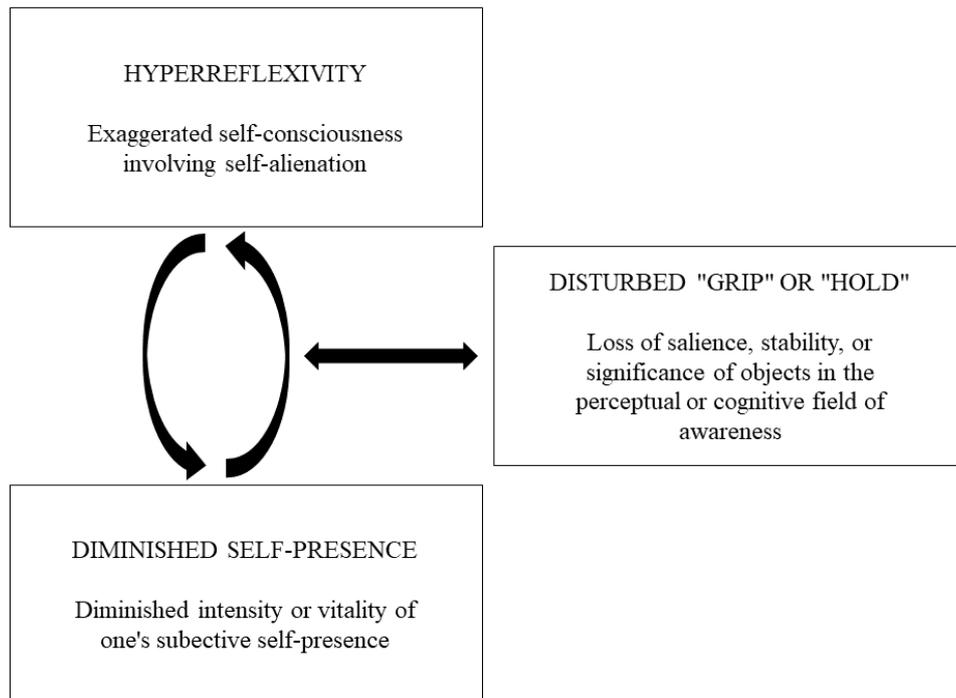


Figure 2. Diagram about the phenomenological concept of psychosis as a disturbance of the ipseity. Adapted from Sass et al. (2018).

The results in the dissertation bring new light in the view of phenomenology of treatment and conceptualization of psychoses. Mindfulness has been introduced as a way of being-in-the-world from a phenomenological perspective (Warren-Brown & Cordon, 2009). Hence, as mindfulness training promotes decentered awareness and acceptance of the experience, it can be understood as a program that teaches to live in spite of the symptoms. As the person experiencing persistent psychotic symptoms learns

to accept them as transient experiences, the chance to live and enjoy other aspects of life become a possibility (Gaudiano, 2015). In sum, mindfulness constructs a context where the person can redefine his relationship with the context (Hayes, Follette, & Linehan, 2004). In other words, mindfulness can create the conditions to reconnect with the world where the person links up oneself. Moreover, the use of a person-based formulation of the treatment – where the person is not seen as a bearer of a defective brain – builds up an empathic relationship between the clinician and the client that promotes where the therapist offers a second-person view of the contents reported by the latter. This helps people with psychosis to develop a first-person perspective of oneself and a second-person perspective when relating with other people. Thus, the results reported in this thesis about the effect of mindfulness increasing well-being and cognition, can be explained from phenomenology as the consequence of reconnection with the world, and the promotion of a second-person perspective that results in increased Theory of Mind performance and better executive functioning. Additionally, the finding about the mediational effect of active coping over the relationship of psychotic symptoms and quality of life can be interpreted from a phenomenological perspective. In this regard, people experiencing psychosis whose efforts dealing with stressors are oriented towards means of solving them, are supposed to be more connected to the world, and therefore the effect of symptoms over well-being is blunted.

e. Future directions: towards a personal encounter

Our findings give enough rationale to take further steps in basic and applied research in psychosis from a person-centered approach. Adoption of person-centered conceptualization in the assessment of people experiencing psychosis is crucial in future research. Up to our paper about the mediator effect of coping over psychotic symptoms

and quality of life, the research reported consistent effects of the negative influence of symptoms over the latter. However, this evidence changed when the assessment tools are oriented towards the person instead of using the opinion of an expert: when the person is asked the relationship between symptoms and quality of life appears, but it can be altered by the context where the symptoms occur and how the person perceives this relationship. This shift in the way of the assessment should be done with other constructs to test if evidence accumulated by objective measures is replicated. Also, if any discrepancy arises, it could be interesting study whether the difference between objective and subjective assessment is representing a bias of the professionals involved in psychosis research. Research using subjective measures could be extended not only to the people experiencing psychosis but to the family of the person. Family and interpersonal context are key factors for recovery and well-being, and usually are involved in the treatment plan of psychoses cases.

Regarding mindfulness as a suitable person-centered intervention, there is a need to replicate the findings with larger samples and with an active and blinded control group. Keeping in mind that implementation follows a pilot study design, it is desirable that further studies use larger samples covering from people diagnosed with psychosis to people experiencing psychosis but without a diagnosis. The continuum between “normal” and “psychotic” experience includes a vast majority of intermediate stadiums that could help to clarify the mechanism of mindfulness applied to the psychotic phenomena. Also, further research should use an active and masked control group to control the effects of expectation of participants. Additionally, it is important to study whether the effects are maintained over time and whether they affect drug prescription.

Mindfulness applied to psychosis has shown that can increase executive functioning and theory of mind performance. Although the numerous studies reporting comparable effects on healthy people and other clinical manifestations, little is known about how mindfulness practice promotes the enhancement of cognition. Phenomenology approximation to psychoses may help to understand how to conduct research on this topic. This approach highlights the relevance of using a bio-pheno-social model of schizophrenia to understand the complex interaction between the person, the context, and the underlying biological and cognitive processes (Sass et al., 2018). However, as noted by Nelson and Sass (2017), research in the neuropsychological correlates of psychosis has been constrained by cognitive assessment tools for neurological disorders, focused on structural brain imaging techniques, and focused on the biological mechanism as the only explicative level. To overcome this, the phenomenological approach proposes the use of high temporal resolution neuroimage to detect processes and adapt cognitive tasks centered on aberrant salience and source monitoring processes (Sass & Borda, 2015).

In sum, a phenomenological approximation to psychoses advocates for overcoming the bio-psycho-social model due it is still trapped in the distinction between mind and body. Hence, the proposal is based on the meeting point where mind and body encounter, this is, the environment and how the person experiences it. Therefore, research must connect the three domains for a scientific study and correlate the domains that conform the ipseity disorder of psychosis. A summary of the research topics related through the three levels is shown in Table 1.

Table 1. Research domains across the phenomenological, cognitive and neural levels and their relationship with experimental paradigms.

	Neural/electrophysiological	Behavioral/Cognitive	Phenomenological
Source Monitoring Deficits	<ul style="list-style-type: none"> - Efference copy - Corollary discharge - Reduced functional connectivity - Elevated “resting state” brain activity 	<ul style="list-style-type: none"> - Endogenous-exogenous confusion - Prediction errors 	<ul style="list-style-type: none"> - Diminished ownership of mental content - Self-other boundary confusion - Hyper-reflexivity
Aberrant salience	<ul style="list-style-type: none"> - Latent inhibition - Mismatch negativity 	<ul style="list-style-type: none"> - Attention and memory disturbances - Failed suppression of attention to irrelevant stimuli - Weakening of contextual constraint - Prediction errors 	<ul style="list-style-type: none"> - Hyper-reflexivity - Rigidity and perplexity in interaction with the world - Disturbance of “common sense” - Disturbed “grip” or hold” on conceptual and perceptual field - Diminished “affordance value” of objects

5. Conclusions

The PhD thesis shows the feasibility and benefits of adopting a person-based conception of psychotic disorders in a public health setting, without risk the standard treatment nor the devices attending people diagnosed with psychosis.

The results confirm the previous rationale underlying inclusion of mindfulness-based interventions for persistent psychotic symptoms in the context of public health system. Our data support the use of mindfulness as a therapeutic tool that when combined with standard treatment helps to increase well-being and cognitive functioning of people experiencing psychoses. Mindfulness can be easily included in the standard treatment delivered to people experiencing psychosis, and its associated costs are far cheaper than other frequent interventions delivered to this client group.

Person-based research in factors related with well-being showed that although psychotic symptoms affect quality of life of people that suffer them, the effect is mediated by the daily life coping with stressors. Like any mental event, psychotic experiences are sensitive to the relationship of the person with his/her context. Therefore, if the demands of the context exceed the person's abilities to deal with, the negative influence of the psychotic symptoms over quality of life will increase. This result is important for two reasons: on one hand, coping is an ability easily trainable through psychotherapy, on the other hand the mediator relationship is an evidence of the cognitive continuum between psychosis and other mental experiences.

In summary, this dissertation has shown that a person-centered approach to psychoses is feasible in the public health system, and has benefits for people experiencing persistent psychotic symptoms and for the knowledge about the psychotic

phenomena as well. I hope that this work will help foster research on psychosis from a phenomenological point of view and bring back the person – and not only his/her brain – as the cornerstone of treatment and study of psychotic phenomena.

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7. Appendix

I. Mindfulness standard instructions

1. First, I would like to ask your permission to do another experiential exercise. Are you willing to do that? [Get clients' permission and then move on.]
2. Go ahead and get in a comfortable position in your chair. Sit upright with your feet flat on the floor, your arms and legs uncrossed, and your hands resting in your lap (palms up or down, whichever is more comfortable). Allow your eyes to close gently [pause 10 seconds].
3. Take a few moments to get in touch with the movement of your breath and the sensations in your body [pause 10 seconds]. Bring your awareness to the physical sensations in your body, especially to the sensations of touch or pressure, where your body makes contact with the chair or floor [pause 10 seconds].
4. Now, slowly bring your attention to the gentle rising and falling of your breath in your chest and belly. Like ocean waves coming in and out, your breath is always there. Notice its rhythm in your body [pause 10 seconds]. Notice each breath. Focus on each inhale ... and exhale [pause 10 seconds]. Notice the changing patterns of sensations in your belly as you breathe in, and as you breathe out [pause 10 seconds]. Take a few moments to feel the physical sensations as you breathe in and as you breathe out [pause 10 seconds].
5. There is no need to try to control your breathing in any way—simply let the breath breathe itself [pause 10 seconds]. As best you can, also bring this attitude of generous allowing and gentle acceptance to the rest of your experience. There is nothing to be fixed, no particular state to be achieved. As best as you can, simply allow your experience to be your experience, without needing it to be other than what it is [pause 15 seconds].
6. Sooner or later, your mind will wander away from the breath to other concerns, thoughts, worries, images, bodily sensations, planning, or day dreams, or it may just drift along. This is what minds do much of the time. When you notice that your

mind has wandered, gently congratulate your self—you have come back and are once more aware of your experience! You may want to acknowledge briefly where your mind has been (Ah, there's thinking or there's feeling). Then, gently escort your attention back to the sensation of the breath coming in and going out [pause 10 seconds]. As best you can, bring a quality of kindness and compassion to your awareness, perhaps seeing the repeated wanderings of your mind as opportunities to bring patience and gentle curiosity to your experience [pause 15 seconds].

7. When you become aware of bodily sensations and feelings, tension, or other intense sensations in a particular part of your body, just notice them, acknowledge their presence, and see if you can make space for them [pause 10 seconds]. Do not try to hold on to them or make them go away [pause 10 seconds]. See if you can open your heart and make some room for the discomfort, for the tension, for the anxiety, just allowing them be there [pause 10 seconds]. Is there enough space in you to welcome in all of your experience? [pause 15 seconds]
8. Watch the sensations change from moment to moment. Sometimes they grow stronger [pause 10 seconds], sometimes they stay the same [pause 10 seconds], and sometimes they grow weaker — it does not matter [pause 10 seconds]. Breathe calmly in to and out from the sensations of discomfort, imagining the breath moving in to and out from that region of the body [pause 10 seconds]. Remember, your intention is not to make you feel better but to get better at feeling [pause 15 seconds].
9. If you ever notice that you are unable to focus on your breathing because of intense physical sensations of discomfort in your body, let go of your focus on the breath and shift your focus to the place of discomfort. Gently direct your attention on and into the discomfort and stay with it, no matter how bad it seems [pause 10 seconds]. Take a look at it. What does it really feel like? [pause 10 seconds] Again, see if you can make room for the discomfort and allow it to be there [pause 10 seconds]. Are you willing to be with whatever you have? [pause 15 seconds].
10. Along with physical sensations in your body, you may also notice thoughts about the sensations and thoughts about the thoughts [pause 10 seconds]. You may notice

your mind coming up with evaluative labels such as “dangerous” or “getting worse.” If that happens, you can thank your mind for the label [pause] and return to the present experience as it is, not as your mind says it is, noticing thoughts as thoughts, physical sensations as physical sensations, feelings as feelings—nothing more, nothing less [pause 15 seconds].

- 11.** To help you experience the difference between yourself and your thoughts and feelings, you can name thoughts and feelings as you notice them. For instance, if you notice you are worrying, silently say to yourself, “Worry ... there is worry,” just observing worry and not judging yourself for having these thoughts and feelings [pause 10 seconds]. If you find yourself judging, just notice that and call it “Judging ... there is judging” and observe that with a quality of kindness and compassion [pause 10 seconds]. You can do the same with other thoughts and feelings and just name them as planning, reminiscing, longing, or whatever you experience. Label the thought or emotion and move on [pause 10 seconds]. Thoughts and feelings come and go in your mind and body. You are not what those thoughts and feelings say, no matter how persistent or intense they may be [pause 15 seconds].
- 12.** As this time for formal practice comes to an end, gradually widen your attention to take in the sounds around you... notice your surroundings [pause] and slowly open your eyes with the intention to bring this awareness to the present moment and into the upcoming moments of the day.