DISSERTATION:

EFFICACY OF THE COGNITIVELY-BASED COMPASSION TRAINING (CBCT®) PROGRAM FOR THE IMPROVEMENT OF QUALITY OF LIFE AND FEAR OF CANCER RECURRENCE IN A SAMPLE OF BREAST CANCER SURVIVORS

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“Compassion is not religious business, it is human business, it is not luxury, it is essential for our own peace and mental stability, it is essential for human survival.”

— Dalai Lama XIV

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SUMMARY

There is growing evidence of how compassion training enhances psychological and physical well-being (Zessin, Dickhäuser, & Garbade, 2015), however, there are very few studies analyzing the efficacy of Compassion-Based Interventions (CBI) on breast cancer survivors (BCS) (Dodds et al., 2015). According to the World Health Organization (WHO), breast cancer (hereafter referred to as BC) is the most common neoplasm among women and is a major public health problem worldwide (22.7% of all female cancers) (McGuire, 2016; Perou, Sorlie, Eisen, & Van De Rijn, 2000; R. L. Siegel, Miller, & Jemal, 2015; R. L. Siegel, Miller, & Jemal, 2016; Torre et al., 2015). For this and many other reasons, it is important to begin and continue doing research that addresses the after-treatment-breast-cancer-emotional-turmoil with new psychological approaches (Dodds et al., 2015; Thewes et al., 2014).

According to the American Society of Clinical Oncology (ASCO), being a BCS means different things, depending on who experiences it. For some, it means having no signs of cancer after finishing treatment. Survivors may experience a mixture of strong feelings, including joy, concern, relief, guilt, and fear (Mols, Vingerhoets, Coebergh, & Franse, 2005). Others become very anxious about their health and uncertain about coping with everyday life. Some people may even prefer to put the experience behind them and feel that their lives have not changed in a major way (Mayer, 2017).

A vast body of research evaluating the effects of psychosocial interventions on psychological adaptation during cancer treatment has been done (Antoni, 2013; Guo et al., 2013; Stanton, 2006; Stanton, Luecken, MacKinnon, & Thompson, 2013). In a systematic review (Fors et al., 2011), data show that psychoeducational programs,

cognitive behavioral therapy and social and emotional support are the most significant therapies for improving mood, quality of life (QoL), and observed fatigue. The impact of psychological interventions on cancer survival is relevant and a growing number of evidence confirms it. In a review of studies, Stanton et al. (2005) found that persistent psychological and physical decrements occur for a subset of cancer survivors.

During the last decade, a growing number of empirical data for new intervention approaches has arisen. There is a call for empirical attention to a broader range and relevant ways to intervene with complementary approaches (Goldstein et al., 2005; Richardson, Sanders, Palmer, Greisinger, & Singletary, 2000). Research is beginning to accumulate valuable data on such interventions for cancer survivors as yoga (Cohen, Warneke, Fouladi, Rodriguez, & Chaoul-Reich, 2004), massage (Hernandez-Reif et al., 2004) and mindfulness meditation (Carlson, Speca, Patel, & Goodey, 2003).

In oncological settings, Mindfulness-Based Interventions (MBI) have proved their efficacy in promoting well-being and QoL domains (Sinatra & Black, 2018; Zainal, Booth, & Huppert, 2013). These kind of interventions have shown to be effective in training coping strategies when dealing with psychosocial stress related to the disease, relieving anxiety, stress, fatigue, general mood, sleep disturbance, and improving psychological aspects of QoL (Carlson et al., 2003; Carlson & Garland, 2005). Moreover, data show that MBI can significantly improve psychological domains such as anxiety, depression, and stress in cancer survivors not only after intervention but at long-term (Cramer, Lauche, Paul, & Dobos, 2012; Piet, Wurtzen, & Zachariae, 2012).

The concept of compassion has appeared in psychology in relation to the mindfulness and MBI. In the last two decades, compassion has extended to other

domains such as the medical field (Kemper, Larrimore, Dozier, & Woods, 2006; Mascaro et al., 2016; Rousseau, 2004; Strasser et al., 2005; Von Dietze & Orb, 2000), psychotherapy (Gilbert, 2010a; Gilbert & Procter, 2006; Gilbert, 2013), and others (Davidson & Harrington, 2002; Desbordes et al., 2012; Dodds et al., 2015; Mascaro, Rilling, Tenzin Negi, & Raison, 2012; Ozawa-de Silva et al., 2012; Pace et al., 2009; Pace et al., 2012; Reddy et al., 2013; Singer & Bolz, 2013).

Well designed contemplative-based programs have highlighted the benefits of compassion training on physical health, evocation of positive emotions, mental health, social belonging parameters (Grant, 2013; Mascaro, Pace, & Raison, 2013; Neff & Germer, 2013) and on bringing first and third person methods together into the scientific paradigm (Klimecki, Ricard, & Singer, 2013; Kok, 2013). In the last decade CBI have shown to improve psychological functioning and well-being in clinical and educational settings (Kirby, Tellegen, & Steindl, 2015; Kirby, 2017).

As for the empirical framework, we should point out that the main aim of this study is to analyze the efficacy of Cognitively-Based Compassion Training (CBCT) Program in a Randomized Clinical Trial (RCT) on a sample of BCS. The specific objectives are aimed to analyze the efficacy of CBCT in variables related to QoL, psychological symptomatology, psychological dimensions linked to fear of cancer recurrence (FCR), self-compassion, compassion and mindfulness trait facets and the influence of CBCT over participants' compassion and self-compassion semantic construct, when compared to a treatment as usual (TAU) control group. Hypothesis of this study predicts that CBCT group will show improvement in all of the variables showed above. Moreover, participants' semantic construction, of what is a compassionate and self-compassionate

individual, will be modified in the direction of what CBI and compassion-based contemplative traditions propose after going through the CBCT program.

A RCT was designed. Participants (n = 56) were randomly assigned to CBCT (n = 28) or a treatment-as-usual control group (n = 28). Pre-post intervention and 6-month follow-up measures took place to evaluate health-related quality of life; psychological symptomatology; psychological stress, coping strategies, and triggering cognitions for FRC; self-compassion and compassion; mindfulness facet traits; and semantic construction of compassion and self-compassion concepts in both intervention and wait-list groups

CBCT was effective in diminishing stress caused by fear of FCR (F [2, 96.863] = 3.521, $p < .05$), fostering self-kindness (F [2, 97.453] = 5.769, $p < .01$) and common humanity (F [2, 98.323] = 6.161, $p < .01$), and increasing overall self-compassion scores (F [2, 96.277] = 5.423, $p < .01$), mindful observation (F [2, 96.052] = 4.709, $p < .05$), and acting with awareness skillsets (F [2, 98.598] = 3.444, $p < .05$). CBCT also proved to influence participants' mental construction of what is a self-compassionate and compassionate being.

This research project is another call for deepening scientific knowledge and paying more attention to the mechanisms and implications of training in compassion and exploring the potential of these type of programs for cancer survivorship contexts. In this line of reasoning, a promising potential of compassion programs is the explicit intent to cultivate skills to cope with internal (feelings, thoughts, sensations, memories, self-criticism, etc) and external (lost, sickness, death, criticism) difficulties and turn them into opportunities for growth from the

basis of a selflessness perspective (Dambrun & Ricard, 2011; Dambrun et al., 2012). Moreover, more efforts should be focused in dapating compassion training programs to Latin-Mediterranean-Catholic settings.

Keywords

Breast cancer survivorship, compassion training, self-compassion, fear of cancer recurrence, contemplative training

RESUM

Hi ha una evidència creixent de com l'entrenament en compassió millora el benestar físic i psíquic (Zessin, Dickhäuser, & Garbade, 2015), però hi ha molt pocs estudis que analitzen l'eficàcia de les intervencions basades en compassió (IBC) en supervivents de càncer de mama (Dodds et al., 2015). Segons l'Organització Mundial de la Salut (OMS), el càncer de mama és la neoplàsia més freqüent entre les dones i és un important problema de salut pública a tot el món (22,7% de tots els càncers femenins) (McGuire, 2016; Perou, Sorlie, Eisen i Van De Rijn, 2000; RL Siegel, Miller, & Jemal, 2015; RL Siegel, Miller, & Jemal, 2016; Torre et al., 2015). Per això i per molts altres motius, és important començar i seguir investigant sobre les dificultats emocionals que s'experimenten després del càncer (Dodds et al., 2015; Thewes et al., 2014).

Segons la Societat Americana d'Oncologia Clínica, ser una supervivent de càncer de mama significa coses diferents, depenent de qui ho experimenta. Per a algunes, significa no tindre signes de càncer després d'acabar el tractament. Les supervivents poden experimentar una barreja de sentiments forts, com ara l'alegria, la preocupació, l'aullegerament, la culpa i la por (Mols et al., 2005). D'altres es tornen molt ansiosos per la seua salut i l'incertesa sobre com fer front a tasques de la vida quotidiana. Algunes persones poden fins i tot preferir posar l'experiència en el pasat i sentir que les seues vides no han canviat de manera important (Mayer, 2017).

S'ha realitzat una amplia recerca que avalua els efectes de les intervencions psicosocials sobre l'adaptació psicològica durant el tractament del càncer (Antoni, 2013; Guo et al., 2013; Stanton, 2006; Stanton, Luecken, MacKinnon i Thompson, 2013). En una revisió sistemàtica (Fors et al., 2011) sobre aquest tipus d'intervencions, les dades

mostren que els programes psicoeducatius, la teràpia conductual cognitiva i el suport social i emocional són les teràpies més importants per millorar l'estat d'ànim, la qualitat de vida i la fatiga. L'impacte de les intervencions psicològiques sobre la supervivència del càncer és rellevant i un nombre creixent d'evidència ho confirma. En una revisió d'estudis, Stanton et al. (2005) va trobar que es produeixen decrements persistents psicològics i físics per a un subconjunt de supervivents del càncer.

Durant l'última dècada, s'han produït un nombre creixent de dades empíriques per a nous enfocaments d'intervenció. Es demana atenció empírica a un rang més ampli i maneres rellevants d'intervenir amb enfocaments complementaris (Goldstein et al., 2005; Richardson, Sanders, Palmer, Greisinger i Singletary, 2000). La investigació comença a acumular dades valuoses sobre aquestes intervencions per a supervivents del càncer com el ioga (Cohen, Warnedo, Fouladi, Rodríguez i Chaoul-Reich, 2004), el massatge (Hernandez-Reif et al., 2004) i la meditació (Carlson, Speca , Patel, & Goodey, 2003).

En els entorns oncològics, les intervencions basades en mindfulness han demostrat la seua eficàcia en la promoció dels àmbits de benestar i qualitat de vida (Sinatra & Black, 2018; Zainal, Booth, & Huppert, 2013). Aquest tipus d'intervencions han mostrat eficàcia en la formació d'estratègies per a fer front a l'estrès psicosocial relacionat amb la malaltia, alleujar l'ansietat, l'estrès intraperonal, la fatiga, l'estat d'ànim general, la pertorbació del son i la millora dels aspectes psicològics de qualitat de vida (Carlson et al., 2003; Carlson & Garland, 2005). A més, les dades mostren que les intervencions basades en la atenció plena poden millorar significativament els dominis psicològics com l'ansietat, la depressió i l'estrès en supervivents del càncer no

només després de la intervenció, sinó a llarg termini (Cramer, Lauche, Paul i Dobos, 2012; Piet, Wurtzen, & Zachariae, 2012).

El concepte de compassió ha aparegut en la psicologia en relació amb mindfulness i les intervencions basades en l'atenció plena. En les dues últimes dècades, la compassió s'ha estès a altres dominis com el camp mèdic (Kemper, Larrimore, Dozier, & Woods, 2006; Mascaro et al., 2016; Rousseau, 2004; Strasser et al., 2005; Von Dietze & Orb, 2000), psicoteràpia (Gilbert, 2010a; Gilbert & Procter, 2006; Gilbert, 2013) i altres (Davidson & Harrington, 2002; Desbordes et al., 2012; Dodds et al., 2015; Mascaro, Rilling, Tenzin Negi, & Raison, 2012; Ozawa-de Silva i altres, 2012; Pace et al., 2009; Pace et al., 2012; Reddy et al., 2013; Singer & Bolz, 2013).

Els programes basats en la contemplació ben dissenyats han destacat els beneficis de l'entrenament en compassió sobre la salut física, evocació d'emocions positives, salut mental, paràmetres de pertinença social (Grant, 2013; Mascaro, Pace, & Raison, 2013; Neff & Germer, 2013) i aportar mètodes de primera i tercera persona al paradigma científic (Klimecki, Ricard, & Singer, 2013; Kok, 2013). En l'última dècada les intervencions basades en la compassió han demostrat millorar el funcionament i el benestar psicològics en els entorns clíclins i educatius (Kirby, Tellegen i Steindl, 2015; Kirby, 2017).

Pel que fa al marc empíric, cal assenyalar que l'objectiu principal d'aquest estudi és analitzar l'eficàcia de l'entrenament en compassió de base cognitiva en un assaig clínic aleatoritzat sobre una mostra de supervivents del càncer de mama. Els objectius específics s'orienten a analitzar l'eficàcia de l'entrenament en compassió de base cognitiva (CBCT) en variables relacionades amb la qualitat de vida, la simptomatologia

psicològica, les dimensions psicològiques lligades a la por a la recurrència del càncer, a la habilitat d'auto-compassió, compassió i facetes tret de mindfulness. D'altra banda, també es va avaluar la influència de CBCT sobre la construcció semàntica del concepte d'auto-compassió i compassió, en comparació amb un grup control amb tractament habitual. La hipòtesi d'aquest estudi prediu que el grup de l'entrenament en compassió de base cognitiva mostrarà una millora en totes les variables mostrades anteriorment. A més, la construcció semàntica dels participants, del que és una persona compassiva i autocompassiva, es modificarà en la direcció del que proposen les intervencions basades en la compassió i les tradicions contemplatives basades en la compassió després de passar pel programa de l'entrenament en compassió de base cognitiva.

Els participants (n = 56) van ser assignats aleatòriament a CBCT (n = 28) o un grup control de tractament habitual (n = 28). Es va dur a terme una evaluació prèvia a la intervenció i es van realitzar mesures de seguiment de 6 mesos per avaluar la qualitat de vida relacionada amb la salut; sintomatologia psicològica; estrès psicològic, estratègies per a fer front a cognicions desencadenades per por a la recurrència del càncer; auto-compassió i compassió; facetes tret de mindfulness; i la contrucción semàntica dels conceptes d'auto-compassió i compassió tant en el grup experimental com en el grup control.

CBCT va ser eficaç en disminuir l'estrès provocada per la por a la recurrència del càncer ($F [2, 96.863] = 3.521$, $p < .05$), fomentant l'auto-amabilitat ($F [2, 97.453] = 5.769$, $p < .01$) i la humanitat compartida ($F [2, 98.323] = 6.161$, $p < .01$), i augmentant les puntuacions totals d'auto-compassió ($F [2, 96.277] = 5.423$, $p < .01$), observación conscient ($F [2, 96.052] = 4.709$, $p < .05$), i actuant amb habilitats de atenció plena (F [2,

98.598] = 3.444, $p < .05$). CBCT també va provar d'influir en la construcció mental dels participants del que és un ésser auto-compassiu i compassiu.

Aquest projecte de recerca és una altra crida per aprofundir el coneixement científic i prestar més atenció als mecanismes i implicacions dels entrenaments en compassió i explorar el potencial d'aquest tipus de programes per als contextos de supervivència del càncer. En aquesta línia de raonament, un potencial prometedor de programes de compassió és la intenció explícita de cultivar habilitats per afrontar problemes interns (sentiments, pensaments, sensacions, records, autocrítica, etc.) i externs (pèrdua, malaltia, mort, crítica) i convertir-los en oportunitats de creixement des de la base d'una perspectiva no centrada en el jo (Dambrun & Ricard, 2011; Dambrun et al., 2012). D'altra banda, cal centrar més esforços en el process de adapatació del programes d'entrenament en compassió en els entorns latins-mediterranis-catòlics.

Paraules clau

supervivència del càncer de mama, entrenament en compassió, auto-compassió, por a la recurrència del càncer, entrenament contemplatiu

INRTODUCTION

BC is a major socio-sanitary problem. (Galceran et al., 2017). During treatment and recovery rise of negative emotions (Bauer-Wu et al., 2017) and feelings of dislike to oneself and one's body may arise (Krumwiede & Krumwiede, 2012). According to the American Society of Clinical Oncology (ASCO), being a breast cancer survivor (hereafter referred to as BCS) means different things depending on the patients emotional background (Mayer, 2017).

Survivors experience a very intense emotional turmoil with a wide range of different emotions and feelings (Mols et al., 2005). Breast cancer survivorship (BCShip) implies an important change in physical, social and emotional demands. Home management, health and welfare services, finances, employment, legal matters, relationships, sexuality and body image and recreation are some of the categories in which BC and BCship impacts the patient's life (Catt, Starkings, Shilling, & Fallowfield, 2017).

Even though there have been significant advances in psychotherapeutic approaches, design of effective interventions that benefit BC patients remains a challenge (Kristeller, Sheedy Zumbrun, & Schilling, 1999; Pillai, 2012). MBI have proven to significantly improve psychological domains such as anxiety, depression, and stress in cancer survivors not only after intervention but at long-term (Cramer, Lauche, Paul, & Dobos, 2012; Piet, Wurtzen, & Zachariae, 2012). Over the last 10-15 years, there has been a substantive increase in research in these new contemplative interventions aiming to improve psychological functioning and well-being (Kirby, Tellegen, & Steindl, 2015; Kirby, 2017). In a recent study done by Dodds et al., (2015), these contemporary

interventions have shown significant improvements in depression features, functional impairments related to FCR, avoidance related to traumatic stress, and an increase in vitality.

In light of all the exposed above we have considered convenient to evaluate the efficacy of the CBCT program in a sample of BCS. For this reason we have evaluated its efficacy in variables related to QoL (physical, social, emotional and functional domains), psychological symptomatology (somatic, depressive and anxious related difficulties), psychological dimensions linked to FCR, self-compassion, compassion and mindfulness trait facets and its influence of CBCT over participants' compassion and self-compassion semantic construct. We also included the evaluation participants' acceptance, adherence, and satisfaction with CBCT intervention. From all this, we expect that CBCT participants show improvements in the variables listed above.

THEORETICAL FRAMEWORK

1 INTRODUCTION TO BREAST CANCER AND BREAST CANCER SURVIVORSHIP

Due to its high incidence, BC is a major socio-sanitary problem. Due to the introduction of mammography screening campaigns and new medical treatments, oncological medicine has come up with many notable improvements when treating this particular disease and survival rates have increased over the last three decades (Galceran et al., 2017). Cancer, in general, and BC, in particular, implies a great amount of emotional implication attention focus to the body. During treatment and recovery rise of negative emotions (Bauer-Wu et al., 2017; Bullen et al., 2012; Given & Given, 2013; Sharpe, Patel, & Clarke, 2011) and feelings of dislike to oneself and one's body may arise (Krumwiede & Krumwiede, 2012).

1.1 BREAST CANCER: DEFINITION AND EPIDEMIOLOGY

Breast carcinoma can be defined as a multifactorial degenerative disease, where a group of cells escape the organism's normal control growth mechanisms, forming a tumor (Cucarella, 2013; Mayer, 2017). BC usually begins in the mammary ducts, although 10% starts in the mammary lobes. It is suspected that most ductal carcinomas are initiated in a non-invasive (and therefore non-severe) form called intraductal carcinoma.

According to the WHO, BC is the most common neoplasm among women and is a major public health problem worldwide (22.7% of all female cancers) (McGuire, 2016; Perou et al., 2000; R. L. Siegel et al., 2015; R. L. Siegel et al., 2016; Torre et al., 2015). It is estimated that more than 1.2 million cases are diagnosed each year around the world. BC results in 500,000 deaths annually in both, developed and developing countries. It is the first or second leading cause of cancer death in women depending on the country (it is behind lung carcinoma in many developed countries). If we consider both genders, only lung, stomach and colorectal cancer surpass it (Jemal et al., 2011; Martín, Herrero, & Echavarría, 2015).

About 1 in 8 women in the U.S. (about 12%) will develop invasive BC over the course of her lifetime. In 2015 there were 231,840 new cases of BC (BC) in the United States and it is this type of cancer with more new cases from all the rest (R. L. Siegel et al., 2015; R. L. Siegel et al., 2016). In 2017, an estimated 252,710 new cases of invasive breast cancer are expected to be diagnosed in women in the U.S., along with 63,410 new cases of non-invasive (in situ) BC (Narod, Iqbal, & Miller, 2015; Weiss, 2017).

In Europe, a woman's chance of developing BC before age 75 is 8-10%. Its incidence increases with the economic level, so that more than half of the cases of BC are diagnosed in developed countries: 370,000 cases per year in Europe (27.4%) and 230,000 cases in North America (31.3%) (Ferlay, Héry, Autier, & Sankaranarayanan, 2010). According to the GLOBOCAN, Belgium presented the highest rate of BC, followed by Denmark and France. Slightly more BC cases were diagnosed in less developed countries (53%). In addition, the highest incidence of BC was located in Northern America and Oceania; and the lowest incidence in Asia and Africa (Ferlay et al., 2015).

The incidence in Spain is one of the lowest, although it has increased progressively in the last decades. There is an estimated 26,000 new cases per year (which represents almost 30% of all tumors manifested in women in this country) and about 5,000 annual deaths due to the tumor. Most cases are diagnosed between thirty-five (35) and eighty (80) years of age (Galceran et al., 2017). There is no clear geographical pattern, highlighting only the province of Gran Canarias as an area of higher mortality for BC. An increase in the diagnosis of this disease in the early stages (stage I and II) can now be observed, representing 75% of the total number of cases that are diagnosed (Pollán et al., 2009). Taking these data into account, BC is possibly the most well-known malignant tumor and one of the most common. Survival at 5 years is close to 85% in Spain (Cucarella, 2013; Ferlay, 2004).

Considering this, it is important to begin and continue doing research that addresses the after-treatment-BC-emotional-turmoil (Dodds et al., 2015; Thewes et al., 2014).

1.2 ETIOLOGY AND TREATMENT

Although the precise causes of BC are unclear, main risk factors have been explored. In developed countries early age at menarche, older age at first birth, reduced parity, lack of breast feeding, and late menopause have all been linked to an increased risk of developing BC (McPherson, Steel, & Dixon, 2000). In addition, the use of oral contraceptives and hormone replacement therapies (HRT) have been shown to increase the risk of BC for up to five years after being discontinued, compared to women who have never used hormone therapy (Million Women Study Collaborators, 2003). Lifestyle issues such as poor diet and obesity, alcohol intake and low levels of physical activity have all been explored and associated with BC. Obesity in post-menopausal women and increased alcohol consumption have all been found to increase risk of BC, while participating in physical activity offers some protection (Baan et al., 2007; Chan et al., 2007; Reeves et al., 2007) . The evidence linking diet to BC is not conclusive although fat consumption is considered to increase risk (McPherson et al., 2000).

In Spain, age, socio-economic background, place of residence, going through few pregnancies (the first at very late ages) overweight and sedentarism, hereditary factors and hormonal treatment (long term exposition to estrogens) are considered as main risk factors (Ferlay et al., 2015; Martín et al., 2015)

The advances in oncological medicine, especially the emergence of chemotherapy, have been one of the many lifesaving agents that have successfully aid millions of women to survive. Nevertheless, this treatment has multiple side effects. Change in cognitive function is one side effect of chemotherapy that has been reported as one

hindrance in some BCS (Kanaskie & Loeb, 2015). Between sixteen (16) to fifty (50) percent (%) of women receiving chemotherapy for BC, experience symptoms of cognitive impairment (Tannock, Ahles, Ganz, & Van Dam, 2004). Memory, concentration, and some higher order processes that include psychomotor speed and executive functioning are one of the documented symptoms (Hess & Insel, 2007). These symptoms may persist even years after completion of treatment (Ahles et al., 2003; Saykin, Ahles, & McDonald, 2003). This is the reason why specific emotional and cognitive supportive investigations should be done in BCS (Osborn, Demoncada, & Feuerstein, 2006).

Furthermore, approximately 16-25% of patients who have just been diagnosed with cancer suffer depression or an adjustment disorder with depressed mood (Sellick & Crooks, 1999). Depression has also been linked with functional limitations in BC patients (Wang, Van Belle, Kukull, & Larson, 2002). Data also reveals that anxiety and depression can independently influence functional and overall well-being (Dausch et al., 2004; Simmonds, 2002). An increase in pain and declination in the domains of physical and social function, vitality, and ability to perform emotional and physical roles, are also experienced by patients (Stanton, 2006).

The extension or phase of BC is a crucial factor when considering the best treatment. Treatment methods vary depending on the criteria mentioned above (Davidson, 2016; Harris, Morrow, & Norton, 1997):

- ✓ Phase 0: Treatment of Lobular Carcinoma in Situ and Ductal Carcinoma in situ are the most used and recommended non-invasive treatments.
- ✓ Phase I to III: Generally includes radiotherapy and surgery. Often treatment with chemotherapy and other drug treatments before or after surgery are used.

- ✓ Phase IV (Advanced BC): In general, treatment consist of systemic therapies (medication)
    - Inflammatory BC: Treatment could include chemotherapy or other systemic therapies, radiation therapy or surgery.
    - Recurrent BC: This kind of BC treatment depends on which treatments have been done to the patient before and what part of the breast has the disease recurred

1.3 BREAST CANCER SURVIVAL

According to the ASCO, being a BCS means different things, depending on who experiences it. For some, it means having no signs of cancer after finishing treatment. For others it means living with, through, and beyond cancer. According to this definition, cancer survivorship begins at diagnosis and includes people who continue to have treatment over the long term, to either reduce the risk of recurrence or to manage chronic disease (Mayer, 2017). Reality is that survivorship is one of the most complicated parts of having cancer (Bower et al., 2000; Carlson et al., 2015; Rosenfeld, Krivo, Breitbart, & Chochinov, 2000).

Survivors may experience a mixture of strong feelings, including joy, concern, relief, guilt, and fear (Mols et al., 2005). Others become very anxious about their health and uncertain about coping with everyday life. Some people may even prefer to put the experience behind them and feel that their lives have not changed in a major way (Mayer, 2017).

1.4 IMPACT OF BREAST CANCER SURVIVORSHIP IN DIFFERENT DOMAINS:

BC, its treatment and survivorship process implies an important change in physical, social and emotional demands. This complex new reality impacts the individual's life in different ways. Home management, health and welfare services, finances, employment, legal matters, relationships, sexuality and body image and recreation are some of the categories in which BC and BCship impacts the patient's life (Catt, Starkings, Shilling, & Fallowfield, 2017).

The diagnosis, treatment and survivorship of cancer are considered to be emotionally disturbing or even traumatic. The majority of cancer patients will at least experience elevated levels of emotional distress. A smaller group will develop significant long-term psychological problems in reaction to this potentially traumatic event (Markovitz, Schrooten, Arntz, & Peters, 2015). The emotional impact of a cancer diagnosis and the severities of cancer treatment and its survivorship harmfully affect QoL, and this may persist beyond treatment (Gerber, Freund, & Reimer, 2010; Pedersen, 2010). After the treatment, new worries and challenges arise over time including fear of illness recurrence, sexuality and fertility concerns and financial and workplace issues (Mayer, 2017). Survivors may feel stress when going to frequent visits to the health care team and after completing treatment (Aspinwall & MacNamara, 2005; Loprinzi, Prasad, Schroeder, & Sood, 2011).

There is a vast body of literature that shows how women (especially elderly women) that have gone through BC experience more persistent problems with physical function after BC diagnosis (Cimprich, Ronis, & Martinez-Ramos, 2002; P. Ganz,

Rowland, Meyerowitz, & Desmond, 1998; P. Ganz et al., 2003; Satariano, Ragheb, Branch, & Swanson, 1990; Vinokur, Threatt, Caplan, & Zimmerman, 1989). In a preliminary analysis of data from the Nurses' Health Study (NHS), authors found that women who developed and overcame BC were more likely to have experienced reduced physical function, physical role function, emotional role function, vitality, and social function, and increased bodily pain over time, compared with women who had not gone through BC (Michael, Kawachi, Berkman, Holmes, & Colditz, 2000).

The relation of BCShip and labor market (Bradley, Bednarek, & Neumark, 2002b) shows that negative factors like physical limitations, memory loss, lack of control over schedules, need for transportation, type of work performed, and in some cases discrimination on the part of employers can reduce employment (Berry, 1993; Fow, 1996; Greenwald et al., 1989; Satariano & DeLorenze, 1996; Schagen et al., 1999).

However, some authors suggest that BCS work more hours per week than a non-cancer control group (Bradley, Bednarek, & Neumark, 2002a). Following this viewpoint, other authors have stated that BCS function at a high level (P. A. Ganz et al., 1996). This study concluded that women continued to work and perform their usual roles after treatment for BC. The implication of these studies is that the overall impact of BC on employment status is insignificant.

Family members and friends may also go through periods of transition. A BC supporter or couple plays a very important role in supporting a person diagnosed and surviving cancer, providing physical, emotional, and practical care on a daily or as-needed basis. Many caregivers become focused on providing this support, especially if the treatment period lasts for many months or years (Maly, Umezawa, Leake, & Silliman, 2005). However, as treatment is completed, the caregiver's role often changes.

Eventually, the need for caregiving related to the cancer diagnosis will become much less or come to an end (Halifax, 2009).

As a final concluding reflection, (Stanton, Ganz, Kwan et al., 2005)(Stanton, Ganz, Kwan et al., 2005)(Stanton, Ganz, Kwan et al., 2005) some authors have made a call for the need to put the scientific community's attention to the psychosocial domain in cancer survivorship. Based on reviews and meta-analyzes, these authors state this call in four points (Stanton et al., 2005):

1. Cancer and its treatment distress QoL related to illness and general QoL (Eton & Lepore, 2002). Rates of clinically significant psychological disorder in cancer patients frequently are found to exceed those of the general population. Prevalence of clinically significant depressive symptoms in cancer patients exceeds general population norms, although estimates of prevalence vary widely across studies (Massie, 2004).
2. Anxiety symptoms are experienced by cancer patients. Nevertheless, elevated prevalence of clinically significant anxiety disorder is less consistently documented (van't Spijker, Trijsburg, & Duivenvoorden, 1997).
3. The 48% of prevalence during the first year of diagnosis is twice that of the general population of women for depression, anxiety, or both disorders. Moreover, the prevalence of depression/anxiety disorders decreases and becomes equivalent to that of the general population after the first year, except for women who experience cancer recurrence (Burgess et al., 2005). These data are of relevance, considering the emotional turmoil that people experience during the first year of diagnosis and the importance of applying an intervention of psychological nature. Furthermore,

patients can undergo disconcerting physical symptoms and deteriorations in physical function (Ganz et al., 2002; Helgeson & Tomich, 2005).

4. Psychological interventions during the first year after surgery for BC, predicted lower distress and depressive symptoms 4 to 7 years later (Carver & Antoni, 2004). Additionally, many individuals extract positive meaning and benefit from their experience with cancer, reporting that it prompts enhanced interpersonal relationships, deepens appreciation for life, increases personal strength, greater spirituality, valued change in life priorities and goals, and greater attention to health-promoting behaviors (Stanton, Bower, & Low, 2006). These positive findings reveal that most people with cancer adjust well over time; nevertheless, they do not suggest that attention to psychosocial and physical distresses is not essential. On the contrary, literature addresses the importance of attending unmet needs that persist after completion of primary medical treatments (Stanton et al., 2006).

1.5 PSYCHOSOCIAL INTERVENTIONS IN BREAST CANCER AND BCSHIP

There is a vast amount of evidence of cancer patient's emotional and cognitive difficulties during different stages of the disease (Mehnert & Koch, 2007; Ono et al., 2015). Cognitive, behavioral and social factors can affect how cancer patients adapt to diagnosis and treatment for cancer.

For this reason, a vast body of research evaluating the effects of psychosocial interventions on psychological adaptation during cancer treatment has been done (Antoni, 2013; Guo et al., 2013; Stanton, 2006; Stanton, Luecken, MacKinnon, & Thompson, 2013). These inquiries point out that significant reductions in cancer patients' emotional distress can be achieved with interventions particularly for those patients with high levels of distress (Andersen, 2002; Goodwin et al., 2001; Helgeson, Cohen, Schulz, & Yasko, 2000). Because of its promising outcomes, psychosocial interventions have been successfully adapted to BC and BCShip settings (Carlson et al., 2013; Johannsen, Farver, Beck, & Zachariae, 2013).

1.5.1 Psychosocial interventions for breast cancer

A growing number of authors have documented the benefits of evidence-based psychosocial interventions to address emotional needs and cognitive impairments in different oncological settings (Rehse & Pukrop, 2003; Zimmermann, Heinrichs, & Baucom, 2007). In a systematic review (Fors et al., 2011), about this type of interventions, data show that psychoeducational programs, cognitive behavioral

therapy (CBT) and social and emotional support are the most significant therapies for improving mood, QoL, and observed fatigue. Among the most promising results are those interventions addressed to train relaxation skills for newly diagnosed patients. These types of interventions reflected significant improvement in seven of seven trials on anxiety and six of six trials on depressive symptoms (Jacobsen, Donovan, Swaine, & Watson, 2006). Furthermore, a meta-analysis stated that the most important moderating variable related to the efficacy of the interventions for QoL was the duration of psychosocial intervention with periods of more than 12 weeks being significantly more effective than interventions of shorter duration (Rehse & Pukrop, 2003).

1.5.2 Psychosocial interventions for breast cancer survivorsip

It has been observed that BCS with a cancer history have the highest risk of experiencing significant depressive symptomatology relative to other life diseases (Polsky et al., 2005). For these reasons, the impact of psychological interventions on cancer survival is relevant and a growing number of evidence confirms it. In a review of studies, Stanton et al. (2005) found that persistent psychological and physical decrements occur for a subset of cancer survivors. These and other authors have identified risk and protective factors for these outcomes (Meyerowitz & Oh, 2009; Stanton, Revenson, & Tennen, 2007).

Psychosocial interventions offered are structures of multiple components and paradigms that co-exist together (Stanton, Ganz, Rowland et al., 2005). Education regarding cancer and its treatment, provision of emotional support, training in coping skills, challenging unhelpful thoughts, and relaxation training are some of its variety of

components (Duijts, Faber, Oldenburg, van Beurden, & Aaronson, 2011). Most of psychosocial intervention research has focused on the early diagnostic and treatment phase, due to the increasing distress and uncertainty that patients go through. Some authors have found that a brief orientation program for cancer patients at their initial oncology clinic visit, significantly reduce anxiety, depressive symptoms, and overall distress, and increased healthcare satisfaction (McQuellon et al., 1998). Similarly, in a study that evaluated self-administered stress-management skills for patients that survived cancer, it was found that participants experienced better physical function and vitality, fewer emotional role limitations, and better general mental health than did usual-care participants (Jacobsen et al., 2002).

However, there is growing evidence that suggest how psychosocial interventions can enhance significant positive psychological functioning during survivorship (Devine, 2003; Meyer & Mark, 1995; Sheard & Maguire, 1999; Smedslund & Ringdal, 2004). Meta-analyzes about interventions in BCShip have suggested stronger intervention effects on anxiety than on depressive symptoms (Sheard & Maguire, 1999), a beneficial effect on pain in adults with cancer (Devine, 2003), reduction of depressive symptoms and improvement of physical functioning at 13-month follow-up (Scheier et al., 2005) or reduced physical symptoms and medical appointments for cancer-related morbidities (Stanton et al., 2002).

When exploring interventions for long-term survivors, one trial reveals that a uncertainty-management-based psychological intervention improved knowledge regarding living with long-term adverse effects and with fears of recurrence and improved several coping skills directed toward fear of disease recurrence at a 10-month follow-up (Mishel et al., 2005). Nevertheless, it is important to keep in mind that more

evidence-based interventions targeting specific concerns of long-term survivors are needed.

Whether or not these changes in distress are related to improved survival rates is unknown. In a meta-analysis of randomized studies, of the eight researched studies, four reported a survival benefit (Fawzy et al., 1993; Kuchler et al., 1999; Spiegel, Kraemer, Bloom, & Gottheil, 1989), and four did not (Cunningham et al., 1998; Edelman, Lemon, Bell, & Kidman, 1999; Linn, Linn, & Harris, 1982). According to the authors of this meta-analysis, most of the studies were designed as psychotherapy studies to reduce stress or enhance coping and not designed to test for survival effects (Andersen et al., 2004). This is a call for deepening research and skillful therapeutic means to foster well-being in BCShip.

1.6 COGNITIVE BEHAVIORAL THERAPY-BASED INTERVENTIONS FOR BREAST CANCER AND BREAST CANCER SURVIVORS

Pharmacological treatments had been the only option to treat distress and pain in BC patients until very recently. Antidepressants, anxiolytics and hypnotics were the dominant option to consider (Tatrow & Montgomery, 2006). However, evidence shows how pharmacologic interventions by themselves have not completely eliminated distress and pain in cancer patients and often come with their own set of side effects (Golden-Kreutz & Andersen, 2004). Even though there have been significant advances in psychotherapeutic approaches, design of effective interventions that benefit BC patients remains a challenge (Kristeller, Sheedy Zumbrun, & Schilling, 1999; Pillai, 2012).

Over the years, data show how CBT techniques and approaches can alleviate distress and pain in various cancer populations (Graves, 2003; Meyer & Mark, 1995; Stagl et al., 2015). Many of these CBT approaches have been empirically validated for cancer patients (Luebbert, Dahme, & Hasenbring, 2001). Techniques offered by this method like relaxation, imagery, systematic desensitization have been found to be efficacious for chemotherapy patients (Hidderley & Holt, 2004). Moreover, CBT groups have been found to be useful for distress in BC patients (Edelman et al., 1999; Gudenkauf et al., 2015; Tatrow & Montgomery, 2006)

There is evidence that CBT interventions may provide psychological resources to BCS. A meta-analysis that included 56 studies concludes that CBT improve fatigue, depression, anxiety, and stress (Duijts et al., 2011). In a more modern study, it was observed how participants in in CBT group experienced significant improvements in neuropsychological processing speed, anxiety concerning cognitive problems, general

function, fatigue, and overall anxiety were observed when compared to a control group (Ferguson et al., 2016).

During the last decade, a growing number of empirical data for new intervention approaches has arisen. There is a call for empirical attention to a broader range and relevant ways to intervene with complementary approaches (Goldstein et al., 2005; Richardson, Sanders, Palmer, Greisinger, & Singletary, 2000). Research is beginning to accumulate valuable data on such interventions for cancer survivors as yoga (Cohen, Warneke, Fouladi, Rodriguez, & Chaoul-Reich, 2004), massage (Hernandez-Reif et al., 2004) and mindfulness meditation (Carlson, Speca, Patel, & Goodey, 2003).

1.7 MINDFULNESS-BASED INTERVENTIONS

For some researchers Mindfulness can be considered as a process defined by two central components: attention to present-moment experiences and an attitude of acceptance or openness towards these experiences (Bishop et al., 2004). MBI work on building a present-focused attentional state that emphasizes observing and experiencing rather than evaluating and changing experiences such as thoughts, sensations, feelings, or urges. In modern western psychology a few interventions, including Dialectical Behavior Therapy (DBT), Acceptance and Commitment Therapy (ACT), and Mindfulness-Based Stress Reduction (MBSR), use mindfulness practice to build awareness, acceptance, and distress tolerance and reduce emotional and cognitive reactivity, automatic behavioral patterns, and avoidance of unwanted experiences (Baer, 2015).

1.7.1 General Consideration on Mindfulness-Based Interventions

From all the interventions exposed above, one of the most relevant ones are MBI. In the last thirty five years the interest in Mindfulness has grown exponentially. The concept of Mindfulness has its origins mainly in Hindu and Buddhists contemplative, cultural and philosophical traditions. In this sense, a working definition of mindfulness could be a particular mental state which is both wholesome and capable of clear and penetrating insight into the nature of reality (Cullen, 2011).

If one goes to the Foundational School of Buddhism (Theravada), Mindfulness would be described as recollection, non-forgetfulness. This includes retrospective memory of

things in the past, prospectively remembering to do something in the future, and present-centered recollection in the sense of maintaining unwavering attention to a present reality. We could say that the opposite of mindfulness is forgetfulness. In this sense mindfulness applied to the breath, for instance, involves continuous, unwavering attention to the respiration. In the context of the Buddhist tradition, Mindfulness refers to the sustained attention with continuity to a known object without forgetfulness or distraction (Wallace, 2006; Wallace, 2011a; Wallace, 2011b).

Even though Buddhism contains extensive instructions on Mindfulness principles and practice, the training and practice of Mindfulness can be effectively adopted by any interest individual without adopting any particular philosophical, religious or cultural tradition or vocabulary (Kabat-Zinn, 2000).

In a global context, it has been the work of Jon Kabat-Zinn that has brought attention to the clinical and psychotherapeutic applications of Mindfulness. According to this author Mindfulness involves 'paying attention in a particular way: on purpose, in the present moment, and non-judgmentally (Kabat-Zinn, 2009). This contemporary definition of Mindfulness refers to the cultivation of conscious awareness and attention on a moment-to-moment basis. This includes openness or receptiveness, curiosity and a non-judgmental attitude. An emphasis is placed on seeing and accepting things as they are without trying to change them. Mindfulness is contrasted with habitual mental functioning, or "being on automatic pilot". It is not a goal-directed activity despite the fact that the practice does have its secondary effects. Mindfulness can be cultivated by a variety of techniques, all of which have a meditative component. It includes formal Mindfulness meditation practice (normally a period of sitting or lying meditation),

informal meditation practice (Mindfulness of movement, yoga, mindful walking, etc.), and brief meditation periods (Eberth & Sedlmeier, 2012).

1.7.2 Mindfulness-Based Interventions for oncological settings

In oncological settings, MBI have proved their efficacy in promoting well-being and QoL domains (Sinatra & Black, 2018; Zainal, Booth, & Huppert, 2013). These kind of interventions have shown to be effective in training coping strategies when dealing with psychosocial stress related to the disease, relieving anxiety, stress, fatigue, general mood, sleep disturbance, and improving psychological aspects of QoL (Carlson et al., 2003; Carlson & Garland, 2005). Qualitative studies have reported that Mindfulness is a good approach to help patients feel more open to new and novel experiences, feeling less vulnerable to stress and more tolerant to negative aspects of self and others. This causes a feeling of greater appreciation for life, turning the oncological process into a meaningful one. When going through MBI, patients show less emotional reactivity and greater tolerance for strong emotions when these arise (Bonadonna, 2000; Garland, Carlson, Cook, Lansdell, & Speca, 2007; Ledesma & Kumano, 2009; Saxe et al., 2001; Young, 1999).

A systematic review (Shennan, Payne, & Fenlon, 2011) reported five different types of MBI used in adults with cancer. The vast majority included Mindfulness-Based Stress Reduction (MBSR), two were Mindfulness-based cognitive therapy (MBCT), one brief mindfulness training, two psychoeducational studies with a core Mindfulness component and one ‘one to one’ mindfulness meditation. In all cases, there were significant improvements in anxiety, depression, stress and sexual difficulties

One of the most studied MBI is the MBSR program developed by Jon Kabat-Zinn (Kabat-Zinn, 2003) at the Center for Mindfulness in Medicine, Health Care, and Society at the University of Massachusetts Medical School. MBSR has proved to reduce distress, improve psychological well-being, and improve psychosocial adjustment in patients with different types of cancer (Ledesma & Kumano, 2009) and BC (Zainal et al., 2013). Nevertheless, MBSR has shown to be inferior to CBT for improving insomnia severity in cancer patients immediately after the program, but it demonstrated non-inferiority at follow-up (Garland et al., 2014).

MBCT is a refinement of MBSR that specifically targets the cognitive processes associated with relapse to depression (Teasdale et al., 2002). The goal of this program is to disengage participants from reactivate depressive patterns (e.g., rumination) that may lead to an episode of depression in those with a history of this disorder. Rumination may exacerbate distress in response to a range of stressors, and so MBCT may be more widely applicable (Foley, Baillie, Huxter, Price, & Sinclair, 2010). MBCT has been considered as an effective approach for cancer patients because anxiety, depression and its ruminative processes have been identified as important etiological factors of emotional distress (Sharplin et al., 2010).

Different RCT of MBCT reported significant improvements in distress, depression, and anxiety, QoL, mindfulness or post-traumatic growth after treatment with gains maintained at 3 months post-intervention (Sharplin et al., 2010; Stafford et al., 2013). Placement and length of session adaptations were considering when taking this program to a specific oncological context (Foley et al., 2010). It has also proved to be effective in reducing chronic cancer-related fatigue (van der Lee, Marije L & Garssen, 2012).

Additionally, Mindfulness-Based Cancer Recovery (MBCR) program has also proved to help cancer patients adapt to the emotional difficulties experienced during the disease (Carlson & Speca, 2010). Specifically, it has proved to be effective in reducing stress symptoms and improving QoL and social support (Carlson et al., 2013). Improvements have also been reported at online settings for underserved individuals with cancer (Zernicke et al., 2016) in reduction of mood disturbance and increase in spirituality and mindful acting (Zernicke et al., 2014).

1.7.3 Mindfulness-Based Interventions for oncological survivorship settings

Data show that MBI can significantly improve psychological domains such as anxiety, depression, and stress in cancer survivors not only after intervention but at long-term (Cramer, Lauche, Paul, & Dobos, 2012; Piet, Wurtzen, & Zachariae, 2012).

MBSR program has been adapted to different oncological survivorship settings with significant success (Zainal et al., 2013). One study has adapted the original 8-week MBSR program, developed by Kabat-Zinn to BCS (Lengacher et al., 2009). That adaptation was arranged in a 6-week program adapted for consideration of the BCS' health status. Initial meditation body scan procedures, visualization, sitting meditation with awareness of breathing as primary object of attention, body scan with response to stress, introduction of yoga postures and open awareness exercises were few of the many activities that were adapted to this setting. The goal of this modified intervention was to provide resources for management of specific emotional/psychological symptoms (anxiety, depression, and fear of recurrence) and physical symptoms, such as pain and sleep

through the use of meditation practices (sitting meditation, body scan and walking meditation) and yoga.

Another RCT study gives more support for the use of MBSR in reducing psychological issues among BCS (Lengacher et al., 2009). Patients in MBSR group showed a series of positive effects including increased calm, enhanced sleep quality, more energy, less physical, pain, and increased well-being (Matchim, Armer, & Stewart, 2011). QoL has become an important indicator of cancer treatment outcomes. This is not only due to the increasing number of BCS, but also because the role of women in family and society (Mols et al., 2005). It has been observed how MBCR aids the maintenance of telomere length in distressed cancer survivors (Carlson et al., 2015). Even though there is growing number of evidence on the benefits of MBI on cancer survivorship, very little has been studied in MBCT and cancer survivorship (Piet et al., 2012).

2 INTRODUCTION TO COMPASSION

The concept of compassion has appeared in psychology in relation to the mindfulness and MBI. The importance of compassion is recognized in many segments of society, cultures and religious traditions. In the last two decades, compassion has extended to other domains such as the medical field (Kemper, Larrimore, Dozier, & Woods, 2006; Mascaro et al., 2016; Rousseau, 2004; Strasser et al., 2005; Von Dietze & Orb, 2000), psychotherapy (Gilbert, 2010a; Gilbert & Procter, 2006; Gilbert, 2013), and others (Davidson & Harrington, 2002; Desbordes et al., 2012; Dodds et al., 2015; Mascaro, Rilling, Tenzin Negi, & Raison, 2012; Ozawa-de Silva et al., 2012; Pace et al., 2009; Pace et al., 2012; Reddy et al., 2013; Singer & Bolz, 2013).

2.1 DEFINITION AND MODELS OF COMPASSION

Regardless of the importance of compassion and the increasing interest from researchers, clinicians, teachers, and other professionals, there is lack of consensus on its definition (García-Campayo, Cebolla, & Demarzo, 2016; Strauss et al., 2016). For the Oxford English Dictionary, the word “compassion” derives from the Latin “compati”, which means “to suffer with”. In different texts and scientific literature there have been successful intents of consensus that argues that compassion involves feeling for a person who is suffering and being motivated to act to help them (Halifax, 2011; Lazarus, 1991; Lutz, Greischar, Rawlings, Ricard, & Davidson, 2004; Negi, 2013; Weng et al., 2013). All these definitions highlight a motivational aspect. This includes not only feeling touched by a person's suffering, but also evoking the emotional tone for wanting to act to help that other. It is important to note how the majority of the definitions proposed by different authors are influenced by Buddhism.

From an evolutionary perspective, compassion is considered an evolved motivational system designed to regulate negative affect. Compassion’s origins might have been originated from the same capacities that primates evolved to form attachment bonds and engage in affiliative and cooperative behaviors for group survival (Gilbert, 2010a). From this view, compassion is composed of six “attributes”: sensitivity (involves being responsive to other people's emotions and perceiving when they need help), sympathy (showing concern for the other person's suffering), empathy (putting yourself in their shoes), motivation/caring, distress tolerance (defined as the ability to tolerate difficult emotions in oneself when confronted with someone else's suffering without becoming overwhelmed by them) and non-judgement (ability to remain

accepting of and tolerant towards another person even when their condition, or response to it, gives rise to difficult feelings in oneself, such as frustration, anger, fear or disgust) (Gilbert, 2010c).

In Gilbert's (2010) model, all components are essential for responding compassionately. In this way, compassion could be considered as a complex, interdependent, multi-asset response. The lack of training in these assets could drive us to an over-identification process with a person's suffering that could prevent a compassionate response. If we feel such extreme personal distress in the face of another's suffering, one might become too focused on one's own discomfort, which could impede one's disposition and conduct to help (Gilbert, 2010a; Wispé, 1991).

A definition of compassion for others included in a self-compassion model has also being proposed (Neff, 2003b). For Neff, self-compassion can be viewed as compassion directed towards oneself. Like Gilbert, Neff suggest that the ability to evoke compassionate feelings include different assets: kindness (being kind and non-judgmental towards the self rather than self-critical), mindfulness (which, like "distress tolerance", involves holding painful feelings in mindful awareness rather than over-identifying with them), and common humanity (seeing one's suffering as part of the human condition rather than an isolating experience) (Neff, 2003a)

Pommier (2010) has adapted Neff's (2003a) model of self-compassion to a model of compassion. This author suggests that compassion for others can be seen as involving kindness (being understanding towards others who are suffering instead of being critical or indifferent towards them), mindfulness (ability to notice another person's suffering and remain open to it without feeling so distressed that you disengage from that person) and common humanity (realizing that all humans suffer and that one could find oneself

in the position of the sufferer if one was less fortunate). In an intent to contextualize compassion in the landscape of suffering, a recent paper describes compassion as "an orientation of mind that recognizes pain and the universality of pain in human experience and the capacity to meet that pain with kindness, empathy, equanimity and patience" (Feldman & Kuyken, 2011).

From an evolutionary and early neuroscientific perspective, compassion has been considered an emotion (Goetz, Keltner, & Simon-Thomas, 2010; Singer & Steinbeis, 2009). Nevertheless, richer perspectives have aid neuroscience to deepen its views. Descriptive Buddhist psychology defines compassion as a constitution of the mind or mental factor, which can be developed or cultivated. This constitution may lead to emotions in response to somebody else's suffering or joy. Nevertheless, this perspective does not exclude considering compassion as an emotion, but it states that it is manifested as such in beginner practitioners (Dreyfus, 2002). According to the renowned expert in emotions, Paul Ekman, compassion should not be conceptualized as an emotion, considering that compassion needs to be deliberately cultivated and trained while emotions do not. The author also states that if compassion is cultivated deliberately, it can become into an enduring feature of the person. This is not a characteristic of emotions, because emotions come and go (Ekman, 2008).

According to evolutionary theorists, compassion is reproductively beneficial, for its intrinsic quality to nurture and protect (Goetz et al., 2010). For primatologists, empathy and compassion has not only evolved to protect oneself and those close to us, but also to protect those outside our in-group (De Waal, 2010). Evolutionary theorists also state that compassion might also have evolved because it fosters mate selection and facilitates cooperative relationships with non-kin (Keltner, 2009).

According to Gilbert (2013) compassion implies two basic abilities. First, the ability to turn towards suffering in a non-reactive way. This implies noticing it and be emotionally connected with it. It also implies a cognitive element that facilitates re-appraisal to make sense of it without being overwhelmed. The second ability is what the author calls wisdom. This implies knowing how to hold, alleviate and prevent suffering. Wisdom blooms when all efforts to prevent and alleviate suffering are grounded in the understanding of the biological, psychological, social/cultural and historical causes and conditions that interact in the emergence of suffering (Gilbert, 2010a; Gilbert, 2010c; Gilbert, 2013).

In this line, Singer and Bolz (2013), propose the ReSource Model of Compassion (Bornemann & Singer, 2013). This model suggests that the cultivation of compassion involves the refinement of cognitive, affective, motivational and social domains. Like in Buddhist psychology, this model understands cultivation as a process through which the individual attunes with qualities and dispositions that are already present in him/her, rather than acquiring completely new skills.

From a healthcare perspective, compassion is considered to have numerous pragmatic advantages. Research shows how treating patients compassionately improve clinical outcomes, increases patient satisfaction with services, and enhances the quality of information gathered from patients (Epstein et al., 2005; Redelmeier, Molin, & Tibshirani, 1995; Strauss et al., 2016). On the other hand, lack of compassion may contribute to poor quality of care (Najjar, Davis, Beck-Coon, & Carney Doebbeling, 2009). Data also reveals that treating oneself and others with compassion promotes individual well-being and improves mental health (Mascaro et al., 2016; Pace et al., 2009; Pace et al., 2010; Pace et al., 2012; Pace et al., 2013). Scientific literature is

revealing how compassion diminishes reactivity to stress and is central to the process of recovery from psychopathology (Desbordes et al., 2012; Gilbert, 2010a; Gilbert & Procter, 2006; MacBeth & Gumley, 2012; Mayhew & Gilbert, 2008; Pace et al., 2013).

2.2 BUDDHIST ROOTS OF COMPASSION

Within Buddhist psychology, the role of the cultivation of compassion diminishes self-centered attitudes and fosters a motivation centered in others (other-centeredness) (Dambrun & Ricard, 2011; Dambrun et al., 2012; Ricard, 2015). This way one can take more perspectives into consideration, not biased by an extreme focus of one's own worldview. This permits a recognition process of the actual condition of our existence. This recognition facilitates a process that fosters coping strategies based on kindness when facing mental and emotional sources of dissatisfaction, anxiety and psychological distress. Deliberately developing concern for others is an integral part of one's own growth. The mission of compassion and its cultivation is to offer the right tools to investigate one's and other's existence (Hangartner, 2013).

In this context, compassion is seen not only as an emotional response but also as a response founded on reason and wisdom which is embedded in an ethical framework concerned with the selfless intention of freeing others from dissatisfactions, anxiety and discomfort and facilitating the conditions for lasting well-being (Dambrun & Ricard, 2011; Davidson & Harrington, 2002; Goleman, 2003; Lama, 2009).

Compassion's primary focus is to explore, examine and analyze the causes and conditions of distress rather than the actual distress or suffering that is occurring (Ricard, 2015). From this perspective, suffering that is already taking place is considered a resultant state, a consequence of many conditions that have preceded it (Hangartner, 2013). When one gets in touch with this reality, one can choose to manage those causes and conditions that contribute to our own and other's distress, altering and preventing the current of the resultant discomfort (Gethin, 1998). There are many ways and means

to cultivate compassion. These means can include rich and compound psychological approaches (Shantideva, 2007; Trungpa, 2001) to very pragmatic ones (Hopkins, 2011).

In Buddhist tradition, for example, compassion is trained in combination with other mental states called the four Immeasurables (loving-kindness, compassion, enthusiastic joy and equanimity) (Hangartner, 2013; Wallace, 1999). These practices include the development of motivational assets (Shantideva, 2007) and wisdom (Sik et al., 2015).

All definitions cited above consider compassion as awareness of someone's suffering, being emotionally and cognitively moved by it, being able to tolerate uncomfortable feelings (feelings of disgust, frustration or anger) that arise in oneself as a result of seeing suffering, and acting or feeling motivated to help (Strauss et al., 2016). Several definitions suggest that compassion involves recognizing a commonality with the sufferer (from self-compassion to compassion) and acknowledging that as human beings we all could find ourselves in a similar position (common-humanity). In this sense, Strauss et al., (2016) makes a clear statement about the necessity of creating a consensus definition of self-compassion and compassion and how the current discussions between Buddhist contemplatives and scholars and contemporary western psychologist could be of relevance for this purpose.

While Buddhist psychology states that differentiating compassion for others from self-compassion means drawing a false distinction between the self and others, and moreover that self-compassion is a prerequisite for showing 'true' compassion towards others (Strauss et al., 2016), Neff and Pommier (2013) and Pommier (2010) showed how these two constructs were not correlated in a sample of undergraduates, and only weakly correlated in samples of undergraduates and a community of practicing meditators. Recent papers state that it is unclear whether the lack of association

between self-compassion and compassion for others reflects independence between these two constructs or whether it reflects definitional problems, weaknesses of correlational study designs or limitations with current measures (Strauss et al., 2016; Williams, Dalgleish, Karl, & Kuyken, 2014).

2.3 FROM MINDFULNESS TO COMPASSION

The process of transition from Mindfulness to Compassion has made science get in touch with new traditions, especially with Indo-Tibetan. Practices and views that derive from this tradition and psychology are quite different from the way the mind has been understood in the West. Cognitive processes of attention, appraisal and awareness have hardly been connected to socioemotional potentials like kindness, generosity, compassion, equanimity or patience. In fact, these cognitive, emotional and behavioral qualities have been investigated in western psychology, sociology and economy since very recently (Dalai Lama, 2012; Davidson & Schuyler, 2015; Goleman, 2003; Goleman, 2015; Goleman & Davidson, 2017; Layard, 2016).

The traditional goal of Mindfulness training is to deliberately exercise cognitive, socioemotional and ethical assets in embodied acts from moment to moment in the field of possible perception within our bodies and surroundings (Condon, Desbordes, Miller, & DeSteno, 2013; Grossman, 2013). Inherent ethical and socioemotional mindful assets (kindness, tolerance, patience, generosity, courage and equanimity) are often ignored or neglected in contemporary science when defining, measuring or even working with Mindfulness. This may reduce Mindfulness into an attention and metacognitive technique to quite the mind (or the environment) and focus better in daily activities to feel better or to improve our "mindful abilities" (Grossman, 2013; Grossman, 2011; Grossman & Van Dam, 2011; Grossman, 2008; Wallace, 2006).

From an ethical-based approach, Mindfulness becomes a way to create new perspectives, meanings and attitudes towards stillness, reflection, kindness and compassion to self, others and even to the whole world. This can be trained and

accomplished through the embodied experience of attentional and ethical qualities. In this sense, significant and sustaining changes may not come overnight. These come from the constant, progressive and systematic familiarization of body and mind with different assets that one is already geared with. Even though this is a gradual path of growth, well-designed and rigorous studies have pointed out the benefits of initial eight-week programs (Grossman, Niemann, Schmidt, & Walach, 2004).

According to Grossman (2013), the idea that eight week programs are only a beginning of a process that requires continuous nurturance, support and further deepening over the years, is still an unfamiliar idea for modern psychology. Nevertheless, rigorous studies and reports are gradually changing this idea (Davidson & Harrington, 2002; Davidson & Schuyler, 2015; Goleman & Davidson, 2017; Davidson et al., 2012; Lutz et al., 2004; Weng et al., 2013). A new wave of meditation programs have arisen over the last ten years. These programs are focused on the generation of feelings, sensations, emotions and mental patterns that foster nurturance, warmth, empathy, love, self-compassion and compassion (Bornemann & Singer, 2013; Gilbert, 2010c; Halifax, 2013c; Jazaieri et al., 2014; Neff & Germer, 2013; Reddy et al., 2013) and have increased the interest for contemplative practices in the scientific community and in world recognized institutions (Davidson & Schuyler, 2015).

2.4 COMPASSION-BASED INTERVENTIONS

Well-designed contemplative-based programs have highlighted the benefits of compassion training on physical health, evocation of positive emotions, mental health, social belonging parameters (Grant, 2013; Mascaro, Pace, & Raison, 2013; Neff & Germer, 2013) and on bringing first and third person methods together into the scientific paradigm(Klimecki, Ricard, & Singer, 2013; Kok, 2013).

In the following section, scientific-based compassion interventions or trainings will be presented. In this work scientific-based means that the following programs have had scientific evidence to support them or have been enriched or constituted by the scientific inquiries (sociology, neuroscience, psychology, psychiatry, medicine, etc.).

These CBI are The Mindful Self-Compassion (MSC) Training Program (Neff & Germer, 2013), Cultivating Emotional Balance (CEB) (Sansó et al., 2017), Compassion Cultivation Program (CCT) (Jazaieri et al., 2014), 2.4.4 Being with Dying Professional Training Program (Halifax, 2013c), Compassion-Focused Therapy (Gilbert, 2010b) , Attachment-Based Compassion Therapy (García-Campayo, Navarro-Gil, & Demarzo, 2016), The Resource Model (Bornemann & Singer, 2013) and the Cognitively-Based Compassion Training (CBCT) (Reddy et al., 2013). Recently, a new range of contemplative based interventions have come to light (Jazaieri et al., 2014).

2.4.1 Mindful Self-Compassion Training Program

The MSC Training Program is an eight-week training program where participants are invited to explore inner experiences. This program makes special emphasis on

addressing pleasant or unpleasant experiences with curiosity and kindness and whenever difficult memories, images, emotions and self-judgments arise loving awareness should be applied to the participant's inner domain. The authors of this program outline how one of the aspects that most impressed the Dalai Lama and the Tibetan monks when they came to the West was the difficulty people have in to love ourselves, and the excess of self-criticism and self-blame. This point has also been confirmed in specific research (Neff, 2003a).

Like most compassion interventions, one of the goals of MSC is to help participants develop the self-compassion habit, since self-compassion depends on how much a person practices. For Neff and Germer (2013) self-compassion helps participants to apply in daily life a learning process of acceptance and embracement, not expelling nor rejecting emotions in an aversive way nor replacing negative feelings or thoughts for positive ones. The way to cope with these situations with mindful-compassion is to embrace those negative emotions, accepting them and not judging them. A research study, showed how people with high self-compassion are less afraid of failure and more likely to try it again every time they fail because they do not self-punish themselves (Neff, Hsieh, & Dejitterat, 2005).

Along with other authors (Wei, Liao, Ku, & Shaffer, 2011), Neff and Germer (2013) were among the first authors to relate self-compassion to attachment models. They state that people who lack self-compassion are more likely to have been raised in dysfunctional families.

Like most CBI, MSC program is built sequentially upon each other:

- ✓ Session 1. Discovering Mindful Self-Compassion focuses on introducing the structure of the program, and a space is created for the participants to become familiar with one another.
- ✓ Session 2. Practicing Mindfulness which helps participants know when and where they experience stress or emotional pain (which is a necessary precondition for compassion)
- ✓ Session 3. Practicing Loving-Kindness Meditation which is considered the core practice of the program
- ✓ Session 4. Finding Your Compassionate Voice where the participant expands loving-kindness into daily life, approaching with a new outlook the everyday conversations in our minds.
- ✓ Session 5. Living Deeply where core values and commitments are explored
- ✓ Session 6. Managing Difficult Emotions
- ✓ Session 7. Transforming Challenging Relationships
- ✓ Session 8. Embracing Your Life

MSC is a standardized protocol for the development of self-compassion that includes more than 10 meditative practices (two of them nuclear) and more than 20 informal practices. It is a clinical and non-clinical program with a small number of efficacy studies. It could be used as an adjunct therapeutic tool on patients with high from self-criticism and shame mental patterns. It can also be used in a regular basis to foster psychological well-being in healthy individuals.

2.4.2 Cultivating Emotional Balance

Cultivating Emotional Balance (CEB) is a training program that emerged during a Mind & Life Institute dialog between behavioral scientists, a neuroscientist, a monk, a philosopher and the Dalai Lama in 2000 (Ekman & Ekman, 2013; Goleman, 2003).

Encouraged by H.H. Dalai Lama, Paul Ekman, Alan Wallace and scientists Mark Greenberg and Richard Davidson began to draft CEB. Ekman and Wallace continued the planning of CEB with consultation from the original Mind & Life group on training program design and research design to capture the effects of the CEB training.

CEB (Ekman & Ekman, 2013) is a secular, contemplative/emotion training program designed to help participants improve emotional life by cultivating constructive emotional experiences and developing mental balance. The training consists of overarching conceptual knowledge and experiential exercises drawn from Western scientific research on emotions and traditional Eastern attention focus (Shamatha) and contemplative Buddhist practices (Four Immeasurables). The program is designed to provide useful skills for individual development and interpersonal communication across non-clinical populations. CEB encourages participants to set their aspirations for exceptional mental health (genuine happiness) through volitive, attentional, emotional, cognitive and balances.

It is important to note that the authors of this program consider that CEB is not explicitly compassion training. However, the authors state that, learning how to meaningfully attend to the emotional experiences between the self and others coupled with attention focused meditation (Shamatha practices) (Wallace, 2006) and practices of loving kindness, compassion, empathetic joy and equanimity (Four Immeasurables)

(Wallace, 1999) fosters compassion and constructive interpersonal communication. Wallace's four balances are central for this program and constitute the conceptual base for the contemplative practices (Wallace & Shapiro, 2006). The four balances constitute:

- ✓ Conative Balance: provides the healthy motivation to achieve the other balances. This is the emotional antidote for apathy. This balance fosters the aspiration, motivation and intentional goals to boost and maintain the practices proposed in this program.
- ✓ Attentional Balance: Mindfulness of breath practices to develop relaxation, stability and vividness and avoid hyperactivity or laxity of attention.
- ✓ Cognitive Balance: the ability to engage with the world without conceptual assumptions and the skill to develop moment-to-moment awareness to see reality as it is. Cognitive balance entails developing awareness and insight to combat "Obsessive Compulsive Delusional Disorder" (Wallace, 2006).
- ✓ Emotional Balance: the ability to regulate and decrease destructive emotional episodes and increase constructive emotional engagements.

2.4.3 Compassion Cultivation Program

Compassion Cultivation Training (CCT) is an eight-week program designed to develop and enhance the qualities of compassion, empathy, and kindness both for oneself and for others developed at Stanford University. The course integrates contemplative practices, secularized and adapted primarily from the Tibetan tradition,

especially Lam Rim and Lo Jong meditation practices, as well as dyadic interactive exercises with insights from psychology and scientific research (Jazaieri et al., 2014).

CCT is thus embraced of the following four elements (Jinpa & Weiss, 2013):

1. Psycho-cognitive education that focuses on developing skills pertaining to greater awareness and facility with cognitive and affective processes, as well as their connection to behavior and habitual patterns.

2. Training in secularized meditations that draw on visualization and reflective processes adapted from the Tibetan Buddhist contemplative practices.

3. Dyadic interactive exercises that are aimed at eliciting and embodying specific affective states.

4. Informal homework assignments, including a daily guided meditation, that support participants in integrating the skills they are developing into their personal and professional lives.

Classes include pedagogical instruction with active group discussion, guided group meditation, interactive practical exercises, and exercises designed to promote feelings of open-heartedness or connection to others. In this program, compassion training is presented in six steps (Kirby, 2017):

1. Settling the mind and developing mindfulness skills
2. Experiencing loving-kindness and compassion for a loved one
3. Practicing Loving Kindness Meditation and compassion for oneself;
4. Practicing compassion towards others through embracing our shared common humanity;
5. Compassion towards all beings

6. “Active compassion” practice where one imagines taking away others’ pain and sorrow and offering to them one’s own joy and happiness (Tong-leng).

2.4.4 Being with Dying Professional Training Program

Roshi Joan Halifax has designed The Being with Dying (Halifax, 2009; Halifax, 2013b) Professional Training Program (BWD). This program incorporates ethical, spiritual, psychological, existential and social aspects of care of the process of dying. It includes mindful and compassionate approaches to end-of-life care, compassion-based ethics and communication strategies in End-of-Life Care, clinician self-care and contemplative interventions appropriate for clinicians/caregivers and dying people.

The program builds on reflective practices that can regulate attention and emotion, cultivate compassion, aid in the development of a meta-cognitive perspective, promote calm and resilience, reduce stress, and foster emotional balance, embodiment and compassion. It includes basic neuroscience research in relation to the clinical, contemplative and conceptual content of the training (Halifax, 2013a; Halifax, 2009; Halifax, 2013c).

The BWD training has four components that center on the transformation of the clinician, the patient, the community and the institution, respectively. These components are (Halifax, 2013b):

1. Transforming the Clinician/Caregiver
    a. Clarifying the worldview, values, priorities, knowledge of the clinician
    b. Introduction to contemplative interventions, including the neuroscience of attention, insight, compassion

c. Cultivating the development of moral sensitivity and compassion-based ethics

d. Teaching clinicians strategies supporting clinician well-being

2. Transforming the Patient

a. Exploring the relevance of patients' social, cultural, psycho-spiritual issues

b. Addressing issues of pain/suffering/total pain of patients

c. Explicating peri-death phenomena, including active dying and care of the body after death

d. Outlining dimensions of grief, including anticipatory, acute and chronic grief

3. Transforming the Community

a. Defining an approach to caregiving that is compassion-based

b. Giving strategies for compassionate communication around end-of-life issues

c. Fostering compassion-based inter-professional relationships and team development

d. Cultivating a whole community that includes the clinical team and all those in the network of the dying person

4. Transforming the Institution

a. Exploring ethical issues, processes and policies that affect the dying person

b. Developing strategies for implementing compassion-based care in clinician training

c. Outlining applications of compassion-based care, with a neuroscience rationale

d. Instituting research initiatives in compassion-based care

2.4.5 Compassion-Focused Therapy

Over the last two decades, Paul Gilbert developed compassion-focused therapy (CFT). The ground of this program is based on evolutionary psychology, attachment theory, and applied psychology processes from neuroscience and social psychology (Gilbert, 2010a).

CFT focuses on two psychologies of compassion:

1. The motivation to engage with suffering
2. Acting to help alleviate and prevent suffering.

The aim of CFT is to provide psychoeducation on the human mind, specifically in regard to its three basic emotion-regulation systems (Gilbert, 2010c; Gilbert, 2013):

(1) Threat/self-protect system,

(2) Drive–reward system,

(3) Affiliative/soothing system.

CFT includes a range of exercises to develop the individual's own ideal compassionate-self, including exercises to access the soothing system such as imagery (e.g., safe space imagery) and breathing (e.g., rhythm soothing breathing). CFT is the process of applying a compassion model to psychotherapy and as such it has no specific time limitations or restrictions (Kirby, 2017).

When trying to adapt CFT to group therapy, the Compassionate Mind Training (CMT) program was designed. It is a compassion-focused-group-based-therapeutic approach to help people with high levels of shame and self-criticism (Gilbert & Irons, 2004).

2.4.6 Attachment-Based Compassion Therapy

The Attachment-Based Compassion Therapy is (ABCT) is a compassion therapeutic protocol created by Javier García Campayo and his team from Universidad de Zaragoza. This program has been adapted to the cultural and health environment of Spain and Latin American countries. It can be used in both, general and clinical population, and is based on the attachment styles theory.

The theoretical foundations on which this model is structured are the following (García-Campayo et al., 2016):

1. The authors of this program use the Attachment Theory to explain the ways in which a person relates with other people and, therefore, how positive and negative emotions arise when relating to others. One of the goals of this program is to gain insight of one's own attachment style and modify the aspects that cause distress by structuring a secure attachment style (one that is associated with reducing criticism and anger towards ourselves and others).
2. ABCT is nurtured by other compassion models and other therapies (Paul Gilbert's structure of the three brain circuits and a number of practices that most protocols previously took from different traditions). This program also

includes techniques from other cognitive and third-generation therapies (Acceptance and Commitment Therapy and radical acceptance from Dialectical Behavior Therapy).

3. Contributions from world tradition have been incorporated in the form of practices and theoretical foundations from Tibetan Buddhism and Native American beliefs in which compassion plays a core role.

As for the structure, the ABCT has been organized in an eight week basis including (García-Campayo et al., 2016): (1) Preparing ourselves for compassion. Kind attention, (2) Discovering our compassionate world, (3) Developing our compassionate world, (4) Understanding our relationship with compassion, (5) Working on ourselves, (6) Advanced compassion, (7) Advanced compassion (II), (8) Beyond compassion: equanimity. Each of the weekly sessions comprehends a theoretical presentation and activities focused on formal and informal practice to do after each session.

In the present, studies in healthy population, patients with fibromyalgia and a sample of depressive patients are been done.

2.4.7 The ReSource Training Protocol

The ReSource Training Protocol is a research project developed by Bornemann & Singer (2013). This program has been developed as a large scale compassion project currently being evaluated across Europe (https://www.resource-project.org/en/home.html). As mentioned above, this protocol has three core components: Presence, Affective and Perspective. It is structured as a 39-week training

program which includes weekly retreats, and the support of a Web-based platform and smartphone app.

The origin of this program is grounded in Singer's work on the neurological bases of empathy, compassion and cognitive perspective taking. Another strong source of inspiration for some of the exercises was Tania Singer's experience with the "Non-Violent Communication" program (Rosenberg & Chopra, 2015) The first part of the training program (Presence) was strongly influenced by the work of John Kabat-Zinn and his eight-week Mindfulness-Based Stress Reduction program (Kabat-Zinn, 2003). Secondly, the affective part was initially inspired by previous research done in our lab on the effects of loving-kindness, empathy and compassion on subjective well-being and the brain (Klimecki, Leiberg, Lamm, & Singer, 2012; Leiberg, Klimecki, & Singer, 2011), complemented by elements of Neff and Germer's self-compassion program (Neff & Germer, 2013). Thirdly, the perspective part was newly developed on the basis of previous research on cognitive perspective taking, self-work rooted in the Internal Family Systems (Holmes & Holmes, 2007; Schwartz, 1997) guided by and classical contemplative meditation exercises (Swanson & Rinpoche, 2010).

2.4.8 Cognitively-Based Compassion Training

CBCT began as an interdisciplinary pilot project in 2005 to test the psychological and physiological effects of compassion meditation in college undergraduates, an idea that originally stemmed from an Emory University undergraduate, Molly Harrington, who had a concern for students' mental health and the rising number of undergraduate suicides. CBCT is drawn from the Tibetan Buddhist traditions of *Lo Jong* (mind training)

and Lam Rim (the stages of the path for spiritual development), but establishing it as a secular practice for general use (Kirby, 2017; Negi, 2013).

CBCT was designed with the intention of developing a secular meditation protocol that recognized the strengths of existing meditation programs while building on them in a few distinct ways. At the time, the majority of secular meditation programs did not primarily focus on analytical meditation and did not draw from the rich *Lo Jong* tradition. In the Lo Jong tradition, compassion meditation practice requires practitioners to actively work with their emotions in order to develop a deep feeling of affection for others and a strong positive connection with others, employing both attentional and analytical (or cognitively-based) styles of meditation (Negi, 2013; Ozawa-de Silva & Negi, 2013).

CBCT recognizes that all human beings have an innate capacity for compassion, a result of our evolutionary heritage as mammals, which require warm care in order to survive. Nevertheless, it takes active cultivation to bring this level of innate compassion to the state of genuine altruism. The Tibetan *Lo Jong* tradition, a system of "mind training", seeks to bring about this transformation through cognitive, analytical techniques that, when practiced genuinely, will enable an individual to reframe relationships with others. The degree to which a person is able to transform relationships through this process is dependent on the degree to which that person is able to relate to others with affection, which engenders deep feelings of endearment and tenderness towards others.

CBCT is divided into six, interdependent and systematic modules (Negi, 2013; Ozawa-de Silva & Negi, 2013):

1. Developing Attentional Stability and Clarity of Mind
2. Cultivating Insight into the Nature of Mental Experience
3. Cultivating Self-Compassion

4. Developing Equanimity and Impartiality

5. Developing Appreciation, Affection, and Empathy for Others

6. Realizing Engaged Compassion

2.5 EFFICACY OF COMPASSION-BASED INTERVENTIONS

Over the last 10-15 years, there has been a substantive increase in CBI aiming to improve psychological functioning and well-being. In the next section, some of the most representative science-based outcomes will be reflected (Kirby, Tellegen, & Steindl, 2015; Kirby, 2017):

2.5.1 Mental health

In reference to mental health, different CBI have been tested. For example, it was observed that seventy-one female adolescents, with high rates of early life adversity (ELA) reduced salivary concentrations of C-reactive protein (CRP) after going through CBCT program (Pace et al., 2013). This study also sought to evaluate the relationship between CBCT practice time and subsequent changes in the CRP biomarker. Furthermore, increased CBCT practice time was associated with reduced CRP from baseline to the six-week assessment indicating that CBCT practice had a positive impact on this inflammatory biomarker relevant to health and innate stress responses.

In another study, authors proposed that CBCT may be operating in the alleviation of depression by enhancing empathic accuracy and promoting prosocial behaviors (Mascaro et al., 2012). This study conducted at Emory University healthy participants were randomized to either a course in CBCT or to a health discussion control group. Participants underwent fMRI scans while completing an empathic accuracy test, Reading the Mind in the Eyes Test (RME), before and after the intervention. The CBCT participants were significantly more likely to have increased scores on the RME along

with increased neural activity in the inferior frontal gyrus (IFG) and dorsomedial prefrontal cortex (dmPFC). These changes in activity from baseline to the post-intervention assessment were associated with changes in empathic accuracy (Mascaro et al., 2012).

One recent study of CBCT in medical students found how CBCT group reported increased compassion, and decreased loneliness and depression when compared to the wait-list control group. Changes in compassion were most robust in individuals reporting high levels of depression at baseline, suggesting that CBCT may benefit those most in need by breaking the link between personal suffering and a concomitant drop in compassion (Mascaro et al., 2016).

In a systematic review (Leaviss & Uttley, 2015), authors confirm CFT as a promising intervention for mood disorders, particularly for those high in self-criticism. Kirby et al. (2015) conducted a meta-analysis with two CFT RCTs and compared CFT to active control conditions in clinical samples. The studies examined CFT as a treatment for schizophrenia (Braehler, Harper, & Gilbert, 2013) and for wanting to quit smoking (Kelly, Zuroff, Foa, & Gilbert, 2010). Both interventions focused on self-criticism and shame as key moderators in facilitating compassion, a process emphasized in CFT interventions. Braehler et al. (2013) observed how CFT was associated with greater clinical improvement and significant increases in compassion, with the increases in compassion being significantly associated with reductions in depression, shame, entrapment, and in perceived social marginalization. Moreover, Kelly et al. (2010) found that the self-compassion intervention reduced daily smoking more quickly than a baseline self-monitoring condition but at the same rate as two other imagery-based self-

talk active control groups. Effects were shown to be moderated by trait self-criticism, readiness to change, and vividness of imagery.

A recent study showed how a CBI made a significant impact in the degree of improvement in self-compassion and mindfulness facet traits in African American suicide attempters (LoParo, Mack, Patterson, Negi, & Kaslow, 2018). Authors found that self-compassion predicted the level of reduction in depressive symptoms and suicidal ideation and the degree of improvement in mindfulness predicted the level of reduction in depressive symptoms. Results from this study show that CBCT is a potentially valuable intervention for this population.

2.5.2 Well being

The pursuit of well-being is a highly valued goal in psychology. In psycho-oncological settings and interventions it is of important relevance. Different studies have how compassion and self-compassionate mindsets and skillsets contribute to the patients' well-being (Zessin, Dickhäuser, & Garbade, 2015).

Regarding its efficacy in the increase of well-being different programs have been tested, for example MSC has been evaluated in a RCT (Neff & Germer, 2013), and in brief 3-week formats (Albertson, Neff, & Dill-Shackleford, 2015). In the first study mentioned, Neff and Germer (2013) assessed the program with 51 participants, who were randomized to either MSC or a wait-list control condition. Results found significant increases in self-compassion, mindfulness, and on well-being outcomes (e.g., life satisfaction).

In an adaptation of CEB for professional caregivers, Sansó et al., (2017) found meaningful increases in both the five facets of mindfulness and decentering. Additional analyzes suggest that CEB can improve self-care, self-compassion while reducing symptoms of depression and anxiety. The pilot findings suggest that CEB may not only help to enhance the regulation of emotional states but could also be associated with improvement of mindfulness, self-care, and self-compassion.

The CCT program has been evaluated in three different research papers. These demonstrated the impact CCT has on increasing participants levels of compassion (Jazaieri et al., 2013), improving participants mindfulness, mental well-being and emotion regulation (Jazaieri et al., 2014), and how CCT reduced mind wandering to unpleasant topics (Jazaieri et al., 2016). However, for Kirby (2017) the evidence sustaining CCT is still a very young research field, with no other research being conducted, and none by independent evaluators.

In relation to CBCT, one study recruited sixty-one medically healthy adults with a mean age of 18.5 years and no history of significant mental illness. These participants were randomized to 6 weeks of training in compassion meditation (n = 33) or participation in a health discussion control group (n = 28) followed by exposure to a standardized laboratory stressor (the Trier social stress test [TSST]). Both groups were assigned at-home activities, either the practice of CBCT mediations details of which they recorded in a secure online diary, or the completion of a two to three page long self-improvement paper focused on the health topic of the week. Physiologic and behavioral responses to the TSST were determined by repeated assessments of plasma concentrations of interleukin (IL)-6 and cortisol as well as total distress scores on the Profile of Mood States (POMS). Within the meditation group, increased meditation

practice was correlated with decreased TSST-induced IL-6 and POMS distress scores. Moreover, individuals with meditation practice times above the median exhibited lower TSST-induced IL-6 and POMS distress scores compared to individuals below the median, who did not differ from controls (Pace et al., 2009).

Another study to resolve whether the associations between practice time and TSST outcomes reflected the fact that participants with reduced stress responses prior to training were more able to practice compassion meditation, rather than that meditation practice reduced stress responses. This study strengthened the findings from the initial work by supporting the conclusion that in individuals who actively engage in practicing CBCT, compassion meditation may represent a viable strategy for reducing potentially deleterious physiological and behavioral responses to psychosocial stress (Pace et al., 2010).

2.5.3 Physical diseases

Growing evidence have indicated that compassion and self-compassionate mindsets are associated with several key health-related factors including lower perceived stress, attenuated physiological responses to stress, the practice of health-promoting behaviors, and better physical health (Homan & Sirois, 2017).

Moreover, in a feasibility study looking at the effectiveness of CBCT with BCS, pre-/post intervention and follow up questionnaires measured symptom change (depression, intrusive thoughts, perceived stress, FCR, fatigue/vitality, loneliness, and QoL). Participants (n=33) were randomly assigned to either an eight-week long CBCT

course or a wait list. CBCT participants were asked to meditate at least three times per week in between classes. Compared to controls, at post-intervention, CBCT group showed significant improvements in depression, avoidance of intrusive thoughts, functional impairment associated with FCR, mindfulness, and vitality/fatigue. At follow-up, less perceived stress and higher mindfulness were also significant in the CBCT group (Dodds et al., 2015).

2.5.4 Education setting

Compassion Programs and interventions have proved to have great potential and effectiveness for the promotion of a happy life in school settings (Ozawa-de Silva & Dodson-Lavelle, 2011).

CEB program has been evaluated in one RCT with 82 female school teachers, with no psychiatric disorders or prior meditation practice (Kemeny et al., 2012). In this study CEB was compared to a wait-list control condition at pre-, post-, and 5-month follow-up. Measures included: self-report questionnaires (e.g., Beck Depression Inventory and Trait Anxiety Inventory), experimental tasks (e.g., Micro-Expression Training Tool and Trier Social Stress Test), and bodily responses (e.g., autonomic nervous system measurements including blood pressure and respiratory sinus arrhythmia). Compared to control, CEB significantly reduced negative affect, rumination, depression, anxiety, and increased positive affect and mindfulness. This study outlines CEB's effectiveness to increase participants' emotional abilities to cope and recognize emotions in self and others (Kirby, 2017).

A construct, called social, emotional and ethical development has been implemented in different school settings in the United States. This construct fosters self-awareness, consideration of others, connection to others and links the social emotional intelligence and competence development literatures (Seal, Naumann, Scott, & Royce-Davis, 2011). In line with this construct, a more profound and ethical curriculum was demanded in the 2016 World Happiness Report (Layard, 2016). A new curriculum called Social Emotional and Ethical (SEE) Learning for K-12 and higher education has been elaborated at the Center for Contemplative Science and Compassion-Based Ethics in Emory University. This initiative is grounded in a compassion-based ethics curriculum.

3 COGNITIVELY-BASED COMPASSION TRAINING

Drawn from the Buddhist tradition, CBCT is a secularized adaptation of a mental training called *lojong*. CBCT is a secular protocol that presents its content and contemplative practices in a way that is compatible with current understandings of modern psychology and neuroscience. Intentionally designed for use by practitioners of any – or none – faith traditions, CBCT sets aside specifically Buddhist beliefs (e.g. enlightenment, Buddha nature, reincarnation, etc.). These concepts are not prerequisites for the practice of CBCT nor are they necessary for the cultivation of compassion.

The fundamental premise of CBCT might be summarized in this way: if the structure and function of the brain can be changed through experience and meditation training as current views of neuroplasticity suggest and one already has a biological basis for compassion, compassion can be cultivated, trained and expanded through training and practice compassion. Based on this premise, CBCT was initially launched as a research protocol in 2006 precisely to begin testing this hypothesis.

CBCT points out that the cultivation of compassion requires proper and specific conditions. These conditions are linked to specific internal emotional and cognitive strategies. The application of these different strategies, nurture the conditions that give rise to compassion. Moreover, to understand this process it is helpful to look at the program in its totality. It is also useful to look at these topics in reverse order, to understand what conditions are necessary for compassion to arise. Those immediately preceding conditions have their own causes and conditions, and that chain continues

until one reaches the first stage of the practice. By looking at the relationship of each topic to the topics that precede and follow it, the logic of the sequencing and each topic's role in creating the arc of compassion training can be clearly seen. The conditions exposed above, will be explored in the next point.

3.1 GENERAL OVERVIEW OF COGNITIVELY-BASED COMPASSION TRAINING

CBCT is rooted in different foundational concepts, like nurturance, safety and security; attentional stability; nature of mental experience; self-compassion, impartiality; interdependence, appreciation and gratitude; wishful and engaged compassion. In the following each of these foundational concepts are explained and linked to the sequential and interconnected phases of the program.

The cultivation of endearment is one of the main factors. As an strategy to diminish biases that makes one feel the world as something threatening, divided into categorical dimensions (like, dislike or indifferent). These categorical biases hinder the sense of expanded endearment previous to compassion. This is the reason why it is important to deliberately cultivate impartiality as a condition for the development of compassion. Without leveling out strong biases, compassion will remain limited to the few nearest and dearest. The cultivation of impartiality can be seen as the farmer leveling the field by removing rocks and remains so that consistent growth is possible. The development of affection toward others is the moisture that nourishes the seed of compassion to promote healthy growth.

Another important condition that precedes compassion is the cultivation of Self-Compassion - the cultivation of a secure base. In CBCT, a secure base is built from identifying the underlying causes of suffering and generating the determination to cope and emerge from them. This process of recognition and personal exploration helps in identifying the psychological mechanisms that lead to anxiety, dissatisfaction and mental discomfort in oneself. This is a key step in strengthening the sense of a secure

base. Eventually, this process empowers the person to cope, tolerate, and transform internal mechanisms and helps build the resolution to amend the way one interacts with oneself and the world. Progressively, the CBCT practitioner shifts his/her attention toward a longer-term fulfillment and self-care, that is, genuine self-compassion. It is called *self*-compassion because the ability to sustain this perspective is the lasting way to relieve oneself of unnecessary anxiety and dissatisfaction.

The ability to care deeply for one's own well-being (self-compassion) depends on the ability to have insight into the nature of mental experience. This ability is trained through attentional and metacognitive exercises and practices. As this practice turns into a habit the mind is enabled with flexibility when responding to external and mental experiences. In CBCT personal growth and transformation is made possible when one can relate to one's experiences in a non-reactive manner. Non-reactivity makes it easier to notice and use the gap between stimulus and response to decide how to respond to the triggering emotion, perception or event. Through the refinement of attentional and metacognitive abilities, one can practice creating a space between stimulus and response by cultivating insight into one's mental experience through the practice of resting the mind in its natural state (an uncontrived state of mind that merely observes whatever arises in experience in a discriminative-non-judgmental way.

Observing one's inner mental life, whether on the meditation cushion or in the course of daily life, is facilitated by the development of mental stability by focusing on the breath and learning to attend to it moment by moment as it enters and leaves the body. Attentional stability and improved mental clarity provides the foundation for contemplative practice and thus is essential for the cultivation of compassion.

Another powerful condition to develop a strong appreciation of compassion and

its benefits is to attune the mind with a moment of nurturance or imagining a person or place that engenders a felt sense of being cared for, as well as a feeling of security and safety. An important preliminary practice in CBCT is to begin each meditation by taking a few moments to immerse oneself in this kind of nurturing experience. Just as there is a defense system that can be activated, humans (and other animals) also have a safety system. In the absence of threatening cues, the safety system helps one to feel greater calm and to be more open to the kind of exploration necessary if one wants to gain skills or knowledge. The safety system helps a person be less defensive, leading to better integration of internal elements such as feelings of love and compassion, an antidote to depression. And engaging the safety system helps provide appropriate balance when the defense system has been inappropriately aroused. An internal climate of safety, like a caring, supportive environment, is critically important for individual well-being, the reduction of personal suffering, and the ability to maturely interpret life events.

Additionally, any endeavor that requires a sustained effort will depend on the depth of appreciation one has for the end goal of the endeavor. This way, deepening one's personal sense of appreciation for the value of compassion and its many benefits can provide a powerful motivation that will help sustain one's effort as one works to cultivate compassion. By connecting with a sense of caring warmth and protection, it can help the mind find the inspiration to embody these qualities so that they become the source of nurturance for both self and others.

3.2 COGNITIVELY-BASED COMPASSION TRAINING AS A RESEARCH PROTOCOL

During the 2003-2004 academic year at Emory University, increasing signs of mental distress among undergraduates, including several suicides, prompted Emory student Molly Harrington to ask whether there were resources available to help young people deal with stress and depression. Based on her appeal, Geshe Lobsang Negi developed CBCT. In 2005 the Emory-Tibet Partnership and the Emory Mind-Body Program forged an innovative study to examine the impact of compassion meditation in treating depression among undergraduates.

The results of the study showed a clear correlation between the practice of compassion meditation and the prevention and reduction of depression levels in students (Pace et al., 2009; Pace et al., 2008). The promising results of this project encouraged researchers to explore future lines of research.

In addition to employing CBCT as a means of reducing stress and enhancing immune function, CBCT has been shown its efficacy in promoting prosociality and mental flourishing, and ameliorate or protect against the effects of trauma (Pace et al., 2012; Pace et al., 2013).

In a recent LoParo, et al. (2018) showed how CBCT could be considered potentially valuable intervention for African American suicide attempters. Authors showed how CBCT fostered self-compassion and mindfulness facet traits which impacted on reduction of depressive symptoms and suicidal ideation in a significant way.

At the present time, there is a growing body of new research being conducted to examine the benefits of CBCT in medical school faculty members, staff and students, nurses, cancer survivors, veterans with PTSD, HIV+ individuals, school children, and parents of autistic children.

3.3 BACKGROUND IN THE STUDY OF BREAST CANCER SURVIVAL, MINDFULNESS AND COMPASSION

BCS that have passed the initial malignancy and its treatment, still have to deal with functional, behavioral and persistent emotional difficulties, such as depression, fatigue, fear of illness recurrence and cognitive impairments (Dodds et al., 2015).

CBI can provide useful tools and resources to treat and prevent several psychological difficulties (resources for interpersonal relationships, reduction of depressive symptomatology, reduction of social anxiety, marital conflict, anger management and deal with the difficulties of being a caregiver) (Hofmann, Grossman, & Hinton, 2011). In addition, evidence points out that CBI has been associated with decreasing innate immune responses to a psychosocial stressor (Pace et al., 2009).

In a recent study done by Dodds et al., (2015), CBCT group showed significant improvements in depression features, functional impairments related to FCR, avoidance related to traumatic stress, and an increase in vitality. Although there are numerous studies on the efficacy of these interventions in healthy populations as well as clinical settings (Kirby et al., 2015), there are very few data of the benefits of CBI in cancer patients or BCS (Kirby, Tellegen, & Steindl, 2017).

3.4 NEED FOR COMPASSION AND SELF-COMPASSION ADAPTATION AND RE-DEFINITION IN LATIN COUNTRIES THROUGH LAY DEFNITION ANALYZES

There has been a great number of definitions and intents of definitions from this growing field of research. In the scientific literature it is customary to refer to the classical Western religious and philosophical contributions when trying to define compassion (Singer & Bolz, 2013). From Aristotle (Crisp, 2008) through the New Testament's Second Epistle to the Corinthians (Hughes, 1962), Plato (Pence, 1983), Hume (Solomon, 1998), to Schopenhauer (Van Der Cingel, 2009). Some other definitions have drawn from evolutionary theories and some statements made by evolutionary theorists and researchers (Ekman, 2010; Gilbert, 2010a). With the rise of MBI, these intents have been enriched by Buddhist psychology, where compassion is one of the two fundamental pillars (the other being wisdom) of human flourishing (Siegel & Germer, 2012).

Nevertheless, no literature that we know has focused on creating a definition "from the ground up" in Latin countries. This is, from what people understand by the concept of compassion and self-compassion. Even though there is initial literature on the effects of loving-kindness language exposure (Williams, Poljacik, Decety, & Nusbaum, 2017) and analysis via semi-structured interviews of understandings, experiences, and preferences of "sympathy," "empathy," and "compassion" in advanced cancer patients' (Sinclair et al., 2017) in englsih speaking contexts, we consider that little attention has been focused in analyzing the lay definition of these two concepts in spanish speaking countries.

We are not suggesting that definitions from contemplative (philosophical or religious) or scientific traditions should be excluded, but rather suggest how paying attention to the lay definitions of these two terms could enrich our understanding when approaching the study of this new emerging field of study. We are not suggesting to change the definition itself either, but rather consider "where we are starting from" when applying a contemplative program. We consider that this initial understanding of where we are starting could save time, resources and energy when explaining or training the mindsets and skillsets proposed by CBI. In addition, we believe it is important to address the reality of novelty of these concepts. We do not mean that the qualities proposed by CBI are new or novel for our culture. However, the concepts where these concepts come from may need a more refined adaptation process. Concepts such as attention, vigilant introspection, equanimity, impartiality, interdependence, altruism, love and compassion are not understood in the same way as in our culture.

For example, when consulting the Real Academy of the Spanish Language (De la Lengua Española, Real Academia, 2001), compassion is defined as "feeling of commiseration and pity for those who suffer hardship or misfortune". According to Simón (2014), this definition entails a nuance of superiority towards the one who suffers, something that is totally alien to the scientific (and historical) meaning of compassion. This author states "I am confident that, in a short space of time, the original and positive meaning of what the word compassion means will go down in the popular mind" (Simón, 2014).

With this in mind, we make a call for the need to adapt and re-define the concepts of self-compassion and compassion based on empirical evidence of what people understand by these two concepts in Latin countries.

EMPIRICAL FRAMEWORK

4 STUDY'S OBJECTIVES AND HYPOTHESES

4.1 GENERAL OBJECTIVES

The main aim of this study is to analyze the efficacy of CBCT in a RCT on a sample of BCS.

4.2 SPECIFIC OBJECTIVES

1. Examine the efficacy of CBCT in variables related to QoL (physical, social, emotional and functional domains) in CBCT Group and between CBCT group and TAU control.
2. Study the impact of CBCT in psychological symptomatology (somatic, depressive and anxious related difficulties) in CBCT Group and between CBCT group and TAU control group.
3. Observe the benefits of CBCT in psychological dimensions linked to FCR in CBCT group and between CBCT group and TAU control group.
4. Analyze if CBCT group is benefited in self-compassion, compassion and mindfulness trait facets in CBCT group and between CBCT group and TAU control group.
5. Analyze the influence of CBCT over participants' compassion and self-compassion semantic construct.
6. Study the participants' acceptance, adherence, and satisfaction with the intervention in CBCT group.

4.3 HYPOTHESES

1. Participants in the CBCT group will show improvement in variables related to QoL (physical, social, emotional and functional domains), in comparison to TAU.
2. Participants in the CBCT group will show reduction in somatic, depressive, and anxious symptomatology, in comparison to TAU.
3. Participants in the CBCT group will show a decrease in the FCR, in comparison to TAU.
4. Participants that receive CBCT intervention would experience an increase in self-compassion, compassion and mindfulness trait, in comparison to TAU.
5. Participants' semantic construction, of what is a compassionate and self-compassionate individual, will be modified in the direction of what CBI and compassion-based contemplative traditions propose after going through the CBCT program.
6. CBCT program will show high levels of acceptance, adherence, and satisfaction.

5 METHODS

5.1 SAMPLE RECRUITMENT

In order to have access to a sample of BCS, the research group from this project got in contact with the head coordinator of the psycho-oncological staff from the Fundación Instituto Valenciano de Oncología (FIVO), Dr. Rocio Romero Retes. Participants voluntarily showed interest in participating and were contacted by FIVO'S psycho-oncology staff. Most did so in response to the calls that were made through phone call and regular psychology appointment. Participants who met the inclusion criteria became part of the study.

5.1.1 Eligibility Criteria

1. Being aged between 35 and 75 years,
2. Being able to read and write using the Spanish language,
3. History of treated BC within the past 15 years,
4. Free from oncological illness
5. Not receiving any kind of chemotherapy and / or radiotherapy treatment during study.

Eligible participants were contacted by their personal psycho-oncologist either by a telephone call or at psycho-oncology appointment periodical visit to invite them to an explanatory meeting of the study.

5.1.2 Exclusion Criteria

1. Active severe mental disorders (schizophrenia, bipolar disorder, eating disorders, and major depression),
2. Substance use disorders, cognitive impairment,
3. Impaired medical condition.

Past and current psychiatric and medical history was determined by clinician assessment with the Mini International Neuropsychiatric Interview (MINI) (Lecrubier et al., 1997) Spanish version (Lobo et al., 1999).

In relation to the duration of sample recruitment, it began on January 2016 and ended on May 2017.

In terms of sample size, the minimum number of participants that should be part of each experimental condition was considered. Sample size was calculated using the G*Power software (Faul, Erdfelder, Lang, & Buchner, 2007). A total of 42 participants were estimated to be included in the study to detect a moderate effect size (Cohen's d = 0.40) on the primary outcomes, an alpha error of .05, and a statistical power of .80. A moderate effect size was expected taking into account the results of Dodds et al. (2015), where a compassion-based training in BCS (compared to a wait list) showed moderate effect size in QoL-related outcomes (depression, functional impairment, vitality/fatigue) at post-intervention. Nevertheless, as we anticipated dropouts, 14 more participants were randomized.

5.2 SAMPLE DESCRIPTION

Final sample size was composed by 56 women (100%). In terms of educational level 22 participants (39,29%) had University education, 19 (33,93%) had high school studies, 2 (3,57%) had middle school studies and the rest had elementary school studies or less (5.6%). The age range was between 39-70 years (mean age = 52.13 years of age [SD = 6.96]. Table 1 presents in greater detail these characteristics of the sample.

5.3 INSTRUMENTS OF MEASUREMENT AND EVALUATION

The evaluation protocol included both interviews, and self-report general measures. Also satisfaction, perception and acceptance measures were included to assess the utility of the program. Appendix 6 includes a table summary evaluation shows used assessment instruments, both in evaluating pretreatment, post-treatment and in follow-ups (6 months). The characteristics of such instruments are described below:

5.3.1 Socio-demographic data

These questionnaires record participants' data on age, sex, level of education, employment status, and contemplative or meditative experience (see Appendix 5).

5.3.2 Pre-intervention interview

This initial interview was done to give details about the program and explore specific issues related to the participant's daily life. In this interview the following data was offered and collected: 1) duration of the program, b) general view of CBCT protocol, c) elaborate a conceptual frame about the program, d) functional difficulties due to pain or other physical discomfort, e) family and social background and history. The duration of the interview was variable, although the average time was 90 minutes.

5.3.3 Interview

The Mini International Neuropsychiatric Interview [(MINI) (Lecrubier et al., 1997)Spanish version (Lobo et al., 1999)] is a short structured diagnostic interview, developed jointly by psychiatrists and clinicians in the United States and Europe, for DSM-IV and ICD-10 psychiatric disorders. With an administration time of approximately 15 minutes, it was designed to meet the need for a short but accurate structured psychiatric interview for multicenter clinical trials and epidemiology studies and to be used as a first step in outcome tracking in nonresearched clinical settings.

5.3.4 Self-Administered instruments

Functional Assessment of Cancer Therapy-BC [FACT-B+4, (Brady et al., 1997); Spanish validation (Belmonte Martinez et al., 2011)]. It assesses the health related QoL in BC. It consists of 37 items and respondents are asked to indicate on a scale from 0 (not at all) through 4 (very much). FACT-B+4 is composed by five factors: physical QoL; social / family and social QoL; emotional QoL; functional QoL; and other concerns. In present study, Cronbach's α from 0.74 to 0.86 for the 5 factors was observed.

Fear of Cancer Recurrence Inventory [FCRI (Simard & Savard, 2009)]. It assesses psychological stress and functional difficulties linked to cancer recurrence fear, as well dimensions of associated cognitions. FCRI consists of 42 items grouped into seven components (64% of the variance). However, we will only use 4 of these 7 factors:

(1) Triggers factor refers to potential stimuli activating FCR; (2) Psychological Distress as to emotional disturbances associated with fear cancer recurrence; (3) Coping strategies factor which evaluates the individuals strategies to cope with FCR; (4) Insight factor refers to self-criticism toward FCR intensity. Ranges of Cronbach's α from 0.76 to 0.95 were shown for the four subscales in this study's sample.

Brief Symptom Inventory [BSI-18 (Derogatis, 2001); Spanish version (Andreu et al., 2008)]. It measures general psychological distress, and consists of 18 descriptions of physical and emotional complaints; respondents are asked to indicate on a scale from 0 (not at all) through 4 (very much) to what extent they are troubled by the complaints. This scale is composed by 3 factors: somatization, depression and general anxiety. A General Symptomatology Index (GSI) is also calculated and refers to the sum of all items. In the present study, Cronbach's α for the 3 subscales varied from 0.83 to 0.91.

Self-Compassion Scale-Short Form [SCS-SF;(Raes, Pommier, Neff, & Van Gucht, 2011); Spanish version (Garcia-Campayo et al., 2014)]. It assesses overall self-compassion (total score) and components of self-compassions across six conceptually facets: common humanity, mindfulness, self-judgment, over-identification, isolation and self-kindness. The short version is composed by 12 items rated on a Likert scale from 1 (almost never) to 5 (almost always). Cronbach's α for present study varied from 0.67 to 0.81 for the 6 subscales.

The Compassion Scale [CS (Pommier, 2010)]. It is a 24-item scale designed to assess compassion based on the six factor model from Neff`s Self-Compassion Scale (Neff, 2003a). In this study only the Total Compassion Score was utilized. In the present sample Cronbach's α for Total Compassion Score was 0.83.

Five Facets of Mindfulness Questionnaire – short form [FFMQ-SF (Tran, Glück, & Nader, 2013); Spanish validation (Cebolla et al., 2012)]. It measures participant's Mindfulness states and traits in daily life. It consists of 20 items rated on a scale ranging from 1 (never or very rarely true) to 5 (very often or always true), which assess five factors of mindfulness: Observe, refers to the subject's capacity to pay attention to internal and external experiences such as sensations, thoughts, or emotions; Describe, measures the ability to describe events and personal responses in words; Acting with awareness, includes focusing on the activity being carried out, as opposed to behaving automatically; Non-judging of inner experience, refers to the ability to take a non-evaluative stance toward thoughts and feelings; and Non-reactivity to inner experience, allowing thoughts and feelings to come and go, without getting caught up in them or carried away by them (Baer et al., 2008). The 20 item FFMQ short form has proved to have good internal consistency in a Spanish sample. In the present sample Cronbach's α varied from 0.43 to 0.82.

Osgood's Semantic Differential [OSD (Osgood, 1952)]. Is a type of a rating scale designed to measure the connotative meaning of objects, events, and concepts. The connotations are used to derive the attitude towards the given object, event or concept. It measures the semantics or meaning of words, particularly adjectives, and

their referent concepts. The respondent is asked to choose where his or her position lies, on a scale between two polar adjectives. Semantic differentials can be used to measure opinions, attitudes and values on a psychometrically controlled scale. The Semantic Differential serves as an operational index of the representational mediation process or meaning. The construct of meaning is derived from a general conceptual scheme presented. The Semantic Differential technique employs a multidimensional approach and is considered to be relatively free of response biases. The factors and the scales for compassion and self-compassion concept are as follows: A) an evaluative factor represented by 12 scales (e.g. 1=sensitive-insensitive=7, 1=relaxed-tense=7, and 1=optimistic-pessimistic=7); B) a potency factor was represented by 10 scales (e.g. 1=strong-weak, powerful-powerless, big-small; and C) an activity factor represented by 7 scales (e.g. 1=active-passive=7, 1=fast-slow=7, and 1=fun-boring=7). In general, the test-retest reliability is .85. The three factors account for about 60 per cent of the total variance, and about 70 per cent of the common variance is due to the evaluative factor.

5.3.5 Satisfaction, acceptance and adherence to intervention program

CBCT Evaluation Survey: Is composed of 8 items to evaluate: assistance, time of home practice (minutes), whether participants practiced with audio recordings or not, frequency of practice per day through meditation journal, whether participants intend to attend to future *CBCT* Program courses or not, whether participants would recommend *CBCT* Program or not, satisfaction with *CBCT* Program instructor's performance and whether particpants intend to continue with daily practice at home.

5.3.6 Assessment timings

Three moments of evaluation were established. One before intervention had begun, another after protocol and 6-month-follow-up.

5.4 DESIGN AND EXPERIMENTAL CONDITIONS

A RCT design between groups of repeated measurements with two experimental conditions. This RCT compares the benefits of a CBCT intervention versus a TAU. TAU consisted of individual psychological counseling offered by the clinic to cancer survivors. Therefore, the experimental conditions are:

Intervention Program administered by CBCT Instructor. Participants assisted to an eight week CBCT Program with one weekly two hour long sessions. At first session participants were given a personal password to have access to materials and audio recordings to continue their practice at home.

TAU control group continued with their normal rehabilitation program, attendance at briefings given at FIVO, pharmacological treatment, and psychological counseling. TAU participants were offered the CBCT course at the end of research.

With regard to participants flow throughout the research process (See Figure 1) a total of 95 people were contacted. 23 of them showed no interest in the study. All interested people were contacted to explain what their participation in the study consisted of. After this call, 3 people were not included for not meeting with eligibility criteria. 2 of them for Major Depressive Disorder and 1 for Obsessive-Compulsive Disorder. Moreover, 13 people could not continue study for schedule incompatibility. Thus, 56 people met the requirements to participate in the study and were randomly assigned to the two possible experimental conditions (CBCT, n= 28; TAU, n = 28,). During the implementation of the program there were 3 dropouts in CBCT group and 3 dropouts in TAU group. Moreover, 3 more dropouts were registered at six-month-follow-up.

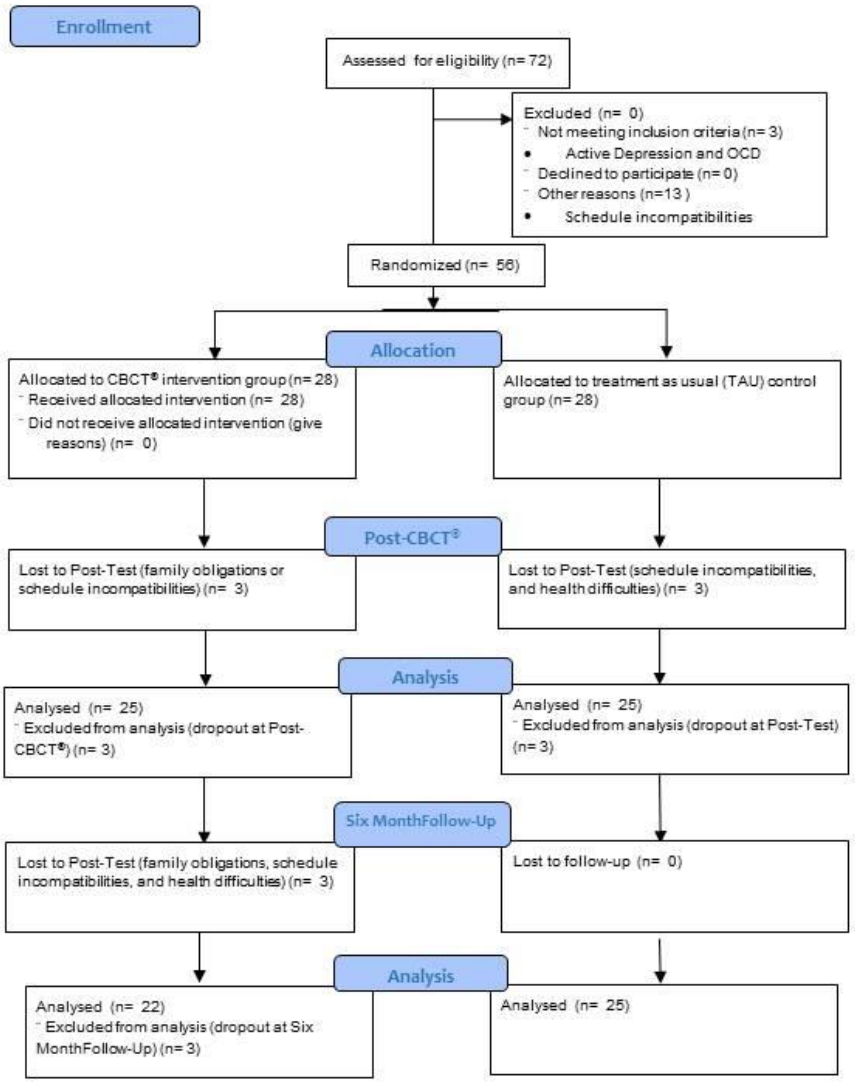

Figure 1. CONSORT 2010 flow diagram for randomized controlled trial of CBCT versus TAU condition. Abbreviations: CBCT, Cognitively-Based Compassion Training; OCD, obsessive compulsive disorder.

5.5 COGNITIVELY-BASED COMPASSION TRAINING PROTOCOL

The first step before making the intervention utilizable for this research was to adapt. Adaptations regarding language and other cultural differences in written materials were considered. Audio recordings for home practice were also translated and adapted to this research needs.

The steps of the program consist of six distinct modules. The first to modules can be placed under the heading of what has popularly been called “mindfulness practices”. The following modules can be placed into the analytical meditations category. The program is organized in the following way:

1. Developing Attentional Stability and Mental Clarity: The foundation for the practice of compassion is the cultivation of a basic degree of refined attention and mental stability. One of the basic requirements for this module is the deliberate intention for cultivating a state of relaxation, stillness and alertness.

2. Cultivating Insight into the Nature of Mental Experience: the stabilized mind is then employed to gain insight into the nature of the inner world of thoughts, feelings, emotions and reactions through non-judgmental awareness and resulting into a mental state of non-reactivity and equanimity.

3. Cultivating Self-Compassion: participants tune in their innate aspirations for happiness and well-being as well as those for freedom from unhappiness and dissatisfactions. This is, progressively realizing which mental states contribute to well-being and which ones bring about anxiety, disappointment and dissatisfaction. Afterwards, participants learn to bring to mind the determination and skills to transcend the mental patterns and emotional states that promote distress.

4. Developing Equanimity and Impartiality: this module focuses on creating balanced relationships with others promoting the initial mental and emotional conditions for constructive social connections. This is relevant due to the social disconnection that human beings experience when going through traumatic and stressful life events.

5. Developing Appreciation, Affection, and Empathy for Others: social connection and gratitude is fostered through the emotional insight of interdependence. This prevents the feeling of isolation. Social connection and gratitude weakens self-centeredness and strengthens endearment and affection towards others that serves as the catalyst for compassion. Endearment and affection fosters a perception of the world based on kindness and not on threat.

6. Realizing Engaged Compassion: by resting in a compassionate state of mind, participants cultivate the essential skillsets and mindsets for interacting in a proactive way with personal and social difficulties preventing burnout.

The six modules that build this program are distinct, yet integrated, and each constructs upon the previous. Each session included lecture, discussion, experiential exercises, and guided meditations. Over the course, participants were led through the entire series of integrated, cumulative meditations – and provided with guided recordings for each module to support the systematic development of compassion. In between class sessions, participants were encouraged to meditate daily using the recorded meditations and to gradually increase both the length of time for an individual meditation session as well as the cumulative amount of practice time.

5.6 THERAPISTS, FACILITATORS AND RESREACH STAFF

A total of 3 psychologists participated in the adaptation, implementation and elaboration of this study. All of them were trained in the implementation of the MINI, had experience in clinical evaluation, clinical research and application of third generation psychological intervention programs. CBCT facilitator and instructor was accredited and supervised by Emory University and the Center for Contemplative Science and Compassion-Based Ethics in Emory University staff.

5.7 PROCEDURE

The study was approved by FIVO's Clinical Research Ethics Committee (December 2015) and was conducted in compliance with the study protocol, following the CONSORT statement (Consolidated Standards of Reporting Trials), the Declaration of Helsinki, and good clinical practice. The trial was registered at the US National Institute of Health at ClinicalTrials.gov (#NCT 03305952) on October 9th, 2017.

Telephone calls started on January 2016 informing the launch of a study focused on the cultivation of positive emotions for BCS. The people interested in the study were listed at the facilities of psycho-oncology at FIVO. Each person who showed interest in participating was assigned for interview and pre-test evaluation.

During interview, the techniques and tools that constituted the program explained to each participant. It was also explained how this techniques and tools would allow them to increase their capacity to resist and cope with daily difficulties and enhance positive emotions.

During the interview, the presence or absence of the inclusion and exclusion criteria of the study were also delimited. This interview was conducted in person in all cases. In this interview a staff member explained the study and the participant signed informed consent (voluntary participation, different experimental conditions, and commitment to complete questionnaires and consent to the use of data for research purposes) (See appendix 2 and appendix 3). If the participant agreed to these conditions, he / she would fill in a room a series of questionnaires.

All participants who met the inclusion criteria after the initial interview became part of the study and were assigned randomly to one of two experimental conditions (CBCT or TAU).

After the 8 sessions of the program, the participants of both groups performed the post-treatment evaluation with the same self-report questionnaires as in the pre-treatment evaluation. In addition, they filled out a survey related to satisfaction, acceptance and adherence to intervention program.

Finally, 6 months after the post-treatment evaluation, team members contacted participants of both conditions to fill out the measurement instruments included in the evaluation protocol.

After the TAU group 6 month waiting period, participants were asked if they wished to participate in the intervention program. Recruitment was finalized on May 2017.

During June 2017, all the questionnaires were sent anonymously to the Universitat de València Psychology Department, where database was processed through synthesis and tabulation with SPSS 23 statistical program.

5.8 DATA ANALYZES

Group differences at baseline on demographic characteristics and clinical variables were analyzed using independent-samples *t*-tests for continuous data and chi-square tests for categorical variables. Intent-to-treat (ITT) mixed models analyzes without any ad hoc imputation were used to handle missing data (Chakraborty & Gu, 2009). This approach is appropriate for RCTs with multiple time points and pre-to post-only designs and does not assume that the last measurement is stable (the last observation carried forward assumption). This method is conducted using all available observations (Gueorguieva & Krystal, 2004; Salim, Mackinnon, Christensen, & Griffiths, 2008). For each outcome measure, a linear mixed-model was implemented with *time* (pre, post and 6-month follow-up) as within-group factor and *group* (CBCT and TAU) as between-group factor using the MIXED procedure with one random intercept per subject. An identity covariance structure was specified to model the covariance structure of the random intercept. Significant effects were followed up with pairwise comparisons. Effect sizes (Cohen's *d;* 95% CI) were calculated for within- and between-group comparisons (Botella & Meca, 2015; J. Cohen, 1988; Cumming, 2013; Cumming & Calin-Jageman, 2016).

For the Semantic evaluation of Compassion and Self-Compassion concepts analyzes, separate 2 x 2 repeated-measures of analysis of variance (ANOVA) for within-group comparisons. Within-group's effect size was reported by Cohen's *d* (*d*; 95% CI). A univariate ANCOVA test (controlling pre data) was used to analyze the post-test and 6 months follow-up between CBCT and TAU groups. Between-group's effect size was

reported by $\eta^2 p$. All statistical analyzes were performed using IBM SPSS version 23 for Windows.

6 RESULTS

6.1 DIFFERENCES BETWEEN THE TWO EXPERIMENTAL CONDITIONS BEFORE TREATMENT

There were no significant differences between groups in all demographic characteristics or outcome measures at baseline, except for clinical severity (oncological stage when at first diagnosed) and Insight factor from the FCRI ($F [1, 97.17] = 4.176$; $p < .05$). As for clinical severity when at first diagnosed, the CBCT group showed a larger number of participants with Oncological Stage III when compared to TAU group. CBCT group also showed larger scores at Insight factor when compared to TAU group.

Table 1. Sociodemographic and clinical data in CBCT and WL groups

Sociodemographic and clinical data	CBCT (n=28)	WL (n=28)	*Student* t / χ^2	*p*
Age (in years)	51.64 (6.87)	52.63 (7.16)	0.52	0.60
Time since first diagnosis (years)	11.32 (1.44)	10.46 (2.90)	-1.40	0.17
Oncological state at first diagnosis			18.49	0.047
I	1 (3.6)	3 (10.7)		
II	13 (46.4)	18 (64.3)		
III	14 (50)	7 (25)		
IV	---	---		
Breast Cancer Treatments			41.48	0.21
Partial mastectomy	5 (17.9)	7 (25)		
Total mastectomy	17 (60.7)	12 (42.9)		
Radiotherapy	19 (67.9)	18 (64.3)		
Chemotherapy	25 (89.3)	23 (82.1)		
Other	14 (50)	18 (64.3)		
Educational level			2.12	0.55
Elementary school or less	7 (25)	6 (21.40)		
Middle School	1 (3.6)	1 (3.60)		
High school	7 (25)	12 (42.9)		
University Studies or more	13 (46.4)	9 (32.1)		
Employment status			1.12	0.77
Employed	17 (60.7)	18 (64.3)		
Unemployed	1 (3.6)	0 (0)		
Retired	4 (14.3)	5 (17.9)		
Off work	6 (21.4)	5 (17.9)		

6.2 EFFICACY IN PRE-POST AND FOLLOW UP EVALUATION.

Next, we present the data related to the efficacy of CBCT in different domains of quality of life, symptomatology, and psychological dimensions linked to FCR, self-compassion, compassion, and mindfulness facets.

6.2.1 Primary Outcomes

6.2.1.1 Physical, Social, Emotional and Functional Quality of Life

Despite the fact that no time x group effect was observed in any of the health related QoL subscales that compose FACT-B+4 (all $p > .05$), a time x group tendency was observed for social/family QoL ($F [2, 94.758] = 2.710$, $p = .072$) where participants allocated to the CBCT group scored somewhat higher than the TAU control group. Results from within-group comparisons revealed a significant pre-to-post change for emotional and general QoL in the CBCT group with moderate effect sizes (-.56 and -.46, respectively). No significant changes were found in TAU (Table 2).

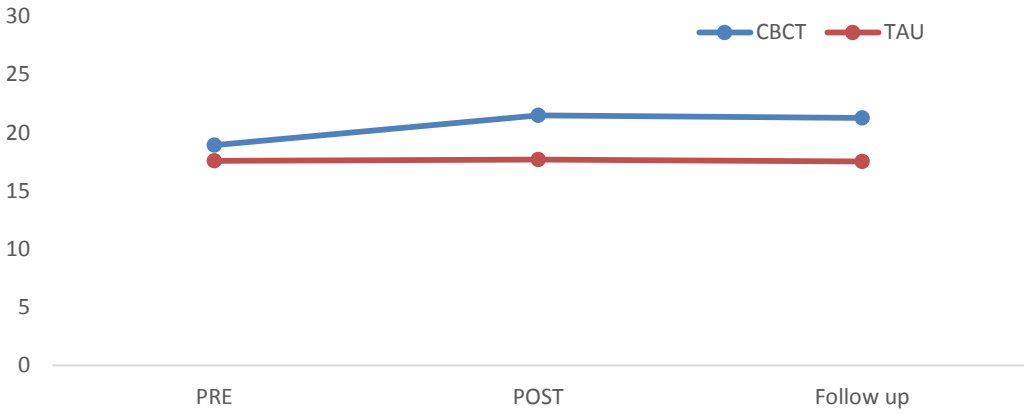

Figure 2. Physical Quality of Life Mean Scores in CBCT and TAU groups

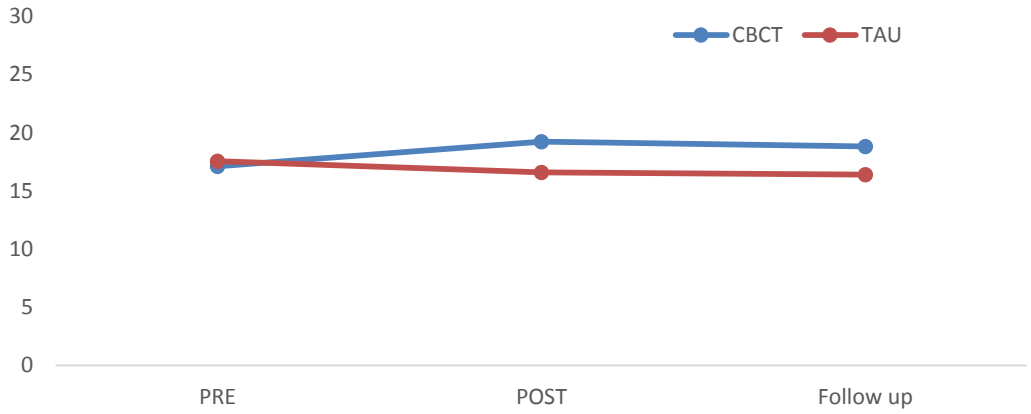

Figure 3. Family/Social Quality of Life Mean Scores in CBCT and TAU groups

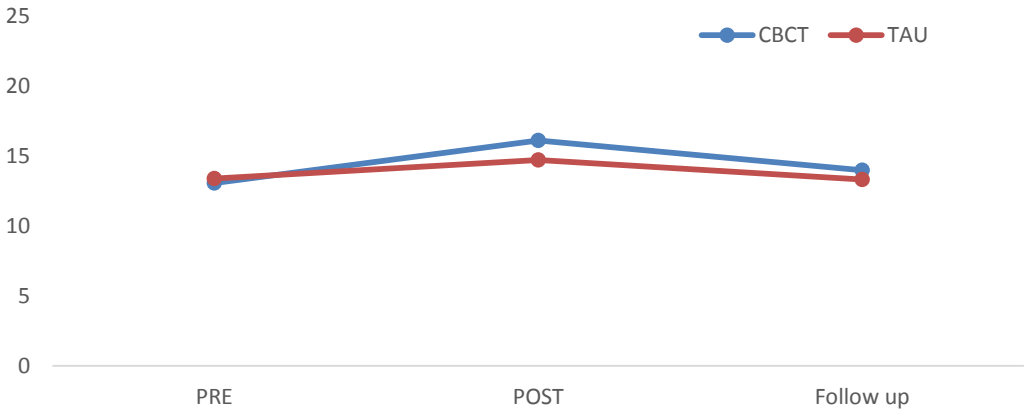

Figure 4. Emotional Quality of Life Mean Scores in CBCT and TAU groups

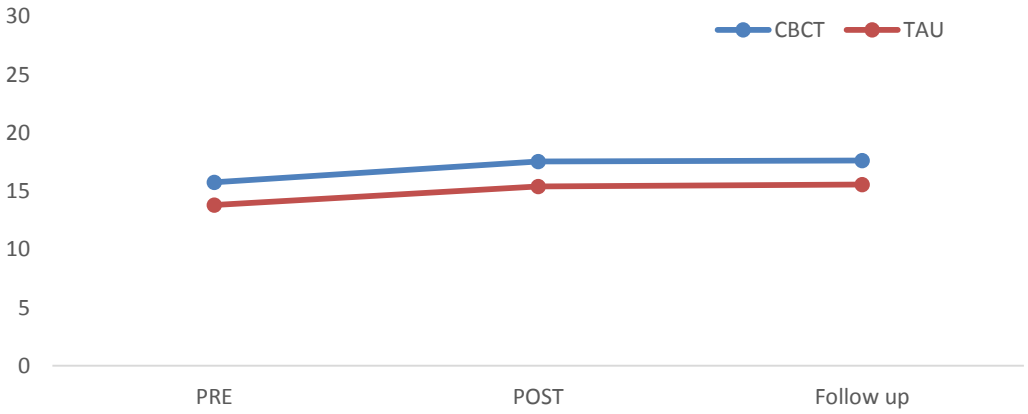

Figure 5. Functional Quality of Life Mean Scores in CBCT and TAU groups

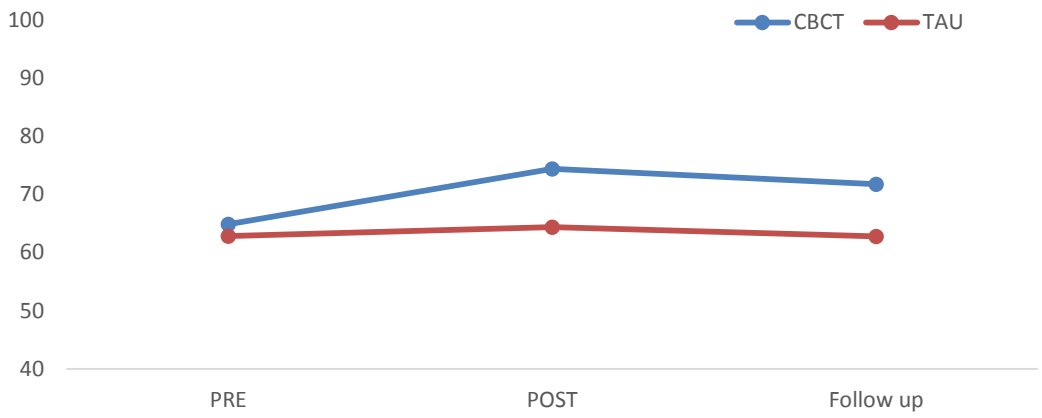

Figure 6. General Quality of Life Mean Scores in CBCT and TAU groups

Table 2. Within-group comparisons and effect sizes at pre, post and 6-month follow-up for Physical, Social, Emotional, Functional and General Quality of Life measured with the Functional Assessment of Cancer Therapy for BC (FACT-B+4).

	CBCT					TAU				
				Pre vs. Post	*Pre vs. FW*				Pre vs. Post	*Pre vs. FW*
	Pre (*n* = 28)	Post (*n* = 26)	Follow-up (*n* = 22)	Mean dif. *d* [CI 95%]	Mean dif. *d* [CI 95%]	Pre (*n* =28)	Post (*n* = 25)	Follow-up (n =25)	Mean dif. *d* [IC 95%]	Mean dif. *d* [IC 95%]
Physical	18.93 (5.70)	21.50 (3.93)	21.27 (4.09)	-2.24 -.44 [-.87, -.01]	-2.20 -.40 [-.89, .09]	17.57 (5.96)	17.68 (6.16)	17.52 (5.34)	-.08 -.02 [-.24, .20]	.07 .01 [-.35, .36]
Social	17.11 (6.05)	19.23 (5.51)	18.82 (5.79)	-1.81 -.34 [-.65, -.03]	-1.12 -.27 [-.59, .04]	17.56 (5.46)	16.60 (5.39)	16.40 (5.07)	.86 .17 [-.07, .41]	1.06 .21 [-.14, .55]
Emotional	13.07 (5.26)	16.12 (4.09)	14.00 (4.69)	-2.84** -.56 [-.92, -.20]	-.68 -.17 [-.56, .22]	13.39 (4.94)	14.72 (4.63)	13.32 (5.32)	-1.33 -.26 [-.46, -.07]	.07 .01 [-.40, .43]
Functional	15.75 (6.10)	17.54 (3.20)	17.64 (4.61)	-1.55 -.29 [-.72, .15]	-1.68 -.30 [-.76, .16]	13.82 (5.68)	15.40 (4.39)	15.56 (4.81)	-1.41 -.27 [-.55, .01]	-1.57 -.30 [-.75, .16]
General	64.86 (20.04)	74.38 (11.48)	71.73 (15.45)	-8.45* -.46 [-.82, -.10]	-5.73 -.33 [-.73, .06]	62.85 (15.86)	64.40 (14.73)	62.80 (17.63)	-1.60 -.09 [-.33, .14]	.00 .00 [-.40, .41]

Note: Mean and standard deviation (SD) are represented. Mean dif. Mean differences. d. Cohen's d. CI. Confidence Interval. FW = 6-months follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * p < .05, ** p < .01, *** p < .001

Table 3. Between-group comparisons and effect sizes at post- and 6-month follow-up for Physical, Social, Emotional, Functional and General Quality of Life measured with the Functional Assessment of Cancer Therapy for BC (FACT-B+4).

	CBCT vs. TAU			
	Post		Follow-up	
	Mean dif.	*d* [95% CI]	Mean dif.	*d* [95% CI]
Physical	3.02*	.73 [.16, 1.30]	3.13	.77 [.18, 1.36]
Social	1.38	.48 [-.08, 1.03]	.88	.44 [-.14, 1.02]
Emotional	.32	.32 [-.24, .87]	-.44	.13 [-.44, .71]
Functional	1.72	.55 [-.01, 1.11]	1.69	.43 [-.15, 1.01]
General	6.52	.75 [.18, 1.31]	5.40	.53 [-.06, 1.11]

Note: Mean dif. Mean differences. d. Cohen's d. CI. Confidence Interval. FW = 6-months follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * $p < .05$, ** $p < .01$, *** $p < .001$

6.2.1.2 Psychological Dimensions Related to Cancer Recurrence Fear

Psychological Stress factor from the FCRI showed significant time x group interaction (F [2, 96.863] = 3.521, $p < .05$). No significant interaction effects were found for any other of the FCRI factors (all $p > .05$). Within-group comparisons showed significant pre-post and pre-to-follow-up changes for psychological stress in CBCT group with effects sizes of .68 and .49, respectively. No significant changes were found in TAU group (Table 6).

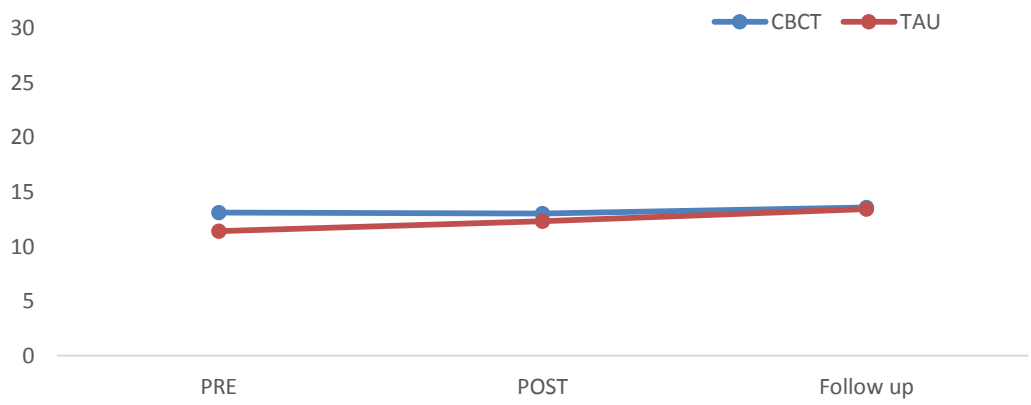

Figure 7. Triggers due to fear of illness recurrence in CBCT and TAU groups

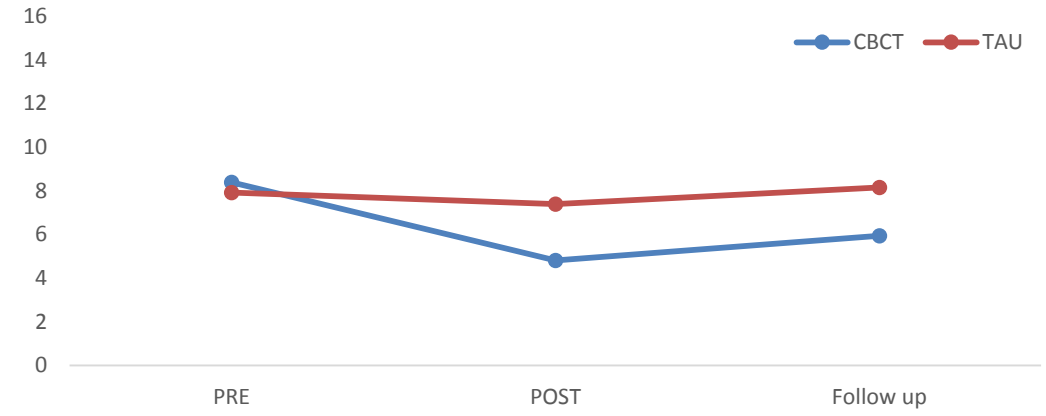

Figure 8. Stress due to fear of illness recurrence in CBCT and TAU groups

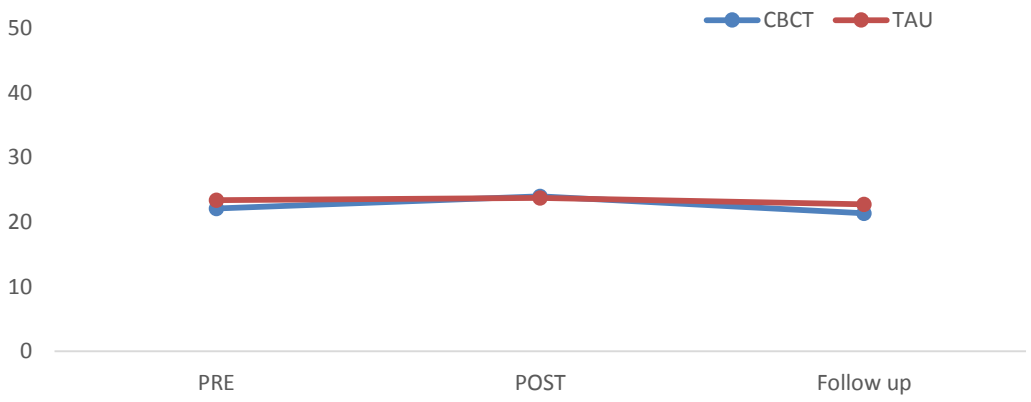

Figure 9. Fear of illness recurrence Coping Strategies in CBCT and TAU groups

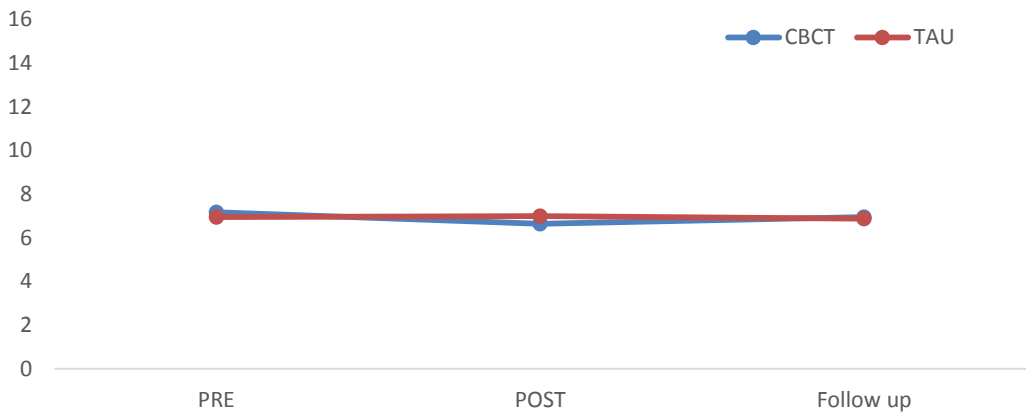

Figure 10. Fear of illness recurrence Insight in CBCT and TAU groups

Table 4. Within-group comparisons and effect sizes at pre, post and 6-month follow-up for Psychological Dimensions Related to Cancer Recurrence Fear (Triggers, Psychological Stress, Coping Strategies, and Insight) measured with the FCRI

	CBCT					TAU				
				Pre vs. Post	*Pre vs. FW*				Pre vs. Post	*Pre vs. FW*
	Pre (n = 28)	Post (n = 26)	Follow-up (n = 22)	Mean dif. *d* [CI 95%]	Mean dif. *d* [CI 95%]	Pre (n =28)	Post (n = 25)	Follow-up (n =25)	Mean dif. *d* [IC 95%]	Mean dif. *d* [IC 95%]
Triggers	13.11 (9.30)	13.04 (8.12)	13.59 (9.28)	.00 .01 [-.32, .33]	-.49 .14 [-.32]	11.43 (8.81)	12.32 (8.98)	13.44 (7.42)	-1.08 -.10 [-.27, .08]	-2.20 -.22 [-.47, .03]
Stress	8.39 (5.12)	4.81 (3.43)	5.95 (4.50)	3.41*** .68 [.36, 1.00]	2.34* .46 [.06, .86]	7.93 (4.45)	7.40 (3.96)	8.16 (4.05)	.57 .12 [-.14, .37]	-.20 -.05 [-.41, .31]
Coping	22.11 (5.41)	23.96 (3.84)	21.36 (4.75)	-1.61 -.33 [-.89, .22]	1.07 .13 [-.27, .54]	23.39 (5.69)	23.72 (6.26)	22.76 (4.56)	-.08 -.06 [-.26, .15]	.88 .11 [-.22, .44]
Insight	7.18 (5.29)	6.65 (4.91)	6.95 (5.20)	.43 .10 [-.11, .31]	.12 .04 [-.14, .22]	6.96 (5.05)	7.00 (4.75)	6.88 (3.52)	-.04 -.01 [-.23, .22]	.08 -.02 [-.27, .30]

Note: Mean and standard deviation (SD) are represented. Mean dif. Mean differences. d. Cohen's d. CI. Confidence Interval. FW = 6-months follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * p < .05, ** p < .01, *** p < .001

Table 5. Between-group comparisons and effect sizes at post- and 6-month follow-up for Psychological Dimensions Related to Cancer Recurrence Fear (Triggers, Psychological Stress, Coping Strategies, and Insight) measured with theFCRI

	CBCT vs. TAU			
	Post		Follow-up	
	Mean dif.	*d* [95% CI]	Mean dif.	*d* [95% CI]
Triggers	1.90	.08 [-.47, .63]	1.273	.02 [-.56, .59]
Stress	-1.66	-.76 [-1.33, -.19]	-1.35	-.51 [-1.09, .07]
Coping	.23	.05 [-.50, .59]	1.49	-.30 [-.87, .28]
Insight	1.82	-.07 [-.62, .48]	2.25	.02 [-.56, .59]

Note: Mean dif. Mean differences. d. Cohen's d. CI. Confidence Interval. FW = 6-months follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * $p < .05$, ** $p < .01$, *** $p < .001$

6.2.2 Secondary Outcomes

6.2.2.1 Psychological Symptomatology

In relation to symptomatology, no significant time x group effect was observed for any of the BSI-18 factors (all $p > .05$). However, within-group comparisons revealed significant pre-to-post and pre-to-follow-up improvements for depressive and general distress symptomatology in the CBCT group with moderate effect sizes (Cohen's *d* ranging from .44 to .55, respectively), and no significant changes were observed in TAU group (Table 4).

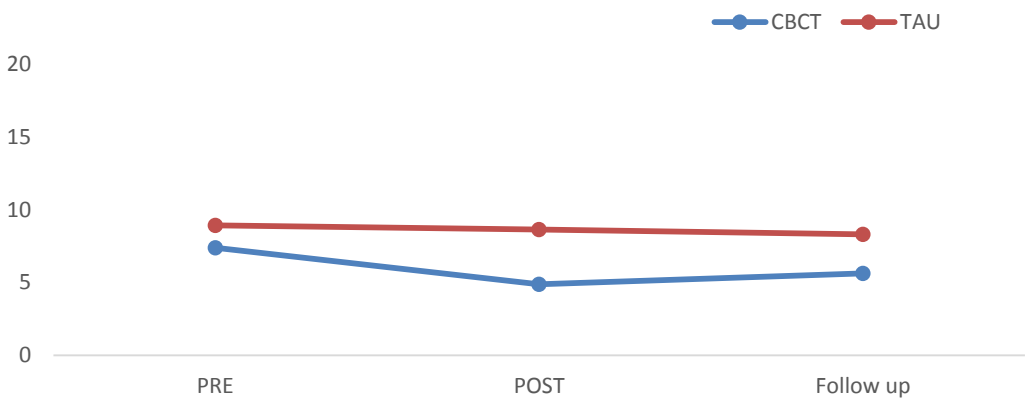

Figure 11. Physical Symptomatology Mean Scores in CBCT and TAU groups

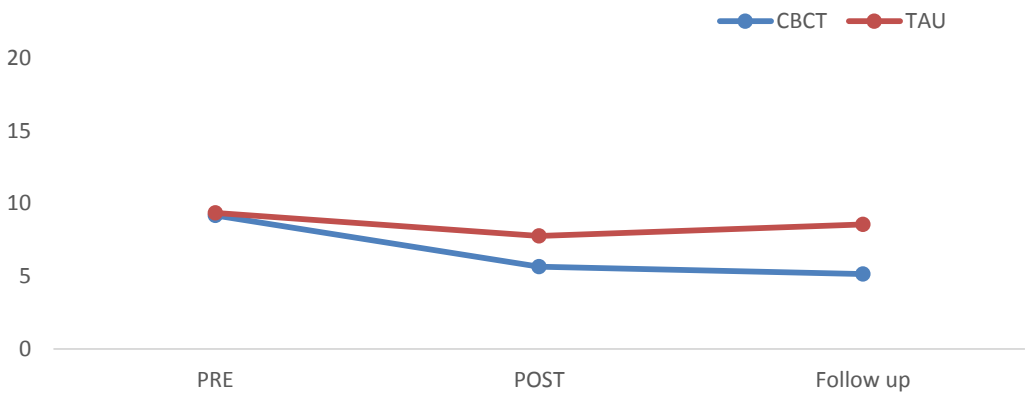

Figure 12. Depressive Symptomatology Mean Scores in CBCT and TAU groups

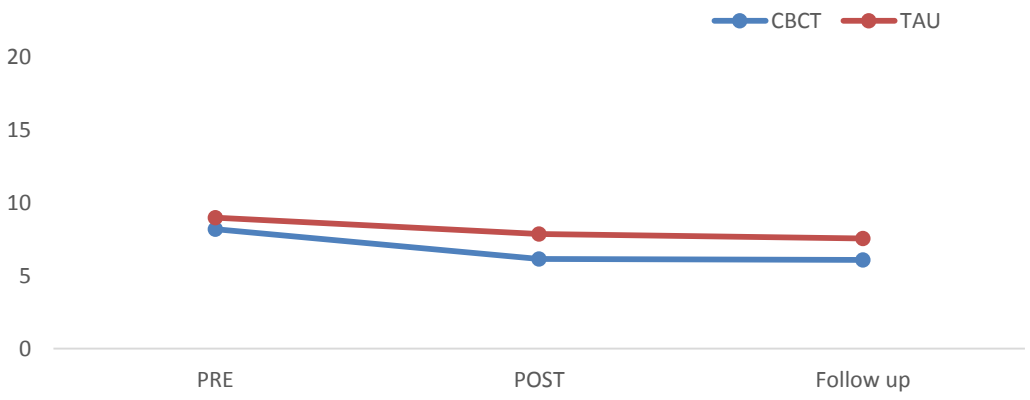

Figure 13. Anxious Symptomatology Mean Scores in CBCT and TAU groups

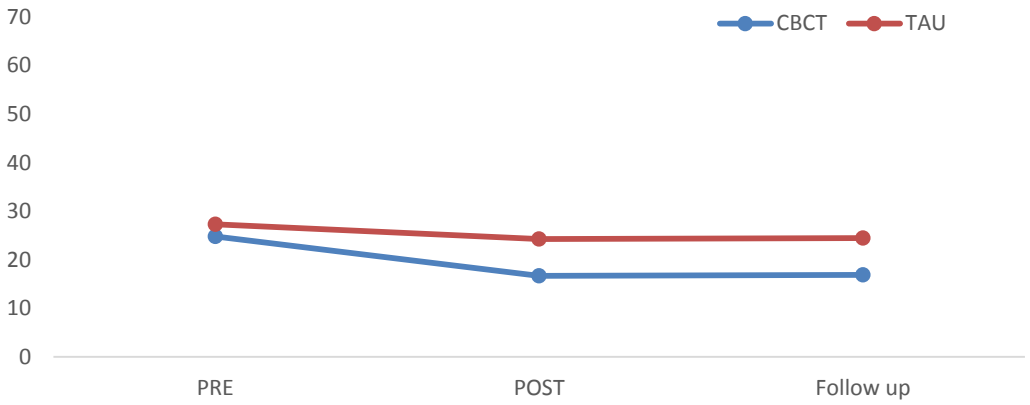

Figure 14. General Symptomatology Index scores in CBCT and TAU groups

Table 6. Within-group comparisons and effect sizes at pre, post and 6-month follow-up for Psychological Well-Being (Somatic, Depressive, Anxiety and General Symptoms) measured with the Brief Symptom Inventory (BSI-18).

	CBCT					TAU				
				Pre vs. Post	*Pre vs. FW*				Pre vs. Post	*Pre vs. FW*
	Pre (n = 28)	Post (n = 26)	Follow-up (n = 22)	Mean dif. *d* [CI 95%]	Mean dif. *d* [CI 95%]	Pre (n =28)	Post (n = 25)	Follow-up (n =25)	Mean dif. *d* [IC 95%]	Mean dif. *d* [IC 95%]
Somatic	7.39 (5.87)	4.88 (4.04)	5.64 (4.18)	2.00 .42 [.11, .72]	1.53 .29 [-.16, .74]	8.93 (5.47)	8.64 (5.70)	8.32 (5.03)	.31 .05 [-.17, .27]	.63 .11 [-.24, .46]
Depression	9.18 (7.13)	5.65 (5.27)	5.14 (5.19)	2.91* .49 [.11, .87]	3.55* .55 [.13, .97]	9.36 (6.24)	7.76 (6.54)	8.56 (5.87)	1.68 .25 [.00, .50]	.88 .12 [-.16, .41]
Anxiety	8.21 (5.93)	6.15 (5.01)	6.09 (5.38)	1.69 .34 [-.05, .73]	1.96 .35 [-.12, .81]	9.00 (6.51)	7.88 (5.94)	7.56 (5.49)	1.27 .17 [-.02, .35]	1.59 .21 [-.10, .53]
General	24.79 (17.55)	16.69 (13.12)	16.86 (13.12)	6.51* .45 [.10, .79]	6.98* .44 [.00, .88]	27.29 (16.84)	24.28 (16.74)	24.44 (15.26)	3.28 .17 [-.03, .37]	3.12 .16 [-.14, .47]

Note: Mean and standard deviation (SD) are represented. Mean dif. Mean differences. d. Cohen's d. CI. Confidence Interval. FW = 6-months follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group.* p < .05, ** p < .01, *** p < .001

Table 7. Between-group comparisons and effect sizes at post- and 6-month follow-up for Psychological Well-Being (Somatic, Depressive, Anxiety and General Symptoms) measured with the Brief Symptom Inventory (BSI-18).

	CBCT vs. TAU			
	Post		Follow-up	
	Mean dif.	*d* [95% CI]	Mean dif.	*d* [95% CI]
Somatic	3.02*	.73 [.16, 1.30]	3.13*	.77 [.18, 1.36]
Depression	1.38	.48 [-.08, 1.03]	.88	.44 [-.14, 1.02]
Anxiety	.32	.32 [-.24, .87]	-.44	.13 [-.44, .71]
General	1.72	.55 [-.01, 1.11]	1.69	.43 [-.15, 1.01]

Note: Mean dif. Mean differences. d. Cohen's d. CI. Confidence Interval. FW = 6-months follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group.* p < .05, ** p < .01, *** p < .001

6.2.2.2 Self-Compassion and Compassion Facets

Regarding self-compassion questionnaire, a significant time by group interaction was yielded for self-kindness (F [2, 97.453] = 5.769, $p < .01$), common humanity (F [2, 98.323] = 6.161, $p < .01$), and self-compassion overall score (F [2, 96.277] = 5.423, $p < .01$). Overall, participants scored higher on those measures at post- and follow-up time compared to TAU, although no significant differences were found except for self-kindness indicating that CBCT scored significantly higher compared to TAU at 6-month follow-up ($p < .05$) (Cohen's $d = .94$, 95% CI [.34, 1.55]). Within-group analyzes showed significant pre-to-post changes for self-kindness, self-judgment, common humanity, over identification, and self-compassion overall scores in the CBCT group (Table 8). These changes were maintained at follow-up for all those outcomes, except for over identification subscale. In TAU group, non-significant changes were found.

For Compassion measure, results showed no significant time x group effect. Within-group comparisons revealed a significant pre-to-post change in CBCT group with moderate effect size ($d = .75$), and non-significant change in TAU (Table 8).

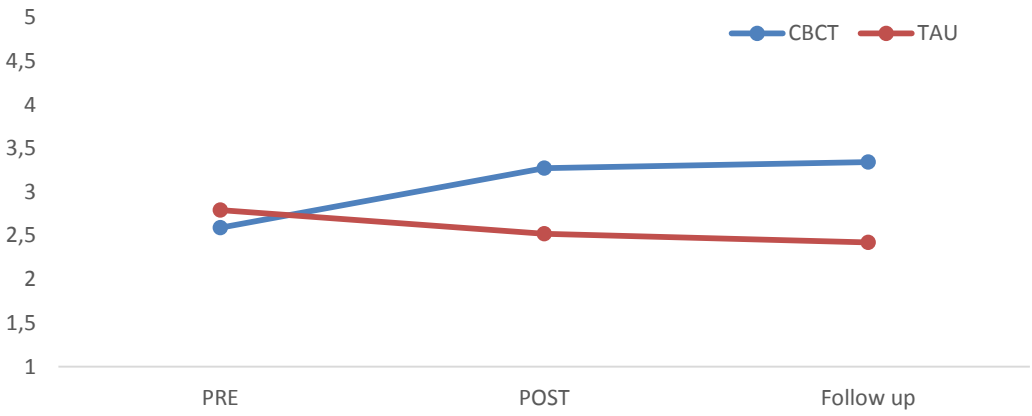

Figure 15. Self-Kindness Scores In CBCT and TAU Groups

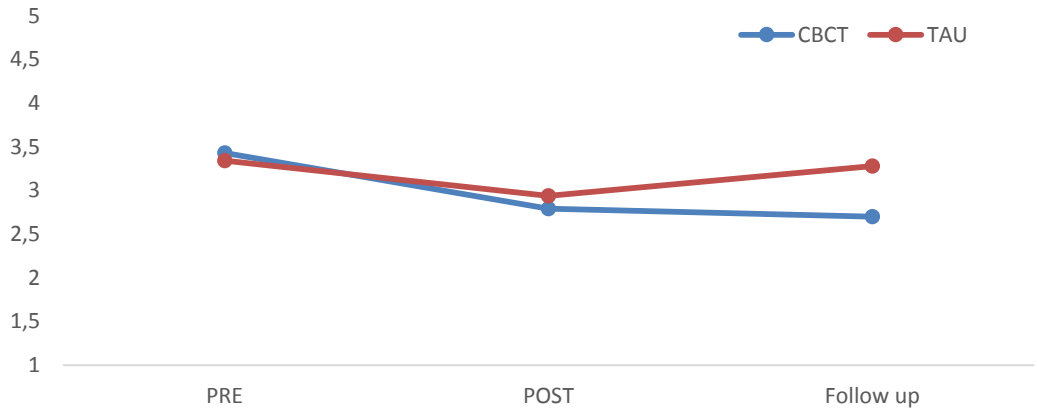

Figure 16. Self-judgment scores in CBCT and TAU groups

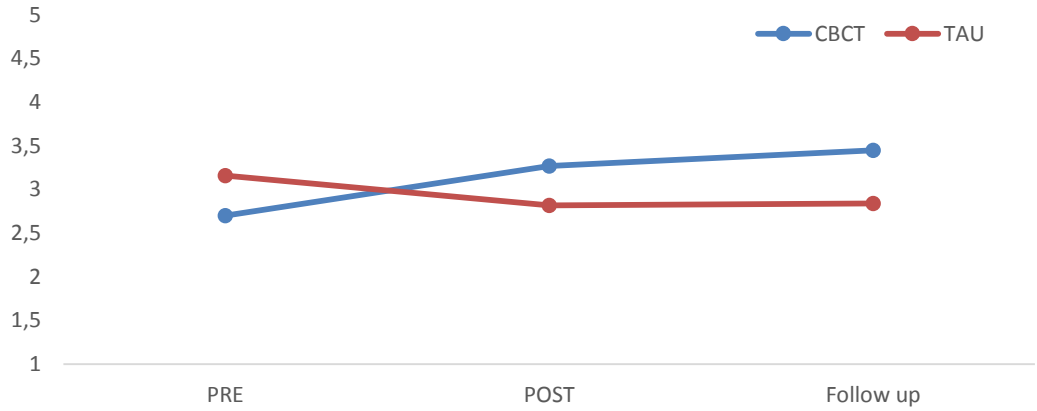

Figure 17. Common Humanity scores in CBCT and TAU groups

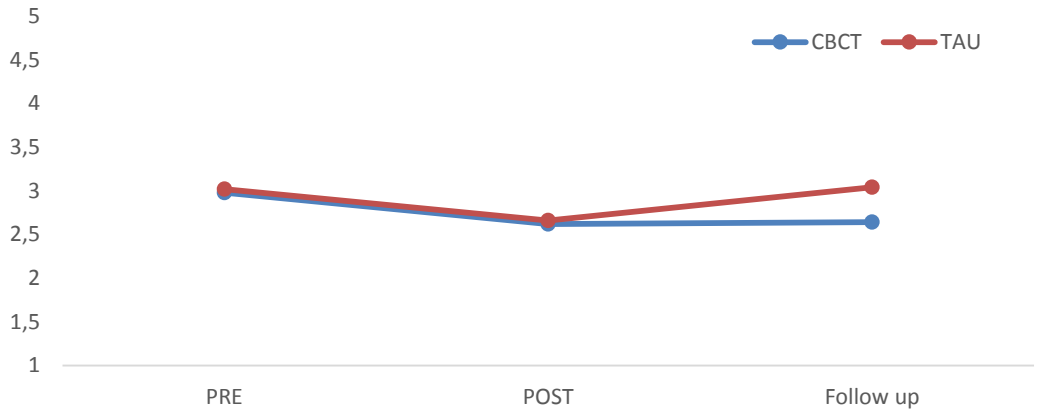

Figure 18. Isolation scores in CBCT and TAU groups

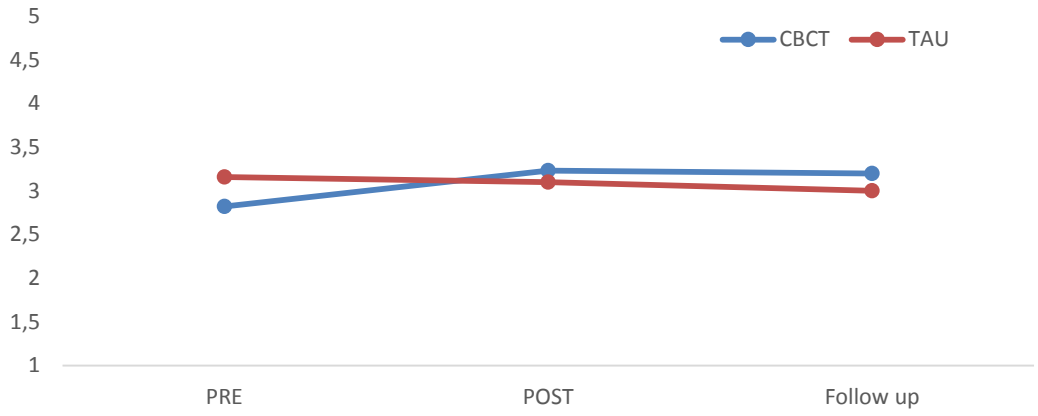

Figure 19. Mindfulness scores in CBCT and TAU groups

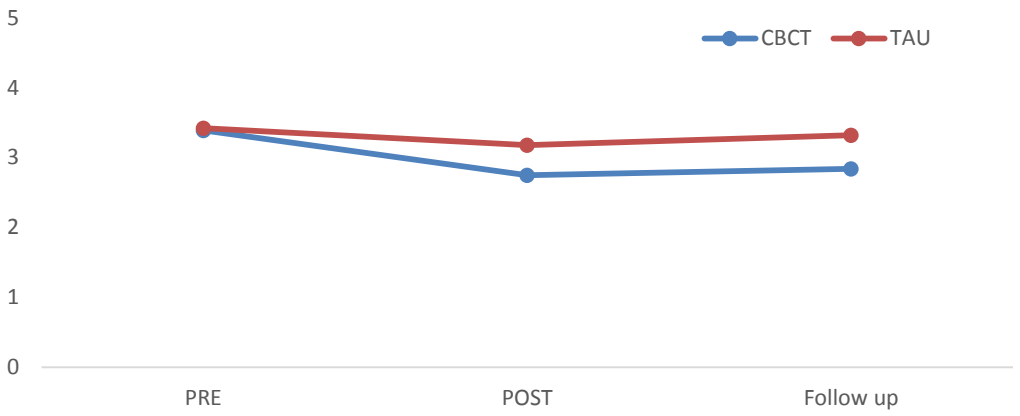

Figure 20. Over-Identification scores in CBCT and TAU groups

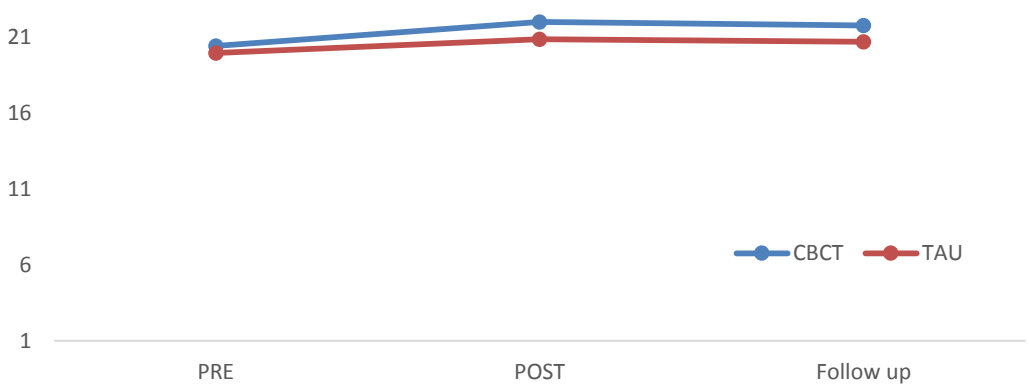

Figure 21. Overall Self-Compassion scores in CBCT and TAU groups

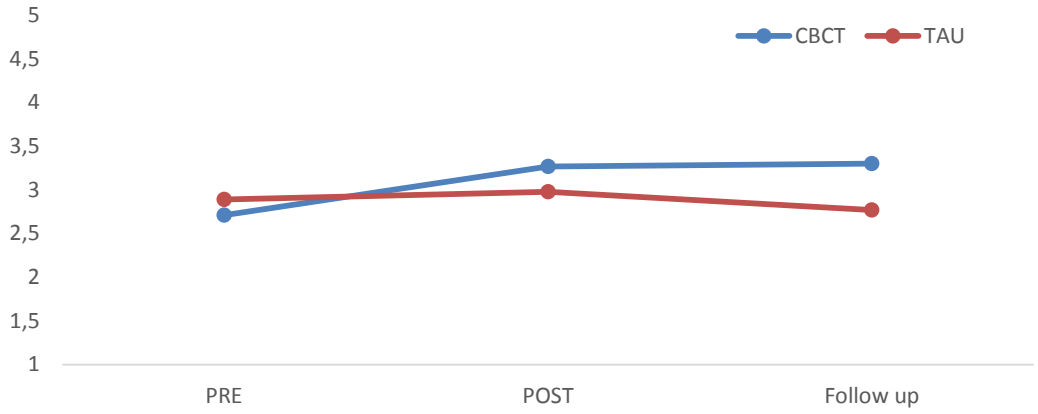

Figure 22. Overall Compassion scores in CBCT and TAU groups

Table 8. Within-group comparisons and effect sizes at pre, post and 6-month follow-up for Self-Compassion (Self-Kindness, Self-Judgment, Common Humanity, Isolation, Mindfulness, Over Identification and General Self Compassion) measured with Self-Compassion Scale-Short Form (SCS-SF) and Compassion Facets (General Compassion) measured with the Compassion Scale (CS)

	CBCT					TAU				
				Pre vs. Post	*Pre vs. FW*				Pre vs. Post	*Pre vs. FW*
	Pre (n = 28)	Post (n = 26)	Follow-up (n = 22)	Mean dif. *d* [CI 95%]	Mean dif. *d* [CI 95%]	Pre (n =28)	Post (n = 25)	Follow-up (n =25)	Mean dif. *d* [IC 95%]	Mean dif. *d* [IC 95%]
Self-Kindness	2.59 (1.11)	3.27 (.86)	3.34 (.78)	-.63* -.60 [-1.08, -.11]	-.70** -.66 [-1.2, -.11]	2.79 (1.19)	2.72 (1.19)	2.42 (1.09)	.04 .06 [-.20, .31]	.34 .30 [-.10, .70]
Self-Judgmt.	3.43 (1.26)	2.79 (1.03)	2.70 (1.01)	.57* .49 [.07, .92]	.72** .56 [.19, .93]	3.34 (1.27)	2.94 (1.42)	3.28 (1.01)	.40 .31 [.01, .60]	.06 .05 [-.24, .33]
Common Humanity	2.70 (1.02)	3.27 (1.03)	3.45 (.82)	-.54* -.54 [-1.01, -.07]	-.75** -.71 [-1.18, -.25]	3.16 (1.20)	2.82 (1.00)	2.84 (.98)	.32 .28 [-.20, .75]	.30 .26 [-.18, .70]
Isolation	2.98 (1.21)	2.62 (1.18)	2.64 (1.13)	.29 .29 [-.06, .64]	.31 .27 [-.13, .67]	3.02 (1.26)	2.66 (1.26)	3.06 (.93)	.35 .28 [.03, .52]	-.49 -.03 [-.40, .34]
Mindfulnss	2.82 (1.02)	3.23 (.82)	3.20 (.87)	-.36 -.39 [-.87, .08]	-.35 -.36 [-.81, .08]	3.16 (1.11)	3.10 (1.11)	3.00 (.90)	.07 .05 [-.30, .41]	.17 .14 [-.18, .46]
Over-Ident.	3.39 (1.17)	2.75 (.96)	2.84 (.99)	.60* .53 [.16, .90]	.52 . 46 [.14, .78]	3.42 (1.17)	3.18 (1.33)	3.32 (1.07)	.27 .20 [-.10, .50]	.13 .08 [-.33, .50]
General Self-Comp	2.71 (.90)	3.27 (.76)	3.30 (.73)	-.49** -.60 [-.98, -.23]	-.55** -.64 [-1.00, -.28]	2.89 (.91)	2.98 (.93)	2.77 (.69)	-.10 -.10 [-.33, .14]	.11 .13 [-.20, .45]
General Comp.	20.41 (2.89)	22.01 (2.36)	21.76 (2.75)	-1.53* -.54 [-.95, -.13]	-1.49 -.45 [-.90, -.01]	19.95 (2.68)	20.87 (2.80)	20.70 (3.15)	-.88 -.33 [-64, -.03]	-.71 -.27 [-.68, .14]

Note: Mean and standard deviation (SD) are represented. Mean dif. Mean differences. d. Cohen's d. CI. Confidence Interval. FW = 6-months follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group.. * p < .05, ** p < .01, *** p < .001

Table 9. Between-group comparisons and effect sizes at post- and 6-month follow-up for Self-Compassion (Self-Kindness, Self-Judgment, Common Humanity, Isolation, Mindfulness, Over Identification and General Self Compassion) measured with Self-Compassion Scale-Short Form (SCS-SF) and Compassion Facets (General Compassion) measured with the Compassion Scale (CS)

	CBCT vs. TAU			
	Post		Follow-up	
	Mean dif.	*d* [95% CI]	Mean dif.	*d* [95% CI]
Self-Kindness	.42	.52 [-.04, 1.08]	.79**	.94 [.34, 1.55]
Self-Judgmt.	.10	-.12 [-.67, .43]	-.40	-.56 [-1.15, .02]
Common Humanty	.34	.44 [-.12, .99]	.53	.66 [.07, 1.25]
Isolation	.13	-.03 [-.58, .52]	-.29	-.40 [-.98, .18]
Mindfulnss	.18	.13 [-.42, .68]	.27	.22 [-.35, .80]
Over-Ident.	-.21	-.37 [-.92, .19]	-.27	-.46 [-1.04, .12]
General Self-Comp	.10	.34 [-.22, .89]	.37	.74 [.14, 1.33]
General Comp.	.96	.43 [-.12. .99]	1.10	.35 [-.23, .93]

Note: Mean dif. Mean differences. d. Cohen's d. CI. Confidence Interval. FW = 6-months follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * p < .05, ** p < .01, *** p < .001

6.2.2.3 Mindfulness Trait Facets

For FFMQ, results showed a significant interaction of time by group for observing (F [2, 96.052] = 4.709, $p < .05$), and awareness facets (F [2, 98.598] = 3.444, $p < .05$) from FFMQ. Participants in CBCT scored significantly higher than those in TAU group for observing at post- ($p < .05$; $d = .37$, 95% CI [-.19, .92]) and follow-up ($p < .05$; $d = .43$, 95% CI [-.15, 1.01]), as well as for awareness ($p < .05$; $d = .45$, 95% CI [-.12, 1.04]) at follow-up. Within-group comparisons revealed a significant pre-post change for observing in CBCT with large effect size (-.86), and a significant pre to follow-up change for awareness in TAU with moderate effect size (.50) (Table 10).

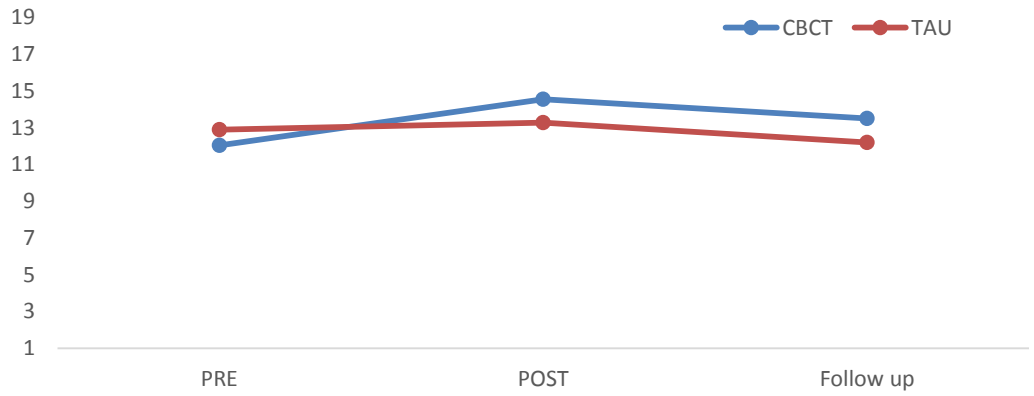

Figure 23. Mindful Observation scores in CBCT and TAU groups

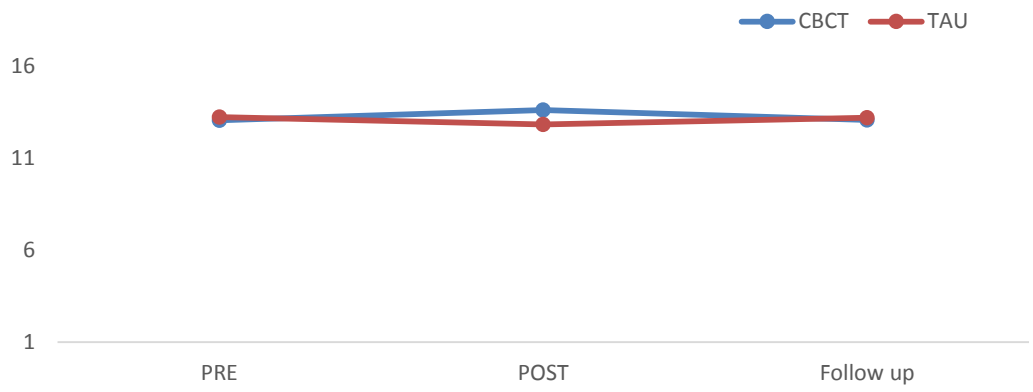

Figure 24. Mindful Description scores in CBCT and TAU groups

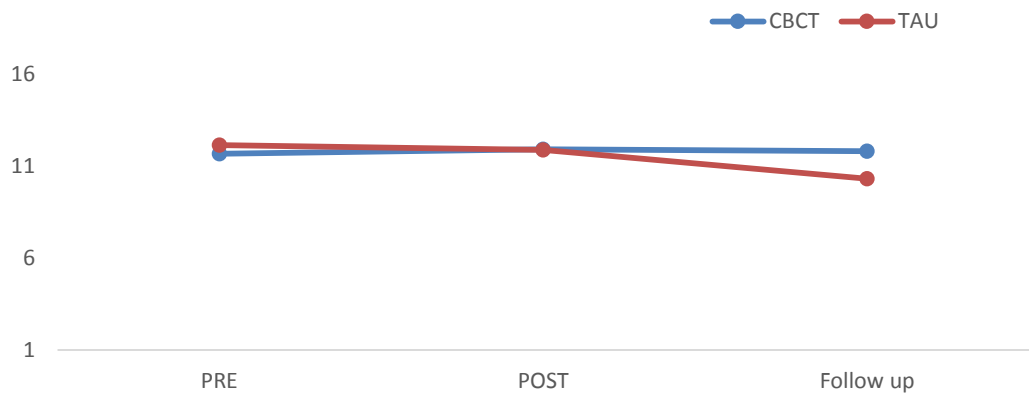

Figure 25. Acting with Awareness scores in CBCT and TAU groups

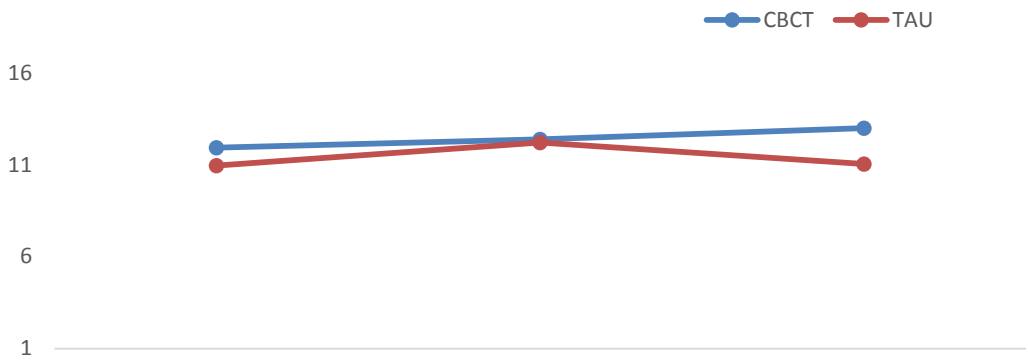

Figure 26. Non-judgement scores in CBCT and TAU groups

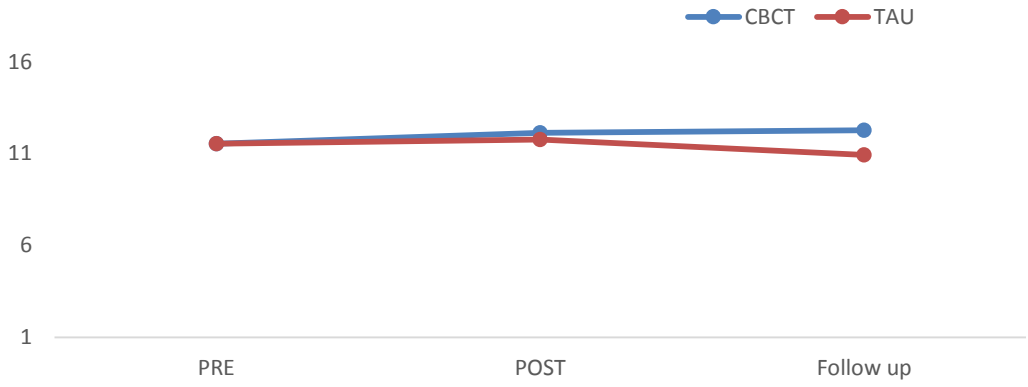

Figure 27. Non-reactivity scores in CBCT and TAU groups

Table 10. Within-group comparisons and effect sizes at pre, post and 6-month follow-up for Mindfulness Trait Facets (Observe, Describe, Awareness, Non-judgmental and Non-reactivity) measured with the Five Facets of Mindfulness Questionnaire – short form (FFMQ-SF).

	CBCT					TAU				
				Pre vs. Post	*Pre vs. FW*				Pre vs. Post	*Pre vs. FW*
	Pre (n = 28)	Post (n = 26)	Follow-up (n = 22)	Mean dif. *d* [CI 95%]	Mean dif. *d* [CI 95%]	Pre (n =28)	Post (n = 25)	Follow-up (n =25)	Mean dif. *d* [IC 95%]	Mean dif. *d* [IC 95%]
Observe	12.03 (2.85)	14.54 (2.93)	13.50 (2.81)	-2.41*** -.86 [-1.26, -.45]	-1.25 -.50 [-.93, -.07]	12.89 (2.71)	13.28 (3.82)	12.20 (3.14)	-.41 -.14 [-.34, .06]	.67 .25 [-.07, .56]
Describe	13.07 (4.45)	13.62 (3.32)	13.09 (4.02)	-.37 -.12 [-.36, .12]	-.13 .00 [-.25, .24]	13.25 (3.28)	12.84 (3.39)	13.20 (2.93)	.37 .12 [-.18, .42]	.01 .01 [-.39, .42]
Awareness	11.68 (3.62)	11.92 (3.31)	11.82 (3.59)	-.29 -.06 [-.40, .27]	-.54 -.04 [-.45, .37]	12.14 (3.57)	11.88 (4.10)	10.32 (2.87)	.14 .07 [-.18, .32]	1.70* .50 [.14, .85]
Non-judgmental	11.93 (3.83)	12.38 (3.68)	13.00 (4.07)	-.42 -.11 [-.47, .24]	-.93 -.27 [-.62, .07]	10.96 (4.26)	12.20 (4.62)	11.04 (4.17)	-1.12 -.28 [-.52, -.05]	.05 -.02 [-.36, .32]
Non-reactivity	11.54 (2.50)	12.12 (2.49)	12.27 (2.96)	-.51 -.23 [-.68, .23]	-.59 -.28 [-.67, .10]	11.54 (2.47)	11.76 (2.37)	10.92 (2.84)	-.15 -.09 [-.50, .32]	.69 .24 [-.12, .60]

Note: Mean and standard deviation (SD) are represented. Mean dif. Mean differences. d. Cohen's d. CI. Confidence Interval. FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * p < .05, ** p < .01, *** p < .001

Table 11.Between-group comparisons and effect sizes at post- and 6-month follow-up Mindfulness Trait Facets (Observe, Describe, Awareness, Non-judgmental and Non-reactivity) measured with the Five Facets of Mindfulness Questionnaire – short form (FFMQ-SF).

	CBCT vs. TAU			
	Post		Follow-up	
	Mean dif.	*d* [95% CI]	Mean dif.	*d* [95% CI]
Observe	1.79*	.37 [-.19, .92]	1.71*	.43 [-.15, 1.01]
Describe	.276	.23 [-.32, .78]	-.33	.07 [-.51, .64]
Awareness	.18	.01 [-.54, .56]	-1.99*	.45 [-.12, 1.04]
Non-judgmental	-.545	.04 [-.51, .59]	1.12	.47 [-.11, 1.05]
Non-reactivity	.60	.05 [-.49, .60]	-1.51*	.46 [-.12, 1.04]

Note: Mean dif. Mean differences. d. Cohen's d. CI. Confidence Interval. FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group.* p < .05, ** p < .01, *** p < .001

6.3 SEMANTIC EVALUATION OF COMPASSION AND SELF-COMPASSION CONCEPTS

In relation to the semantic changes in “compassion” and “self-compassion” concepts before and after going through CBCT program in CBCT and TAU groups the following data will be presented.

6.3.1 Evaluative Scale of compassion concept for CBCT within-group comparisons at pre, post and 6 month follow-up

When analizing each measure of compassion and self-compassion concept, we considered describing each scale (evaluative, potency and activity) highlighting the significant differences at post-test and 6 month follow-up.

Thus, considering the evaluative scale for the compassion concept within-group analyzes in the CBCT group, data showed how at pre-post assesment all paired items changes were aligned with the concept of compassion prosposed by CBI and CBCTS, except for “empathic-non empathic” paired items. These changes were significant in more than 50% of the paired items (from $d = 0.43$ to $d = 1.95$). Over 85% of the significant changes were maintained at follow-up. As stated above and interestingly enough, when compared with all of the items of the evaluative scale, the pair “empathic-non empathic” showed significant changes in the opposite direction.

Table 12. CBCT within-group comparisons and effect sizes at pre, post and 6 month follow-up for Evaluative Scale of compassion concept.

	CBCT				
	Pre (n =26)	Post (n = 26)	Follow-up (n = 22)	*Pre vs. Post*	*Pre vs. FW*
loving -hateful	2.69 (0.88)	2.27 (0.67)	2.09 (1.12)	F = 3.39 *d* = 0.54	F= 5.22* *d* = 1.60
sensitive-insensitive	4.19 (1.17)	3.23 (0.71)	2.52 (1.28)	F = 11.35** *d* = 0.99	F = 25.44*** *d* = 1.31
relaxed -tense	3.30 (1.52)	3.34 (1.72)	3.68 (1.76)	F = 0.01 *d* =-0.02	F = 1.51 *d* = -0.34
grateful-ungrateful	2.85 (1.16)	1.92 (0.85)	1.36 (0.59)	F = 9.92** *d* = 0.91	F = 37.80*** *d* = 2.63
friend-unfriend	3.62 (0.94)	2.50 (0.95)	2.50 (1.54)	F = 28.22*** *d* = 1.19	F = 10.93** *d* = 0.89
optimist-pessimist	3.15 (1.19)	2.27 (1.04)	1.82 (0.91)	F = 15.58** *d* = 0.79	F = 12.46** *d* = 1.17
cheerful-sad	3.50 (1.45)	3.00 (0.80)	2.86 (1.04)	F = 5.00* *d* = 0.43	F = 1.88 *d* = 0.42
kind-unkind	2.38 (1.02)	2.46 (1.24)	2.27 (1.35)	F = 0.42 *d* = -0.71	F = 0.04 *d* = 0.07
satisfied-dissatisfied	3.12 (1.40)	2.73 (0.87)	2.50 (1.30)	F = 2.52 *d* = 0.33	F = 1.93 *d* = 0.46
empathic-non empathic	2.73 (1.22)	3.77 (1.42)	3.77 (1.48)	F = 5.27* *d* = -0.79	F= 5.32* *d* = -0.75
generous-selfish	3.54 (1.14)	1.62 (0.80)	1.90 (0.83)	F = 50.24*** *d* = 1.95	F = 38.64*** *d* = 1.72
sincere-hypocrite	3.92 (1.65)	2.12 (0.91)	3.95 (1.43)	F = 21.67*** *d* = 1.35	F = 0.10 *d* = -0.08

Note: Mean and standard deviation (SD) are represented. *d*= Cohen's *d*. FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. * $p < .05$, ** $p < .01$, *** $p < .001$

6.3.2 Potency Scale of compassion concept for CBCT within-group comparisons at pre, post and 6 month follow-up

For the CBCT group potency scale, within-group analyzes revealed that all paired items were aligned with CBI and compassion-based contemplative tradition's definition of a compassionate being. Significant pre-post changes with large effect sizes (from *d* = 0.71 to *d* = 1.54) were observed in 90% of the items. 67% of the significant changes were maintained at follow-up.

Table 13. CBCT within-group comparisons and effect sizes at pre, post and 6 month follow-up for Potency Scale of compassion concept.

	CBCT				
	Pre (n =26)	Post (n = 26)	Follow-up (n = 22)	*Pre vs. Post*	*Pre vs. FW*
strong-weak	3.58 (1.60)	2.15 (1.19)	1.73 (0.83)	F = 14.57** d = 1.01	F = 23.00*** d = 1.62
admirable-deplorable	2.62 (1.06)	2.46 (1.17)	1.91 (0.87)	F = 0.22 d = 0.14	F = 9.90** d = 0.84
large-small	3.31 (1.54)	2.35 (1.23)	2.91 (1.19)	F = 7.61* d = 0.69	F = 2.03 d = 0.42
bravely-cowardly	3.54 (1.61)	2.31 (1.09)	2.14 (0.89)	F = 10.41** d = 0.71	F = 17.37*** d = 1.26
merciful-ruthless	3.19 (1.20)	2.19 (0.90)	3.05 (1.33)	F = 11.61** d = 0.94	F = 0.29 d = 0.17
perfect-imperfect	3.65 (1.57)	2.24 (1.10)	2.18 (0.85)	F = 10.41** d = 1.54	F = 15.40** d = 1.20
rested-tired	3.88 (1.48)	1.92 (1.13)	2.05 (0.95)	F = 41.03*** d = 1.49	F = 25.36*** d = 1.45
powerful-powerless	3.58 (1.53)	2.19 (1.06)	1.91 (1.19)	F = 15.55** d = 1.06	F = 20.29*** d = 1.30
intelligent-unintelligent	3.27 (1.49)	2.08 (1.02)	2.59 (1.50)	F = 10.04** d = 0.93	F = 2.88 d = 0.54
healthy-sick	3.69 (1.67)	2.42 (1.14)	2.05 (1.05)	F = 11.49** d = 0.89	F = 11.10** d = 1.07

Note: Mean and standard deviation (SD) are represented. d= Cohen's d. FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. * p < .05, ** p < .01, *** p < .001

6.3.3 Activity Scale of compassion concept for CBCT within-group comparisons at pre, post and 6 month follow-up

In relation to the activity scale within-group analyzes, eventhough all paired items that seemed to be coherent with the scientific, phylosophical and theoretical propposal of compassion, only the paired items “young-old”, “active-passive”, “fast-slow”, “fun-boring”, “agile-clumsy” showed statistically significant differences (effect sizes from *d* = 0.56 to *d* = 1.36). Out of these 5 pairs of items, 80% maintained significant changes at follow-up.

Table 14. CBCT within-group comparisons and effect sizes at pre, post and 6 month follow-up for Activity Scale of compassion concept.

	CBCT				
	Pre (n =26)	Post (n = 26)	Follow-up (n = 22)	*Pre vs. Post*	*Pre vs. FW*
young-old	4.08 (1.13)	3.19 (1.50)	2.50 (1.10)	F = 6.15* *d* = 0.67	F = 15.44** *d* = 1.34
active-passive	3.08 (1.44)	2.38 (1.02)	2.86 (1.32)	F = 5.23* *d* = 0.56	F = 0.52 *d* = 0.23
fast-slow	3.65 (0.98)	2.85 (0.97)	2.45 (1.01)	F = 7.31* *d* = 0.82	F = 14.85** *d* = 1.28
hard worker-apathetic	3.12 (1.28)	2.50 (1.42)	3.55 (1.26)	F = 2.20 *d* = 0.46	F = 0.67 *d* = -0.29
fun-boring	4.04 (1.08)	2.73 (0.83)	2.14 (0.94)	F = 35.24*** *d* = 1.36	F = 37.67*** *d* = 1.85
appeased-anxious	3.96 (1.61)	3.38 (1.36)	3.18 (1.71)	F = 2.45 *d* = 0.39	F = 1.94 *d* = 0.41
agile-clumsy	4.08 (1.26)	2.77 (1.24)	2.68 (1.00)	F = 13.98** *d* = 1.05	F = 15.21** *d* = 1.13

Note: Mean and standard deviation (SD) are represented. *d*= Cohen's *d*. FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. * $p < .05$, ** $p < .01$, *** $p < .001$

6.3.4 Evaluative Scale of compassion concept for TAU within-group comparisons at pre, post and 6 month follow-up

TAU group's evaluative scale within-group analyzes, revealed that participants tended to consider a compassionate being more hateful than loving, more insensitive than sensitive, more tense than relaxed, more ungrateful than grateful, unfriendly than friendly, more pessimist than optimist, more sad than cheerful, more unkind than kind, more selfish than generous, and more hypocrite than sincere at pre-post assesment. This tendency was significant (effect sizes from d = - 0.52 to d = - 0.99) for 67% of the items. 62,5% of this significant tendency was maintained at follow-up.

Table 15. TAU within-group comparisons and effect sizes at pre, post and 6 month follow-up for Evaluative Scale of compassion concept.

	TAU				
	Pre (n =25)	Post (n = 25)	Follow-up (n = 25)	*Pre vs. Post*	*Pre vs. FW*
loving -hateful	2.24 (1.23)	2.92 (1.08)	3.56 (1.16)	F = 6.39* *d* = -0.59	F = 15.50** *d* = -1.10
sensitive-insensitive	2.04 (1.34)	2.76 (1.33)	3.44 (1.39)	F = 6.91* *d* = -0.54	F = 15.89** *d* = -1.03
relaxed -tense	2.88 (1.39)	3.48 (1.45)	3.64 (1.32)	F = 3.60 *d* = -0.42	F = 4.78* *d* = -0.56
grateful-ungrateful	2.32 (1.11)	2.96 (1.34)	2.96 (1.21)	F = 5.62* *d* = -0.52	F = 3.52 *d* = -0.55
friend-unfriend	2.96 (1.10)	3.76 (1.13)	3.52 (1.05)	F = 24.00** *d* = - 0.72	F = 3.47 *d*= -0.52
optimist-pessimist	2.88 (1.42)	3.68 (1.07)	3.56 (1.33)	F = 13.71** *d* = - 0.63	F = 2.58 *d* = -0.49
cheerful-sad	3.44 (1.50)	3.76 (1.23)	3.52 (0.92)	F = 0.74 *d* = - 0.23	F = 0.05 *d* = -0.06
kind-unkind	2.16 (0.94)	3.16 (1.07)	3.15 (1.31)	F = 25.00*** *d* = -0.99	F = 9.38** *d* = -0.88
satisfied-dissatisfied	3.20 (1.26)	4.16 (1.11)	3.24 (1.20)	F = 6.22* *d* = -0.81	F = 0.01 *d* = -0.03
empathic-non empathic	2.16 (1.07)	2.88 (1.09)	3.44 (1.76)	F = 8.40** *d* = -0.67	F = 10.13** *d* = -0.88
generous-selfish	2.24 (1.27)	2.80 (1.16)	2.60 (1.16)	F = 3.75 *d* = -0.46	F = 1.05 *d* = -0.30
sincere-hypocrite	3.00 (1.35)	3.36 (1.22)	4.04 (1.33)	F = 1.22 *d* = - 0.27	F = 8.22* *d* = -0.77

Note: Mean and standard deviation (SD) are represented. *d*= Cohen's *d*. FW = 6-month follow-up. TAU = treatment as usual control group. * $p < .05$, ** $p < .01$, *** $p < .001$

6.3.5 Potency Scale of compassion concept for TAU within-group comparisons at pre, post and 6 month follow-up

TAU goup's within-group analyzes evidenced that 90% of paired items in the potency scale (except for large-small) distanced away from "compassionate-like" adjectives when comparing baseline data with post-test. Out of this 90% of paired items, "strong-weak", "admirable-deplorable", "merciful-ruthless", "perfect-imperfect", "rested-tired", "powerful-powerless", "intelligent-unintelligent" showed significant changes with large effect sizes (Cohen *d* from - 0.71 to - 1.54). Paired items "strong-weak", "admirable-deplorable", and "perfect-imperfect" maintained significant changes at follow-up.

Table 16.TAU within-group comparisons and effect sizes at pre, post and 6 month follow-up for Potency Scale of compassion concept.

	TAU				
	Pre (n =25)	Post (n = 25)	Follow-up (n = 25)	*Pre vs. Post*	*Pre vs. FW*
strong-weak	2.92 (1.38)	3.60 (1.16)	3.68 (1.22)	F = 5.00* d = -0.54	F = 4.30* d = -0.58
admirable-deplorable	2.68 (1.25)	3.48 (1.12)	3.52 (1.39)	F = 7.39* d = -0.67	F = 4.74* d = -0.64
large-small	3.28 (1.17)	2.84 (1.28)	3.80 (1.08)	F = 2.93 d = 0.35	F = 2.19 d = -0.46
bravely-cowardly	3.32 (1.07)	3.80 (1.23)	3.64 (1.00)	F = 2.37 d = -0.42	F = 0.91 d = -0.31
merciful-ruthless	2.32 (1.03)	3.28 (1.34)	2.84 (1.03)	F = 15.82** d = -0.80	F = 3.51 d = -0.50
perfect-imperfect	3.64 (0.70)	4.20 (1.26)	4.16 (1.03)	F = 8.49** d = -0.55	F = 5.75* d = -0.59
rested-tired	3.64 (0.70)	4.24 (1.36)	3.88 (1.05)	F = 4.91* d = -0.55	F = 0.81 d = -0.27
powerful-powerless	3.28 (0.98)	3.84 (1.28)	3.16 (1.11)	F = 6.24* d = -0.49	F = 0.17 d = 0.11
intelligent-unintelligent	3.12 (1.01)	3.84 (1.21)	3.48 (1.19)	F = 7.98** d = -0.65	F = 1.22 d = -0.33
healthy-sick	3.48 (0.82)	3.76 (1.17)	3.36 (0.82)	F = 1.34 d = -0.28	F = 0.35 d = 0.14

Note: Mean and standard deviation (SD) are represented. d= Cohen's d. FW = 6-month follow-up. TAU = treatment as usual control group. * p < .05, ** p < .01, *** p < .00

6.3.6 Activity Scale of compassion concept for TAU within-group comparisons at pre, post and 6 month follow-up

Table 17 shows, once again, how changes were not aligned with the concept of compassion prosposed by CBI and CBCTS, this time in TAU group's activity scale. These changes were significant in more than 70% of the paired items with large effect sizes (from *d* = - 0.44 to *d* = - 0.98). None of the significant changes were maintained at follow-up.

Table 17. TAU within-group comparisons and effect sizes at pre, post and 6 month follow-up for Activity Scale of compassion concept.

	TAU				
	Pre (n =25)	Post (n = 25)	Follow-up (n = 25)	*Pre vs. Post*	*Pre vs. FW*
young-old	3.72 (0.74)	4.32 (0.90)	3.88 (0.60)	F = 13.50*** d = -0.72	F = 0.89 d = -0.24
active-passive	2.92 (0.91)	3.60 (1.23)	3.12 (0.88)	F = 7.83* d = -0.63	F = 0.57 d = -0.22
fast-slow	3.60 (0.82)	4.16 (1.07)	3.48 (0.77)	F = 8.49** d = -0.59	F = 0.42 d = 0.15
hard worker-apathetic	3.08 (1.00)	3.56 (1.19)	3.20 (0.82)	F = 5.70* d = -0.44	F = 0.14 d = -0.13
fun-boring	3.64 (0.76)	4.12 (1.17)	3.36 (0.70)	F = 3.62 d = -0.49	F = 1.74 d = 0.38
appeased-anxious	3.20 (1.32)	3.64 (1.44)	2.76 (0.88)	F = 2.63 d = -0.32	F = 1.93 d = 0.39
agile-clumsy	3.20 (1.04)	4.28 (1.17)	3.52 (1.05)	F = 17.57*** d = -0.98	F = 1.35 d = -0.31

Note: Mean and standard deviation (SD) are represented. d= Cohen's d. FW = 6-month follow-up. TAU = treatment as usual control group. * p < .05, ** p < .01, *** p < .001

6.3.7 Evaluative Scale of self-compassion concept for CBCT within-group comparisons at pre, post and 6 month follow-up

Similar to what was observed in the compassion concept CBCT group within-group analyzes, the self-compassion concept evaluative scale data showed, how participants considered a self-compassionate individual more non empathic than empathic after going through CBCT program (d = - 0.56). All the rest paired items (except for “sincere-hypocrite”) showed significant changes aligned with the concept of self-compassion (from *d* = 0.67 to *d* = 0.98). 90% of the significant changes were maintained at follow-up.

Table 18. CBCT within-group comparisons and effect sizes at pre, post and 6 month follow-up for Evaluative Scale of self-compassion concept.

	CBCT				
	Pre (n =26)	Post (n = 26)	Follow-up (n = 25)	*Pre vs. Post*	*Pre vs. FW*
loving -hateful	3.56 (1.06)	1.88 (0.86)	2.18 (1.05)	F = 47.74*** d = 1.74	F = 29.53*** d = 1.33
sensitive-insensitive	3.77 (1,18)	2.54 (1.17)	2.64 (1.05)	F = 21.12*** d = 1.05	F = 19.51*** d = 1.59
relaxed -tense	4.62 (1.42)	3.04 (1.54)	2.64 (1.36)	F = 13.89** d = 1.07	F = 1.61 d = 1.37
grateful-ungrateful	3.27 (1.15)	1.62 (0.70)	2.64 (0.95)	F = 46.93*** d = 1.73	F = 3.42 d = 0.64
friend-unfriend	3.73 (0.72)	2.69 (1.16)	1.95 (0.90)	F = 15.19*** d = 2.11	F = 34.56*** d = 1.12
optimist-pessimist	4.35 (1.59)	2.00 (1.06)	2.45 (1.01)	F = 48.43*** d = 1.74	F = 23.39*** d = 1.38
cheerful-sad	4.65 (1.67)	2.81 (1.23)	2.36 (1.00)	F = 23.72*** d = 1.25	F = 34.76*** d = 1.67
kind-unkind	3.35 (1.09)	2.42 (1.65)	2.27 (1.12)	F = 7.71** d = 0.67	F = 8.28** d = 0.93
satisfied-dissatisfied	4.42 (1.72)	2.54 (1.17)	2.50 (1.14)	F = 22.49*** d = 1.28	F = 20.78*** d = 1.40
empathic-non empathic	3.23 (1.31)	3.96 (1.28)	3.77 (1.38)	F= 4.62* d = -0.56	F= 3.32 d = -0.52
generous-selfish	3.31 (1.46)	1.46 (0.65)	2.14 (1.42)	F = 30.18*** d = 1.64	F = 6.41** d = 1.74
sincere-hypocrite	3.54 (1.17)	3.23 (1.14)	3.68 (1.64)	F = 1.19 d = 0.27	F = 0.38 d = -0.23

Note: Mean and standard deviation (SD) are represented. d= Cohen's d. FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. * p < .05, ** p < .01, *** p < .001

6.3.8 Potency Scale of self-compassion concept for CBCT within-group comparisons at pre, post and 6 month follow-up

Within-group analyzes in CBCT group potency scale, showed that 90% of paired items had significant pre-post changes with large effect sizes (from $d = 0.71$ to $d = 1.54$) aligned with the concept of a self-compassionate individual. Over 85% of the significant changes were maintained at 6-month follow-up.

Table 19. CBCT within-group comparisons and effect sizes at pre, post and 6 month follow-up for Potency Scale of self-compassion concept.

	CBCT				
	Pre (n =26)	Post (n = 26)	Follow-up (n = 25)	*Pre vs. Post*	*Pre vs. FW*
strong-weak	4.38 (1.65)	2.19 (1.06)	1.73 (0.83)	F = 27.40*** d = 1.58	F = 44.48*** d = 2.17
admirable-deplorable	3.38 (1.02)	3.04 (2.03)	1.91 (0.87)	F = 0.63 d = 0.21	F = 33.19*** d = 1.50
large-small	4.04 (1.22)	2.54 (1.42)	2.91 (1.19)	F = 17.31*** d = 1.13	F = 10.25** d = 1.08
bravely-cowardly	4.38 (1.39)	2.23 (1.10)	2.14 (0.89)	F = 36.16*** d = 1.72	F = 38.27*** d = 1.97
merciful-ruthless	3.58 (1.30)	2.35 (1.16)	3.05 (1.33)	F = 10.63** d = 1.00	F = 1.57 d = 0.41
perfect-imperfect	4.35 (1.16)	2.65 (1.02)	2.14 (0.99)	F = 33.52*** d = 1.56	F = 54.75*** d = 2.13
rested-tired	4.31 (1.59)	2.73 (0.96)	2.36 (1.05)	F = 17.50*** d = 1.20	F = 24.10*** d = 1.44
powerful-powerless	4.54 (1.36)	2.35 (0.98)	2.27 (0.88)	F = 40.03*** d = 1.85	F = 54.81*** d = 2.15
intelligent-unintelligent	3.88 (1.17)	2.84 (1.41)	2.77 (1.27)	F = 9.69** d = 0.80	F = 9.05** d = 0.95
healthy-sick	4.12 (1.66)	2.12 (1.07)	1.86 (0.94)	F = 39.39*** d = 1.43	F = 19.53*** d = 1.50

Note: Mean and standard deviation (SD) are represented. *d*= Cohen's *d*. FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. * p < .05, ** p < .01, *** p < .001

6.3.9 Activity Scale of self-compassion concept for CBCT within-group comparisons at pre, post and 6 month follow-up

In CBCT group's activity scale, within-group analyzes revealed that all paired items seemed to be coherent with self-compassion concept. The paired items "young-old", "active-passive", "fast-slow", "fun-boring", "appeased-anxious", "agile-clumsy" showed statistically significant differences (effect sizes from d = 0.54 to d = 2.26). "Young-old", "active-passive", "fun-boring", "agile-clumsy" maintained significant changes at follow-up.

Table 20. CBCT within-group comparisons and effect sizes at pre, post and 6 month follow-up for Activity Scale of self-compassion concept.

	CBCT				
	Pre (n =26)	Post (n = 26)	Follow-up (n = 22)	*Pre vs. Post*	*Pre vs. FW*
young-old	3.96 (0.82)	3.42 (1.14)	3.45 (0.80)	F = 6.19* *d* = 0.54	F = 4.45* *d* = 0.55
active-passive	4.12 (1.58)	2.85 (1.43)	3.05 (0.93)	F = 9.78* *d* = 0.85	F = 9.72** *d* = 0.86
fast-slow	4.38 (0.98)	2.62 (1.13)	2.67 (0.66)	F = 33.57*** *d* = 1.66	F = 3.90 *d* = 1.93
hard worker-apathetic	3.65 (1.29)	2.81 (1.79)	3.25 (1.07)	F = 3.90 *d* = 0.54	F = 1.30 *d* = 0.41
fun-boring	4.54(1.24)	2.50 (0.65)	2.55 (0.91)	F = 49.14*** *d* = 2.06	F = 38.50*** *d* = 1.82
appeased-anxious	4.15 (1.81)	1.81 (0.75)	3.41 (1.82)	F = 85.42*** *d* = 2.26	F = 1.87 *d* = 0.41
agile-clumsy	4.35 (1.20)	2.62 (0.94)	2.86 (0.94)	F = 39.64*** *d* = 1.61	F = 17.21** *d* = 1.28

Note: Mean and standard deviation (SD) are represented. *d*= Cohen's *d*. FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. * $p < .05$, ** $p < .01$, *** $p < .001$

6.3.10 Evaluative Scale of self-compassion concept for TAU within-group comparisons at pre, post and 6 month follow-up

In reference to self-compassion in TAU group, evaluative scale within-group at pre-post analyzes evidenced that participants tended to consider a self-compassionate person more hateful than loving, more insensitive than sensitive, more relaxed than tense, more ungrateful than grateful, more friendly than unfriendly, more pessimist than optimist, more cheerful than sad, more unkind than kind, more dissatisfied than satisfied, more non empathic than empathic, more generous than selfish, and more hypocrite than sincere at pre-post assesment. This tendency was significant (effect sizes from d = - 0.54 to d = 0.54) for “generous-selfish” and “sincere-hypocrite” paired items. No significant tendency was observed at follow-up.

Table 21. TAU within-group comparisons and effect sizes at pre, post and 6 month follow-up for Evaluative Scale of self-compassion concept.

	TAU				
	Pre (n =25)	Post (n = 25)	Follow-up (n = 25)	*Pre vs. Post*	*Pre vs. FW*
loving -hateful	3.52 (1.68)	3.76 (1.64)	3.56 (1.16)	F = 0.66 *d* = -0.30	F = 0.01 *d* = -0.02
sensitive-insensitive	2.64 (1.52)	3.12 (1.61)	3.04 (1.17)	F = 1.13 *d* = -0.31	F = 0.98 *d* = -0.29
relaxed -tense	4.56 (1.61)	4.28 (1.51)	4.56 (1.12)	F = 1.27 *d* = 0.18	F = 0.00 *d* = 0.00
grateful-ungrateful	3.56 (1.85)	3.28 (1.57)	3.40 (1.63)	F = 1.21 *d* = 0.16	F = 0.13 *d* = 0.09
friend-unfriend	3.72 (1.21)	3.68 (0.99)	3.64 (1.15)	F = 0.05 *d* = 0.04	F = 0.07 *d* = 0.07
optimist-pessimist	4.00 (1.83)	4.68 (1.89)	3.84 (1.86)	F = 2.32 *d* = - 0.37	F = 0.09 *d* = 0.09
cheerful-sad	4.20 (1.66)	3.76 (1.56)	3.68 (1.80)	F = 0.21 *d* = 0.22	F = 1.00 *d* = 0.30
kind-unkind	3.08 (1.35)	3.60 (1.38)	3.28 (1.10)	F = 2.89 *d* = -0.38	F = 0.32 *d* = -0.16
satisfied-dissatisfied	4.12 (1.81)	4.28 (1.43)	3.92 (1.68)	F = 0.27 *d* = -0.10	F = 0.15 *d* = 0.11
empathic-non empathic	3.28 (1.49)	3.60 (1.47)	3.48 (1.09)	F = 1.73 *d* = -0.22	F = 0.30 *d* = -0.15
generous-selfish	3.29 (1.57)	2.53 (1.69)	3.56 (1.33)	F = 7.72** *d* = -0.47	F = 0.40 *d* = -0.19
sincere-hypocrite	3.56 (1.39)	4.32 (1.41)	3.76 (1.30)	F = 7.14 *d* = - 0.54	F = 0.29 *d* = -0.15

Note: Mean and standard deviation (SD) are represented. *d*= Cohen's *d*. FW = 6-month follow-up. TAU = treatment as usual control group. * $p < .05$, ** $p < .01$, *** $p < .001$

6.3.11 Potency Scale of self-compassion concept for TAU within-group comparisons at pre, post and 6 month follow-up

Table 22 reflects how the paired items in TAU group's self-compassion activity scale "strong-weak", "large-small", "bravely-cowardly", "merciful-ruthless", "perfect-imperfect", "rested-tired", "powerful-powerless", and "intelligent-unintelligent" were not aligned with the concept of self-compassion prosposed by CBI and CBCTS at pre-post assesment. These changes were significant in the paired items "perfect-imperfect" (with effect size of *d* = - 0.47). No significant changes were maintained at follow-up.

Table 22. TAU within-group comparisons and effect sizes at pre, post and 6 month follow-up for Potency Scale of self-compassion concept.

	TAU				
	Pre (n =25)	Post (n = 25)	Follow-up (n = 25)	*Pre vs. Post*	*Pre vs. FW*
strong-weak	4.04 (1.90)	4.44 (1.58)	3.84 (1.65)	F = 2.00 d = -0.23	F = 0.13 d = 0.09
admirable-deplorable	3.96 (1.31)	3.84 (1.31)	3.88 (1.05)	F = 0.21 d = 0.09	F = 0.06 d = 0.05
large-small	4.04 (1.06)	4.28 (1.31)	4.12 (0.97)	F = 1.13 d = -0.20	F = 1.07 d =-0.07
bravely-cowardly	4.00 (1.32)	4.36 (1.25)	3.68 (1.31)	F = 1.96 d = -0.28	F = 0.56 d = 0.24
merciful-ruthless	3.40 (1.55)	3.92 (1.26)	3.40 (1.08)	F = 2.61 d = -0.37	F = 0.00 d = 0.00
perfect-imperfect	4.00 (1.16)	4.48 (0.82)	4.32 (1.25)	F = 5.70* d = -0.47	F = 1.19 d = -0.27
rested-tired	4.08 (1.15)	4.24 (0.97)	3.68 (1.15)	F = 0.27 d = -0.15	F = 1.55 d = 0.35
powerful-powerless	4.04 (1.14)	4.12 (0.88)	4.04 (1.21)	F = 0.22 d = -0.08	F = 0.00 d = 0.00
intelligent-unintelligent	3.56 (1.12)	4.00 (1.04)	3.60 (1.12)	F = 3.85 d = -0.41	F = 0.01 d = -0.04
healthy-sick	4.16 (0.90)	4.16 (1.18)	3.92 (0.99)	F = 0.00 d = 0.00	F = 0.78 d = 0.25

Note: Mean and standard deviation (SD) are represented. *d*= Cohen's *d*. FW = 6-month follow-up. TAU = treatment as usual control group. * p < .05, ** p < .01, *** p < .001

6.3.12 Activity Scale of self-compassion concept for TAU within-group comparisons at pre, post and 6 month follow-up

TAU goup's within-group activity scale analyzes evidenced a slight tendency to sense a self-compassion individual as old, passive, slow, apathetic, boring, anxious, and clumsy at pre-post evaluation. Nevertheless, this tendency was not statistically significant. Only "young-old" paired items showed a significant change at follow-up (with effect size of d = - 0.79).

Table 23. TAU within-group comparisons and effect sizes at pre, post and 6 month follow-up for Activity Scale of self-compassion concept.

	TAU				
	Pre (n =25)	Post (n = 25)	Follow-up (n = 25)	*Pre vs. Post*	*Pre vs. FW*
young-old	3.84 (0.80)	4.04 (0.61)	4.40 (0.61)	F = 2.00 *d* = -0.28	F = 8.49** *d* = -0.79
active-passive	3.76 (1.09)	3.88 (1.01)	4.12 (0.93)	F = 0.52 *d* = -0.11	F = 1.12 *d* = -0.36
fast-slow	4.04 (0.94)	4.24 (0.93)	3.84 (1.03)	F = 2.00 *d* = -0.21	F = 0.43 *d* = 0.20
hard worker-apathetic	3.76 (1.17)	3.84 (1.18)	3.88 (1.30)	F = 0.14 *d* = -0.07	F = 0.10 *d* = -0.09
fun-boring	4.00 (1.50)	4.28 (1.31)	3.92 (1.47)	F = 2.24 *d*= -0.20	F = 0.03 *d*= 0.05
appeased-anxious	3.80 (1.73)	4.04 (1.49)	3.56 (1.53)	F = 0.95 *d* = -0.15	F = 0.29 *d* = 0.15
agile-clumsy	4.00 (1.08)	4.04 (0.84)	3.72 (0.94)	F = 0.05 *d* = -0.04	F = 0.96 *d* = 0.28

Note: Mean and standard deviation (SD) are represented. *d*= Cohen's *d*. FW = 6-month follow-up. TAU = treatment as usual control group. * $p < .05$, ** $p < .01$, *** $p < .001$

6.3.13 Evaluative Scale of compassion concept for between-group comparisons at pre, post and 6 month follow-up

Significant ANCOVA effect was observed in post-test for “loving –hateful” ($F[1,48] = 8.06$; $p < 0.05$; $\eta^2p=0.14$), “grateful-ungrateful” ($F[1,48] = 12.81$; $p < 0.05$; $\eta^2p=0.21$), “friendly-unfriendly” ($F[1,48] = 23.78$; $p < 0.05$; $\eta^2p=0.33$), “optimist-pessimist” ($F[1,48] = 39.20$; $p < 0.05$; $\eta^2p=0.45$), “cheerful-sad” ($F[1,48] = 7.60$; $p < 0.05$; $\eta^2p=0.14$), “kind-unkind” ($F[1,48] = 4.40$; $p < 0.05$; $\eta^2p=0.08$), “satisfied-dissatisfied” ($F[1,48] = 25.71$; $p < 0.05$; $\eta^2p=0.35$), “empathic-non empathic” ($F[1,48] = 7.59$; $p < 0.05$; $\eta^2p=0.14$), “generous-selfish” ($F[1,48] = 19.15$; $p < 0.05$; $\eta^2p=0.29$), “sincere-hypocrite” ($F[1,48] = 16.00$; $p < 0.05$; $\eta^2p=0.25$) in evaluative scale of compassion concept. This effect showed a more pronounced tendency in participants of the CBCT group, when compared to TAU group, to use adjectives related to a more compassionate individual. At 6-month follow-up this tendency was maintained and embraced more adjectives related to this same compassionate profile.

Table 24. Between-group comparisons and effect sizes at post- 6-month follow-up for Evaluative Scale of compassion concept.

	CBCT vs. TAU			
	Post		6 month follow-up	
	Mean dif.	η^2p	Mean dif.	η^2p
loving -hateful	0.72**	0.14	1.50***	0.30
sensitive-insensitive	-0.47	0.00	1.34**	0.14
relaxed -tense	0.15	0.00	1.96***	0.40
grateful-ungrateful	0.98**	0.21	1.55***	0.41
friendly-unfriendly	1.26***	0.33	1.13**	0.15
optimist-pessimist	1.41***	0.45	1.72***	0.37
cheerful-sad	0.76**	0.14	0.66*	0.11
kind-unkind	0.70*	0.08	0.82*	0.09
satisfied-dissatisfied	1.43***	0.35	-0.26*	0.09
empathic-non empathic	-1.01**	0.14	-0.38	0.01
generous-selfish	1.38***	0.29	0.72*	0.09
sincere-hypocrite	1.27**	0.25	0.17	0.00

Note: Mean dif. Mean differences are presented. η^2p. Partial Eta Squared. CI. 6FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * $p < .05$, ** $p < .01$, *** $p < .00$

6.3.14 Potency Scale of compassion concept for between-group comparisons at pre, post and 6 month follow-up

Additionally, in the potency scale of compassion concept at pre-post analyzes, significant ANCOVA effect reflects that participants in CBCT group tend to perceive a compassionate person more of a strong person than a weak one ($F[1,48] = 21.25$; $p < 0.05$; $\eta^2p=0.31$), more admirable than deplorable ($F[1,48] = 9.76$; $p < 0.05$; $\eta^2p=0.17$), more of a large person than a small one ($F[1,48] = 18.22$; $p < 0.05$; $\eta^2p=0.28$), a person with more brave tendencies than coward ones ($F[1,48] = 20.82$; $p < 0.05$; $\eta^2p=0.30$), more merciful than ruthless ($F[1,48] = 15.89$; $p < 0.05$; $\eta^2p=0.25$), more perfect than imperfect ($F[1,48] = 29.26$; $p < 0.05$; $\eta^2p=0.38$), more rested than tired ($F[1,48] = 48.52$; $p < 0.05$; $\eta^2p=0.50$), more powerful than powerless ($F[1,48] = 28.33$; $p < 0.05$; $\eta2p=0.37$), intelligent than unintelligent ($F[1,48] = 31.44$; $p < 0.05$; $\eta^2p=0.40$), and more of a healthy individual than a sick one ($F[1,48] = 17.99$; $p < 0.05$; $\eta^2p=0.28$) when compared to participants in TAU group. At follow-up, this significant effect was maintained for all paired items but “admirable-deplorable” ($F[1,44] = 3.19$; $p > 0.05$; $\eta^2p=0.07$) and “merciful-ruthless” ($F[1,44] = 0.84$; $p > 0.05$; $\eta^2p=0.02$).

Table 25. Between-group comparisons and effect sizes at post- 6-month follow-up for Potency Scale of compassion concept.

	CBCT vs. TAU			
	Post		6 month follow-up	
	Mean dif.	η^2p	Mean dif.	η^2p
strong-weak	1.45***	0.31	1.43***	0.28
admirable-deplorable	1.02**	0.17	0.70	0.07
large-small	1.50***	0.28	1.41***	0.30
bravely-cowardly	0.52***	0.30	1.69***	0.43
merciful-ruthless	1.32***	0.25	0.29	0.02
perfect-imperfect	1.78***	0.38	1.98***	0.53
rested-tired	2.39***	0.50	1.83***	0.46
powerful-powerless	1.72***	0.37	1.27**	0.24
intelligent-unintelligent	1.78***	0.40	0.86*	0.10
healthy-sick	1.37***	0.28	1.31***	0.34

Note: Mean dif. Mean differences are presented. η^2p. Partial Eta Squared. CI. 6FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * p < .05, ** p < .01, *** p < .001

6.3.15 Activity Scale of compassion concept for between-group comparisons at pre, post and 6 month follow-up

For activity scale of compassion concept at pre-post evaluation, significant ANCOVA effect reflects that, when compared to TAU group, participants in CBCT tend to perceive a compassionate person more of a young person than an old one ($F[1,48] = 11.94$; $p < 0.05$; $\eta^2p=0.20$), more active than passive ($F[1,48] = 16.94$; $p < 0.05$; $\eta^2p=0.26$), more of a fast person than a slow one ($F[1,48] = 21.30$; $p < 0.05$; $\eta^2p=0.31$), more of a hard working person than an apathetic one ($F[1,48] = 8.23$; $p < 0.05$; $\eta^2p=0.15$), more fun than boring ($F[1,48] = 27.93$; $p < 0.05$; $\eta^2p=0.37$), and more agile than clumsy ($F[1,48] = 20.13$; $p < 0.05$; $\eta^2p=0.30$). At follow-up this significant effect was maintained for all paired items, but "active-passive" ($F[1,44] = 0.52$; $p > 0.05$; $\eta^2p=0.01$) and "hard worker-apathetic" ($F[1,44] = 1.42$; $p > 0.05$; $\eta^2p=0.03$).

Table 26. Between-group comparisons and effect sizes at post- 6-month follow-up for Activity Scale of compassion concept.

	CBCT vs. TAU			
	Post		6 month follow-up	
	Mean dif.	η^2p	Mean dif.	η^2p
young-old	1.13**	0.20	1.34***	0.38
active-passive	1.22***	0.26	0.24	0.01
fast-slow	1.32***	0.31	1.03***	0.26
hard worker-apathetic	1.06**	0.15	-0.37	0.03
fun-boring	1.49***	0.37	1.22***	0.36
appeased-anxious	0.51	0.04	-0.40	0.02
agile-clumsy	1.63***	0.30	0.90**	0.16

Note: Mean dif. Mean differences are presented. η^2p. Partial Eta Squared. CI. 6FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * $p < .05$, ** $p < .01$, *** $p < .001$

6.3.16 Evaluative Scale of self-compassion concept for between-group comparisons at pre, post and 6 month follow-up

When comparing evaluative scale of self-compassion concept scores between CBCT and TAU group, a significant ANCOVA effect was observed in post-test for "loving -hateful" ($F[1,48] = 35.23$; $p < 0.05$; $\eta^2p=0.42$), "relaxed-tense" ($F[1,48] = 9.50$; $p < 0.05$; $\eta^2p=0.17$), "grateful-ungrateful" ($F[1,48] = 238.02$; $p < 0.05$; $\eta 2p=0.37$), "friendly-unfriendly" ($F[1,48] = 14.93$; $p < 0.05$; $\eta^2p=0.24$), "optimist-pessimist" ($F[1,48] = 38.74$; $p < 0.05$; $\eta^2p=0.45$), "cheerful-sad" ($F[1,48] = 13.48$; $p < 0.05$; $\eta^2p=0.22$), "kind-unkind" ($F[1,48] = 8.19$; $p < 0.05$; $\eta^2p=0.15$), "satisfied-dissatisfied" ($F[1,48] = 22.15$; $p < 0.05$; $\eta^2p=0.32$), " generous-selfish" ($F[1,48] = 22.06$; $p < 0.05$; $\eta^2p=0.32$), "sincere-hypocrite" ($F[1,48]= 10.41$; $p < 0.05$; $\eta^2p=0.18$). This effect showed a more pronounced tendency in participants of the CBCT group, when compared to TAU group, to use adjectives related to a more self-compassionate profile individual. At 6-month follow-up this tendency was maintained for most of the paired items.

Table 27. Between-group comparisons and effect sizes at post- 6-month follow-up for Evaluative Scale of self-compassion concept.

	CBCT vs. TAU			
	Post		6 month follow-up	
	Mean dif.	η^2p	Mean dif.	η^2p
loving -hateful	1.93***	0.42	1.84***	0.39
sensitive-insensitive	0.70	0.05	0.43	0.03
relaxed -tense	1.24**	0.17	1.90***	0.39
grateful-ungrateful	1.80***	0.37	0.76	0.07
friendly-unfriendly	1.19***	0.24	1.69***	0.42
optimist-pessimist	2.70***	0.45	1.39**	0.18
cheerful-sad	1.45**	0.22	1.30**	0.17
kind-unkind	1.23**	0.15	0.95**	0.17
satisfied-dissatisfied	1.74***	0.32	1.40**	0.19
empathic-non empathic	-0.36	0.02	-0.30	0.02
generous-selfish	1.94***	0.32	1.42**	0.22
sincere-hypocrite	1.09***	0.18	0.12	0.00

Note: Mean dif. Mean differences are presented. η^2p. Partial Eta Squared. CI. 6FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * p < .05, ** p < .01, *** p < .001

6.3.17 Potency Scale of self-compassion concept for between-group comparisons at pre, post and 6 month follow-up

Moreover, in the potency scale of self-compassion concept at pre-post analyzes, significant ANCOVA effect reflects that participants in CBCT group tend to perceive a self-compassionate person more of a strong person than a weak one ($F[1,48] = 42.70$; $p < 0.05$; $\eta^2p=0.47$), more of a large person than a small one ($F[1,48] = 21.78$; $p < 0.05$; $\eta^2p=0.31$), a person with more brave tendencies than coward ones ($F[1,48] = 44.89$; $p < 0.05$; $\eta^2p=0.48$), more merciful than ruthless ($F[1,48] = 21.67$; $p < 0.05$; $\eta^2p=0.31$), more perfect than imperfect ($F[1,48] = 44.98$; $p < 0.05$; $\eta^2p=0.54$), more rested than tired ($F[1,48] = 30.01$; $p < 0.05$; $\eta^2p=0.39$), more powerful than powerless ($F[1,48] = 49.55$; $p < 0.05$; $\eta^2p=0.51$), intelligent than unintelligent ($F(1,48) = 13.57$; $p < 0.05$; $\eta^2p=0.22$), and of a healthy individual than a sick one ($F[1,48] = 45.14$; $p < 0.05$; $\eta^2p=0.49$) when compared to participants in TAU group. At follow-up, this significant effect was maintained for all paired items but “merciful-ruthless” ($F[1,44] = 0.96$; $p > 0.05$; $\eta^2p=0.02$).

Table 28. Between-group comparisons and effect sizes at post- 6-month follow-up for Potency Scale of self-compassion concept.

	CBCT vs. TAU			
	Post		6 month follow-up	
	Mean dif.	η^2p	Mean dif.	η^2p
strong-weak	2.34***	0.47	2.05***	0.39
admirable-deplorable	0.60	0.03	1.92***	0.49
large-small	1.74***	0.31	1.19***	0.25
bravely-cowardly	2.21***	0.48	1.46***	0.31
merciful-ruthless	1.59***	0.31	0.35	0.02
perfect-imperfect	1.90***	0.54	2.25***	0.51
rested-tired	1.50***	0.39	1.32***	0.27
powerful-powerless	1.85***	0.51	1.75***	0.40
intelligent-unintelligent	1.26**	0.22	0.78*	0.10
healthy-sick	2.03***	0.49	2.11***	0.55

Note: Mean dif. Mean differences are presented. η^2p. Partial Eta Squared. CI. 6FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * p < .05, ** p < .01, *** p < .001

6.3.18 Activity Scale of self-compassion concept for between-group comparisons at pre, post and 6 month follow-up

Significant ANCOVA effect was observed for activity scale of self-compassion concept at pre-post evaluation. These results reflect that, when compared to TAU group, participants in CBCT tend to perceive a self-compassionate person more of a young person than an old one ($F[1,48] = 8.21$; $p < 0.05$; η^2p=0. 0.15), more active than passive ($F[1,48] = 10.62$; $p < 0.05$; η^2p=0. 0.18), more of a fast person than a slow one ($F[1,48] = 36.64$; $p < 0.05$; η^2p=0.43), more of a hard working person than an apathetic one ($F[1,48] = 5.70$; $p < 0.05$; η^2p=0.11), more fun than boring ($F[1,48] = 58.96$; $p < 0.05$; η^2p=0.55), more appeased than anxous ($F[1,48] = 86.29$; $p < 0.05$; η^2p=0. 0.64)and more agile than clumsy ($F(1,48) = 40.16$; $p < 0.05$; η^2p=0.46). At follow-up this significant effect was maintained for all paired items, except for “hard worker-apathetic” ($F[1,44] = 3.14$; $p > 0.05$; η^2p=0.07) and “appeased-anxious” ($F[1,44] = 0.11$; $p > 0.05$; η^2p=0.00).

Table 29. Between-group comparisons and effect sizes at post- 6-month follow-up for Activity Scale of self-compassion concept.

	CBCT vs. TAU			
	Post		6 month follow-up	
	Mean dif.	η^2p	Mean dif.	η^2p
young-old	0.68**	0.15	0.96***	0.31
active-passive	1.11**	0.18	1.05**	0.24
fast-slow	1.72***	0.43	1.17***	0.31
hard worker-apathetic	1.01*	0.11	0.63	0.07
fun-boring	1.98***	0.55	1.33**	0.23
appeased-anxious	2.39***	0.64	0.17	0.00
agile-clumsy	2.33***	0.46	0.85**	0.17

Note: Mean dif. Mean differences are presented. η^2p. Partial Eta Squared. CI. 6FW = 6-month follow-up. CBCT = Cognitively-Based Compassion Training. TAU = treatment as usual control group. * $p < .05$, ** $p < .01$, *** $p < .001$

These results confirm that CBCT program has a significant influence in participants' semantic elaboration in the evaluative, potency and activity domains of what is a compassionate and self-compassionate individual.

6.4 ADHERENCE, FEACEBILITY, ACCEPTANCE AND SATISFACTION WITH COGNITIVELY-BASED COMPASSION TRAINING PROGRAM

In this section we will present the data referring to the adherence, feacebility, acceptance and satisfaction with CBCT program of the people who participated in the study.

Regarding the data in CBCT group, 27 participants (96.4%) attended to 5 or more of the 8 sessions of the program. Twenty-five (89.30%) participants practiced at home from 12 to 24 or more minutes total, across all 8 weeks. Twenty-five (89.30%) of participants practiced on their own with the meditation recordings. Nine (32.15%) of the thwenty-eight participants used the pre-recorded meditation between sixty to ninty percent of the time (for more details see table 30). Thirteen (46.50%) participants practiced from four to seven days a week. Twenty-five participants (89.30%) indicated that they would participate in future CBCT courses if offered, and that they would continue to practice after the course program ended. Twenty-six (92.90%) said they were satisfied with the program, that they would recommend CBCT to other participants, and confirmed that they felt satisfied with the instructor's ability to facilitate the course sessions.

Table 30a. Participants' enrollment, satisfaction, adherence to program and contemplative practice experience data in CBCT and TAU groups. Percentage shown in parenthesis.

Data Description	
Number of sessions attended	
0	0 (0.00)
1	1 (3.55)
2	0 (0.00)
3	0 (0.00)
4	0 (0.00)
5	3 (10.70)
6	5 (17.90)
7	9 (32.15)
8	10 (35.70)
Mean time of practice after session	
0 mins	2 (7.15)
9 mins	1 (3.55)
12 mins	3 (10.70)
15 mins	6 (21.40)
18 mins	4 (14.30)
more than 24 mins	12 (42.90)
Percentage of home practice with meditation recordings	
0 %	2 (7.15)
10 %	1 (3.55))
20%	0 (0.00)
30%	0 (0.00)
40%	0 (0.00)
50%	0 (0.00)
60%	3 (10.70)
70%	0 (0.00)
80%	4 (14.30)
90%	2 (7.15)
100%	16 (57.15)

Table 31b. Participants' enrollment, satisfaction, adherence to program and contemplative practice experience data in CBCT and TAU groups. Percentage shown in parenthesis.

Data Description	
Frequency of practice (days)	
0	2 (7.15)
1	2 (7.15)
2	5 (17.90)
3	6 (21.40)
4	4 (14.30)
5	5 (17.90)
6	2 (7.15)
7	2 (7.15)
Intention to attend to future CBCT groups	
Yes	25 (89.30)
No	3 (10.70)
Intention to continue CBCT personal practice	
Yes	25 (89.30)
No	3 (10.70)
CBCT recommendation to others	
Yes	26 (92.9)
No	2 (7.10)
Satisfaction with Instructor	
Yes	26 (92.9)
No	2 (7.10)

7 DISCUSSION

The main objective of this study was to analyze the efficacy of the CBCT protocol in a BCS sample. To achieve this objective, the improvement of health related to QoL, emotional symptomatology, fear of illness recurrence, self-compassion, compassion and mindfulness traits were evaluated in the Fundación Instituto Valenciano de Oncología in Spain. The program consisted of weekly meetings with BCS patients, where different contemplative skills were taught to have a more constructive way to relate with themselves, their experience and their environment.

OBJECTIVE/HYPOTHESIS 1

The first objective of the study was to analyze the efficacy of CBCT in variables related to QoL (physical, social, emotional and functional domains). To do this, we compared the effectiveness of the program in a group that received CBCT intervention against a TAU control group at baseline-post-follow-up intervention.

Despite the fact that no time x group effect was observed in any of QoL domains, a tendency was observed for social/family QoL. This could be explained by the fact that one of the main goals of most CBI, is to enhance a sense of unity and oneness when experiencing hardship and difficult. This process of sense of unity is cultivated from inside-out, in a triple focus way. The first focus is oneself. This focus is the ground for learning how to cultivate self-care strategies and "jump" to creating abilities to focus on others (second focus). This second focus enhances a sense of connection with our in and

out group, increasing the feeling of social support. Once this social support perspective is enhanced, the third focus is oriented to cultivate a systemic outlook of our world based on interdependence, affection and closeness. There is vast literature that support this idea embedded in CBCT (Mehnert & Koch, 2008).

It is possible that this tendency to experience more social QoL impacts on patients' physical QoL. In our study, the data revealed how CBCT group showed significant improvements when compared to TAU group in physical QoL at post and follow-up. Within CBCT group pre-post analysis showed significant improvements on emotional and general QoL factors. These data can be explained as a cascade effect in the sense that when improvements in perceived social/family QoL take place, the probability of improvements in physical and emotional quality could increase. Some studies have outlined the importance of perceived social support for improvements in general, physical and emotional well-being (Mols et al., 2005; Sammarco, 2001). Despite these initial data, it is worth noting the importance of continuing to investigate how CBI affect the different QoL domains.

At the light of the results, we can say that even though CBCT showed to impact in a significant and positive way domains and variables related to social/family, emotional and general QoL, it did not prove to be efficacious for QoL as presented in this study.

OBJECTIVE/HYPOTHESIS 2

The second objective of this study was to analyze the impact of CBCT in emotional symptoms (somatic, depressive, anxious symptomatology) before, after intervention

and at six month follow-up and between CBCT group and TAU control. To do this, we compared the effectiveness of the program at baseline-post-follow-up intervention and in a group that received the intervention against a TAU control group.

Even though no significant time x group effects were observed for any of the symptomatology factors, somatic symptomatology domains experienced a significant reduction in CBCT, when compared to TAU group at pre-post intervention. Depressive symptomatology and general symptomatology showed significant improvements at CBCT group, showing high effect sizes. We appraise these results of important relevance considering recent data on emotion processing in cancer survivors (Jim & Jacobsen, 2008; Kashdan & Kane, 2011; Park, Zlateva, & Blank, 2009). Recently, it has been observed how cancer survivors are capable of developing a new positive outlook associated with greater meaning, purpose, and fulfillment. As a result of this new outlook, cancer survivors may become increasingly engaged with positive events relative to negative ones, thereby establishing greater knowledge about positive events (Bauer-Wu et al., 2017).

Growing literature has validated MBI to be effective for diminishing depression and increasing general psychological well-being in oncological survivorship (Goldberg et al., 2017; Zainal et al., 2013). More specifically, CBCT has also been validated as a promising intervention for treating with depressive symptomatology in healthy population (Mascaro et al., 2016) and specific clinical oncological settings (Dodds et al., 2015). These results could be explained by the fact that CBCT A possible explanation for this results could be that one of the main objectives of CBCT is to train a positive outlook in the face of difficulties (e.g. illness, aging, losses) based on kindness. It is possible that this process

may facilitate the search for meaning, decreasing levels of despair and depression. This decrease of negative emotions could result in the decrease of somatic symptomatology.

Even though CBCT showed to impact in a significant and positive way domains and variables related to depressive and general distress symptomatology, it did not prove to be efficacious for psychological symptomatology as presented in this study.

Our results and the literature showed, highlights the importance of uniting more efforts in adapting CBCT to BCS to improve its efficaciousness. Cancer survivors' emotion processing is an important variable to be considered for future CBCT interventions in these specific patients.

OBJECTIVE/HYPOTHESIS 3

Our third objective was focused on observing and assessing the benefits of CBCT in psychological dimensions linked to FCR. With-in group data suggest how CBCT intervention helped improve stress linked to FCR right after intervention and was maintained at 6 month follow-up at group. Moreover, participants in CBCT group showed significant improvements as time went by when compared to TAU group.

Our results confirmed data from other MBI and CBI studies that suggest how these interventions for BCS resulted in significant reductions in FCR which, in turn, could be related to the significant reductions in perceived stress and anxiety (Lengacher et al., 2014). In one study, CBCT has shown suggestions of significant improvements in functional impairment associated with fear of recurrence (Dodds et al., 2015). In our present study CBCT has proved to be efficacious in facilitating motivational, attentional,

cognitive and emotional resources and abilities to BCS for coping with the distress that evokes thoughts, images or memories related to FCR. All other dimensions of FCR were not affected by CBCT. This could be explained by the fact that CBI include a new range of coping strategies and insights that are not included in any FCR BC specific assessment instruments.

Thus, we can confirm that CBCT proved to be efficacious in diminishing perceived stress due to FCR.

OBJECTIVE/HYPOTHESIS 4

Our fourth objective was focused in analyzing if CBCT group is benefited in self-compassion, compassion and dispositional mindfulness and whether these improvements were significant when compared to TAU group.

Self-compassion with-in group analyzes revealed that self-kindness, self-judgement, common humanity and overall self-compassion scores improved not only after receiving the intervention but at 6 month follow-up. Only over-identification factor improved at post-test. CBCT proved to improve the ability to be kind at one's own inadequacies and vulnerabilities, not feeling alienated when experiencing difficulties (self-kindness and common humanity - self-compassion traits) and overall self-compassion as time went by and when compared to TAU group.

Related to compassion scores, with-in group data showed improvements at post-test for CBCT group and no significant for TAU. Nonetheless, between-group comparisons showed no significant improvements in compassion scores. As listed above in the results section, data revealed that CBCT could be considered an effective intervention that

fosters abilities to observe external and internal phenomena or stimuli with awareness and acting mindfully in daily activities.

Literature is coherent with our fourth hypothesis. Self-compassion dimensions have been strongly related to well-being, happiness and resilience in different studies (Baer, Lykins, & Peters, 2012; Campos et al., 2016; LoParo, Mack, Patterson, Negi, & Kaslow, 2018; Neely, Schallert, Mohammed, Roberts, & Chen, 2009; Neff & McGehee, 2010; Sansó et al., 2017; Van Dam, Sheppard, Forsyth, & Earleywine, 2011). According to Neff (2003, 2011), the constituents of self-compassion that have been highlighted by her studies' data are central to fostering a self-compassionate mindset when coping with one's own inadequacies, personal failures, and external circumstances that are hard to bear. This perspective realizes imperfection as part of the shared human condition, so that one's weaknesses are seen from a broad, inclusive perspective. Similarly, difficult life circumstances are framed in light of the shared human experience, fostering connection instead of disconnection and isolation when experiencing suffering. In this sense, when assuming a non-self-compassionate outlook people tend to feel isolated, harsh and emotionally reactive when considering personal flaws, weaknesses or hardship. Improvements in self-compassion, especially those related to self-kindness, self-judgment, common-humanity and over identification, are of important relevance given the emotional turmoil related to guilt and shame that oncological patients go through in survivorship (Dodds et al., 2015; Hall, Row, Wuensch, & Godley, 2013; Pinto-Gouveia, Duarte, Matos, & Fráguas, 2014).

As for compassion measures we can state that our findings are also coherent with previous results (Brito, Campos, & Cebolla, 2017; Penberthy et al., 2017). These could be explained by several factors. Although CBCT has reported different benefits in

variables related to compassionate mindsets and behaviors (Kirby et al., 2017; Kirby, 2017), in this study, improvements in compassion scores were only significant at CBCT group pot-test. This could be due to the fact that more efforts should be focused in adapting CBCT program to Latin-Mediterranean-Catholic cultural contexts. In these contexts, compassion as proposed by CBI is relatively new and need a longer time to be integrated into the individual and collective scheme. Other CBCT studies have been done with an extended format (Mascaro et al., 2016). This extension is relevant given the complex and numerous psychosocial and physiological impairments in survivorship when trying to adapt CBCT in future studies. Another possible explanation for these results could be that in order to build a significant compassionate mindset, participants in CBCT group first had to integrate not only concepts, but also skills related to self-compassionate mindsets and skillsets. This process of integration could be time dependent.

In relation to different facets evaluated by the FFMQ in oncological settings, our results are aligned with the ones offered in previous studies that sate how contemplative training fosters a significant increase in Mindfulness skillsets (Bränström, Kvillemo, Brandberg, & Moskowitz, 2010; Bränström, Kvillemo, & Moskowitz, 2012).

Moreover, we can also state that our hypothesis related to the improvement of the observing and acting with awareness facets evaluated by the FFMQ in CBCT group when compared TAU group was confirmed. Interestingly these improvements could be considered as “long term changes” due to the fact that these were also observed at 6 month follow-up. This may be due to the orientation of this program, which pays special attention and care to the cognitive strategies and techniques that have been tested to enhance well-being (Desbordes et al., 2012; Mascaro et al., 2012; Mascaro et al., 2016;

Pace et al., 2009; Pace et al., 2010; Pace et al., 2012; Pace et al., 2013; Reddy et al., 2013). We consider that efforts to accurately assess Mindfulness facets are highly needed in contemplative training programs that include analytical approaches that enhance well-being (Grossman, 2013; Grossman & Van Dam, 2011; Ozawa-de Silva et al., 2012). We think this point is relevant due to the importance of the cognitive constituents that have been highlighted as central in compassion mind training (Dahl, Lutz, & Davidson, 2015; Dahl, Lutz, & Davidson, 2016).

Our hypothesis, on the efficacy of a CBCT intervention, in improving self-compassion scores in BCS receives confirmation in light of the data showed above. Nevertheless, in relation to compassion facets our fourth hypothesis is partially confirmed, due to the fact that significant differences were observed in with-in analyzes but not in between group data. In this way we can confirm that CBCT has proven its effectiveness in the self-compassion dimensions of self-kindness, common humanity, overall self-compassion, and mindfulness dimensions of mindful observation and in the increase of conscious acts in daily life.

OBJECTIVE/HYPOTHESIS 5

Our fifth objective was focused in analyzing the influence of CBCT over participants' compassion and self-compassion semantic construct.

In order to evaluate this objective, we compared the effects of the program on participants' index of change in meaning and mental representation of compassion and self-compassion in three different time periods (base-line-post-follow-up) in both CBCT and TAU group. We also compared the effects of this program in CBCT against a TAU

control group's perceived significance of compassion and self-compassion at same time periods.

Specific with-in group data analyzes indicate how CBCT participants' compassion concept changes in (a) the evaluative, (b) activity, and (c) potency meaning of what is a compassionate individual. The direction of change is congruent with what is proposed by scientific and contemplative literature (Davidson & Harrington, 2002).In relation to the evaluative domain, we should highlight that the paired items "empathic-non empathic" did not follow the direction of change expected. This could be related to how empathy is only a necessary step that fosters compassion and altruism, but it is not compassion itself. If the individual dwells in the empathy stage of the training, he/she could experience "empathic distress" (Klimecki et al., 2013). This principle is taught and deepened during the training and being empathic is only a pre-requisite to enhance and foster compassionate predisposition and activity. In contrast to CBCT group, most of the evaluative, activity, and potency TAU's paired items experienced change in the opposite direction of what is a compassionate individual.

Regarding self-compassion general with-in group analyzes, data suggests that CBCT intervention influenced participants' mental representation at post and follow-up evaluation in the direction of what is a compassionate individual. On the other hand, TAU showed change in participants' semantic construction at post time period in the opposite direction.

Specific CBCT self-compassion with-in group data analyzes show a very similar change of direction to the compassion with-in group analyzes in the evaluative, activity, and potency categories. Interestingly enough and in a very similar direction of change as in the compassion concept, the "empathic-non empathic" paired items, data revealed

the opposite direction expected. This could be explained by how self-compassion mechanisms enhance a non-self-identified and non-self-centered view of suffering, but a more global, integrative and focused on our common humanity (Dambrun & Ricard, 2011; Neff & Germer, 2013). It is possible that participants perceive a self-compassionate individual as someone who does not empathize too much with one's own suffering, fostering a less self-centered life perspective. Contrary to CBCT group, most of the evaluative, activity, and potency TAU's paired items experienced a slight change in the opposite direction of what is a self-compassionate individual.

When comparing CBCT against TAU groups, a very similar tendency was observed in the evaluative, activity, and potency categories of compassion and self-compassion concepts. Nevertheless, it gets our attention that the same paired items "empathic-non empathic" manifested significant differences in the opposite direction that we expected, when compared to TAU.

Another relevant point to highlight in this discussion section is how, despite the fact that the participants of this study tended to score more towards poles related to the concepts of self-compassion and compassion, the scores reflected the lack of a well-defined construction of both constructs at a conceptual level. This may be due to the fact that, unlike the concepts and skills proposed and trained in different MBI, compassion training programs have a vast body of concepts that can take time to integrate into the mindset of the participants and their everyday lives.

Moreover, we consider as a very relevant point how most of changes occurred in CBCT group (except for empathic-non empathic paired items) in opposite direction than in TAU. Also, these changes experienced an increase in its effect sizes as time went by in the study. These changes over time suggest that, given the richness of skills and

concepts that compassion training contains, it takes time for these new concepts and skills to integrate. It is important to bear in mind that the proposal made by compassionate training is not only to train attentional skills but to go a step further in personal transformation. This personal transformation involves making changes in our own scales of values in relation to how we relate to intra, inter and transpersonal levels. Seeing the world from this new perspective implies a progressive deconstruction of the self and the world around us. The data showed how this process of conceptual change occurred more pronounced in time in the construct of self-compassion than in that of compassion.

Conducted for the purposes of preparing the work, a systematic review of the scientific literature— (search conducted up until February 2018; PubMed, PsycINFO and Medline electronic databases)—demonstrated that no studies on the semantic construction of compassion and self-compassion in Latin countries have been done or published to date.

In a recent study (Morales-Vives, De Raad, & Vigil-Colet, 2014), it has been observed that compassion has been classified as a virtue related to concepts and ideas as generosity, open-handedness, benevolence, charitable, clemency, mercy, humanitarian, help people, goodness, compassion, gratitude, do good, solidarity, hospitality, humility, and tolerance.

In light of the results presented above, there is a manifested need to cultivate intents to re-define and deconstruct the concept of compassion and self-compassion. Latin countries have a profound influence of Christianity (García-Campayo, Demarzo, Shonin, & Van Gordon, 2017). Despite the fact that the concept of compassion and self-compassion has been under the influence of this cultural-conceptual umbrella, data in

this study reflect how participants don´t tend to associate these two concepts with pity and/or superiority, but rather a tendency to not really knowing what these two concepts may be associated with. We could say participants have a neutral conceptual tendency when trying to evoke these terms. For this reason, we consider the efforts to analyze scientifically the participant's base-line conceptual knowledge of these two terms to be important.

After what has been discussed in this section, we can confirm that there is a change of tendency in the semantic construction of compassion and self-compassion constructs. This trend is directed towards the description of both constructs in the CBCT group. In the TAU group it has been observed that this tendency occurs in the opposite direction.

OBJECTIVE/HYPOTHESIS 6

Our sixth objective was focused on studying the participants' acceptance, adherence, and satisfaction with the intervention.

Results from this RCT study also suggest that CBCT is a feasible and highly satisfactory 8-week intervention among BCS. Moreover, adherence rate was higher than previous studies with CBCT and BCS (Dodds et al., 2015). In this previous study adherence was assessed in two ways: logged home practice time between participant and attendance at weekly classes as recorded by the teacher. In the present study, data suggest that CBCT has high rates of attendance, high rates of adherence to home practice and high scores in minutes of practice between sessions. Moreover, most of participants had a high rate of practice frequency a day after finishing each session. A high percentage of these participants wish to continue with CBCT training if offered and

would recommend CBCT to other patients. Data confirms a high level of satisfaction with the program. Finally, most of the participants intend to continue practicing CBCT in a daily basis.

Our sixth hypothesis, on the acceptance, adherence, and satisfaction with the intervention is high after delivering CBCT program in BCS, receives confirmation in light of the data.

7.1 LIMITATIONS AND METHODOLOGICAL ISSUES

In summary, we can affirm that CBCT has been shown to be effective in improving the main psychological domains of BCS: These improvements have been maintained over time in the majority of the clinical variables evaluated (at least, during the 6 months after the intervention) and that has been well accepted and valued by the participants.

Finally and with a view to future research, we think it is necessary to mention some limitations of our study: (1) We would highlight the limited size of the sample. (2) The fact that participants actively showed interest in carrying out the study, which could especially influence the follow-up results showed above. (3) These results might be influenced by participants' contemplative experience prior to study. (4) For this present study no instruments to measure specific constituents of CBCT program were found. Especially those which make reference to Impartiality, Interdependence, Affection, Nurturance and Mindfulness related to analytical meditation abilities. (5) We have not included any correlation analysis with variables associated with well-being, as it has been done in other CBCT studies (Dodds et al., 2015; Mascaro et al., 2016; Pace et al., 2013). (6) All patients that participated in study were recruited in one specific clinical setting with some social characteristics and needs that need to be considered and that can be diverged from other patients from different clinical contexts. (7) No male representation in this study's recruited sample. Being aware of the high prevalence of BC and the related emotional turmoil related to the disease, we clearly see the essential need for innovative interventions that focus on the cultivation of positive emotions.

In view of the results obtained, we consider that the present study has contributed to improve knowledge regarding CBI. An important contribution of this work is that it is

the first validated CBCT study in a Spanish-Catholic-Mediterranean context with promising results.

8 CONCLUSIONS

From this research project the conclusions that are listed below are extracted:

1. In the field of BCShip, CBCT interventions can be used within an ethical scientific framework in clinical settings. We consider this point as especially important for the growth of the contemplative cognition field of research to be rigorous and fruitful.
2. CBCT interventions can be beneficial in promoting different QoL dimensions. In this study, a positive tendency of improvement was observed in social/family QoL and significant improvements in emotional and general for experimental group.
3. CBCT interventions can be efficient in enhancing well-being by diminishing depressive and general symptomatology.
4. CBCT interventions can be effective when promoting self-compassion skillsets and mindsets. Specifically, those related to being kind to oneself and non-judgmental when experiencing difficulties or inadequacies, being able to not "stick" to one's own feelings, sensations, thoughts and emotions (over-identification), experience life's ups and downs as part of our common humanity, and overall self-compassion scores. These results are promising and relevant for the impact that these self-compassionate facets have been related to mental health.
5. It is possible to intervene in mindfulness related facets through CBCT. Observing and acting with awareness showed notorious improvements. One of the goals of

CBCT's modules is to train the right attentional and cognitive abilities for resilience. These mindfulness facets are embedded in the ability to recuperate in less time to difficult emotions and life´s challenges.

6. In BCShip settings, CBI, in general and CBCT, in particular, are fundamental pieces for a more constructive adaptation to daily life after oncological processes due to the fact that these interventions offer useful emotional and cognitive resources and techniques for this purpose.
7. More Compassion and BCShip research is needed with scientific validated research protocols that offer participants qualified instructors, rigorous validated methodologies and communities to deepen and maintain the skills obtained during intervention.
8. More Compassion and BCShip research is needed to deepen not only in the construct of compassion, but also in the constituents that compose it. This way, the scientific community can have more evidence on what are the specific constituents that can beneficial to specific populations.
9. In research contexts, CBCT protocol should be facilitated by well trained staff in this program, in order to respect the basic bioethical principles in healthcare.
10. Our research project confirms that CBI, in general, and CBCT, in particular, are still a challenge in clinical settings. For this reason, more studies are needed to thoroughly adapt and apply these specific programs to the different needs of each specific population.
11. Our research project reflects how compassion research is a fertile domain of study and CBCT studies demonstrate its promising potential.

12. Our research suggests the need for serious study on the adaptation and re-definition of self-compassion and compassion in our Latin context. This implies including the definitions offered by contemplative, religious and scientific traditions, but also the lay definitions offered by individuals that are not engaged in the traditions named above.
13. Our results suggest that CBCT is a feasible and highly satisfactory intervention for BCS.

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10 APPENDIXES

10.1 APPENDIX 1: CLINICAL RESEARCH ETHICS COMMITTEE AUTHORIZATION

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FUNDACIÓN
INSTITUTO VALENCIANO DE ONCOLOGÍA

Profesor Beltrán Báguena, 8
46009 – VALENCIA
Tfno.: 96 111 40 00
Fax: 96 111 43 42

CONFORMIDAD DE LA DIRECCIÓN DEL CENTRO

Dª Asunción Perales Marín, Directora del Hospital Fundación Instituto Valenciano de Oncología, vista la autorización del Comité Ético de Investigación Clínica,

CERTIFICA

Que conoce la propuesta realizada por el promotor para que sea realizado en este Centro el ensayo clínico titulado EFICACIA DE UN PROGRAMA ENTRENAMIENTO EN COMPASIÓN DE BASE COGNITIVA PARA LA MEJORA DEL BIENESTAR PSICOLÓGICO EN PACIENTES SUPERVIVIENTES DE CÁNCER DE MAMA, código CBCT-16 y que será realizado por la Dr. Rosa María Baños Rivera como Investigadora Principal.

Que está de acuerdo con el contrato firmado entre el Centro y el promotor en el que se especifican todos los aspectos económicos de este ensayo clínico.

Que acepta la realización de dicho ensayo clínico en este Centro.

Lo que firma en Valencia, 30 de Diciembre de 2015.

Firmado:

Dª Asunción Perales Marín

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Profesor Beltrán Báguena, 8
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En Valencia a 28 de Diciembre de 2015

REUNIDOS

De una parte Dª ASUNCIÓN PERALES MARÍN en nombre y representación de la FUNDACIÓN INSTITUTO VALENCIANO DE ONCOLOGÍA (en adelante, CENTRO) con domicilio en la calle Prof. Beltrán Báguena, 8, de Valencia, con C.P. 46009 y C.I.F. nº G46129698.
D. CARLOS J. ANDRES BLASCO actúa en nombre y representación de la FUNDACIÓN DE INVESTIGACIÓN CLÍNICA DEL INSTITUTO VALENCIANO DE ONCOLOGÍA (en adelante FUNDACIÓN), con domicilio en la calle Prof. Beltrán Báguena, 8, de Valencia, con C.P. 46009 y C.I.F. nº G-98119456.

De otra parte (Promotor) D/Dña. Rosa María Baños Rivera en su calidad de Catedrática de la Universidad de Valencia, en nombre y representación de la Universidad de Valencia con C.I.F. nº. 11399076-T, y con domicilio social en Avenida Blasco Ibañez, 21 46010 – Valencia con capacidad legal para la firma del presente contrato.

Y de otra parte (Investigador Principal) D Rosa María Baños Rivera con D.N.I. 11399076-T adscrito a la Facultad de Psicología de la Universitat de València en calidad de Investigador Principal y actuando en su propio nombre.

CONSIDERANDO

Lo dispuesto en la legislación española vigente en materia de estudios postautorización de tipo observacional con medicamentos y productos sanitarios y acatando las normas éticas y de Buena Práctica Clínica y de laboratorio aplicables a la realización de Ensayos Clínicos.

MANIFIESTAN

Las partes se reconocen respectivamente la capacidad necesaria y suficiente para obligarse por el presente contrato.

El presente contrato tiene por OBJETO la realización en el CENTRO FUNDACIÓN INSTITUTO VALENCIANO DE ONCOLOGÍA del ESTUDIO POSTAUTORIZACIÓN DE TIPO OBSERVACIONAL titulado "Eficacia de un programa Entrenamiento en Compasión de Base Cognitiva para la mejora del bienestar psicológico en pacientes supervivientes de cáncer de mama" código CBCT-16 (en adelante protocolo) promovido por Rosa María Baños Rivera y que será dirigido por Rosa María Baños Rivera (denominado Investigador Principal) de la Facultad de Psicología de la Universitat de

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València (denominado CENTRO), de acuerdo con el Protocolo estudio postautorización de tipo observacional código CBCT-16

I. Que para ello, el PROMOTOR ha seleccionado al investigador más adecuado según su cualificación y medios disponibles para realizar, dirigir y supervisar el ensayo en las instalaciones del CENTRO, de acuerdo con el Protocolo de fecha 28/12/2015, que se acompaña al presente contrato.

II. Que dicho estudio tiene por objeto determinar la efectividad, seguridad, obtener información sobre los patrones de utilización del medicamento del Producto o conocer su efecto desde la perspectiva del paciente. Todo ello de acuerdo con el Protocolo nº CBCT-16 que se adjunta y que describe detalladamente los procedimientos y alcance del estudio observacional a realizar.

III. Que el estudio se realizará tras la obtención de la preceptiva autorización en los estudios prospectivos, de la Agencia Española de Medicamentos y Productos Sanitarios, de la Conselleria de Sanitat de la Generalitat Valenciana y la conformidad de la Dirección del CENTRO.

Que en base a los anteriores principios y objetivos, las partes acuerdan celebrar el presente contrato bajo las siguientes:

ESTIPULACIONES

PRIMERA.- Objeto

Por el presente contrato, el CENTRO autoriza la realización en sus instalaciones del Estudio Postautorización de tipo observacional objeto del presente contrato y la memoria económica que será realizado, dirigido y, supervisado personalmente por el INVESTIGADOR a quien se confiere expresamente la labor de investigación. Por otra parte, el Estudio se realiza con un número estimado de .52 sujetos participantes y en un plazo máximo estimado de 24 meses, tal y como se detalla en el Protocolo, pudiendo modificarse dicho número y plazo cuando se estime necesario, previa aprobación del correspondiente presupuesto. Cualquier desviación sobre esta cantidad, será comunicada por el promotor al Comité Ético de Investigación Clínica (CEIC) correspondiente.

SEGUNDA.- Condiciones de realización.

2.1.- Protocolo.- Las condiciones de realización del estudio serán las establecidas en la legislación vigente y en el presente contrato con su protocolo anexo. Las partes cumplirán con lo estipulado en el Protocolo, incluidas las enmiendas o modificaciones que puedan introducir en él en cada momento siempre que hayan sido firmadas y aceptadas por el INVESTIGADOR y el PROMOTOR, los cuales

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conservarán en sus archivos copias de las enmiendas y modificaciones que vayan introduciéndose en el Protocolo, previa aprobación de las modificaciones y enmiendas por parte del CEIC.

2.2.- Periodo de vigencia y duración.
El inicio del estudio será con fecha 11/04/2016 y con una duración estimada de 12 meses.

La fecha de finalización del estudio se estima para 24/04/2016

Se estima que el periodo de inclusión finalice alrededor de 12/04/2016

En el supuesto de que o bien el inicio o la duración del estudio sean modificados, deberá ser comunicado por el PROMOTOR al CENTRO y al CEIC.

2.3.- Modificación.- El Protocolo no podrá ser modificado unilateralmente por el INVESTIGADOR PRINCIPAL sino que requerirá consentimiento y aprobación previas del PROMOTOR. Cualquier modificación en las condiciones autorizadas para un estudio que se consideren relevantes no podrá llevarse a cabo sin el previo dictamen favorable, en su caso, del Comité Ético, de la Consellería de Sanidad y de la Agencia Española del Medicamento y productos Sanitarios. En todo caso, deberá contar con el visto bueno del Investigador Principal del estudio. La modificación del Protocolo autorizado deberá ser notificada al Comité Ético pertinente, a la Agencia Española de Medicamentos y Productos Sanitarios, y deberá contar con el visto bueno del Investigador Principal del estudio.

Las modificaciones o enmiendas del Protocolo deberán ser comunicadas al CENTRO, a través del CEIC local. El centro podrá, si las considera como una modificación o enmienda esencial, rescindir el contrato o, de mutuo acuerdo con el promotor, proceder a la realización de una renovación del mismo.

2.4.- Normas ético-Legales:

- Todas las partes se comprometen a cumplir la legislación española vigente en materia de estudios observacionales: la Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos, Real Decreto 1344/2007, de 11 de octubre, que regula la farmacovigilancia de medicamentos de uso humano Convenio de 4 de Abril de 1.997, para la Protección de los Derechos Humanos y la Dignidad del ser humano con respecto a las obligaciones de la Biología y la medicina, ratificado por instrumento de 23 de Julio de 1999- fecha de entrada en vigor en España el día 1 de Enero de 2.000, y demás normas concordantes.

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- Se acuerda su realización conforme a las Disposiciones de la Declaración de Helsinki, en su última versión.

- El CENTRO cuidará de que en la realización del Ensayo se respeten íntegramente los derechos fundamentales de la persona, de acuerdo con las normas esenciales de la Bioética, normas sanitarias y de Buena Práctica aplicables al Ensayo, sin sustituir las funciones encomendadas a PROMOTOR, INVESTIGADOR y COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA

- y en los temas que sean de aplicación de la Ley 14/2007, de 3 de julio, de Investigación biomédica.

2.5.- Consentimiento informado del paciente.- De conformidad con lo previsto en la Ley 41/2002, de 14 de noviembre, reguladora de la autonomía de los pacientes, en los estudios post-autorización de tipo observacional prospectivos, es imprescindible que el sujeto otorgue libre y voluntariamente el consentimiento informado antes de ser incluido en el estudio. Antes de incluir a cualquier paciente en el Estudio, el Investigador Principal o sus colaboradores que tengan delegada esta función deberá informar al paciente en lenguaje comprensible de forma verbal y escrita de la naturaleza del estudio, y obtendrá el consentimiento informado de dicho paciente y/o de su representante, de conformidad a la legislación vigente. El paciente recibirá una copia de este documento.

El consentimiento será previo a la inclusión del sujeto en el estudio, y estará fechado y firmado. El sujeto participante en el estudio debe ser capaz de dar su consentimiento tras haber sido debidamente informado acerca de la naturaleza, importancia, implicaciones y riesgos de la participación en el mismo, así como de los tratamientos alternativos y las condiciones de confidencialidad de conformidad con la Ley de Protección de Datos. Cuando el sujeto no sea capaz de dar su consentimiento o no esté en condiciones de hacerlo, la decisión deberá adoptarse, teniendo en cuenta las exigencias del Real Decreto 223/2004.

En el caso de estudios que impliquen la participación de menores o incapacitados, se informará al ministerio fiscal conforme establece la legislación vigente. Si en el estudio se va a recoger información de sujetos menores o incapaces, el consentimiento lo otorgará siempre por escrito su representante legal, tras haber recibido y comprendido la información mencionada.

Las versiones a utilizar de la hoja de información al paciente (HIP) y consentimiento informado (CI) serán las que hayan sido aprobadas por el Comité Ético. El CEIC del Centro debe aprobar la Hoja de Información al Paciente (HIP) y el Consentimiento Informado (CI). En la historia clínica del paciente se archivará con la debida custodia una copia del consentimiento informado.

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2.6.- Acceso.- El CEIC tendrá acceso en cualquier momento a la documentación relativa al estudio, necesaria para llevar a cabo el seguimiento de lo establecido en la normativa, especialmente al consentimiento informado de los pacientes que participen en el mismo.
El monitor del estudio también tendrá acceso en cada visita que realice a la documentación clínica pertinente de los pacientes incluidos en el estudio. En todo caso, deberá respetar la confidencialidad de los datos de conformidad con la legislación vigente.
Igualmente las Autoridades Sanitarias competentes tendrán acceso a la documentación clínica del paciente, al realizar las inspecciones.

2.7.- Publicación de resultados.- El promotor se compromete a la publicación de los resultados del presente estudio. Dicha publicación será remitida obligatoriamente a los CEICs implicados en la realización del estudio y los investigadores principales para su conocimiento. El Investigador Principal podrá presentar los resultados en una reunión científica apropiada y/o publicarlos en una revista de reconocido prestigio, comprometiéndose a suministrar al Promotor una copia del manuscrito u original, con la suficiente antelación, a efectos de que éste tenga oportunidad de conocer dicha información o material informativo para la realización de sus comentarios sobre el contenido de tales comunicaciones/publicaciones en un plazo de 30 días a contar desde la recepción de los mismos.
El investigador se compromete a respetar los acuerdos establecidos en el protocolo del estudio que hacen especial referencia a la publicación de los datos, evitando realizar comunicaciones de los datos de un centro y presentando siempre los datos del estudio en su conjunto.
Si el Promotor así lo solicita, con el fin de asegurar apropiadamente la protección de invenciones o desarrollos derivados del estudio, el Investigador Principal acepta retrasar la presentación de la publicación propuesta, durante un plazo no superior a 6 meses.
El promotor se compromete a no impedir y/o dificultar la difusión de aquellos resultados conjuntos que, siendo científicamente sólidos e incuestionables, pongan de manifiesto la ausencia de eficacia o efectos adversos del tratamiento.
Transcurridos 6 meses, se podrán hacer públicos los resultados en el Programa de Investigación Clínica de Medicamentos y Productos Sanitarios en la Comunidad Valenciana (PICME) de la página Web de la Conselleria de Sanitat.

2.8.- Confidencialidad y Protección de datos- Todas las informaciones relativas a la realización del estudio, sean anteriores o posteriores al mismo, suministradas u obtenidas, son confidenciales. En todo caso, si la información se revelara a un tercero, éste se comprometerá por escrito a respetar el secreto y confidencialidad de la información en estos mismos términos.

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Finalmente, todas las partes y personal colaborador deberán tomar las medidas oportunas para guardar la confidencialidad de los datos de carácter personal de los que tuvieran conocimiento como consecuencia de la realización del estudio, impidiendo el acceso a los mismos a terceros no autorizados. El CENTRO procurará su respeto, y junto al INVESTIGADOR PRINCIPAL, restringirá el acceso a la información a aquellos supuestos necesarios para la correcta ejecución del protocolo.
En este sentido, deberá ser objeto de estricta observancia la Ley Orgánica 15/1999 de 13 de diciembre, de protección de Datos de Carácter Personal, la Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica y la Ley 1/2003, de 28 de enero, de derechos y de información al paciente de la Comunidad Valenciana, así como el Real Decreto 1720/2007, de 21 de diciembre, por el que se aprueba el Reglamento de desarrollo de la Ley Orgánica 15/1999 de 13 de diciembre, de protección de datos de carácter personal.
Siempre y cuando se respeten los postulados del artículo 2.7, el CENTRO no estará facultado para desvelar o difundir por cualquier medio los resultados, datos e informaciones que resulten directa o indirectamente de la realización del estudio ni siquiera con fines científicos, salvo autorización escrita del PROMOTOR.

2.9.- Archivo de la documentación.- Las historias clínicas de los pacientes dispondrán de un sistema permanente, ágil y rápido para identificar que un paciente participa o ha participado en un estudio.
El CEIC, debe mantener archivada la documentación relacionada con su funcionamiento y actividad. En caso de cese de la misma, esta documentación debe conservarse en la institución durante al menos tres años, transcurridos desde la finalización del último estudio evaluado.
En el caso de que hayan procesos judiciales abiertos, convendría se conservaran en formato papel mientras no haya una decisión judicial firme. Esta documentación debe archivarse preferentemente agrupada, en un lugar que permita garantizar la confidencialidad de la información durante el tiempo de archivo requerido.
Se deben garantizar las obligaciones recogidas en la Ley 15/1999, de 13 de diciembre, de protección de datos de carácter personal y su posterior desarrollo (Real Decreto 1720/2007, de 21 de diciembre, por el que se aprueba el Reglamento de desarrollo de la Ley Orgánica 15/1999 de 13 de diciembre, de protección de datos de carácter personal)
Los soportes utilizados para conservar los documentos esenciales deberán garantizar que los documentos permanecen completos y legibles y que estén a disposición de las autoridades competentes en caso de que lo soliciten durante el periodo provisto de conservación.
Cuando los soportes utilizados para conservar los documentos esenciales sean en formato electrónico deberán garantizar que cualquier modificación de los registros

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sea trazable, permitiendo conocer el dato inicial y el corregido, así como la fecha y firma del autor, incluyendo como mínimo lo siguiente:

- Resoluciones de acreditación y de posteriores modificaciones.
- Currículum vital de los miembros actuales o que hayan pertenecido al Comité.
- Convocatoria y actas de las reuniones del Comité.
- Procedimientos normalizados de trabajo del Comité, versión actual y archivo histórico.
- Libro de Registro.

TERCERA.- Participantes y lugar de realización

3.1.- Participantes

3.1.1.- Promotor

3.1.2.- Investigador Principal.- El INVESTIGADOR PRINCIPAL cuidará y garantizará que todos los participantes en el ensayo y, especialmente, los colaboradores cumplen fielmente con este contrato y su anexo, habiendo sido informados suficientemente sobre el mismo.

3.1.3. – Colaboradores-.
El equipo de colaboradores del INVESTIGADOR deberá ser aprobado y estar capacitado para cumplir con éxito el estudio previsto, cumpliendo los requisitos del certificado de idoneidad correspondiente.
El investigador principal tiene el compromiso de comunicar al CEIC y a la Dirección del Centro todas las modificaciones y actualizaciones de las funciones del equipo implicado en el contrato.

3.1.4. - Otro personal.- Si para el desarrollo del presente estudio se precisa la contratación de personal ajeno al CENTRO. La contratación será notificada al centro a los efectos de inspección y autorización de acceso y participación en el protocolo mediante la acreditación pertinente.
Ninguna de las prescripciones del presente contrato constituye o puede constituir relación laboral entre el CENTRO y las personas ajenas al mismo que participe en el ensayo.

3.2.- Lugar de realización
El ensayo clínico objeto de este contrato se realizará en el Servicio, **Unidad, Departamento/s, centro/s** de Psicología del centro sanitario Fundación Instituto Valenciano de Oncología.

CUARTA.- Relaciones económicas

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4.1.- Memoria económica

El coste económico global del estudio, se cifra en " 0 euros" por paciente (IVA excluido). El desglose del mismo se recoge en el Anexo I del presente contrato (Memoria económica del estudio), en el que se especifican tanto los costos directos como indirectos del estudio (compensación económica para los investigadores, gastos de Administración y gestión, gastos del centro en pruebas y procesos, compensación económica para los sujetos del ensayo, y otros gastos).

4.2. Formas de pago:

La memoria económica del estudio es 0 por lo que no se prevén pagos en este estudio

La Entidad Promotora hace constar que no se han establecido ni se establecerán acuerdos ajenos al presente contrato con el Investigador Principal, sus colaboradores ni con ninguna institución implicada directa o indirectamente con la realización de este estudio, de los que deriven retribuciones económicas adicionales o contraprestaciones en especie. En el caso de que por algún motivo sea necesaria la firma de un contrato complementario, se anexará al presente.

QUINTA.- Obligaciones del promotor y monitor del estudio:

Establecidas según la legislación vigente en materia de estudios postautorización de tipo observacional con medicamentos y productos sanitarios. El promotor del estudio deberá comunicar la fecha de inicio del estudio.

SEXTA.- Obligaciones del investigador principal.

Establecidas según la legislación vigente en materia de estudios postautorización de tipo observacional con medicamentos y productos sanitarios.

SÉPTIMA.- Obligaciones del CENTRO.

- El CENTRO se obliga a aportar las instalaciones, recursos humanos, medios diagnósticos, terapéuticos y de investigación de que dispone, así como a realizar las exploraciones y pruebas extraordinarias que así se determinen, contenidas en el Protocolo del estudio y expresadas en la Memoria Económica del mismo.
- Las obligaciones del CENTRO son independientes de las de los investigadores y del personal vinculado al estudio y se circunscriben a las actividades que son ordinarias y propias de la Institución.

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OCTAVA.- Obligaciones de la FUNDACIÓN.

Son obligaciones de la FUNDACIÓN, la gestión económica del presente estudio, recibiendo los pagos realizados por el PROMOTOR y distribuyéndolos conforme a lo establecido en el Anexo I.

NOVENA.- Archivo de Documentación del Estudio.

a) El promotor del ensayo es responsable del archivo de la documentación del estudio.

b) El investigador se ocupará de que los códigos de identificación de los sujetos se conserven durante al menos quince años después de concluido o interrumpido el estudio.

c) Las historias clínicas de los pacientes y demás datos originales se conservarán de acuerdo a la legislación vigente

d) El promotor o propietario de los datos conservará toda la restante documentación relativa al estudio durante el periodo de validez del medicamento. Estos documentos son los siguientes:

- El protocolo, incluyendo su justificación, objetivos, diseño estadístico y metodología del estudio, con las condiciones en las que se efectúe y gestione, así como los pormenores de los medicamentos objeto del estudio.
- Los procedimientos normalizados de trabajo.
- Todos los informe escritos sobre el protocolo y los procedimientos.
- La ficha técnica del medicamento a estudio.
- El cuaderno de recogida de datos de cada paciente.
- Los documentos administrativos correspondientes a las autorizaciones del protocolo y posteriores modificaciones.
- El informe final: el promotor o propietario subsiguiente conservará el informe final hasta cinco años después de haberse agotado el plazo de validez del medicamento.
- El certificado de auditoría, cuando proceda.

e) Se documentará todo cambio que se produzca en la posesión de los datos.

f) Todos los datos y documentos se pondrán a disposición de las autoridades competentes si éstas así lo solicitan.

g) Se asegurará, en todo caso, la confidencialidad de los datos y documentos contenidos en el archivo.

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h) En todo caso, las partes acuerdan que se adaptará al modelo de las normas ICH (International Conference of Harmonization Guideline) para las Buenas Prácticas Clínicas (BPC).

DÉCIMA.-Informes y propiedad de los resultados

10.1. - ***Informes.***- El promotor del estudio postautorización de tipo observacional con medicamentos deberá elaborar el informe final, y deberá remitir una copia del mismo en el plazo de seis meses desde la finalización del mismo. El informe será enviado independientemente de la finalización anticipada del estudio. Además, el promotor deberá enviar el informe final o el anual al CEIC.

10.2. - ***Propiedad de los resultados***.- Las partes acuerdan que todos los derechos, datos, resultados y descubrimientos o inventos, patentables o no, realizados, obtenidos o generados en relación con el estudio serán propiedad exclusiva del PROMOTOR.

En el caso de contratos con memoria económica cero, las partes acuerdan que la propiedad intelectual e industrial de los resultados derivados del presente estudio sea compartida, en proporción a la aportación de cada una de ellas a la presente investigación. En los instrumentos de protección del conocimiento generado, se hará constar de manera expresa dicha circunstancia de co-titularidad. Los gastos derivados necesarios para la protección de dicha propiedad, serán asumidos por las partes en los mismos términos.

UNDÉCIMA.- Seguros y responsabilidades

11.1. Al ser un estudio observacional el investigador deberá limitarse a observar la realidad sin modificarla, sin introducir activamente la intervención farmacológica, y sin realizar visitas o pruebas extraordinarias. En ningún caso, podrán utilizarse los medicamentos cuya observación se realiza en este estudio para indicaciones no autorizadas o en condiciones de uso diferentes a las establecidas en la ficha técnica delos mismos, garantizando el promotor y el investigador que así se cumplirá.

14.2. En todo caso, el CENTRO acuerda notificar al PROMOTOR cada vez que tenga conocimiento de una querella, denuncia, reclamación o acción legal, real o potencial si es conocida.

DUODÉCIMA.- Representación de las partes

El CENTRO no ostenta representación alguna del PROMOTOR frente a terceros.

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El Promotor se compromete a notificar al centro, a través del Comité Ético de Investigación Clínica, toda modificación del protocolo surgida durante la realización del mismo, tales como ampliaciones del periodo de reclutamiento, así como el informe final de cierre del estudio, con la relación de pacientes incluidos.

Ninguna información acerca de datos del estudio podrán ser revelados a medios de comunicación o a personal relacionado con entidades operadoras del mercado financiero. El Investigador Principal, en nombre propio y en el de los colaboradores, se compromete a no hacer uso en beneficio propio de la información privilegiada que su participación en el ensayo pudiera suponer.

DECIMOTERCERA.- Facultad de inspección y supervisión

El CENTRO y el INVESTIGADOR PRINCIPAL y sus colaboradores y el Promotor posibilitarán a las autoridades sanitarias a inspeccionar sus Registros del estudio y fuentes asociadas al estudio, cuando se solicite.

El CENTRO y el INVESTIGADOR PRINCIPAL y sus colaboradores posibilitarán a cualquier asesor o auditor externo designado por el PROMOTOR, inspeccionar sus Registros del estudio y fuentes asociadas al estudio, cuando se solicite.

DECIMOCUARTA.- Regulación y Jurisdicción.

14.1.- Contractual.- Ambas partes convienen que sus relaciones se regulan exclusivamente por el contenido del presente contrato, siendo nulo y quedando sin efecto, cualquier acuerdo anterior, expreso o tácito, documentado o no. El presente contrato sólo se entenderá modificado o enmendado por acuerdo escrito de las partes y según lo dispuesto en la estipulación 2.1.- del mismo.

14.2.- Legislativa.- El presente contrato se somete a las leyes y normas españolas.

14.3.- Jurisdicción.- Las partes se someten, con renuncia expresa al fuero que pudiera corresponderles, a los Tribunales del domicilio del CENTRO.

DECIMOQUINTA.- Causas de terminación

15.1.- *Ordinaria*.- El contrato finalizará cuando concluya la realización del estudio.

15.2.- *Resolución*.- Este contrato podrá ser resuelto por cualquiera de las Partes con efecto inmediato mediante notificación por escrito, a no ser que la parte incumplidora subsane sus actos en el plazo de los 30 días siguientes de recibir la notificación, si se incumplen las cláusulas del contrato o de la normativa legal aplicable.

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15.3.- ***La finalización del contrato*** conllevará la liquidación de las relaciones económicas entre las partes, sin perjuicio de la responsabilidad asegurada en el apartado séptimo.

En caso de suspensión del ensayo, El INVESTIGADOR PRINCIPAL deberá devolver al PROMOTOR el material suministrado por éste y toda la medicación no utilizada, que continúe en su poder.

El PROMOTOR estará obligado al pago de todas aquellas prestaciones estipuladas que hubieran sido realizadas, salvo:

- Al CENTRO, de aquellas prestaciones que realizadas de forma defectuosa, hubieren originado la suspensión del estudio.
- Al INVESTIGADOR PRINCIPAL, si la suspensión derivase del incumplimiento de sus funciones y obligaciones.

En el caso de finalización anticipada, el investigador Principal entregará al Promotor un informe de los resultados obtenidos hasta el momento de la interrupción de la investigación.

En todos estos casos, el Promotor abonará al Departamento/Centro, a los sujetos del estudio y en su caso a la Fundación, las cantidades correspondientes al trabajo correctamente realizado.

En señal de conformidad y después de leído el presente contrato, todas las partes lo firman por cuadriplicado en el lugar y fecha indicados en el encabezamiento.

POR EL CENTRO

Dª ASUNCIÓN PERALES MARÍN
Rivera

DIRECTORA GENERAL

POR EL PROMOTOR

Fdo.: Rosa María Baños

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FUNDACIÓN
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POR LA FUNDACIÓN

CARLOS ANDRÉS
SECRETARIO

POR EL INVESTIGADOR

Fdo.: Rosa María Baños Rivera

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---ANEXO I:
MEMORIA ECONÓMICA----

PRESUPUESTO TOTAL DEL ENSAYO:	COSTE POR PACIENTE	TOTAL
I. Costes extraordinarios	.0€	.0€
I.a. Gestión administrativa estudio	.0€	.0€
I.b. Compensación a los pacientes	.0€	.0€
II. Costes ordinario del estudio (paciente reclutado)	.0€	.0€
II.a. Costes indirectos (42% del presupuesto establecido por cada paciente reclutado)	.0€	.0€
II.b. Compensación por la labor del Investigador, Colaboradores y Servicios (47% del presupuesto calculado por cada paciente reclutado evaluable)	.0€	.0€
II.c. Compensación por la labor de farmacia y otros (6%)	.0€	.0€
III. Pacientes que no finalizan el estudio (se estará a lo dispuesto en la tabla de prorrateo)	.0€	.0€
TOTAL PRESUPUESTO ENSAYO	**.0€**	**.0€**

ESTAS CANTIDADES NO INCLUYEN IVA

EL INVESTIGADOR PRINCIPAL,
Fdo.: Rosa María Baños Rivera

Fdo.: Rosa María Baños Rivera

EL DIRECTORA DEL CENTRO,
Fdo.: Asunción Perales Marín

POR LA FUNDACIÓN
Fdo.: Carlos J. Andrés Blasco

10.2 APPENDIX 2: PATIENTS' INFORMED CONSENT

HOJA DE INFORMACIÓN AL PACIENTE

Se le ofrece la posibilidad de participar en el estudio de investigación titulado **"*Eficacia de un programa Entrenamiento en Compasión de Base Cognitiva para la mejora del bienestar psicológico en pacientes supervivientes de cáncer de mama*"** que está siendo realizado por la Dra. Rosa María Baños Rivera, Catedrática de la Universidad de Valencia, y que ha sido ya evaluado y aprobado por el Comité Ético de Investigación Clínica de la Fundación Instituto Valenciano de Oncología.

Antes de que decida participar en este estudio, es importante que comprenda por qué se realiza el estudio y qué se espera de usted, así como los beneficios e inconvenientes que puedan estar asociados con su participación en este estudio.

¿Cuál es el objetivo de este estudio?

Los objetivos generales del estudio son los siguientes:

Se pretende valorar en los pacientes supervivientes de cáncer de mama las siguientes variables psicológicas:

Sintomatología ansioso-depresiva.

Estrategias de afrontamiento.

Niveles de Compasión y Auto-Compasión

Niveles de Mindfulness

Los objetivos específicos del estudio son los siguientes:

Valoración de la eficacia del programa de Entrenamiento en Compasión de Base Cognitiva.

Analizar la eficacia del programa CBCT para el aumento de los niveles de Mindfulness, compasión y auto-compasión.

Analizar la eficacia del programa CBCT en la reducción de sintomatología de ansiedad, depresión, temor a la recurrencia de la enfermedad y afrontamiento al estrés.

¿Por qué se le ha pedido que participe?

Queremos mostrar si este programa de intervención es eficaz, para eso necesitamos evaluar y probar sus efectos.

¿En qué consiste su participación?

La participación en el presente estudio tiene carácter voluntario y no supone ninguna alteración del tratamiento médico ni seguimiento que esté llevando en el hospital. Su participación en el estudio permitirá obtener los datos necesarios

para conseguir el objetivo del estudio. El programa de Entrenamiento en Compasión de Base Cognitiva consta de una sesión de dos horas a la semana durante ocho semanas. En este programa se facilitarán audios para la continuación de la práctica en casa y materiales de apoyo que puedan ser de utilidad.

Se le solicita permiso para:

Poder acceder a sus datos clínicos y a utilizarlos con la finalidad investigadora que se aquí se le propone.

Grabar las sesiones con fines de desarrollo profesional y de investigación para para el óptimo desarrollo de este estudio. Las grabaciones se utilizarán como apoyo para las supervisiones que se realizan por parte del equipo profesional para asegurar la máxima eficiencia, eficacia y excelencia en el programa que se le ofrece. Una vez utilizadas las grabaciones de vídeo y audio y habiendo obtenido la información requerida para este estudio, se destruirán inmediatamente para así mantener completa confidencialidad.

En caso que cumpla con los criterios de inclusión del estudio (no presentar psicopatología), se le invitará a formar parte del estudio. En caso que acepte se hará entrega de documentos de evaluación al antes de comenzar la intervención y una vez finalizada. Además, se le solicitará hacer esa misma evaluación seis y doce meses después de haber finalizado el programa.

Puede estar en el grupo control (con inicio del programa aproximadamente en Mayo 2016) o en el grupo experimental (con inicio del programa aproximadamente en Noviembre 2015). Esto se determinará de manera aleatoria.

Protocolo a Aplicar

El programa por el que usted pasará se lllama CBCT y tiene una duración de ocho semanas en sesiones de dos horas de duración. En las sesiones se darán materiales didácticos, se discutirá en clase y se harán prácticas de meditación guiadas. Los temas que se cubrirán son los siguientes:

Sesión 1: Desarrollando concentración y atención.

Sesión 2: Entrenando Mindfulness.

Sesión 3: Explorando y examinando las causas del estrés y la reactividad emocional.

Sesión 4: Entrenamiento en aceptación del sufrimiento.

Sesión 5: Práctica en el cultivo del aprecio y la gratitud hacia los demás.

Sesión 6: Entrenamiento en empatía y compasión.

Sesión 7: Profundizando en la compasión.

Sesión 8: Trabajando la motivación para ser feliz.

Práctica de compasión y auto-compasión para casa

Se le aconseja practicar los conocimientos y habilidades adquiridas en cada sesión por lo menos tres veces a la semana utilizando grabaciones de meditaciones guiadas (con una duración media de 30 minutos) junto con un diario/hoja de registro de meditación. Se le facilitará acceso a las grabaciones por medio de un CD o de un flash drive.

¿Cuáles son los riesgos generales de participar en este estudio?

No se prevé ningún riesgo para usted por participar en el presente estudio.

¿Cuáles son los beneficios de la participación en este estudio?

Ni usted ni el investigador principal recibirán ninguna remuneración económica por la realización del presente estudio.

¿Qué pasará si decido no participar en este estudio?

Su participación en este estudio es totalmente voluntaria. En caso de que decida no participar en el estudio, esto no modificará el trato y seguimiento que de su enfermedad realicen ni su médico ni el resto del personal sanitario que se ocupa de su enfermedad. Asimismo, podrá retirarse del estudio en cualquier momento, sin tener que dar explicaciones, y sin que esto repercuta en los cuidados médicos. Además, si en algún momento del estudio usted desea dejar de participar en la grabación de las sesiones, le rogamos que nos lo comunique y a partir de ese momento se dejará de hacer las grabaciones con fines de desarrollo profesional y de investigación para esa sesión. Se le ruega realizar la evaluación final (post-test) posterior a la aplicación del programa, aunque haya abandonado el estudio. Para nosotros es muy valioso.

¿A quién puedo preguntar en caso de duda?

Podrá solicitar cualquier explicación que desee sobre cualquier aspecto del estudio y sus implicaciones a lo largo del mismo contactando con la Psicooncóloga Dra. Rocío Romero Retes al teléfono 961114033.

Confidencialidad:

Todos sus datos personales, así como toda la información médica relacionada con su enfermedad serán tratados con absoluta confidencialidad por parte del personal encargado de la investigación. Los datos serán codificados y anonimizados. Asimismo, si los resultados del estudio fueran susceptibles de publicación en revistas científicas, en ningún momento se proporcionaran datos personales de los pacientes que han colaborado en esta investigación. Se le hace conocimiento que la información que se facilitará se destruirá inmediatamente después de haber obtenido la información requerida para este estudio.

Tal y como contempla la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal, podrá ejercer su derecho a acceder, rectificar o cancelar sus datos contactando con el investigador principal de este estudio.

CONSENTIMIENTO INFORMADO

TÍTULO DEL ESTUDIO: "***Eficacia de un programa Entrenamiento en Compasión de Base Cognitiva para la mejora del bienestar psicológico en pacientes supervivientes de cáncer de mama***"**.**

Y cuya investigadora principal es: Dra. Rosa María Baños Rivera, Catedrática del Departamento de Personalidad, Evaluación y Tratamientos Psicológicos de la Universidad de Valencia.

Yo, D./Dª _____ he sido informado personalmente por el personal del Instituto Valenciano de Oncología, y declaro que:

He leído la Hoja de Información que se me ha entregado.

He podido hacer preguntas sobre el estudio.

He recibido respuestas satisfactorias a mis preguntas.

He recibido suficiente información sobre el estudio.

Comprendo que mi participación es voluntaria.

Comprendo que en ningún caso mis datos se harán públicos y serán tratados confidencialmente, según la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal, y los datos serán codificados y anonimizados y que.

Comprendo que puedo retirarme del estudio:

- Cuando quiera.

- Sin tener que dar explicaciones.

- Sin que esto repercuta en mis cuidados médicos.

Presto libremente mi conformidad para participar en el estudio sobre "***Eficacia de un programa Entrenamiento en Compasión de Base Cognitiva para la mejora del bienestar psicológico en pacientes supervivientes de cáncer de mama***" y consiento expresamente a que el personal investigador pueda acceder a mis datos personales y de salud.

Fecha:	Fecha:
Firma del paciente:	Firma del Investigador:

10.3 APPENDIX 3: PATIENTS' INFORMED CONSENT FOR AUDIO AND VIDEO RECORDINGS

HOJA CONSENTIMIENTO GRABACIONES

EN VIDEO / AUDIO

Nombre y Apellidos: _____

En este estudio titulado "Eficacia de un programa Entrenamiento en Compasión de Base Cognitiva para la mejora del bienestar psicológico en pacientes supervivientes de cáncer de mama", se realizará grabación de las sesiones en vídeo y/o audio. Las grabaciones proporcionan una información muy valiosa que se utiliza para la mejora de las sesiones del programa que está a punto de realizar. Por esta razón se le solicita autorización para:

- Grabar las sesiones con fines de desarrollo profesional y de investigación para el óptimo desarrollo de este estudio. Las grabaciones se utilizarán como apoyo para las supervisiones que se realizan por parte del equipo profesional para asegurar la máxima eficiencia, eficacia y excelencia en el programa que se le ofrece. Una vez utilizadas las grabaciones de vídeo y audio y habiendo obtenido la información requerida para este estudio, se destruirán inmediatamente para así mantener completa confidencialidad.

MANIFIESTO:

Que he sido informado suficientemente de la utilización de las grabaciones de las sesiones que se realizarán durante el el Entrenamiento en Compasión de Base Cognitiva en la Fundación Instituto Valenciano de Oncología.

Que, salvaguardando siempre mi derecho a la intimidad y al anonimato, estoy de acuerdo y acepto libre y voluntariamente la grabación en video/ audio de las sesiones de este programa.

Que en función de esta opción libre, puedo cambiar mi opinión y pedir que no se lleve a cabo la grabación de las sesiones en el momento que quiera.

El interesado/a, Dra. Rosa María Baños Rivera Catedrática del Departamento de Personalidad, Evaluación y Tratamientos Psicológicos de la Universidad de Valencia

Valencia, __ de _____ del 20__

10.4 APPENDIX 4: PATIENT'S ORIENTATIVE BOOKLET

Cartas a un poeta

¿Cómo podríamos olvidar aquellos antiguos mitos que están en el inicio de todos los pueblos, los mitos sobre dragones que en el ultimo instante se transforman en princesas? Quizás todos los dragones en nuestras vidas sean princesas esperando que actuemos solamente una vez, con coraje y belleza. Quizás todo lo que nos asusta sea, en su más profunda esencia, algo indefenso que anhela nuestro amor.

Por eso, no te sientas asustada, si se alza ante ti, la tristeza más grande que jamás hubieras imaginado. Si un desasosiego como nubarrones de luz y sombra, se posa en tus manos y en todo tú hacer. Debes darte cuenta de que algo ha sucedido en ti, que la vida no te ha olvidado; ella te sostiene en sus manos y no te dejará caer. ¿Por qué, entonces, quieres excluir de tu vida cualquier inquietud, dolor o tristeza? Si después de todo, no sabes que labor estas sensaciones están produciendo dentro de ti.

Rainer Maria Rilke, "Cartas a un poeta: Letters to a young poet."

"Eficacia de un programa de 'Entrenamiento en Compasión de Base Cognitiva' para la mejora del bienestar psicológico en pacientes supervivientes de cáncer de mama"

Manual Orientativo

¿Qué es el estudio de Entrenamiento en Compasión?

Es un programa orientado al cultivo de mayor bienestar por medio de ejercicios que facilitan el cultivo de emociones positivas calmando nuestro cuerpo y mente, descubriendo el potencial de ser feliz que todos tenemos.

A continuación se presenta un calendario para que lo tengas en cuenta o lo apuntes en tu agenda:

Calendario

Lunes 26 de Septiembre	Claridad y Calma
Lunes 03 de Octubre	Descansando en nuestro estado natural
Lunes 10 de Octubre	Auto-cuidado I
Lunes 17 de Octubre	Auto-cuidado II
Martes 24 de Octubre	Aceptación Activa
Lunes 7 de Noviembre	Alegría Entusiasta
Lunes 14 de Noviembre	Compasión
Lunes 21 de Noviembre	Motivación para ser feliz, Despedida y Evaluación

¿En que consiste este programa?

Oomo refleja el Calendario, este curso consta de una sesión de dos horas a la semana durante ocho semanas. En este programa se facilitarán audios para la continuación de la práctica en casa y materiales de apoyo que puedan ser de utilidad.

¿En qué consiste mi participación?

Para nosotros y para la elaboración de este curso es sumamente importante su participación. Nosotros haremos todo lo posible para que se sienta cómoda y segura. Así, para el buen funcionamiento del estudio sobre los beneficios de este curso, le rogamos, en la medida de lo posible, asista a todas las sesiones. En caso que no sea posible, le rogamos nos lo haga saber para tenerlo en cuenta a la hora de elaborar cada sesión.

Su participación en el presente estudio tiene carácter voluntario y no supone ninguna alteración del tratamiento médico ni seguimiento que esté llevando en el hospital. Su participación en el estudio permitirá obtener los datos necesarios para conseguir el objetivo del estudio y que más gente se beneficie del mismo.

MUCHAS GRACIAS POR SU
PARITCIPACIÓN CONTINUA

Información importante

Si necesitas alguna aclaración o ayuda, puedes solicitarla a:

- Dra. Rocío Romero Retes al teléfono 961114033 o
- Edgar González al teléfono 6364045561

10.5 APPENDIX 5: SOCIO-DEMOGRAPHIC DATA

Nombre:_____ Apellidos: _____

Código (Últimas 4 cifras del DNI):_____

Edad y fecha de nacimiento: _____ Sexo: _____

DNI: _____

Lugar de nacimiento:_____

Dirección actual: _____

Población: _____ CP: _____

Tfnos.: _____

e-mail:_____

Profesión: _____ Nivel de estudios:_____

Religión:_____ ¿Practicante?_____

Señale las personas que habitualmente viven en su casa: _____

¿Has recibido asistencia psicológica antes de ser diagnostica de un cáncer? ¿Cuando? ¿Durante cuánto tiempo? ¿Para qué problema?

_____

_____

_____

¿Tienes experiencia en meditación o yoga?_____

10.6 APPENDIX 6: SELF-ADMINISTERED INSTRUMENTS OF ASSESMENT

BSI-18

NID:

Por favor, señale de la lista de problemas que aparecen a continuación la alternativa que mejor describa en qué grado ha estado molesto/a o cuánto ha sufrido, durante los últimos 7 días.

Me he sentido molesto/a por:	Nada	Poco	Regular	Bastante	Mucho
1S. Sensación de desmayo o mareos	0	1	2	3	4
2D. No sentir interés por las cosas	0	1	2	3	4
3A. Nerviosismo o temblor	0	1	2	3	4
4S. Dolores en el corazón o en el pecho	0	1	2	3	4
5D. Sentirse solo	0	1	2	3	4
6A. Sentirse tenso o alterado	0	1	2	3	4
7S. Nauseas o malestar en el estómago	0	1	2	3	4
8D. Sentimientos de tristeza	0	1	2	3	4
9A. Sustos repentinos y sin razón	0	1	2	3	4
10S. Falta de aire	0	1	2	3	4
11D. Sentir que usted no vale nada	0	1	2	3	4
12A. Ataques de terror o pánico	0	1	2	3	4
13S. Adormecimiento u hormigueo en ciertas partes del cuerpo	0	1	2	3	4
14D. Sentirse sin esperanza en el futuro	0	1	2	3	4
15A. Sentirse tan inquieto que no puede permanecer sentado	0	1	2	3	4
16S. Sentirse débil en partes del cuerpo	0	1	2	3	4
17D. Pensamientos de poner fin a su vida	0	1	2	3	4
18A. Sentirse con miedo	0	1	2	3	4

S= D= A= GLOBAL=

FACT-B (4ª Versión)

NID:

A continuación encontrará una lista de afirmaciones que otras personas con su misma enfermedad consideran importantes. **Marque un solo número por línea para indicar la respuesta que corresponde a los <u>últimos 7 días</u>.**

	ESTADO FÍSICO GENERAL DE SALUD	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchí-simo**
GP1	Me falta energia	0	1	2	3	4
GP2	Tengo náuseas 0	0	1	2	3	4
GP3	Debido a mi estado físico, tengo dificultad para atender a las necesidades de mi família	0	1	2	3	4
GP4	Tengo dolor 0	0	1	2	3	4
GP5	Me molestan los efectos secundarios del tratamiento 0	0	1	2	3	4
GP6	Me siento enfermo(a) 0	0	1	2	3	4
GP7	Tengo que pasar tiempo acostado(a) ……	0	1	2	3	4

	AMBIENTE FAMILIAR Y SOCIAL	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchí-simo**
GS1	Me siento cercano(a) a mis amistades 0	0	1	2	3	4

GS2	Recibo apoyo emocional por parte de mi familia 0	0	1	2	3	4
GS3	Recibo apoyo por parte de mis amistades 0	0	1	2	3	4
GS4	Mi familia ha aceptado mi enfermedad 0	0	1	2	3	4
GS5	Estoy satisfecho(a) con la manera en que se comunica mi familia acerca de mi enfermedad 0	0	1	2	3	4
GS6	Me siento cercano(a) a mi pareja (o a la persona que es mi principal fuente de apoyo) ……..	0	1	2	3	4
Q1	*Sin importar su nivel actual de actividad sexual, conteste a la siguiente pregunta. Si prefiere no contestarla, marque esta casilla* ☐ *continúe con la siguiente sección.*					
GS7	Estoy satisfecho(a) con mi vida sexual	0	1	2	3	4

Marque un solo número por línea para indicar la respuesta que corresponde a los <u>últimos 7 días</u>.

	<u>ESTADO EMOCIONAL</u>	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchí-simo**
GE1	Me siento triste 0	0	1	2	3	4
GE2	Estoy satisfecho(a) de cómo me estoy enfrentando a mi enfermedad	0	1	2	3	4
GE3	Estoy perdiendo las esperanzas en la lucha contra mi enfermedad 0	0	1	2	3	4
GE4	Me siento nervioso(a) 0	0	1	2	3	4
GE5	Me preocupa morir 0	0	1	2	3	4
GE6	Me preocupa que mi enfermedad empeore 0	0	1	2	3	4

	CAPACIDAD DE FUNCIONAMIENTO PERSONAL	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchí-simo**
GF1	Puedo trabajar (incluya el trabajo en el hogar) 0	0	1	2	3	4
GF2	Mi trabajo me satisface (incluya el trabajo en el hogar) 0	0	1	2	3	4
GF3	Puedo disfrutar de la vida 0	0	1	2	3	4
GF4	He aceptado mi enfermedad 0	0	1	2	3	4
GF5	Duermo bien 0	0	1	2	3	4
GF6	Disfruto con mis pasatiempos de siempre 0	0	1	2	3	4
GF7	Estoy satisfecho(a) con mi calidad de vida actual 0	0	1	2	3	4

Marque un solo número por línea para indicar la respuesta que corresponde a los <u>últimos 7 días</u>.

	OTRAS PREOCUPACIONES	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchí-simo**
B1	Me ha faltado el aire para respirar 0	0	1	2	3	4
B2	Estoy preocupada con la manera de vestirme 0	0	1	2	3	4
B3	Tengo el brazo o los brazos hinchados o doloridos 0	0	1	2	3	4
B4	Me siento físicamente atractiva 0	0	1	2	3	4

B5	Me molesta la pérdida de cabello 0	0	1	2	3	4
B6	Me preocupa que, algún día, otros miembros de mi familia puedan padecer de la misma enfermedad 0	0	1	2	3	4
B7	Me preocupan las consecuencias del estrés (la tensión) en mi enfermedad 0	0	1	2	3	4
B8	Me molestan los cambios de peso 0	0	1	2	3	4
B9	Me sigo sintiendo una mujer 0	0	1	2	3	4
P2	Tengo dolor en ciertas partes del cuerpo 0	0	1	2	3	4

Escala de Auto-Compasión

NID:

COMO SUELO ACTUAR CONMIGO MISMO EN MOMENTOS DIFICILES

Por favor, lea cada enunciado cuidadosamente antes de contestar. A la izquierda de cada ítem, indique con qué frecuencia se comporta de la manera que se expone, utilizando la siguiente escala

Casi Nunca **Casi Siempre**

1 2 3 4 5

	1	2	3	4	5
Cuando fracaso en algo que es importante para mí, me consumen sentimientos de insuficiencia					
Intento ser comprensivo y paciente con aquellos aspectos de mi personalidad que no me agradan					
Cuando ocurre algo doloroso, Intento tomar una visión equilibrada de la situación					
Cuando me siento triste, tiendo a sentir que la mayoría de la gente son más felices que yo					
Intento ver mis errores y fracasos como parte de la condición humana					
Cuando lo estoy pasando mal, me doy a mí mismo el cuidado y la ternura que necesito					
Cuando algo me disgusta intento mantener mis emociones equilibradas					
Cuando fracaso en algo que es importante para mí, tiendo a sentirme solo con mi fracaso					

Cuando me siento triste, suelo obsesionarme y fijarme en todo lo que está mal					
Cuando me siento insuficiente de alguna manera, intento recordarme que estos sentimientos de insuficiencia son compartidos por la mayoría de personas					
Tiendo a desaprobar y juzgar mis errores e insuficiencias					
Soy intolerante e impaciente hacia aquellos aspectos de mi personalidad que no me agradan					

FFMQ

NID:

Elija en cada ítem la alternativa que mejor refleje el grado en que está de acuerdo con cada uno de los enunciados que se indican a continuación.

1	2	3	4	5
Nunca o muy raramente verdad	Raramente verdad	Algunas veces verdad	A menudo verdad	Muy a menudo o siempre verdad

Cuando hago algo, mi mente divaga y me distraigo fácilmente	1	2	3	4	5
No presto atención a lo que hago porque sueño despierto, porque me preocupo o porque me distraigo.	1	2	3	4	5
Observo mis sentimientos sin perderme en ellos.	1	2	3	4	5
Me distraigo fácilmente	1	2	3	4	5
Creo que algunos de mis pensamientos no son normales o son malos y que no debería pensar así.	1	2	3	4	5
Presto atención a las sensaciones que produce el viento en el pelo o el sol en la cara.	1	2	3	4	5
Tengo problemas para pensar en las palabras que expresan correctamente cómo me siento	1	2	3	4	5
Me es difícil permanecer centrado/a en lo que está sucediendo en el presente.	1	2	3	4	5
Cuando tengo pensamientos o imágenes perturbadoras, soy capaz de dar un paso atrás, y me doy cuenta del pensamiento o la imagen sin que me atrape.	1	2	3	4	5
Presto atención a sonidos como el tic-tac del reloj, el gorjeo de los pájaros o los coches que pasan	1	2	3	4	5
En situaciones difíciles, puedo parar sin reaccionar inmediatamente	1	2	3	4	5
Cuando tengo sensaciones en el cuerpo es difícil para mí describirlas, porque no puedo encontrar las palabras adecuadas.	1	2	3	4	5
Cuando tengo pensamientos o imágenes perturbadoras, me calmo en poco tiempo.	1	2	3	4	5
Me digo a mi mismo/a que no debería pensar como pienso.	1	2	3	4	5
Percibo el olor y el aroma de las cosas.	1	2	3	4	5

Creo que algunas de mis emociones son malas o inapropiadas y que no debería sentirlas.	1	2	3	4	5
Percibo elementos visuales en la naturaleza o en el arte, como colores, formas, texturas o patrones de luces y sombras.	1	2	3	4	5
Mi tendencia natural es poner mis experiencias en palabras.	1	2	3	4	5
Cuando tengo pensamientos o imágenes perturbadoras, me juzgo como bueno o malo, dependiendo del contenido.	1	2	3	4	5
Normalmente puedo describir como me siento con considerable detalle.	1	2	3	4	5

Inventario del Miedo a la Recurrencia de Cáncer

NID:

A continuación encontrará una lista de afirmaciones que otras personas con su misma enfermedad consideran importantes. **Marque un solo número por línea para indicar la respuesta que corresponde a los <u>últimos 7 días</u>.**

	DESENCADENANTES	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchí-simo**
D1	Cuando tengo conversaciones que giran en torno al cáncer o a cualquier tipo de enfermedad en general, me vienen pensamientos de que la enfermedad volverá.....	0	1	2	3	4
D2	Cuando escucho o veo a alguien que está enfermo, comienzo a pensar que yo enfermaré de nuevo 0	0	1	2	3	4
D3	Tengo pensamientos de que enfermaré otra vez cuando veo o escucho noticias relacionadas con el cáncer o con cualquier enfermedad	0	1	2	3	4
D4	Cuando voy a algún funeral o cuando leo la sección necrológica de le prensa, tengo pensamiento que volveré a enfermar	0	1	2	3	4
D5	Cuando tengo cita con mi médico o cualquier otro profesional de la salud, me vienen pensamientos recurrentes de que voy a enfermar de nuevo 0	0	1	2	3	4
D6	Cuando me hago revisiones (chequeo anual , análisis de sangre , rayos X), empiezo a pensar que enfermaré 0	0	1	2	3	4
D7	Tengo pensamientos de que volveré a enfermar de cáncer cuando no me siento bien por una enfermedad no grave	0	1	2	3	4

D8	En general , evito situaciones o cosas que me hacen pensar en la posibilidad de recurrencia del cáncer	0	1	2	3	4

	ESTRÉS PSICOLÓGICO	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchí-simo**
EP1	Me siento frustrada, enfadada o indignada 0	0	1	2	3	4
EP2	Me siento triste, desesperanzada o decepcionada 0	0	1	2	3	4
EP3	Me siento impotente o resignada 0	0	1	2	3	4
EP4	Me siento preocupada, temerosa o ansiosa 0	0	1	2	3	4

	ESTRATEGÍAS DE AFRONTAMIENTO	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchí-simo**
EAF1	Cuando tengo pensamientos desagradables, intento reemplazarlos por unos más agradables 0	0	1	2	3	4
EAF2	Intento convencerme a mí misma de que todo irá bien y pienso en positivo	0	1	2	3	4
EAF3	Intento deshacerme de ideas desagradables para no pensar en ellas 0	0	1	2	3	4
EAF4	Intento distraerme (haciendo muchas cosas, viendo la televisión, leer, trabajar) 0	0	1	2	3	4
EAF5	Intento entender que es lo que pasa en mi vida y lidiar con ello 0	0	1	2	3	4
EAF6	Me digo a mi misma “para ya!” 0	0	1	2	3	4
EAF7	Rezo, medito o hago técnicas de relajación	0	1	2	3	4

EAF8	Intento encontrar una solución	0	1	2	3	4
EAF9	Hablo con alguien sobre mi situación	0	1	2	3	4

	INSIGHT	**Nada**	**Un poco**	**Algo**	**Mucho**	**Muchí-simo**
I1	Siento que me preocupo en exceso sobre los resultados de mis pruebas 0	0	1	2	3	4
I2	Pienso que me preocupo más que los demás acerca de los próximos resultados de mis análisis 0	0	1	2	3	4
I3	Siento que me preocupo demasiado que me diagnostiquen el cáncer de nuevo 0	0	1	2	3	4
I4	Las gente me dice que me preocupo en demasía sobre los resultados de análisis de sangre 0	0	1	2	3	4

CUESTIONARIO DE PERCEPCIÓN DE LA ENFERMEDAD (IPQ-R)

Beléndez et al, 2005

Estamos interesados en conocer su punto de vista acerca del cáncer. Por favor, indique en qué grado está de acuerdo o desacuerdo con las siguientes afirmaciones acerca de su enfermedad, haciendo una círculo en el sitio correspondiente.

1	**2**	**3**	**4**	**5**
Totalmente en desacuerdo	**En desacuerdo**	**Indiferente**	**De acuerdo**	**Totalmente de acuerdo**

1	Puedo hacer mucho para controlar mis síntomas	1	2	3	4	5

2	De lo que yo haga depende que mi enfermedad vaya mejor o peor	1	2	3	4	5
3	El curso de mi enfermedad depende de mí	1	2	3	4	5
4	Nada de lo que yo haga afectará a mi enfermedad	1	2	3	4	5
5	Puedo influir en mi enfermedad	1	2	3	4	5
6	Mis acciones no tendrán efecto en las consecuencias de mi enfermedad	1	2	3	4	5
7	Hay poco que pueda hacerse para mejorar mi enfermedad	1	2	3	4	5
8	Mi tratamiento será efectivo para controlar mi enfermedad	1	2	3	4	5
9	Los efectos negativos de mi enfermedad pueden prevenirse (evitarse) con mi tratamiento	1	2	3	4	5
10	Mi tratamiento puede controlar mi enfermedad	1	2	3	4	5
11	No hay nada que pueda ayudar a mi situación de enfermedad	1	2	3	4	5
12	Mi enfermedad es una circunstancia seria	1	2	3	4	5
13	Mi enfermedad tiene consecuencias importantes en mi vida	1	2	3	4	5
14	Me deprimo cuando pienso en mi enfermedad	1	2	3	4	5
15	Cuando pienso en mi enfermedad me preocupo	1	2	3	4	5
16	Mi enfermedad hace que me sienta disgustado/a	1	2	3	4	5
17	Mi enfermedad no me preocupa	1	2	3	4	5
18	Tener ésta enfermedad hace que me sienta ansioso/a	1	2	3	4	5
19	Mi enfermedad hace que me sienta asustado/a	1	2	3	4	5
20	Mi enfermedad durará poco tiempo	1	2	3	4	5
21	Es más probable que mi enfermedad sea permanente que temporal	1	2	3	4	5
22	Mi enfermedad durará mucho tiempo	1	2	3	4	5
23	La enfermedad pasará rápidamente	1	2	3	4	5
24	Tendré ésta enfermedad durante el resto de mi vida	1	2	3	4	5
25	Los síntomas de mi enfermedad cambian mucho de un día para otro	1	2	3	4	5
26	Mis síntomas van y vienen por rachas	1	2	3	4	5
27	Mi enfermedad es muy impredecible	1	2	3	4	5
28	Paso por rachas en las que mi enfermedad va mejor y otras que empeora	1	2	3	4	5
29	Mi enfermedad es un misterio para mí	1	2	3	4	5

30	No entiendo mi enfermedad	1	2	3	4	5
31	Comprendo o tengo una idea clara de mi enfermedad	1	2	3	4	5

Nos interesa conocer su opinión sobre que causó su enfermedad. Por favor, indique en qué grado está de acuerdo o desacuerdo con las siguientes afirmaciones acerca las posibles causas de su enfermedad, haciendo una círculo en el sitio correspondiente.

1	**2**	**3**	**4**	**5**
No estoy nada de acuerdo	**No estoy de acuerdo**	**Ni de acuerdo, ni en desacuerdo**	**Estoy de acuerdo**	**Estoy completamente de acuerdo**

El azar o la mala suerte	1	2	3	4	5
El poco cuidado médico en el pasado	1	2	3	4	5
El envejecimiento	1	2	3	4	5
La alimentación o los hábitos de comida	1	2	3	4	5
El alcohol	1	2	3	4	5
Fumar	1	2	3	4	5
Estrés o preocupaciones	1	2	3	4	5
Los problemas o preocupaciones familiares	1	2	3	4	5
El exceso de trabajo	1	2	3	4	5
Mi actitud mental	1	2	3	4	5
Mi estado emocional	1	2	3	4	5
Mi personalidad	1	2	3	4	5
Herencia	1	2	3	4	5

A continuación indique por orden de importancia los tres factores que usted considera que causaron su enfermedad. Puede utilizar cualquiera de las causas de la tabla de arriba o puede aportar sus propias ideas. Si no se le ocurren tres causas de su enfermedad, puede escribir solo una o dos.

Las causas más importantes de mi enfermedad son:
1.
2.

3.

EVALUACIÓN II

En esta parte se le presentarán una serie de adjetivos opuestos. Usted deberá señalar con una “X”, para cada par de adjetivos, aquel segmento o valor que exprese mejor el significado que para usted tiene la expresión: ser compasivo. Por ejemplo:

	Muy	Bastante	Levemente	Ni lo uno ni lo otro	Levemente	Bastante	Muy	
Agradable		X						Desagradable

Esto significa que para usted ser compasivo es bastante agradable

Nunca ponga más de una cruz en un renglón y no imita ninguno de los renglones. Recuerde que sus respuestas deben reflejar lo que para usted significa *ser compasivo.*

	Muy	Bastante	Levemente	Ni lo uno ni lo otro	Levemente	Bastante	Muy	
Odioso								Amoroso
Sensible								Insensible
Tenso								Relajado
Agradecido								Desagradecido

A continuación se le presentarán una serie de adjetivos opuestos. Usted deberá señalar con una “X”, para cada par de adjetivos, aquel segmento o valor que exprese mejor el significado que para usted la expresión: ser auto-compasivo. Por ejemplo:

Simpático								Antipático
Optimista								Pesimista
Alegre								Triste
Amable								Grosero
Satisfecho								Insatisfecho
Empático								Cruel
Generoso	Muy	Bastante	Levemente	Ni lo uno ni lo otro	Levemente	Bastante	Muy	Egoísta
Hipócrita						X		Sincero
Agradable								Desagradable
Fuerte								Débil
Admirable								Despreciable
Grande								Pequeño
Audaz								Cobarde
Piadoso								Cruel
Perfecto								Imperfecto
Descansado								Cansado
Potente	Muy	Bastante	Levemente	Ni lo uno ni lo otro	Levemente	Bastante	Muy	Impotente

Esto significa que para usted ser auto-compasivo es bastante desagradable

Nunca ponga más de una cruz en un renglón y no imita ninguno de los renglones. Recuerde que sus respuestas deben reflejar lo que para usted significa *ser compasivo.*

Obediente								Tonto
Sensible								Insensible
Joven								Viejo
Agradecido								Desagradecido
Rápido								Lento
Trabajador								Perezoso
Alegre								Triste
Amable								Grosero
Satisfecho								Insatisfecho
Empático	Muy	Bastante	Levemente	Ni lo uno ni lo otro	Levemente	Bastante	Muy	Cruel
Generoso								Egoísta
Hipócrita								Sincero
Fuerte								Débil
Admirable								Despreciable
Grande								Pequeño
Audaz								Cobarde

Piadoso								Cruel
Perfecto								Imperfecto
Descansado								Cansado
Potente								Impotente
Inteligente								Tonto
Sano								Enfermo
Joven								Viejo
Activo								Pasivo
Rápido								Lento
Trabajador								Perezoso
Divertido								Aburrido
Calmado								Nervioso
Ágil								Torpe
	Muy	Bastante	Levemente	Ni lo uno ni lo otro	Levemente	Bastante	Muy	

Compassion Scale

(Pommier, E. A.)

COMO SUELE COMPORTARSE HACIA LOS DEMÁS

Por favor, lea cada enunciado cuidadosamente antes de responder. Responda utilizando la siguiente escala sobre como suele comportarse hacia los demás:

Casi Nunca				**Casi Siempre**
1	**2**	**3**	**4**	**5**

_____1. Cuando la gente llora delante de mí, no suelo sentir nada en absoluto

_____2. A veces cuando la gente habla de sus problemas, siento como si no me importara

_____3. No me siento emocionalmente conectado/a con la gente que experimenta dolor

_____4. Presto atención cuidadosamente cuando la gente me habla

_____5. Me siento distante de los demás cuando me cuentan sus penas

_____6. Si veo a alguien que los está pasando mal, intento acoger a esa persona

_____7. Suelo desconectar cuando la gente me habla de sus problemas

_____8. Me gusta estar apoyando a los demás cuando están pasando por momentos difíciles

_____9. Noto cuando la gente está disgustada, aunque no digan nada

_____10. Cuando veo a alguien triste, siento como si no pudiera relacionarme con esa persona

_____11. Todos nos sentimos tristes alguna vez, es parte del ser humano

_____12. A veces soy frio con los demás cuando están tristes y desencajados

_____13. Tiendo a escuchar pacientemente cuando las personas me cuentan sus problemas

_____14. No me ocupo de los problemas de los demás.

_____15. Es importante reconocer que todas las personas tenemos debilidades y que nadie es perfecto

_____16. Mi corazón está con todos los que no son felices

_____17. A pesar de mis diferencias con los demás, sé que todos experimentan dolor igual que yo

_____18. Cuando los demás se sienten agobiados, por lo general dejo que otra persona les asista

_____19. No pienso demasiado en las preocupaciones de los demás

_____20. El sufrimiento es parte de la experiencia de humanidad compartida

_____21. Cuando la gente me habla de sus problemas, intento mantener una perspectiva equilibrada sobre la situación

_____22. No puedo realmente conectar con los demás cuando están sufriendo

_____23. Intento evitar a la gente que está experimentando mucho dolor

_____24. Cuando los demás se sienten tristes, intento reconfortarles

Submissive Compassion Scale

(Catarino, Gilbert, McEwan, Baião, 2014)

Las siguientes afirmaciones se refieren a las formas en que uno piensa o siente acerca de ser compasivo o atento hacia los demás. Sabemos que hay muchas razones por las que ser atento, tales como: que le conmueva la angustia de los demás, disfrutar de ser de ayuda, evitar conflictos o ser querido. Estamos interesados en estas diferentes razones. Así que lea cada razón por la que ser atento y considere la importancia que esa razón tiene para usted, y cuanto **"se parece a usted"** cada una de esas razones. Marque con un círculo el número con el que se sienta más identificado.

	Nada parecido a mi	Un poco parecido a mi	Moderadamente parecido a mi	Algo parecido a mi	Extremadamente parecido a mi
Cuando soy atento con los demás, espero que me vean como una buena persona	0	1	2	3	4
Me preocupa que si no soy lo suficientemente atento, los demás me rechazarán	0	1	2	3	4
Intento hacer lo que los demás quieren para no quedarme solo	0	1	2	3	4
Intento ayudar a otras personas tanto como puedo para que me aprecien	0	1	2	3	4
Hago un esfuerzo por siempre estar allí para otros para que ellos piensan que soy importante en sus vidas	0	1	2	3	4
Estoy de acuerdo en ayudar, pero puedo arrepentirme por las exigencias que se me demandan	0	1	2	3	4
Intento ser atento y amable para evitar discusiones y conflictos	0	1	2	3	4
Presto atención a los demás para que me vean como una persona atenta	0	1	2	3	4
Intento mostrar que me importan los sentimientos de los demás para que me vean como una persona considerada y sensible	0	1	2	3	4
Siempre pongo las necesidades de los demás por encima de las mías, porque eso es lo que se necesita para ser amado	0	1	2	3	4

10.7 APPENDIX 7: PUBLISHED ARTICLE IN INTEGRATIVE CANCER THERAPIES MAGAZINE

(see article in page 311)

Integrative Cancer Therapies 1–13

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Cognitively-Based Compassion Training (CBCT) in BCS: A Randomized Clinical Trial Study

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Abstract

Context. Breast cancer (BC) requires a significant psychological adaptation once treatment is finished. There is growing evidence of how compassion training enhances psychological and physical well-being, however, there are very few studies analyzing the efficacy of CBIon BC survivors. *Objective.* To study the efficacy of the Cognitively-Based Compassion Training (CBCT) protocol in a BC survivor sample on quality of life, psychological well-being, fear of cancer recurrence, self-compassion, and compassion domains and mindfulness facets. Furthermore, enrollment, adherence, and satisfaction with the intervention were also analyzed. *Methods.* A randomized clinical trial was designed. Participants (n = 56) were randomly assigned to CBCT (n = 28) or a treatment-as-usual control group (TAU; n = 28). Pre-post intervention and 6-month follow-up measures took place to evaluate health-related quality of life, psychological well-being; psychological stress, coping strategies, and triggering cognitions; self-compassion and compassion; and mindfulness in both intervention and wait-list groups. *Results.* Accrual of eligible participants was high (77%), and the drop-out rate was 16%. Attendance to CBCT sessions was high and practice off sessions exceeded expectations). CBCT was effective in diminishing stress caused by FCR, fostering self-kindness and common humanity, and increasing overall self-compassion scores, mindful observation, and acting with awareness skillsets. *Conclusion.* CBCT could be considered a promising and potentially useful intervention to diminish stress caused by FCR and enhance self-kindness, common humanity, overall self-compassion, mindful observation, and acting with awareness skillsets. Nevertheless, future randomized trials are needed and a process of deeper cultural adaptation required.

Keywords

breast cancer, survivorship, compassion training, well-being, self-compassion, fear of cancer recurrence, contemplative training

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Introduction

Breast cancer (BC) has been the second most common can-cer in the world and the most frequent cancer among women, with an estimated 1.67 million new cancer cases diagnosed in 2012 (25% of all cancers).[1] BC has been associated with a number of physical, social, and psychological impairments, such as problems of adaptation, difficulties in communication, or depressive and anxious symptoms.[2-4] It has been observed how psychological and emotional stress increased the experience of pain in patients and reduced overall social performance and is a fundamental factor of suicidal ideation and suicide attempts.[5,6]

In addition to confronting intrusive medical procedures (chemotherapy and/or radiotherapy) and side effects,[7] it has been reported how BC treatment requires a significant

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psychological adaptation.[4] Furthermore, once treatment is finished, fear of cancer recurrence (FCR) occurred in around 70% of patients, which has been associated with long-term functional impairments.[8,9] In nearly half of the survivors, intrusive thoughts about the disease and its treatment (unwanted thoughts, images and memories) occurred years after successful treatment.[10] In such patients, it has been observed that even when the rates of depression decreased, overall well-being did not improve.[11] Fatigue and sleep problems were also clinically significant in 60% of patients, which diminished quality of life (QoL).[12,13]

Nowadays, several psychological interventions have been shown to be beneficial for BC patients.[14] Recently, interest in Mindfulness-Based Interventions (MBI) for BC patients has increased significantly,[15,16] especially for those patients who have passed the initial malignancy and its treatment but had to deal with functional, behavioral, and persistent emotional difficulties, such as depression, fatigue, fear of illness recurrence, and cognitive impairments.[17,18] A systematic review has shown that a specific MBI for cancer patients can be considered an effective coping strategy that diminishes anxiety, stress, fatigue, general mood, and sleep disturbances and enhances QoL.[19]

Compassion is a construct closely related to mindful-ness[20] and can be defined as the desire to alleviate the suf-fering and its causes in one's self and those around us.[21] When compassion is directed toward oneself, it is called self-compassion.[22] This process involves kindness and understanding toward oneself in terms of pain or failure, instead of being self-judgmental; perceiving one's difficulties as part of the human experience rather than experiencing them with a sense of isolation; and observing the thoughts and painful feelings with mindfulness instead of overidentifying with them.[23]

Like mindfulness, compassion can be trained using specific techniques and procedures (CBI[CBI]) designed to specifically generate cognitive and emotional compassionate habits.[20] Some authors have argued that CBI could provide useful skills to treat and prevent several psychological difficulties (resources for interpersonal relationships, reduction of depressive symptomatology, reduction of social anxiety, marital conflict, and anger management and deal with the difficulties of being a caregiver).[24] In addition, evidence points out that CBI has been associated with decreased inflammatory responding to a psychosocial stressor.[25]

Different studies have shown how loving-kindness and compassion practices (included in CBI) have been associated with less physical pain, lower anger, reduced feeling of loneliness, and increased positive emotions.[26,27] Other authors have found an increase in positive emotions in everyday experiences after training in compassion, which, in turn, enhanced purpose in life, social connection, and decrease in disease symptoms.[28]

Today, there are several CBI protocols[29-31]: Zaragoza University's Attachment-Based Compassion Therapy,[32] Stanford University's Compassion Cultivation Training,[33] Compassion Focused Therapy,[34] Mindfulness and Self-compassion,[22] Cultivating Emotional Balance Training,[35,36] and Cognitively-Based Compassion Training (CBCT).[37] Although there are numerous studies on the efficacy of these interventions in healthy populations as well as in clinical settings,[38,39] there is not much data of the benefits of CBI in cancer patients.

CBCT is a secular protocol to teach compassion.[21] CBCT has been shown to be effective in reducing hormone levels related to psychoimmunological stress systems as well as regulation of inflammatory processes in the adolescent population with early-life adverse events.[25,40-44] Recently, Dodds et al[17] found that CBCT, when compared with a wait-list control, resulted in improvements in depression features, functional impairments related to FCR, and avoidance related to traumatic stress and an increase in vitality in a sample of BC survivors (BCS). Nevertheless, effects of CBCT on QoL have not been thoroughly explored to date in cancer survi-vors and require further study in other populations.

The main aim of this study was to analyze the efficacy of a CBCT protocol in a randomized clinical trial (RCT; NCT03305952 October 9 to November 2017) on a sample of BCS. Our primary outcome measure for this study was health-related QoL (physical, social, emotional, and functional domains). Physical and psychological well-being (somatic, depressive, anxious symptomatology), psychological dimensions linked to FCR, mindfulness, self-compassion, and compassion were secondary outcome measures. Moreover, acceptance, adherence, and satisfaction with the intervention were also evaluated.

Methods

Study Design

This RCT compared the benefits of a CBCT intervention ver-sus a treatment-as-usual control group (TAU). The study was approved by FIVO's Clinical Research Ethics Committee (December 2015) and was conducted in compliance with the study protocol, following the CONSORT statement (Consolidated Standards of Reporting Trials), the Declaration of Helsinki, and good clinical practice. The trial was registered at ClinicalTrials.gov (NCT 03305952) on October 9, 2017.

Sample Size

Sample size was calculated a priori using the G*Power software.[45] A total of 42 participants were estimated to be needed in the study to detect a moderate effect size (Cohen's $d = 0.50$) on the primary and secondary outcomes, an α error of .05, and a statistical power of 0.80. A moderate effect size was expected taking into account the results of Dodds et al,[17]

where a compassion-based training in BCS (compared with a wait-list) showed moderate effect size in QoL-related outcomes (depression, functional impairment, vitality/fatigue) at postintervention. Nevertheless, because we anticipated dropouts, 14 more participants were randomized.

Participants, Recruitment, and Randomization

Eligible participants were recruited and randomized from January 2016 to May 2017. The eligibility criteria were as follows: (1) age between 18 and 75 years, (2) being able to read and write using the Spanish language, (3) history of treated BC within the past 15 years, (4) being free from oncological illness, (5) not receiving any kind of chemo-therapy and/or radiotherapy treatment during study, and (6) being free from severe psychiatric disorders assessed with the Mini International Neuropsychiatric Interview (MINI)[46] Spanish version.[47] Eligible participants were contacted by their personal psychooncologist either by a telephone call or at a periodic psychooncology appointment visit where they were invited to an explanatory meeting of the study. Potential participants were excluded at the beginning of the study for active severe mental disorders (schizophrenia, bipolar disorder, eating disorders, and major depression), substance use disorders, cognitive impairment, or impaired medical condition. Past and current psychiatric and medical history was determined by clinician assessment with the MINI[46] Spanish version.[47]

A total of 95 patients were invited to participate in the study, 72 showed interest and 56 met all the inclusion criteria. After signing the informed consent, participants were ran-domly assigned (by a list of random numbers generated by Research Randomizer software [http://www.randomizer.org]) to either 8 weeks of CBCT or TAU. TAU participants were offered the CBCT protocol at the end of research. Study par-ticipants were blinded to group assignment until completion of all baseline assessments. Moreover, outcome assessors, data analysts, and staff were blinded to the allocation at all times during study. Participants were evaluated before and after intervention and at the 6-month follow-up (see Figure 1).

Measures

Measures were obtained on all study participants (CBCT and TAU) at 3 time points: recruitment into the study pre-test), two months after baseline evaluation (posttest) and at 6 months (follow-up). Data were collected on satisfaction, acceptance, and adherence to the CBCT Program, demographic factors, and medical history.

Psychological variables were assessed using standard-ized and validated self-administered questionnaires. Primary outcome measures included health-related QoL in BC as measured by the Functional Assessment of Cancer Therapy– Breast Cancer (FACT-B+4[48]; Spanish validation[49]) using the physical QoL, social/family, and social QoL; emotional QoL; functional QoL; and other concern measures. Secondary measurements included the following: somatic, emotional, and general well-being as measured by the Brief Symptom Inventory (BSI-18),[50] Spanish version[51]; Cancer Recurrence Fear assessed with the Fear of Cancer Recurrence Inventory (FCRI)[52]; self-compassion evaluated with the Self-Compassion Scale–Short Form,[53] Spanish version[54]; compassion as measured by the The Compassion Scale[55]; mindfulness facets measured with the Five Facets of Mindfulness Questionnaire–Short Form (FFMQ-SF),[56] Spanish validation.[57] Acceptance satisfaction and adherence was measured with the CBCT Evaluation Survey.[58]

Intervention

CBCT was delivered over 8 continuous weeks, in a 2-hour session format through didactics, class discussion, and guided meditation practice. CBCT is a CBI designed by study contemplative investigator Lobsang Tenzin Negi, Ph.D. Although secular in presentation, CBCT is derived from Tibetan Buddhist mind-training (Tibetan *lojong*) prac-tices. These practices differ in important ways from the MBI practices; whereas MBI practices emphasize the development and maintenance of a nonjudgmental stance toward thought processes and emotional reactions, CBCT practices apply a cognitive, analytic approach. CBCT intro-duces participants to attentional and mindfulness-based techniques (modules 1-2) to improve attention and aware-ness before beginning specific compassion practices in training modules 3 to 6. The training protocol modules are sequential and iterative, such that once the 6 modules are completed, each student's daily meditation practice (guided by audio recordings) begins with a brief period of *shamatha* to calm and focus the mind, followed by analytical practices designed to challenge unexamined assumptions regarding feelings and actions toward others with a focus on generat-ing spontaneous empathy and compassion for themselves and others. A sequence of 8 sessions included didactic teaching combined with meditations designed to build a suite of skills. The CBCT instructor was a clinically trained psychologist, researcher, and experienced 18-year medita-tor fulfilling requirements for CBCT teacher certification of Emory University Center for Contemplative Science and Compassion-Based Ethics (CCSCBE). To ensure fidelity, 80% of classes taught were video recorded and reviewed by the CBCT training supervisor at CCSCBE. The supervisor reviewed CBCT class plans weekly. The CBCT teacher manual[21] guided class content. CBCT components of each module were as described below.

Module I: Developing attentional stability and mental clarity. This component was delivered in week 1. The foundation for the practice of compassion is the

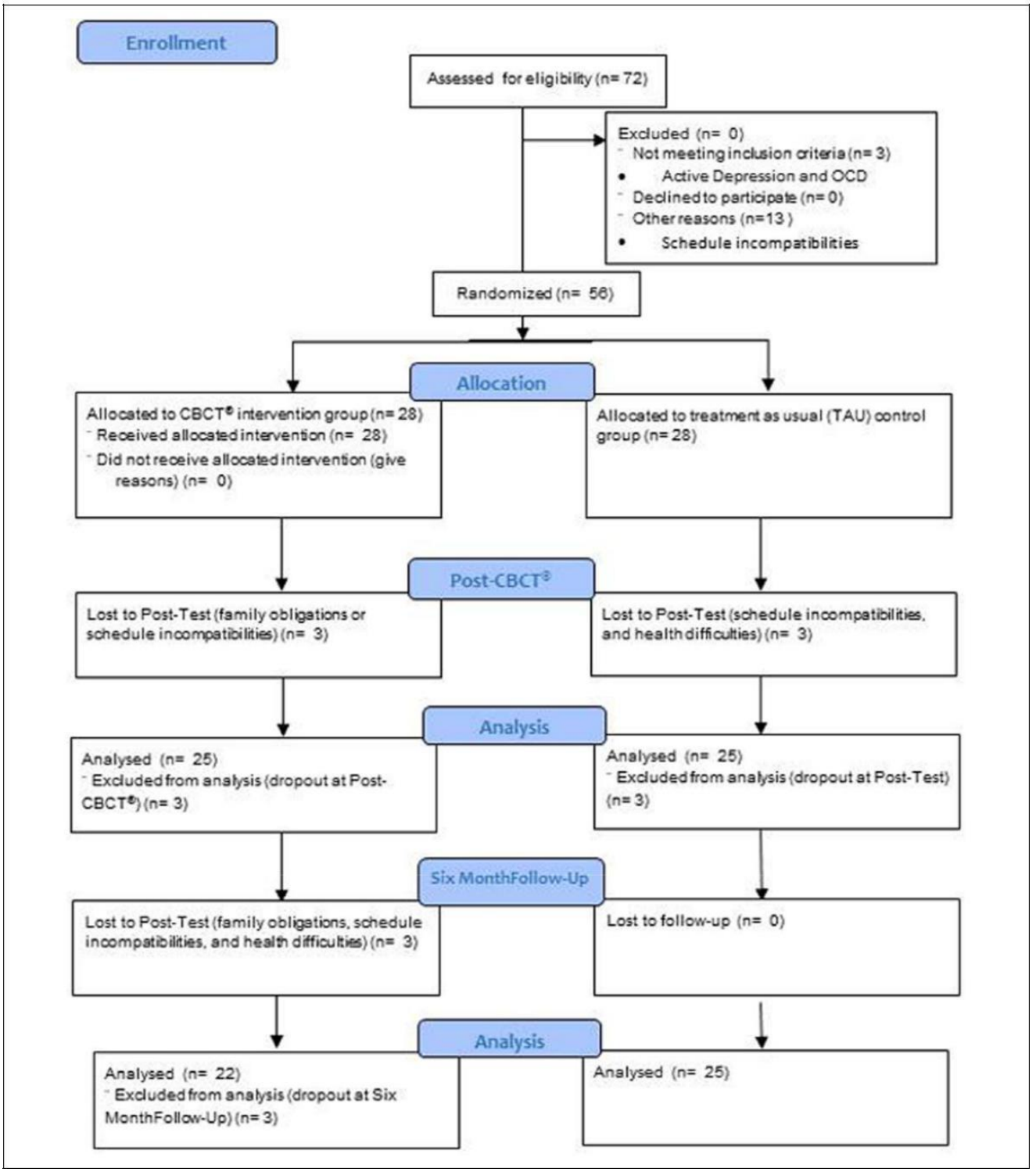

Figure 1. CONSORT 2010 flow diagram for randomized controlled trial of CBCT versus TAU condition.
Abbreviations: CBCT, Cognitively-Based Compassion Training; OCD, obsessive compulsive disorder.

cultivation of a basic degree of refined attention and mental stability. One of the basic skills trained in this module is the deliberate intention for cultivating a state of awareness, relaxation, stillness, and alertness.

Module II: Cultivating insight into the nature of mental experience. This module is trained through week 2. The stabilized mind is then used to gain insight into the nature of the inner world of thoughts, feelings, emotions,

and reactions through nonjudgmental awareness and resulting in a mental state of nonreactivity and equanimity.

Module III: Cultivating self-compassion. Participants tune in their innate aspirations for happiness and well-being as well as those for freedom from unhappiness and dissatisfactions. This is progressively realizing which mental states contribute to well-being and which ones bring about anxiety, disappointment, and dissatisfaction. Afterward, participants learn to bring to mind the deter-mination and skills to transcend the mental patterns and emotional states that promote distress. These mindsets and skillsets are covered in weeks 3 and 4.

Module IV: Developing equanimity and impartiality. This module focuses on creating balanced relationships with others promoting the initial mental and emotional conditions for constructive social connections through week 5. This is relevant because of the social disconnec-tion that human beings experience when going through traumatic and stressful life events.

Module V: Developing appreciation, affection, and empathy for others. Social connection and gratitude is fostered through the emotional insight of interdepen-dence. This prevents the feeling of isolation. Social con-nection and gratitude weakens self-centeredness and strengthens endearment and affection toward others, which serves as the catalyst for compassion. Endearment and affection foster a perception of the world based on kindness and not on threat. These emotional states were trained and fostered through week 6.

Module VI: Realizing engaged compassion. During weeks 7 and 8, patients were taught and invited to rest in a compassionate state of mind. The primary focus of this session was to cultivate the essential skillsets and mindsets for interacting in a proactive way with personal and social difficulties, preventing burnout and fostering a motivational readiness to act altruistically.

Each session included lecture, discussion, experiential exercises, and guided meditations. Over the intervention, participants were led through the entire series of integrated, cumulative meditations and provided with guided record-ings for each module to support the systematic development of compassion. In between class sessions, participants were encouraged to meditate daily using the recorded medita-tions and to gradually increase both the length of time for an individual meditation session as well as the cumulative amount of practice time.

The TAU control group continued with their normal rehabilitation program, attendance at briefings given at FIVO, pharmacological treatment, and psychological coun-seling. TAU participants were offered the CBCT course at the end of research.

Data Analyses

Group differences at baseline on demographic characteris-tics and clinical variables were analyzed using indepen-dent-samples *t*-tests for continuous data and χ^2 tests for categorical variables. Intent-to-treat mixed-models analy-ses without any ad hoc imputation were used to handle missing data.[59] This approach is appropriate for RCTs with multiple time points and pre-to-post-only designs and does not assume that the last measurement is stable (the last observation carried forward assumption). This method is conducted using all available observations.[60,61] For each outcome measure, a linear mixed model was implemented with Time (pre, post, and 6-month follow-up) as within-group factor and Group (CBCT and TAU) as between-group factor using the MIXED procedure with 1 random intercept per subject. An identity covariance structure was specified to model the covariance structure of the random intercept. Significant effects were followed up with pair-wise comparisons. Effect sizes (Cohen's *d*; 95% CI) were calculated for within- and between-group comparisons.[62-65] All statistical analyses were performed using IBM SPSS version 23 for Windows.

Results

Participant Flow

The final sample was composed of 56 women between 39 and 70 years old (mean age = 52.13 years [SD = 6.96]; 100% female; see Figure 1). During the study, 3 of the 28 participants from the CBCT condition dropped out because of family obligations or schedule incompatibilities at post-test, and 3 more participants could not continue with the study at follow-up because of family obligations, schedule incompatibilities, and health difficulties. Regarding TAU condition, 3 of the 28 participants dropped out because of schedule incompatibilities and health difficulties at posttest. There were no dropouts at follow-up in the TAU group (for more details, please see Figure 1).

Baseline Data

Table 1 shows sociodemographic characteristics and Table 2 clinical features for the CBCT and TAU groups. There were no significant differences between groups in all demographic characteristics or outcome measures at baseline, except for clinical severity (oncological stage when first diagnosed) and Insight factor from the FCRI: $F(1, 97.17) = 4.176$; $P <$ .05. As for clinical severity when first diagnosed, the CBCT group had a larger number of participants with oncological stage III when compared with the TAU group. The CBCT group also had larger scores for the Insight factor when com-pared with the TAU group.

Table 1. Sociodemographic and Clinical Data in CBCT and WL Groups.

Sociodemographic and Clinical Data	CBCT (n = 28)	WL (n = 28)	Student t/χ^2	*P*
Age (in years)	51.64(6.87)	52.63(7.16)	0.52	.60
Time since first diagnosis (years)	11.32(1.44)	10.46(2.90)	−1.40	.17
Oncological stage at first diagnosis			18.49	.047
I	1(3.6)	3(10.7)		
II	13(46.4)	18(64.3)		
III	14(50)	7(25)		
IV	—	—		
Breast cancer treatments			41.48	.21
Partial mastectomy (removal of tumor along with some of the breast tissue around it)	5(17.9)	7(25)		
Total mastectomy (removal of entire breast)	17(60.7)	12(42.9)		
Radiotherapy	19(67.9)	18(64.3)		
Chemotherapy	25(89.3)	23(82.1)		
Other	14(50)	18(64.3)		
Educational level			2.12	.55
Elementary school or less	7(25)	6(21.40)		
Middle school	1(3.6)	1(3.60)		
High school	7(25)	12(42.9)		
University studies or more	13(46.4)	9(32.1)		
Employment status			1.12	.77
Employed	17(60.7)	18(64.3)		
Unemployed	1(3.6)	0(0)		
Retired	4(14.3)	5(17.9)		
Off work	6(21.4)	5(17.9)		

Health-Related QoL in BC Survival

Even though, no Time × Group effect was observed in any of the health-related QoL subscales that compose FACT-B+4 (all $P > .05$), a Time × Group tendency was observed for social/family QoL [$F(2, 94.758) = 2.710$; $P = .072$], where participants allocated to the CBCT group scored somewhat higher than the TAU control group. Results from within-group comparisons revealed a significant pre-to-post change for emotional and general QoL in the CBCT group with moderate effect sizes (−0.56 and −0.46, respectively). No significant changes were found in TAU (Table 3).

Somatic, Emotional, and General Well-being

In relation to our secondary outcomes, no significant Time × Group effect was observed for any of the BSI-18 factors. However, within-group comparisons revealed significant pre-to-post and pre-to-follow-up improvements for depressive and general distress symp-tomatology in the CBCT group, with moderate effect sizes (Cohen's *d* ranging from 0.44 to 0.55, respec-tively); no significant changes were observed in the TAU group (Table 3).

Cancer Recurrence Fear

Psychological Stress factor from the FCRI showed -significant Time × Group interaction: $F(2, 96.863) = 3.521$; $P < .05$. No significant interaction effects were found for any other of the FCRI factors (all $P > .05$). Within-group comparisons showed significant pre-post and pre-to-follow-up changes for psychological stress in the CBCT group, with effects sizes of 0.68 and 0.49, respectively. No signifi-cant changes were found in the TAU group (Table 3).

Self-compassion

A significant Time × Group interaction was seen for self-kindness [$F(2, 97.453) = 5.769$; $P < .01$], common humanity [$F(2, 98.323) = 6.161$; $P < .01$], and Self-compassion Scale overall score [$F(2, 96.277) = 5.423$; $P < .01$]. Overall, participants scored higher on those measures at post- and fol-low-up time compared with TAU, although no significant differences were found except for self-kindness, indicating that CBCT scored significantly higher compared with TAU at the 6-month follow-up ($P < .05$; Cohen's $d = 0.94$; 95% CI = [0.34, 1.55]).Within-group analyses showed significant pre-to-post changes for self-kindness, self-judgment, common humanity, over identification, and self-compassion

Table 2. Participants' Enrollment, Satisfaction, Adherence to Program, and Contemplative Practice Experience Data in the CBCT and TAU Groups.[a]

Data Description	
Number of sessions attended	
0	0(0.00)
1	1(3.55)
2	0(0.00)
3	0(0.00)
4	0(0.00)
5	3(10.70)
6	5(17.90)
7	9(32.15)
8	10(35.70)
Mean time of practice after session (minutes)	
0	2(7.15)
9	1(3.55)
12	3(10.70)
15	6(21.40)
18	4(14.30)
More than 24	12(42.90)
Percentage of home practice with meditation recordings	
0%	2(7.15)
10%	1(3.55)
20%	0(0.00)
30%	0(0.00)
40%	0(0.00)
50%	0(0.00)
60%	3(10.70)
70%	0(0.00)
80%	4(14.30)
90%	2(7.15)
100%	16(57.15)
Frequency of practice (days)	
0	2(7.15)
1	2(7.15)
2	5(17.90)
3	6(21.40)
4	4(14.30)
5	5(17.90)
6	2(7.15)
7	2(7.15)
Intention to attend to future CBCT groups	
Yes	25(89.30)
No	3(10.70)
Intention to continue CBCT personal practice	
Yes	25(89.30)
No	3(10.70)
CBCT recommendation to others	
Yes	26(92.9)
No	2(7.10)
Satisfaction with instructor	
Yes	26(92.9)
No	2(7.10)

Abbreviations: CBCT, Cognitively-Based Compassion Training; TAU, treatment-as-usual.

[a]Percentage shown in parentheses.

Table 3. Within-Group Comparisons and Effect Sizes at Preintervention, Postintervention, and 6-Month Follow-up.[a]

	CBCT					TAU				
	Preintervention (n = 28)	Postintervention (n = 26)	Follow-up (n = 22)	Preintervention vs Postintervention, Mean Difference *d* [95% CI]	Preintervention vs FW, Mean Difference *d* [95% CI]	Preintervention (n =28)	Postintervention (n = 25)	Follow-up (n = 25)	Preintervention vs Postintervention, Mean Difference *d* [95% CI]	Preintervention vs FW, Mean Difference *d* [95% CI]
FACTGP	18.93(5.70)	21.50(3.93)	21.27(4.09)	−2.24, −0.44 [−0.87, −0.01]	−2.20, −0.40 [−0.89, 0.09]	17.57(5.96)	17.68(6.16)	17.52(5.34)	−0.08, −0.02 [−0.24, 0.20]	0.07, 0.01 [−0.35, 0.36]
FACTGS	17.11(6.05)	19.23(5.51)	18.82(5.79)	−1.81, −0.34 [−0.65, −0.03]	−1.12, −0.27 [−0.59, 0.04]	17.56(5.46)	16.60(5.39)	16.40(5.07)	0.86, 0.17[−0.07, 0.41]	1.06, 0.21 [−0.14, 0.55]
FACTGE	13.07(5.26)	16.12(4.09)	14.00(4.69)	−2.84,** −0.56 [−0.92, −0.20]	−0.68, −0.17 [−0.56, 0.22]	13.39(4.94)	14.72(4.63)	13.32(5.32)	−1.33, −0.26[−0.46, −0.07]	0.07, 0.01 [−0.40, 0.43]
FACTGF	15.75(6.10)	17.54(3.20)	17.64(4.61)	−1.55, −0.29 [−0.72, 0.15]	−1.68, −0.30 [−0.76, 0.16]	13.82(5.68)	15.40(4.39)	15.56(4.81)	−1.41, −0.27[−0.55, 0.01]	−1.57, −0.30 [−0.75, 0.16]
FACTGEN	64.86(20.04)	74.38(11.48)	71.73(15.45)	−8.45,* −0.46 [−0.82, −0.10]	−5.73, −0.33 [−0.73, 0.06]	62.85(15.86)	64.40(14.73)	62.80(17.63)	−1.60, −0.09[−0.33, 0.14]	0.00, 0.00 [−0.40, 0.41]
BSI SOM	7.39(5.87)	4.88(4.04)	5.64(4.18)	2.00, 0.42[0.11, 0.72]	1.53, 0.29[−0.16, 0.74]	8.93(5.47)	8.64(5.70)	8.32(5.03)	0.31, 0.05[−0.17, 0.27]	0.63, 0.11 [−0.24, 0.46]
BSI DEP	9.18(7.13)	5.65(5.27)	5.14(5.19)	2.91,* 0.49[0.11, 0.87]	3.55,* 0.55[0.13, 0.97]	9.36(6.24)	7.76(6.54)	8.56(5.87)	1.68, 0.25[0.00, 0.50]	0.88, 0.12 [−0.16, 0.41]
BSI ANX	8.21(5.93)	6.15(5.01)	6.09(5.38)	1.69, 0.34[−0.05, 0.73]	1.96, 0.35[−0.12, 0.81]	9.00(6.51)	7.88(5.94)	7.56(5.49)	1.27, 0.17[−0.02, 0.35]	1.59, 0.21 [−0.10, 0.53]
GSI	24.79(17.55)	16.69(13.12)	16.86(13.12)	6.51,* 0.45[0.10, 0.79]	6.98,* 0.44[0.00, 0.88]	27.29(16.84)	24.28(16.74)	24.44(15.26)	3.28, 0.17[−0.03, 0.37]	3.12, 0.16 [−0.14, 0.47]
FCRTRIG	13.11(9.30)	13.04(8.12)	13.59(9.28)	0.00, 0.01[−0.32, 0.33]	−0.49, 0.14[−0.32]	11.43(8.81)	12.32(8.98)	13.44(7.42)	−1.08, −0.10 [−0.27, 0.08]	−2.20, −0.22 [−0.47, 0.03]
FCRPSTR	8.39(5.12)	4.81(3.43)	5.95(4.50)	3.41,*** 0.68[0.36, 1.00]	2.34,* 0.46[0.06, 0.86]	7.93(4.45)	7.40(3.96)	8.16(4.05)	0.57, 0.12 [−0.14, 0.37]	−0.20, −0.05 [−0.41, 0.31]
FCRCOP	22.11(5.41)	23.96(3.84)	21.36(4.75)	−1.61, −0.33[−0.89, 0.22]	1.07, 0.13[−0.27, 0.54]	23.39(5.69)	23.72(6.26)	22.76(4.56)	−0.08, −0.06 [−0.26, 0.15]	0.88, 0.11 [−0.22, 0.44]
FCRINS	7.18(5.29)	6.65(4.91)	6.95(5.20)	0.43, 0.10[−0.11, 0.31]	0.12, 0.04[−0.14, 0.22]	6.96(5.05)	7.00(4.75)	6.88(3.52)	−0.04, −0.01 [−0.23, 0.22]	0.08, −0.02 [−0.27, 0.30]
SCS_SK	2.59(1.11)	3.27(0.86)	3.34(0.78)	−0.63,* −0.60[−1.08, −0.11]	−0.70,** −0.66[−1.2, −0.11]	2.79(1.19)	2.72(1.19)	2.42(1.09)	0.04, 0.06[−0.20, 0.31]	0.34, 0.30 [−0.10, 0.70]
SCS_SJ	3.43(1.26)	2.79(1.03)	2.70(1.01)	0.57,* 0.49[0.07, 0.92]	0.72,** 0.56[0.19, 0.93]	3.34(1.27)	2.94(1.42)	3.28(1.01)	0.40, 0.31[0.01, 0.60]	0.06, 0.05 [−0.24, 0.33]
SCS_CH	2.70(1.02)	3.27(1.03)	3.45(0.82)	−0.54,* −0.54[−1.01, −0.07]	−0.75,** −0.71[−1.18, −0.25]	3.16(1.20)	2.82(1.00)	2.84(0.98)	0.32, 0.28[−0.20, 0.75]	0.30, 0.26 [−0.18, 0.70]
SCS_I	2.98(1.21)	2.62(1.18)	2.64(1.13)	0.29, 0.29[−0.06, 0.64]	0.31, 0.27[−0.13, 0.67]	3.02(1.26)	2.66(1.26)	3.06(0.93)	0.35, 0.28[0.03, 0.52]	−0.49, −0.03 [−0.40, 0.34]
SCS_M	2.82(1.02)	3.23(0.82)	3.20(0.87)	−0.36, −0.39[−0.87, 0.08]	−0.35, −0.36[−0.81, 0.08]	3.16(1.11)	3.10(1.11)	3.00(0.90)	0.07, 0.05[−0.30, 0.41]	0.17, 0.14 [−0.18, 0.46]
SCS_OI	3.39(1.17)	2.75(0.96)	2.84(0.99)	0.60,* 0.53[0.16, 0.90]	0.52, 0.46[0.14, 0.78]	3.42(1.17)	3.18(1.33)	3.32(1.07)	0.27, 0.20[−0.10, 0.50]	0.13, 0.08 [−0.33, 0.50]
SCS_TOTAL	2.71(0.90)	3.27(0.76)	3.30(0.73)	−0.49,** −0.60[−0.98, −0.23]	−0.55,** −0.64[−1.00, −0.28]	2.89(0.91)	2.98(0.93)	2.77(0.69)	−0.10, −0.10[−0.33, 0.14]	0.11, 0.13 [−0.20, 0.45]
COMP_ TOTAL	20.41(2.89)	22.01(2.36)	21.76(2.75)	−1.53,* −0.54[−0.95, −0.13]	−1.49, −0.45[−0.90, −0.01]	19.95(2.68)	20.87(2.80)	20.70(3.15)	−0.88, −0.33[−0.64, −0.03]	−0.71, −0.27 [−0.68, 0.14]
FFMQ_OB	12.03(2.85)	14.54(2.93)	13.50(2.81)	−2.41,*** −0.86[−1.26, −0.45]	−1.25, −0.50[−0.93, −0.07]	12.89(2.71)	13.28(3.82)	12.20(3.14)	−0.41, −0.14[−0.34, 0.06]	0.67, 0.25 [−0.07, 0.56]
FFMQ_D	13.07(4.45)	13.62(3.32)	13.09(4.02)	−0.37, −0.12[−0.36, 0.12]	−0.13, 0.00[−0.25, 0.24]	13.25(3.28)	12.84(3.39)	13.20(2.93)	0.37, 0.12[−0.18, 0.42]	0.01, 0.01 [−0.39, 0.42]
FFMQ_AW	11.68(3.62)	11.92(3.31)	11.82(3.59)	−0.29, −0.06[−0.40, 0.27]	−0.54, −0.04[−0.45, 0.37]	12.14(3.57)	11.88(4.10)	10.32(2.87)	0.14, 0.07[−0.18, 0.32]	1.70,* 0.50 [0.14, 0.85]
FFMQ_NJ	11.93(3.83)	12.38(3.68)	13.00(4.07)	−0.42, −0.11 [−0.47, 0.24]	−0.93, −0.27 [−0.62, 0.07]	10.96(4.26)	12.20(4.62)	11.04(4.17)	−1.12, −0.28[−0.52, −0.05]	0.05, −0.02 [−0.36, 0.32]
FFMQ_NR	11.54(2.50)	12.12(2.49)	12.27(2.96)	−0.51, −0.23 [−0.68, 0.23]	−0.59, −0.28 [−0.67, 0.10]	11.54(2.47)	11.76(2.37)	10.92(2.84)	−0.15, −0.09[−0.50, 0.32]	0.69, 0.24 [−0.12, 0.60]

Abbreviations: CBCT = Cognitively-Based Compassion Training; TAU, treatment as usual control group; FW, 6-month follow-up; FACTGP, Physical quality of life; FACTGS, Social/Family quality of life; FACTGE, Emotional quality of life; FACTGF, Functional quality of life; FACTGEN, General quality of life; BSI Som, Brief Symptom Inventory somatic symptoms; BSI Dep, BSI depressive symptoms; BSI Anx, BSI anxiety symptoms; GSI, General Symptom Index; FCRTRIG, Fear of Cancer Recurrence triggers; FCRPSTR, FCR psychological stress; FCRCOP, FCR coping strategies; FCRINS, FCR insight; SCS_SK, Self-Compassion Scale self-kindness; SCS_SJ, SCS self-judgment; SCS_CH, common humanity; SCS_I, SCS isolation; SCS_M, SCS mindfulness; SCS_OI, SCS overidentification; SCS_Total, SCS total; COMP_ TOTAL, Total Compassion Score; FFMQ_OB, Five Facets of Mindfulness Questionnaire observe; FFMQ_D, FFMQ describe; FFMQ_AW, FFMQ awareness; FFMQ_NJ, FFMQ nonjudgmental; FFMQ_NR, FFMQ NONREACTIVITY.

[a]Means and SDs are represented; *d*: Cohen's *d*; **P* < .05, ***P* < .01, ****P* < .001.

overall scores in the CBCT group (Table 3). These changes were maintained at follow-up for all those outcomes, except for the overidentification subscale. In the TAU group, nonsignificant changes were found.

Compassion

Results showed no significant Time × Group effect. Within-group comparisons revealed a significant pre-to-post change in the CBCT group with moderate effect size (d = 0.75) and nonsignificant change in the TAU group (Table 3).

Mindfulness Facets

Results showed a significant interaction of Time × Group for observing (F[2, 96.052] = 4.709; P < .05) and awareness facets (F[2, 98.598] = 3.444; P < .05) from FFMQ. Participants in the CBCT scored significantly higher than those in the TAU group for observing at postintervention (P < .05; d = 0.37; 95% CI [−0.19, 0.92]) and follow-up (P < .05; d = 0.43; 95% CI [−0.15, 1.01]) as well as for awareness at follow-up (P < .05; d = 0.45; 95% CI [−0.12, 1.04]). Within-group comparisons revealed a significant pre-post change for observing in CBCT, with large effect size (−0.86), and a significant preintervention to follow-up change for awareness in TAU, with moderate effect size (0.50; Table 3).

Acceptance Satisfaction and Adherence

In the CBCT group, 27 participants (96.4%) attended 5 or more of the 8 sessions of the program. In all, 25 (89.30%) participants practiced at home from 12 to 24 or more minutes in total, across all 8 weeks; 25 (89.30%) participants practiced on their own with the meditation recordings, and 9 (32.15%) of the 28 participants used the prerecorded meditation between 60% and 90% of the time (for more details see Table 2); and 13 (46.50%) participants practiced from 4 to 7 days a week. A total of 25 participants (89.30%) indicated that they would participate in future CBCT courses if offered and that they would continue to practice after the course program ended; 26 (92.90%) said that they were satisfied with the program and that they would recommend CBCT to other participants, and confirmed that they felt satisfied with the instructor's ability to facilitate the course sessions.

Discussion

The present article aimed to analyze the efficacy of a CBCT program to improve variables associated with health-related QoL (physical, social, emotional, and functional dimen-sions); somatic, depressive, and anxious symptomatology; psychological dimensions linked to FCR; and self-compassion, compassion, and mindfulness trait in a BCS clinical sample compared with a TAU control group after the intervention and a 6-month follow-up. Feasibility, acceptance, and satisfaction of this program was also evaluated.

Our findings suggest that an 8-week CBCT protocol is efficacious in reducing psychological stress related to FCR and increasing self-kindness, common humanity, general self-compassion, observation, and acting with awareness mindfulness skills. Regarding QoL, CBCT was not shown to be efficacious compared with TAU; however, in the pre-post analysis, it shows effects on emotional and general factors. Regarding symptoms, participants allocated to the CBCT intervention did show reductions in depressive and general distress symptomatology compared with those in the TAU group; however, improvements in pre-post analysis in the CBCT group were observed in depressive and general symptomatology after intervention and at 6-month-follow-up. Growing literature has validated interventions with active mindfulness components to be effective for diminishing depression and increasing general psychological well-being in oncological survivorship.[66] More specifically, previous studies with CBCT have also been validated as a promising intervention for depressive symptomatology in the healthy population[67] and specific clinical oncological settings.[17]

It is widely known how once the physical threat of can-cer is surpassed, FCR is one of the most significant sources of distress in BCS.[68-71] Previous studies showed how implementing a contemplative practice in daily life resulted in significant reductions in FCR which, in turn, mediated significant reductions in perceived stress and anxiety.[72] CBCT has shown hints of significant improvements in functional impairment associated with fear of recurrence.[17] In the present study, CBCT has proved to be efficacious in facilitating motivational, attentional, cognitive, and emo-tional resources and enables BCS to cope with the distress that evokes thoughts, images, or memories related to FCR.

In relation to self-compassion domains, CBCT proved to improve the ability to be kind in the face of one's own inadequacies and vulnerabilities, not feel alienated when experiencing difficulties (self-kindness and common humanity, self-compassion traits), and aid overall self-compassion. These self-compassion dimensions have been strongly related to well-being, happiness, and resilience in different studies.[15,36,73-78] According to Neff and colleagues,[53,79] the constituents of self-compassion that have been highlighted in their studies are central to fostering a self-compassionate mindset when coping with one's own inadequacies, per-sonal failures, and external circumstances that are hard to bear. This perspective realizes imperfection as part of the shared human condition, so that one's weaknesses are seen from a broad, inclusive perspective. Similarly, difficult life circumstances are framed in light of the shared human experience, fostering connection instead of disconnection

and isolation when experiencing suffering. In this sense, when assuming a non–self-compassionate outlook, people tend to feel isolated, harsh, and emotionally reactive when considering personal flaws, weaknesses, or hardship.

CBCT was not seen to be efficacious compared with TAU in the increase of compassion scores; however, data show significant improvements in compassion at posttest for the CBCT group with medium effect size, and no sig-nificant improvements for TAU. These findings are in line with previous results in compassion measures related to CBI.[80,81] These results could be explained by several factors, such as the length of the intervention; other CBCT studies have been done with an extended format.[67] This extension is relevant given the complex and numerous psy-chosocial and physiological impairments in survivorship when trying to adapt CBCT in future studies. Furthermore, more efforts should be focused on adapting the CBCT pro-gram to Latin-Mediterranean-Catholic cultural contexts. In these contexts, compassion as proposed by CBI is rela-tively new and needs a longer time to be integrated into the individual and collective schema.

Regarding mindfulness facets, data reveal that CBCT is an effective intervention that fosters abilities to observe external and internal phenomena or stimuli with awareness (mindful observation factor, FFMQ trait) and act mindfully in daily activities (acting with awareness scores, FFMQ trait). Although CBCT is a protocol that uses meditation to gener-ate mindsets and skillsets related to well-being, no other interaction in mindfulness facets were reported as significant in this study. This may be a result of the orientation of this program, which pays special attention and care to the cognitive strategies and techniques that have been tested to enhance well-being.* However, efforts to accurately assess mindfulness facets are highly needed in contemplative training programs that include analytical approaches that enhance well-being.[84-87] We think that this point is relevant because of the importance of the cognitive constituents that have been highlighted as central in compassion mind training.[88,89]

To sum up, results from this RCT study also suggest that CBCT is a feasible and highly satisfactory 8-week interven-tion among BCS. Moreover, the adherence rate was higher than in previous studies with CBCT and BCS.[17] In this pre-vious study, adherence was assessed in 2 ways: logged home practice time between participant and attendance at weekly classes as recorded by the teacher. In the present study, data suggest that CBCT has high rates of attendance, high rates of adherence to home practice, and high scores in minutes of practice between sessions. Moreover, most of the participants had a high rate of practice frequency a day after finishing each session. A high percentage of these par-ticipants wish to continue with CBCT training if offered and would recommend CBCT to other patients. Data confirm a high level of satisfaction with the program. Finally, most of the participants intend to continue practicing CBCT on a daily basis.

Several limitations and methodological issues with this study should be mentioned: (1) The results might be influ-enced by participants' contemplative experience prior to the study, and this is one variable that should be taken into account in future studies; (2) considering that this is the first CBCT study conducted outside an Anglo-Saxon context, refinement in the adaptation process to Latin-Mediterranean-Catholic cultural contexts must be examined. This will be included in future analyses with samples of Spanish BCS and CBCT.

However, caution must be exercised when considering the effects of compassion training in this study; results sug-gest that CBCT could be considered as a promising protocol that aids BCS in coping with the stress evoked by FCR, fosters self-compassion facets that promote well-being and resilience, and nurtures mindful abilities.

This research is another call for deepening scientific knowledge and paying more attention to the mechanisms and implications of training in compassion. One of the main goals of compassion programs is to cultivate skills to cope with internal (feelings, thoughts, sensations, memories, self-criticism, etc) and external (lost, sickness, death, criticism) difficulties and turn them into opportunities for growth from the basis of a selflessness perspective. According to a theoretical construct discussed by some authors,[90,91] the abilities embedded in CBI offer a selflessness perspective that culti-vate conative, attentional, cognitive, and affective abilities that enhance authentic and lasting well-being.[92] Moreover, as far as we know, this is one of the first studies to evaluate the effects of a CBI in an oncological survivor sample and the first study to measure the efficacy of CBCT in a Latin-Mediterranean-Catholic setting.

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