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DEPARTMENT OF PSYCHOLOGY

ACCEPTANCE AND COMMITMENT THERAPY FOR PRIMARY HEADACHE SUFFERERS: A RANDOMIZED CONTROLLED TRIAL

DOCTOR OF PHILOSOPHY DISSERTATION

VASILIS S. VASILIOU

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ACCEPTANCE AND COMMITMENT THERAPY FOR PRIMARY HEADACHE SUFFERERS: A RANDOMIZED CONTROLLED TRIAL

VASILIS S. VASILIOU

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The present doctoral dissertation was submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy of the University of Cyprus. It is a product of original work of my own, unless otherwise mentioned through references, notes, or any other statements.

Vasilis S. Vasiliou

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ABSTRACT IN GREEK

Η κύρια συμπεριφορική τεχνική για τη διαχείριση των πονοκεφάλων είναι η πρόληψη των επεισοδίων πονοκεφάλων μέσω της αποφυγής εξωτερικών και εσωτερικών ερεθισμάτων που μπορεί να προκαλέσουν πονοκέφαλο. Παρά την ευρέως διαδεδομένη χρήση της αποφυγής ερεθισμάτων, πολύ λίγα εμπειρικά στοιχεία υποστηρίζουν την αποτελεσματικότητα αυτής. Η προσπάθεια αποφυγής των ερεθισμάτων που συνδέονται με την ενεργοποίηση επεισοδίων πονοκεφάλου ή άλλων εσωτερικών γεγονότων που σχετίζονται με πονοκέφαλο (π.χ. σκέψεις ή συναισθήματα σχετιζόμενα με πονοκέφαλο), οδηγεί σε βραχεία απάλυνση του πόνου, αλλά φέρει μακροχρόνιες συνέπειες όπως: η αύξηση της ευαισθησίας στα ερεθίσματα, περιορισμό της ποιότητας ζωής, μείωση της εσωτερικής αίσθησης ελέγχου, και επιδείνωση της αντίληψης του πόνου. Νέες συμπεριφορικές θεραπείες, όπως η Θεραπεία Αποδοχής & Δέσμευσης (ΘΑΔ), σε αντίθεση με θεραπείες που τονίζουν τη συνεχή αποφυγή, ενισχύουν την έννοια της αποδοχής και συνέχισης της ζωής με τον πόνο, βάσει των σημαντικών για τον ασθενή αξιών. Αν και ο Αμερικανικός Ψυχολογικός Σύνδεσμος (APA) χαρακτηρίζει την ΘΑΔ ως μια εμπειρικά τεκμηριωμένη παρέμβαση στους χρόνιους πόνους, πολύ λίγες μελέτες αναδεικνύουν την αποτελεσματικότητα της στους πονοκεφάλους. Ο σκοπός αυτής της κλινικής τυχαιοποιημένης μελέτης ήταν τριπλός. Πρώτον, σκόπευε να εξετάσει κριτικά τον αναποτελεσματικό ρόλο της αποφυγής ως μέθοδο διαχείρισης των πονοκεφάλων και μετέπειτα να προτείνει την ΘΑΔ ως μια εναλλακτική της αποφυγής και του ελέγχου παρέμβασης για την διαχείριση των πονοκεφάλων. Δεύτερον, εξέτασε σε μια κλινική τυχαιοποιημένη συνθήκη, πώς μια θεραπευτική προσέγγιση βασιζόμενη στην ΘΑΔ μειώνει την ανικανότητα σχετιζόμενη με τους πονοκεφάλους και την ποιότητα ζωής, συγκρινόμενη με ομάδα ελέγχου η οποία αποτελείτο από λίστα αναμονής. Τέλος, η μελέτη αυτή σκόπευε να εξετάσει τους διαμεσολαβητικούς μηχανισμούς της ΘΑΔ στην ανικανότητα σχετιζόμενη με τον πονοκέφαλο και την ποιότητα ζωής μέσω θεωρητικά-σχετιζόμενων διαμεσολαβητικών παραγόντων (π.χ., αποδοχή του πόνου, ψυχολογική ακαμψία στον πόνο, δράσεις δέσμευσης, πρόοδο και παρεμβολές στις αξίες, και ενσυνειδητότητα). 94 ασθενείς με πονοκέφαλο τυχαιοποιήθηκαν σε δύο ομάδες: είτε ΘΑΔ ή λίστα αναμονής. Η ανικανότητα σχετιζόμενη με τους πονοκεφάλους και η ποιότητα ζωής (πρωτογενή αποτελέσματα), η συχνότητα πονοκεφάλων, χρήση ιατρικών υπηρεσιών και ψυχολογικής ανησυχίας (δευτερογενή αποτελέσματα) και κλίμακες μέτρησης των διαδικασιών της ΘΑΔ θεραπείας (π.χ., αξιολόγηση της αποδοχής, γνωστικής αποκόλλησης, αξιών, ενσυνειδητότητας κλπ) εξετάστηκαν πριν, στο τέλος της θεραπείας και στους 3 & 6 μήνες μετά το πέρας της θεραπείας. Τα αποτελέσματα έδειξαν στατιστικά σημαντική βελτίωση υπέρ της ομάδας θεραπείας σε σύγκριση με την ομάδα ελέγχου, στους δείκτες ποιότητας ζωής και ανικανότητας. Μη στατιστικά σημαντικά αποτελέσματα φάνηκαν για τους δευτερογενείς δείκτες εκτός από τον δείκτη της κατάθλιψης (ψυχολογική ανησυχία), όπου η ομάδα θεραπείας επέδειξε σημαντική μείωση στην κατάθλιψη, όταν συγκρίθηκε με την ομάδα ελέγχου. Επίσης, όταν εξετάστηκαν τα αποτελέσματα μετά το πέρας 6 μηνών από τη

λήξη της θεραπείας, η ομάδα θεραπείας παρουσίασε στατιστικά σημαντικές μειώσεις στους δείκτες της ανικανότητας εξ αιτίας των πονοκεφάλων και βελτιώσεις στη ποιότητα ζωής σε σύγκριση με την ομάδα ελέγχου. Τέλος, η ομάδα θεραπείας, όταν συγκρίθηκε με την ομάδα ελέγχου, παρουσίασε σημαντικές βελτιώσεις σε αρκετές από τις διαδικασίες της ΘΑΔ (π.χ., αποδοχή του πόνου, αποφυγή, γνωστική σύγκλιση, και παρεμβολή στις αξίες) στο τέλος της θεραπείας, και μετά από 3 μήνες. Επιπρόσθετα, διαμεσολαβητικές αναλύσεις (mediation) χρησιμοποιώντας μη παραμετρικά κριτήρια επέδειξαν ότι οι δείκτες: αποδοχής του πόνου, ψυχολογικής ακαμψίας στον πόνο, αποφυγής και πρόοδο στις αξίες φάνηκαν να διαμεσολαβούν στη σχέση μεταξύ της θεραπείας και ανικανότητα εξ αιτίας των πονοκεφάλων/ ποιότητα ζωής. Τα συμπεράσματα αυτής της μελέτης παρέχουν νέες ενδείξεις σχετικά με τη χρήση συμπεριφορικών προγραμμάτων για τη διαχείριση των πονοκεφάλων. Επίσης, τα συμπεράσματα παρέχουν ευρήματα σχετικά με την ΘΑΔ και τους μηχανισμούς θεραπείας της. Στο σύνολο της, η μελέτη αυτή παρουσιάζει εμπειρικά δεδομένα που μπορούν αν χρησιμοποιηθούν στην κλινική πράξη και προτείνει την χρήση της ΘΑΔ για την διαχείριση των πονοκεφάλων.

Λέξεις Κλειδιά: Αποφυγή, Συμπεριφορική θεραπεία για τους πονοκεφάλους, Ερεθίσματα πονοκεφάλων, Κλινική Τυχαιοποιημένη Μελέτη, Διαμεσολαβητικές αναλύσεις, Θεραπεία Αποδοχής & Δέσμευσης

ABSTRACT IN ENGLISH

The main behavioral treatment suggestion for headache management is the prevention of headaches via avoidance of external and internal headache triggers. Despite the wide use of avoidance in headache management, very little empirical evidence exists to support its effectiveness. Attempts at avoiding headache triggers or other internal private experiences associated with headaches, may increase trigger potency, restrict lifestyle, decrease internal locus of control, and exacerbate and maintain pain perception. New treatment approaches, such as Acceptance and Commitment Therapy (ACT), emphasize acceptance and valued-living as alternatives to avoidance. Though APA characterizes ACT as an empirically supported treatment for chronic pain, there is limited evidence for its effectiveness for headache disorders. The purpose of the present study was threefold. First, it aimed to critically evaluate the detrimental role of avoidance when dealing with head pain, and then proposed the ACT approach as an alternative to the avoidance and control of pain agenda. Second, it examined in a Randomized Controlled Trial (RCT) how an ACT-based intervention for headache sufferers decreases disability and improves quality of life, compared to a Wait List Control group (WL). Finally, it sought to examine the mechanism of ACT treatment on headache-related disability and quality of life outcomes, through ACT-theoretically-based mediators (e.g., pain acceptance, psychological inflexibility in pain, committed actions, values progress and obstruction, and mindfulness). 94 headache sufferers were randomized to either receive ACT or be in a waitlist control condition. Headache-related disability and quality of life (primary outcomes); headache severity, medical utilization and psychological distress (secondary outcomes); and ACT process measures (e.g., assessing acceptance, defusion, values, mindfulness etc.) were assessed before-treatment, at treatment-end, and at 3 and 6-month follow-ups. Results demonstrated substantial improvement in favor of ACT compared to the WL group on primary outcomes. No significant group by time differences was observed for secondary outcomes, except for depression, where ACT demonstrated significant reductions when compared to the control. When 6-month follow-up assessments were examined, ACT resulted in significant effects of time for disability, quality of life, pain severity, frequency of medical utilization, and depression. Also, the ACT group, when compared to the control group presented improvements in several ACT processes (e.g., pain acceptance, avoidance of pain, cognitive fusion, and value obstructions) at treatment-end, and at 3-month follow-up. Further, mediation analyses using a non-parametric cross product of the coefficient approach demonstrated that pain acceptance, psychological inflexibility in pain, avoidance

of pain, and values progress were found to all mediate the effects of treatment on headache disability and quality of life at 3, and 6-month follow-up. Findings from this study offer new evidence for the utility and efficacy of ACT in the management of primary headaches. Also, findings provide evidence that the ACT approach indeed works via its proposed mechanisms of action. Collectively, this study has practical and translational value and suggests the use of ACT for the management of headaches.

Keywords: Avoidance; Behavioral Treatment for Headaches; Headache Triggers; Randomized Controlled Trial; Mediation Analyses; Acceptance and Commitment Therapy

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It is a cold Tuesday afternoon, 20th of December 2016. I am sitting at a university's library desk and reflecting over the last five and half years of my doctoral training. From my desk, I can see the green valley of the National Polytechnic University of Athens campus. A week ago, I successfully defended my Ph.D. thesis at the University of Cyprus. Now, I am completing a small number of topics, suggested by my Ph.D. committee, as points to be addressed in order to further improve the quality of this dissertation. I chose to complete these correction points in Athens, Greece, while enjoying the care and warmness of my parent's house that I have been missing over the last eight months.

As I am reflecting on my Ph.D. path, a path that it would not have been completed without the constant support of a number of different people, many thoughts and memories are popped up in my mind; moments of excitement, agony, happiness, doubt, self-judgment, and rewards. I feel gracious, and I owe a big thank to a number of people with whom I had the chance to meet and create memories on the beautiful Mediterranean island of Cyprus, undoubtedly, a second home!

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Vasilis S. Vasiliou

DEDICATION

To the father, mother, and sister who I deeply and truly love; unconditionally, compassionately, and for the kid that is always there and observes the world with curiosity.

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Study 1: IS HEADACHE CONTROL OVEREMPHASIZED? CONCEPTUALIZING HEADACHES WITH FLEXIBILITY

Abstract

Behavior headache therapies (e.g., relaxation, biofeedback, cognitive-behavior stress management therapies) have been well-documented as effective psychological interventions for head pain, and are considered as first line treatments, along with pharmacotherapy for reducing the burden caused by headaches. Despite their success, headaches are the third leading global cause of disability causing serious difficulties in sufferers' lives, their families, and societies. A careful examination of the empirical evidence on the effectiveness of behavior headache therapies suggests several methodological issues that threaten the validity of existing findings, and create conceptual gaps in our understanding of the mechanisms of behavior therapies, and how they really work. There is a need for updating the dominant behavioral paradigm for headache management with modern practices and theoretical models that improve the existing conceptual gaps. An emerging behavior approach entitled Acceptance & Commitment Therapy (ACT), and a novel theoretical framework, called Psychological Flexibility in pain (PF), may provide an accurate set up for upgrading the dominant behavioral headache paradigm with new practices, and open the field up for further research into the area of head pain. Both ACT and the PF model offer a new perspective in explaining how individuals exacerbate and maintain pain suffering by focusing on the role of the language and the context, two processes that are thought to influence the experience of pain. This paper synopsizes four decades of research in behavioral therapies for headaches and highlights several methodological and conceptual issues in these treatments. It then proposes the theoretical model of PF and the ACT approach as the next generation of behavioral therapies. Finally, it recommends how ACT for headaches can be delivered in a group and face-to-face format, and discusses the limitations and future directions of this approach.

Keywords: Avoidance; Behavioral Treatment for Headaches; Headache Triggers; Psychological Flexibility; Acceptance and Commitment Therapy

Introduction

A headache or cephalalgia refers to pain anywhere in the head, the face, or neck and is considered a disease of a major detrimental impact on a sufferer's life (Vos, Flaxman, Naghavi, Lozano, Michaud, Exxati et al., 2013). Primary headaches, such as migraines or tension-type headaches, cause serious functional impairment, disability, economic costs (e.g., increased medical utilization) and other consequences (e.g., decreased in quality of life, sickness absence or reduced efficiency at work) for sufferers. The prevalence of primary headache disorder is deemed high among both males and females with almost 11 million globally suffering from this debilitating condition (WHO, 2011). In addition, co-occurrences of several primary headache categories (i.e., migraines and tension-type headaches; Jensen & Stovner, 2008), medical illnesses (e.g., ischemic stroke, hypertension, obesity, diabetes, asthma, chronic pain other than headache; Buse, Manack, Serrano, Turkel, & Lipton, 2010) and psychiatric disorders (e.g., panic disorder, phobias, depression; Hamelsky & Lipton, 2006; Radat & Swendsen, 2005) are also high, resulting in marked consequences for those afflicted and their caregivers.

Headaches are the third leading global cause of disability, preceded only by depression and low back pain (Steiner, 2015). The burden of headaches on sufferers' lives, their families, and societies, is considered an important public health issue (Jensen & Stovner, 2008). Fortunately, behavioral headache interventions (e.g., relaxation, biofeedback, cognitive-behavioral stress-management therapies), coupled with pharmacotherapies, can significantly reduce the burden of headache on an individual's life (Penzien, Rains, & Andrasik, 2002), and are recognized as well-supported treatments in managing head pain (Andrasik, 2007; Nestoriuc, Martin, Rief, & Andrasik, 2008; Penzien, Irby, Smitherman, Rain, & Hoole, 2015; Rains, Penzien, Douglas, McCrory, & Gray, 2005; Starling & Dodick, 2015). However, of those individuals offered treatment, only 35% to 50% are considered responders at treatment end (Rains et al., 2005). There is a significant number of headache sufferers who continue to experience serious headache-related disability and low quality of life as a result of uncontrollable and excessive head pain (Huguet, Grath, Stinson, Tougas, & Doucette, 2014; Holroyd & Lipchik, 1999; Kjeldgaard, Forchhammer, Teasdale, & Jensen, 2014). This warrants further investigation.

A careful examination of the empirical evidence on the effectiveness of behavior headache therapies suggests several methodological and conceptual issues pertaining to behavioral headache therapies. Suggestions for improvements in these issues may enhance headache treatments with new methods and practices that can increase the rate of behavior headache treatment success. Emerging behavioral approaches in head pain management

include practices that do not primarily focus on alleviating the severity of pain, but increase sufferers' willingness to experience pain and other unwanted internal experiences (e.g., thoughts, physical sensations, etc.) when doing so serves long-term valued goals (Smitherman, Wells, & Ford, 2015). One such approach is Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 2012). ACT is based on the theoretical model of Psychological Flexibility that assumes cognitive and contextual influences as the core processes of human suffering (PF; McCracken & Morley, 2014). Provided that behavior headache approaches are deemed effective, yet, present with several methodological and conceptual issues, new theoretical models, such as the PF model and the ACT approach, both grounded in behavioral tradition, may indeed integrate and expand headache interventions.

This paper synopsizes the effectiveness of existing behavioral therapies for headache management and highlights several methodological and conceptual issues related to the existing headache therapies. It then proposes an emerging behavior approach for head pain management, ACT, and the theoretical model of the PF for chronic pain as a way to upgrade existent behavior headache therapy approaches with practices that guide researchers and clinicians toward more effective and efficacious approaches to managing head pain. Next, it reviews preliminary empirical findings supporting ACT for head pain management, and presents how ACT can be delivered in a group or face-to-face format. Finally, it examines limitations and future directions of this treatment approach.

The Three Waves of Progress in Behavioral Headache Treatments

Psychological approaches for managing headaches have an extensive history conceptualized here into three "waves" or generations of therapeutic approaches. The term "waves", borrowed from Steven Hayes (2004) defines *"*a set of formulations of dominant assumptions, methods, and goals, some implicit, that help organize research, theory, and practice in behavioral therapy" (page 640. The term "waves" here attempts to organize the empirically supported psychological approaches for headaches. Though different behavioral approaches in headache utilize different methods to achieve their goals (e.g., reduction in headaches episodes, increases in self-efficacy, prevention of headache triggers), there is a common mechanism of action in all approaches. All behavior therapies attempt to help sufferers alleviate pain. Given that emerging behavior therapies do not attempt to change the pain severity per se, but increase sufferers valued living even when the pain is present (Smitherman et al., 2015) the division of behavior therapies into waves can help researchers conceptualize, organize, and evaluate more than four decades of

headache research, and more than 300 behavioral headache intervention studies. Also, this division can help clinicians integrate the current knowledge with novel practices that may upgrade the field up with new practices that lead to more effective behavior headache therapies.

The first "wave" of behavior therapies for headache management.

During the 1960s and 1970s, the emergence of the operant learning practices gave rise to the notion that headaches are influenced by psychosocial factors (e.g., stress) and environmental changes (e.g., triggers; Rains et al., 2005). The operant learning approach to headache management consisted mainly of relaxation and biofeedback techniques. These techniques presumed to decrease headaches by teaching sufferers to exert control over their physiological responses (i.e., stress and muscular tension) and to become skilled in managing physical arousal in their bodies (Penzien et al., 2002). Early experiments through small controlled and uncontrolled studies in the 1960s and 1970s, demonstrated that by learning to control and modify numerous physiological reactions (e.g., blood pressure, skin conductance, heart rate, muscle tension, evoked potentials and electroencephalogram rhythms), individuals could learn to prevent or reduce pain (Budzynski, Stoyva, & Adler, 1970; Hay & Madders, 1971; Mitchell & Mitchell, 1971; Sargent, Green, & Walters, 1972). Indeed, relaxation techniques (e.g., progressive muscle relaxation, cue-controlled relaxation, diaphragmatic breathing, etc.) teach headache sufferers to reduce body arousal and control physiological responses through muscular relaxation. Similarly, biofeedback also teaches sufferers to exert control over physiological responses (e.g., muscle tension) through visual and auditory signals that provide feedback information to individuals about the levels of tension in their body. Demonstrations of the potential success of behavioral therapies in managing head pain in the 1980s increased the interest for clinical trials evaluating the effects of the first wave behavior therapies on headache treatment (Rains et al., 2005).

Behavioral therapies were extensively evaluated and found to be successful in managing uncomplicated forms of MIs and TTHs (Buce & Andransik, 2009; Goslin, Gray, McCrory, Penzien, Rains, & Hasselblad, 1999; McCrory, Penzien, Hasselblad, & Gray, 2001). For MIs, meta-analytic reviews present a 37% to 50% reduction in MIs, relative to wait-list controls with medium to large effect sizes for relaxation and biofeedback (effect sizes d = .55, 95% CI = .52, .96 to d = .77, 95% CI = .24, 1.03, respectively; Goslin et al., 1999). Also, other reviews suggest that biofeedback is considered an effective approach in managing MIs (Buse & Andrasik, 2009; Nestoriuc et al., 2008) when compared to

monitoring alone (i.e., no treatment; *d* = .46, CI 95% .27, .64) and placebo control (*d* = .25, 95% CI .00- .49), but no more effective when compared to relaxation (*d* = .10, CI 95% -.39 - .50). Relaxation training was also considered an effective treatment option to prevent MI episodes, resulting in medium effect sizes when compared to wait-list (*d* = .55; 95% CI = .14, .96; McCrory et al., 2001).

For TTH, meta-analytic reviews suggest that behavioral treatments are effective in lowering the severity of TTHs (McCrory et al., 2001), with 33% reduction in prophylactic medication intake (e.g., amitriptyline; Penzien, Rains, Lipchik, & Creer, 2004), and treatment maintenance for those initially responded to treatment over 5-years after treatment (Blachard, Appelbaum, Guarnieri, Morrill, & Dentinger, 1987). Biofeedback for TTHs was found to significantly reduce headaches almost one standard deviation above the mean of headache index with large effect sizes when compared to no treatment (*d* = .79, 95% CI .40- 1.17), medium effects when compared to placebo controls (*d* = .50, 95% CI .26- .75), and small effects when compared to relaxation (*d* = .18, 95 % CI .06-.30; Nestoriuc et al., 2008). Relaxation was also found to decrease the frequency of TTHs when compared to wait-list control groups (Penzien et al., 2004). However, the evidence is not clear as for the effectiveness of relaxation for chronic TTH, when compared to placebo or no treatment controls (Verhagen, Damen, Berger, Passchier, & Koes, 2009).

Despite their success, the first wave of behavioral approaches did not offer any therapeutic value for dealing with significant aspects of patients' headache experiences, namely internal events, such as disturbing thoughts and emotions related to headaches (Rains et al., 2005). These internal events were seen from a traditional behavioral perspective as internal phenomena being beyond individuals' voluntary control (Phillips & Hunter, 1981), and thus were treated in a similar fashion. Sufferers were taught how to control these internal events by regulating their intense physiological responses (e.g., muscle tension; Andrasik & Holroyd, 1980). Although improvements in disturbing thoughts and emotions were thought to occur as a result of reductions in muscle tension (Holroyd, 2002), this was not supported. Changes in disturbing thoughts and emotions, and consequently, improvements in headache outcomes, were occurred due to changes in cognitive appraisals (e.g., increased locus of control and self-efficacy; Blanchard, Kim, Hermann, & Steffek, 1993; Holroyd, Penzien, Hursey, Tobin, Roger, Holm et al., 1984; Rokicki, Holroyd, France, Lipchik, France, & Kvaal, 1997). This gave rise to cognitive-attributional model that contributed, in-part, to the emergence of the "second wave" of behavior therapies for managing headaches.

The second "Wave" of behavioral therapies for headache management.

In the early 1980s, it was identified that many headache sufferers were not coping effectively with the cognitive and affective components of a headache (e.g., thoughts, emotions), and first "wave" treatments did not adequately address how patients cope with and react to stress (Holroyd & Lipchik, 1999). As a result, and in conjunction with the advent of cognitive therapy, cognitive therapy components were integrated into relaxation and biofeedback approaches. These components include techniques, such as cognitive restructuring, that help headache sufferers detect and modify their cognitive biases related to stress (e.g., misinterpretation of events, catastrophic thinking, distorted thoughts or beliefs). They also consist of practices that increase sufferers' self-efficacy and internal locus of control, by teaching them how to prevent their headache via avoiding environmental stressors and triggers. This development, led to the second "wave" of behavioral therapies for headache management, known as the cognitive-behavioral stress-management training (CBT; Penzien et al., 2015).

Evaluation of the effectiveness of CBT for headaches presents mixed results (Harris, Loveman, Clegg, Easton, & Berry, 2015). Some studies demonstrate the effectiveness of CBT in reducing headache severity, when it compared to wait-list (Basler, Jakle, & Kroner-Herwig, 1996; Richardson & McGrath, 1989), when it combined with relaxation vs. antidepressants (amitriptyline; Holroyd, Nash, Pingel, Cordingley, & Jerome, 1991), or when it combined with pharmacotherapy (Andrasik, Grazzi, Usai, D'Amico, Kass, & Bussone, 2007; Holroyd, O'Donnell, Stensland, Lipchik,, Cordingley, & Carlson, 2001; Holroyd, Cottrell, O'Donnell, Cordingley, Drew, & Carlson, 2010). However, other studies provide no support for the superiority of CBT when it compared with relaxation (Blanckard, Appelbaum, Radnitz, Michultka, Morrill, Kirsch et al., 1999; Mosley, Grothues, & Meeks, 1995; Powers, Kashikar-Zuck, Allen, LeCates, Slater, Zafar et al., 2013; Tobin, Holroyd, Baker, Reynolds, & Holm, 1988), CBT vs. biofeedback (Martin, Forsyth, & Reece, 2007), CBT vs. CBT plus placebo or CBT vs. CBT plus antidepressants medication (Holroyd et al., 2001), and CBT vs. self-management training (Martin, Nathan, Milech, & Kappel, 1989).

Two recent meta-analytic reviews conclude that the findings regarding the effectiveness of psychological approaches for headache management, comprised mostly of CBT components, are not consistent (Harris et al., 2015; Huguet et al., 2014). Inconsistencies in CBT outcomes are thought to occur as a result of several methodological concerns (e.g., sample sizes, recruitment procedures used in headache trials, control groups

selection, adherence and feasibility quality issues) that threaten the validity of findings (Gatchel, Peng, Bo, Madelon, Fuchs, Perry, & Turk, 2007; Penzien & Irby, 2014; Rains et al., 2005). Even though methodological issues in behavior headache therapies derive, in part, due to lack of achieving real double-blindness (Penzien et al., 2015) some improvement in methodologies is warranted.

In addition to methodological issues that will be discussed in this paper, there are some conceptual gaps in cognitive-behavior headache treatments that also warrant attention, and particularly as mechanisms of action for changes are concerned. Studies found that even if CBT reduces the severity of headaches when compared to waiting list control groups, this is not a uniform effect for all, as there are numerous sufferers who fail to increase their life satisfaction, quality of life, or general functioning (Kjeldgaard et al., 2014; Miller & Berman, 2000; Olivares, Alzacar, Sanchez, & Carrillo, 1999; Palermo, Eccleston, Lewandowski, Williams, & Morley, 2010; Stonnignton, Kothari, & Davis, 2016). It is argued that CBT for headache sufferers, can be generally beneficial, yet, it is unknown, for what kind of headache sufferers and outcomes there may be benefits (Huguet et al., 2014; McCrone, Seed, Downson, Clark, Goldstein, Morgan et al., 2011), or which aspects of the CBT maximize headache treatment effects. Given the lack of empirical evidence as for the processes responsible for therapeutic changes in headaches, and a lack of knowledge about how these processes are related to headache treatment outcomes, a more detailed account of mechanisms of headache impact should be highlighted.

Methodological and Conceptual Issues in Psychological Therapies for Headaches

Methodological Issues

One of the methodological problems frequently encountered in trials assessing behavioral headache therapies is the recruitment of study samples. In many cases, behavioral trials recruit individuals with refractory and longstanding headache problems (Penzien et al., 2002), patients from headache clinics/ university medical schools' settings or undiagnosed samples from the general community (Holroyd & Lipchik, 1999). These pools of samples comprise of patients with multiple problems (i.e., comorbidities, other health problem, etc.) that can be managed only in specialized treatment programs. Although these samples appear to effectively respond to behavioral interventions (Tharn, Pence, Ward, Kilgo, Clements, Cross et al., 2007), results cannot be generalized to the average community-based headache sufferer receiving intervention in primary-care settings (Rains et al., 2005). The recruitment of biased- specialized or even undiagnosed

samples may put into question the validity and generalizability of outcomes derived from behavioral trials and even reduce the efficacy of intervention in clinical practice (Rains et al., 2005). Thus, future trials should enhance clarity in treatment outcomes' by recruiting community-based samples and utilize standardized criteria to diagnose their samples (e.g. the International Classification of Headache Disorders-II [ICHD-II]; HIS, 2004).

Another methodological problem that is also frequently encountered in trials assessing behavioral headache treatments is the systematic underrepresentation of non-headache measures as primary outcomes (e.g., emotional functioning, quality of life, head pain interference, etc.), and their explicit focus of trials in assessing headache severity, as the main aim of therapeutic effect (Huguet, et al., 2014; Penzien et al., 2005). Though head pain severity is the main outcome in headache treatment (Penzien et al., 2005), in fact, recent evidence suggests that an excessive focus on decreasing pain may instead lead to unrealistic and misleading expectations for pain patients (Martin, 2010; Sullivan & Ballantyne, 2016), and substantially increase the use of opioid prescriptions (Daubresse, Chang, Yu, Viswanathan, Shah, Stafford, et al., 2013). Given the significant role of psychological factors contributing to head pain adjustment and long-term functioning, lack of assessing such factors may limit the knowledge as for the effects of behavioral headache treatment in reducing the burden caused by headaches.

A third problem refers to the use of inappropriate methodological designs (e.g., comparison of active treatments with double-blind, placebo-controlled groups or other types of psychological placebos, e.g., pseudotherapy, parallel groups, etc. Penzien et al., 2005) that may lead to therapist and patient bias (e.g., inability to blind both). Psychological placebo therapies (e.g., therapies that involve patient-therapist interaction and homework activities without any expected therapeutic effect on headaches) are inherently difficult to formulate equivalence to the tested credible therapies (Rains & Penzien, 2005). For example, they fail to control for a number of non-specific elements of therapeutic processes (e.g., the amount of patient-therapist interaction, group dynamics, and homework activities) involved in active treatments (Rains et al., 2005). Inappropriate psychological placebos can contaminate treatment effects with uncontrolled variables and increase the magnitude of the therapist- patient interaction bias. The use of inappropriate placebos or non-equal to the tested treatment control therapies, as Goslin and colleagues (1999) note, is quite common in behavior headache trials evaluating headache outcomes. It is possible that existent trials, derived from behavior headache therapies, are being afflicted with faulty significant outcomes due to unequal control treatments (e.g., pseudotherapy,

etc). This may lead to misleading information to clinicians, and therefore ineffective treatment to patients (Rains & Penzien, 2005).

A final methodological concern refers to the quality of published trials. For example, the level of internal validity and quality of reporting trials' setting elements (e.g., qualifications, training, and experience of research and practitioners teams, therapists' treatment integrity, adherence to the study protocol, details of the therapeutic intervention) are considered low (Huguet et al., 2014). Also the breadth of statistical analyses used in behavioral headache trials includes inferior statistical methods, which often cannot demonstrate the multifactorial nature of the headache experience (Penzien et al., 2015). Lack of examining quality issues and use of statistically inferior analyses weaken the interpretability and transportability of treatment outcomes across settings and populations (Tolin, McKay, Forman, Klonsky, & Thombs, 2015). Methodological flaws, as the ones mentioned above, threaten the validity of outcomes.

New behavioral headache trials may increase clarity and enhance validity in research evaluating headache treatment outcomes by adopting improved methodologies. To this end, some suggestions for improvements follow. First, the problem of recruitment selection in behavioral headache trials can be addressed with the enrollment of community-based headache sufferers exhibiting a broad range of heterogeneous diagnoses. This practice can reduce the possibility of population bias and increase the transportability of treatment outcomes into the average headache sufferer receiving care in tertiary neurology centers. Second, the inclusion of non-headache variables (e.g., functioning, quality of life, etc.) as the primary outcomes can provide further knowledge regarding the effects of treatment beyond that of head pain reduction. Third, the common problem of double blinding and psychological placebos as control groups in assessing a new treatment protocol, can be addressed, at least partially (see Rains & Penzien, 2005 for a review of this issue), with the use of a "wait-list" condition (no active therapeutic elements). This methodology is thought to be useful for interventions never tested before. It minimizes therapists-patients bias, improves precision of treatment outcomes, and lowers the possibility of eliciting faulty conclusions (Reins & Penzien, 2005). Finally, a better reporting of issues pertaining to the tested protocol, therapists' fidelity, and the adoption of more robust statistical procedures (i.e., mediations for processes of change analyses, clinically meaningful changes for treatment outcomes, effect sizes calculations from outcomes, etc.) may diminish the likelihood of publication bias. Although improvements in methodologies can increase the validity of study findings, contemporary headache researchers propose that the drawbacks contributing to the CBT's mixed outcomes may not

only exist due to methodological problems across studies, but also due to some conceptual issues.

Conceptual Issues

Behavior headache literature has been hindered by a lack of a conceptual definition regarding the behavior headache treatments. Perhaps, these problems appear to stem largely from a fundamental problem of the cognitive-behavior therapy to define its active therapeutic components into a coherent theoretical model, and a lack of knowledge about the mechanism of behavior headache treatment action. At least three conceptual issues, related to the mechanisms of behavior headache action, are identified in contemporary behavior headache literature.

A first conceptual issue lies with the narrow focus of CBT in decreasing headache frequency by primarily teaching sufferers to avoid headache triggers (Chiros & o'Brien, 2011; Jensen, 2011; Martin, Callan, Kaur, & Gregg, 2015; Martin, 2010; Lake, 2009; Stonnington et al., 2016). Behavioral avoidance (BA) refers to the avoidance of external triggers that contribute or have been associated with the activation of a headache. Though behavioral avoidance is widely utilized by headache sufferers, and also constitutes the main part of the CBT approach to headache management (Penzien et al., 2004), very little evidence exist to support that avoiding headache triggers (e.g., visual stimuli, noise; Martin, 2009; 2010b) or restricting activities (e.g., exercise, cancelling social events, etc.), can actually prevent a headache episode (e.g., Blau & Thavapalan, 1988; Grant, 1979; O'Banion, 1981, Radnitz, Blanchard, & Bylina, 1990). The few studies that supported headache trigger avoidance benefits; have been criticized for their methodological weaknesses (e.g., retrospective recall of triggers, case studies, small sample size, lack of follow–up assessments; Wobel, Brannath, Schmidt, Kapitan, Rudel, Wessely, et al., 2007).

BA appears to be based on behavioral accounts of headache development which postulates that headaches are influenced by: (a) antecedent factors precipitating a headache episode (e.g., triggers, lifestyle and life-situation factors), (b) the immediate or long-term sufferers' reactions to their head pain experience, and (c) the consequences following at sufferers' reactions to headaches (Martin, Milech, & Nathan, 1993). Though this functional conceptualization increased awareness of the risk factors and triggers associated with the production of headaches (Martin et al., 1993), yet, it also led to the development of the advice of avoiding headache triggers as a mean to alleviate head pain. Despite the clear rationale behind this approach, in practice, it emerged without consideration of the potential negative consequences (especially in the long term) resulting from altering

headache antecedents (i.e., triggers or certain activities) via avoidance (Martin & MacLeod, 2009). Findings put into question the general advice of advising the avoidance of headaches and headache triggers, and contemporary researchers propose that the advice of avoiding headache triggers should be attenuated (Martin, 2010).

Indeed, recent studies demonstrate that avoidance of headache triggers may be helpful in the short-term (e.g., reduces pain at the moment of avoidance), yet, in the long-run, may lead to less tolerance for triggers (Martin, 2010), increased trigger sensitivity (Martin & McLeod, 2009), diminished quality of life (Ford et al., 2008; Hassinger, Semenchuk, & o'Brien, 1999), and increased headache-related suffering and disability (Chiros & o'Brien, 2011; Foote, Hamer, Roland, Landy, & Smitherman, 2015; Martin etal., 2015). Also, research shows that attempts at avoiding or controlling all the potential physiological and environmental headache triggers (antecedents) is generally difficult to achieve, as there is no clear understanding of (a) how triggers precipitate headaches (Martin, 2010; Martin & MacLeod, 2009), (b) how the descending pain modulate-network in the brain, found to be dysfunctional in headache sufferers, increases sufferers' sensitivity to trigger potency (Welch, Nagesh, Aurora, & Celman, 2001), and (c) which sufferers present with a genetically determined predisposition to headache triggers, thus any avoidance of headache triggers would be futile (Baumber, Sjostrand, Leone, Harty, Bussone, Hillert et al., 2006; Montagna, Cevoli, Marzocchi, Pierangeli, Pini, Cortelli et al., 2003; Russell, & Olesen, 1995). Given the lack of knowledge as for the mechanism behind triggers and production of headache, then encouraging trigger avoidance (i.e., altering headache antecedence) may become problematic as its excessive use in the long-run, increases trigger potency (Martin & MacLeod, 2009), and reduces the threshold for activating headaches (May & Schulte, 2016). The problem with altering headache antecedents via avoidance is further highlighted when one considers that the major headache triggers are internal in nature (e.g., stress, negative emotions; Andress-Rothrock, King, & Rothrock, 2010; Karli, Zarifoglu, Calisir, & Akgoz, 2005). Attempts at altering such headache antecedents eventually lead to even more problems and difficulties through a mechanism known as experiential avoidance.

Avoiding internal triggers, broadly known experiential avoidance (EA),is an inflexibly applied and context incongruent process of deliberate control, purposeful avoidance, or unwillingness to experience private events, such as negative thoughts, sensations and images, and the situations in which they occur (Hayes, Strosahl, & Wilson, 1999; Hayes & Wilson, 1994; Karekla, Forsyth, & Kelly, 2004). In headaches, avoiding internal triggers can be defined as an individual's unwillingness to experience head pain or

headache- related unwanted experiences, such as pain denial, excessive religiousness, wishful thinking, emotional distress, self-blame, and self-criticism (Rollnik, Karst, Matthias, & Dengler, 2001). It is argued that pain suffering does not occur as a result of the aversive experience of pain severity per se, but it is the consequence of individuals' efforts to repeatedly suppress, avoid or in any way control the pain and the unwanted internal experience following at pain sensation (Crombez, Vlaeyen, Heuts, & Lysens, 1999; Esteve & Ramizer-Maestre, 2013; Foote et al., 2015; McCracken, Eccleston, & Bell, 2005). This paradoxically results, in an increase in the experience one is trying to avoid, that in turn leads to preserving and aggravating a needless pain and suffering (Hursey & Jacks, 1992; McCracken et al., 2005). The reason why this occurs lies the EA's tight links with two universally encountered processes: the language and cognition (Hayes & Wilson, 1994).

Relational Frame Theory (RFT; Hayes, Barnes- Holmes, & Roche, 2001), the theory explaining how EA becomes pathogenic, postulates that individuals learn from a very young age to arbitrarily relate events to each other. Individuals via the use of language create arbitrary links, called relational frames, between thoughts, emotions, sensations, and contextual cues (Hayes & Gifford, 1997). Such relational frames result in verbal rules (e.g., rules such as if I think "X", then "Y" will occur, or in the case of headaches: "I will not be happy, unless I get rid of this headache"), instructions (e.g., "If I go out tonight, I will end up with a terrible headache tomorrow"), or self-judgments (e.g., "I am incompetent because of my headaches"). Verbal rules are coordinated by EA because when one deliberately avoids unwanted experiences (e.g., pain) this avoidance involves the verbal rule that contains the avoided item (e.g., "Only if I avoid pain, I can have my life back"; Hayes, Wilson, Gifford, Follette, & Strosahl, 1996). Thus, EA develops when individuals, through cognition (i.e., the mind) and their previous experiences (i.e., where experiences equal previous personal histories within a particular context), create rigid verbal rules about how one should behave in the present of unwanted internal events (e.g., "All the unwanted experiences should be always avoided"), and then follow these verbal rules, irrespective of the contextual consequences (e.g., social isolation, negative self-evaluations, diminished leisure activities, unsuccessful efforts to control the unwanted experience, etc.). From this perspective, EA represents a broader dimension that goes beyond the avoidance of internal experiences (e.g., pain) and includes a class of behavioral responses (e.g., rumination, avoidance, distractions, rules, judgments, etc.) that all serve the same function, that of minimizing the psychological contact with unwanted internal events, when attempts at minimizing them occur at the expense of living according to values (Hayes et al., 1996).

In the case of head pain problems, EA appears to be prominent, negatively reinforced by the sufferers' environmental context (e.g., doctors, family etc.) and the individuals themselves. For example, family members may provide support and relieve the sufferer from duties when a headache appears, thus reinforce future utilization of EA as a mean to cope with headaches (Liakopoulou-Kairis, Alifieraki, Protagora, Korpa, Kondyli, Dimosthenous, et al., 2002; Peterson & Palermo, 2004). Similarly, practitioners providing the advice of preventing internal headache triggers as a way to manage headaches may also unwittingly reinforce the use of EA (Schulman & Silberstein, 1992; Skaer, 1996). Finally, headache sufferers may themselves reinforce the use of avoidance (e.g., cognitive and behavioral avoidance of stressful situations, including head pain) due to its immediate effects in alleviating pain and suffering (Edhe & Holm, 1992; Kokonyei, Szabo, Kocsel, Edes, Eszlari, Pap et al., 2016; Stronks, Tulen, Bussman, Mulder, & Passchier, 2004). Research provides a dozen of empirical evidence demonstrating the long-term detrimental effects of EA (see Chawla & Ostafin, 2007 for a review).

In experimental research, Feldner and colleagues (2006) utilizing a cold-pressor task found that individuals high in EA displayed lower pain endurance and tolerance and slower recovery from pain than individuals exhibiting low EA. In a similar study, Hayes and colleagues (1999) found that participants receiving an acceptance of pain condition (considered the opposite of EA) demonstrated more pain tolerance (minutes under cold water) than the control group. Others have replicated, and further experimentally demonstrated, that high EA leads to lower pain tolerance (Gutierrez, Luciano, & Rodriguez, 2004; Zettle, Barner, Gird, Boone, Renollet, & Bursdal, 2012). Cross-sectional studies also present that excessive use of pain avoidance leads to greater suffering and disability (Asmundson, Norton, & Norton, 1999; McCracken, Gross, Aikens, & Carnrike, 1996; Karademas, Flouri, Karekla, Vasiliou, Kasinopoulos, & Papacostas, under review), heightened distress, more pain (McCracken et al., 2005), and poorer quality of life (Koleck, Mazaux, Rascle, & Brunchon- Schweitzer, 2006). In addition, EA may represents a predisposing risk factor that contributes to more suffering (Abramowitz, Tolin, & Street, 2001; Champan, Gratz, & Brown, 2007; Campbell-Sills, Barlow, Brown, & Hoffman, 2006; Wenger & Gold, 1995), mental health problems (Karekla & Panayiotou, 2011; Kashdan, Barrios, Forsyth, & Steger, 2006), and behavioral difficulties (Fledderus, Bohlmeijer, & Pietersen, 2010; Kingston, Clarke, & Remington, 2010). Finally, cross-sectional studies examining the role of EA in relation to head pain provide similar with the previously presented findings. Chiros & o'Brien (2011) and more recently, Foote and colleagues (2015), demonstrated that MI sufferers exhibiting low EA reported less

avoidance coping responses, higher levels of activity engagement, improvements in functioning and disability, and a better control of behavioral expressions of their MIs, compared to participants high in EA.

Provided that the entire head pain experience is a multifactorial phenomenon (Penzien, & Irby, 2014) being affected by several headache-related conditions beyond the severity of pain (e.g., the intermittent nature of headache episodes, the unpredictability of attacks, and the acute nature of pain), preventing headaches via avoidance of external and internal triggers is considered a major conceptual issue for CBT treatments in headache management. It is argued that not all headache triggers can be avoided, and when avoidance applied to internal triggers, can result in the opposite of pain alleviation, more headache, suffering and lower functioning in the long-run (Martin & MacLeod, 2009; Foote et al., 2015; Dindo, 2015).

A third conceptual issue with CBT involves the use of techniques that aim at changing the content of pain-related thoughts. Although CBT for chronic pain considers changing the content of thoughts as the mechanism of treatment, pain-related thoughts (e.g., reduce in catastrophizing, helplessness, hopelessness and though disputation) can change even when cognitive techniques are not utilized (Smeets, Vlaeyen, Kester, & Knottnerus, 2006; Vowles et al., 2007). Research shows that cognitive changes are neither necessary for reducing pain (Curran, Williams, ACdeC, & Potts, 2009; Linton, McCracken, & Vlaeyen, 2008; Smeets et al., 2006), nor effective at increasing pain tolerance (Severeijns, van den Hout, & Vlaeyen, 2005). In fact, the more sufferers focus on changing their cognitions before taking actions, the more they increase pain perception, rumination, and negative-self judgment through the feedback loop of experiential avoidance, (Goubert, Crombez, Eccleston, & Devulder, 2004; Haeffel, 2010; Hassinger et al., 1999; Masedo & Esteve, 2007; Sullivan, Rouse, Bishop, & Johnston, 1997; Wood & Perunovic, 2009). Further, multiple exposures to either pain-related fearful conditions or exposures to disturbing thoughts are found to lead to direct re-learning (Marco, Simona, Barara, Paola, Fulvio, Calogero, 2013). Although changes in pain-related thoughts are associated with some improvements in sufferers' daily functioning (Mizener, Thomas, Billings, 1988; Spanos, Radtke-Bodorik, Ferguson, & Jones, 1979; Thorn, Pence, Ward, Kilgo, Clements, Cross, et al., 2007; Woby, Watson, Roach, & Urmston, 2004), in fact, these changes occur without the use of cognitive methods (Penzien & Irby, 2014). How thought content changes occur without the use of cognitive techniques and what processes are involved in these changes, it is an empirical issue that remains unanswered.

A final conceptual issue with behavioral headache treatments has to do with the processes that are responsible for headache treatment outcomes. A number of variables have been proposed to mediate headache treatment outcomes; yet, the mechanism of change is still unknown for the most frequently utilized approach to headache management, cognitive-behavioral stress- therapy (CBT; Penzien, Irby, Smithermann, Rains, & Hoole, 2015). Proposed mechanisms of change include: changes in physiological (vascular or muscular) learning via biofeedback (Rokicki, Holroyd, France, Lipchik, France & Kvaal, 1997), change in self-efficacy (Holroyd et al, 2009), alteration of illness perceptions (Hobro, Weinman, & Hankins, 2004), and an increased use of positive coping skills (e.g., avoiding triggers, taking medications, having temporary breaks from work when headache is escalated, etc.; Seng & Holroyd, 2014). Although improvements in these processes as a result of CBT have all been found to significantly predict changes in headache outcomes, they cannot fully explain what accounts for the therapeutic effects of CBT on headache outcomes (Seng & Penzien, 2014).. Most psychological treatments for headaches utilize a wide variety of CBT components, such as self-efficacy, problem-solving, stress reduction, prevention of headaches via avoidance of triggers, and others. However, it is argued that CBT components are neither universally suitable for all headache sufferers, nor always effective in reducing the burden of headaches to individuals (Seng & Penzien, 2014; Holroyd et al., 2009). Thus, it is not yet clear how the processes underlying CBT lead to improvements in headache-related outcomes.

Several conclusions can be drawn from the previously discussed conceptual issues. First, it could be argued that the most frequently utilized coping response of headache trigger avoidance that aims to prevent and control headaches, is problematic. Empirical findings show that avoidance of headache triggers, despite its immediate relief from pain in the short-term, has paradoxically been associated with decreases in headache tolerance, reductions in self-efficacy, and restrictions in valued living, in the long-run. A new stream of research highlights that maximizing acceptance and value-based actions and minimizing avoidance of external and internal triggers reduce headache-related disability and increase daily functioning (Chiros & o'Brien, 2011; Dindo, Recober, Marchman, Turvey, & O'Hara, 2012; Dindo, Recober, Marchman, O'Hara, & Turvey, 2015; Foote, Hamer, Roland, Landy, & Smitherman, 2015; Mo'tamedi, Rezaiemaram, & Tavallaie, 2012; Stonnignton, Kothari, & Davis, 2016). Provided that numerous headache sufferers may never succeed in becoming permanently pain-free, and traditional behavioral or pharmacological interventions are neither always suitable for all patients, nor are they

universally effective, new practices supporting acceptance and values-based processes, may be alternatives to the control or avoidance of head pain intervention.

Second, until empirical findings regarding the therapeutic effects of cognitive components (e.g., changing thought content) are found, it would be useful to keep a scientific distance from cognitive practices. This is not to support that pure cognitive restructuring methods are always problematic or harmful; yet, empirical research indicates that they may not add to the overall therapeutic result. An alternative approach could be to choose to deal with head-pain related thought with methods that do not target at changing thoughts, but change the relation of sufferers with thoughts. Cognitive defusion or a process of diminishing the impact of thoughts on behavior by viewing thoughts as what they are, a stream of words, symbols, or internal phenomena, rather than literally true entities that should drive behaviors, is a new practice that aims to reduce thought believability by treating disturbing thoughts, beliefs etc. without changing their contents (Hayes et al., 2012). Relevant research demonstrates that lower fusion with pain-related thoughts is associated with increased social functioning, and lower depression (McCracken et al., 2014; Vasiliou et al., under review).

Third, given the lack of knowledge about which mechanisms of action are most responsible for therapeutic changes, it could be supported that there is a need for an update in behavioral methods and practices for headache management. This does not primarily require more research on the efficacy and effectiveness of behavioral practices for headaches, as these are all well-studied and known. What is required is a more coherent model that explains what causes sufferers to maintain and exacerbate pain suffering, beyond that of the pain itself, and in turn, what processes can be utilized in clinical practice in order for sufferers increase head pain adjustment. This model will encompass and integrate the current knowledge of the behavior headache therapies with practices that guide researchers to examine what accounts for suffering, and clinicians to utilize therapeutic approaches that lead to a more effective application of behavioral therapies for head pain management.

Notably, three of the processes proposed here as alternatives to the avoidance of internal and external head pain triggers (e.g., pain acceptance and values-based actions), and cognitive change practices (e.g., cognitive defusion) stem from the emerging behavior headache treatment of ACT (Smitherman et al., 2015). Preliminary research shows that when head pain acceptance is targeted in conjunction with other processes from the ACT approach (e.g., values-based actions), headache sufferers report an increase in their functioning and a reduction in headache-related disability (Dindo et al., 2015; Foote et al.,

2015; Mo'tamedi et al., 2012). Driven by the successful implementation of ACT for chronic pain (McCracken & Vowles, 2014), and guided by a dozen of ACT studies for chronic pain demonstrating the efficacy and effectiveness of ACT in reducing pain-related disability and increasing patients' functioning (see Scoot & McCracken, 2015) we suggest ACT as the next generation of behavioral therapies for headache. We believe that this approach and its underlying theoretical model of PF in pain can successfully integrate the current knowledge of behavior headache research and expand on it. ACT and the PF model may provide an accurate set up for upgrading the dominant behavioral headache paradigm with new practices, and open the field up for further research into the area of head pain.

The Third "Wave" of Behavioral Therapies for Headaches

ACT is a an empirically supported approach that is based on behavior analysis, and aims to assist individuals fertilize a flexible responding toward their unwanted behaviors, thoughts, emotions, and bodily sensations, while taking value-guided actions that lead them to a better functioning (Hayes, Levin, Plumb-Vilardaga, Villate, & Pistolero, 2013). To increase individuals' functioning, ACT utilizes psychological flexibility (PF; Hayes et al., 2012). The construct of the PF, coined by Hayes, Follette, & Linehan in 2004, and emerged in pain literature in 2006 (McCracken, 2006), describes a behavioral pattern that represents an open and conscious stance to experience pain without trying to control or avoid it, when doing so in the service of reaching goals(Hayes et al., 2013). The construct of the PF, represents a theoretical model of behavior changes entitled the PF model for chronic pain that navigates ACT-based research and promotes further the development of the ACT approach (see McCracken & Morley, 2014 for a review of this model). It does so by conceptualizing basic scientific principles into models and theoretical premises into applicable processes that can guide clinicians toward effective interventions (Hayes et al., 2013).

The PF model goes beyond the dominant behavior approach for headache that focuses on reducing the pain itself, and instead proposes that the focus should be more on two key processes that influence pain, the language (verbal rules) and the context. The PF model utilizes the behavioral analytic method in examining how direct contingencies of behaviors or verbal rules (given the person's history) lead to human suffering. It does so by examining how contextual consequences (the direct individuals' experiences, such as what one feels, senses, tastes etc.) and rule-governed consequences (verbal rules, judgments, self-appraisals, and other products of cognitions, such as thoughts, memories, etc.) drive

individuals' behaviors. By examining the contextual and rule-governed consequences of sufferers' reactions' to their pain, researchers can understand which responses to pain are more effective than others. This functional and pragmatic distinction between direct and indirect (or verbal) contingencies distinguishes the theoretical model of PF from previous psychological pain models (e.g., fear-avoidance, coping appraisals).

According to this model, any psychological event (e.g., thoughts, emotions, behaviors, bodily sensations, etc.) is an ongoing activity which is analyzed based on its "*function*" (e.g., how an event is influenced by individuals' previous learning histories and the context in which it occurs), and its "*pragmatic*" standpoint (e.g., how individuals' actions help them to achieve their goals and pursue their values; not how true or false the experience of individuals are; Hayes et al., 2013). From this perspective, any event has meaning only with reference to its context (Hayes, 1993). Hence, the main goal of the PF model is to understand the interaction between an individual's content (e.g., what one believes, thinks or behaves) and context (e.g., everything that it is outside of the content but it influences it; an individual's past and current experiences). A better understanding of this interaction can help sufferers respond to pain (behave) in a way that is consistent with reaching his/her long-term goals, rather than respond to pain based on their products of minds (e.g., rule-governed behaviors, self-appraisals, etc.) that may lead to unproductive outcomes (e.g., efforts to reduce pain when this is impossible, rumination, isolation, etc.).

Given that an individual's context comprises of situational (e.g., factors in the environment) and historical (e.g., previous experiences) variables, behaviors can be therefore predicted and influenced by analyzing an individual's direct contingencies (e.g., how a coping response to pain lead to an effective outcome) and verbal influences (e.g., how verbal rules drive individuals' behaviors toward effective responding to head pain). Under this perspective, a functional analysis of the context, the verbal influences, and the anticipated contingencies of behaviors can help individuals predict their behaviors with precision, scope and influence (Hayes et al., 2011). In doing so, individuals' can learn to distinguish whether their behaviors are consistent with their personally-chosen values or controlled by their contextual or verbal consequences.

The pragmatic viewpoint of the PF model (e.g., that every pain sufferer can pursue a vital living, even in the presence of fluctuating pain and distress), can set an alternative to the control of pain agenda, and expand the dominant behavior headache paradigm with new practices that do not aim to change the experience of head pain per se, but change how individual respond to it. While the behavior headache therapies stem from the first and second "waves" focus on increasing psychosocial functioning by reducing the pain, the PF

model for pain postulate that change in pain severity is, for many cases, not helpful in promoting psychosocial functioning, as pain severity is for the most part, not within the direct control of individuals (Dahl, Wilson, Luciano, & Hayes, 2005). Thus, focusing exclusively on alleviating head pain may be impractical or in some cases counterproductive, particular for those individuals experiencing continuous head pain or for those that pain interferes with their daily life. This view is further supported by recent findings showing that improvements in migraine sufferers overall functioning occur without decreasing pain and distress (Dindo et al., 2015; Foote et al., 2014; Mo'tamedi et al., 2012). Indeed, by increasing individuals' willingness to experience unwanted events (e.g., thoughts, emotions, sensation), while guiding their behaviors toward valued actions one can control (McCracken & Vowles, 2014), sufferers may achieve to increase their daily functioning, reduce headache-related disability and facilitate better head pain adjustment. Based on the aforementioned, we propose the PF model and the ACT approach as the next (third wave) generation of behavior headache therapies. We particularly suggest that sufferers instead of avoiding any unwanted experience that is associated with the potential activation of headaches, should develop a flexible response to head pain.

Developing a flexible response to head pain means to make sufferers adhere less to their verbal rules, either self-derived (e.g., "I am disabled due to headaches") or environmentally-reinforced (e.g., "You should always avoid headache triggers"), and in turn, increase contingency congruent behaviors that make them reach their long-term goals. According to the PF model, what increases headache-related disability, and exacerbates suffering, is not the pain severity per se, but how sufferers respond to this pain. To make this argument more clear, a specific example follows.

In order to control head pain, sufferers learn to prevent headaches by avoiding external and internal headache triggers (e.g., certain food, visual stimuli, stress, etc.). Given that not all headache triggers can be readily avoided, and when avoidance is applied to internal triggers results in the opposite of pain alleviation, more headache, suffering and lower functioning in the long-run (Martin & MacLeod, 2009; Foote et al., 2015; Dindo, 2015), the excessively applied use of avoidance make sufferers engage in behaviors (e.g., increase the use of analgesic medication, cancelling meaningful activities, absence from work, become isolated, etc.) that produce long-term suffering. These behaviors are not consistent with making sufferers reach their valued-based actions, but behave in a way that is inconsistent with their long-term goals (e.g., diverse individuals for reaching their goals). For the PF model, this is where psychological inflexibility in pain influences behavioral

responses leading to a series of ineffective outcomes (e. g., more pain, suffering and low quality of life).

The opposite of psychological inflexibility response to pain is to response to pain with flexibility. Responding to pain with flexibility means to: (a) accept head pain posture, particularly when efforts to reduce it results to further suffering, (b) defuse from the literal meaning of verbal rules, (c) adopt a perspective taking and mindful (without judgment) awareness over the pain (an observer self), (d) identify valued-based actions, and (e) a commit to valued-based actions. All these behaviors reflect a flexible response to pain, and facilitate behaviors that help sufferers reach their goals and diminish the detrimental effects of avoidance (see McCracken & Vowles, 2014). The PF model employs ACT to facilitate this aim in clinical practice (Hayes, Vilatte, Levin, & Hildebrandt, 2011), and recent empirical evidence show that a flexible coping with head pain and headache triggers could maximize head pain adjustment and improve headache-related disability (Dindo et al., 2012; Martin, Mackenzie, Bandarian-Balooch, Brunell, Broadley, Reece et al., 2014).

ACT for chronic pain is a theory-driven behavioral approach that helps sufferers to engage in values-based behaviors while remaining in contact with pain (an unwanted experience), especially, when efforts to control or reduce pain via avoidance, has repeatedly failed or contributed to further suffering in the long run (McCracken, 2005). ACT employs six interrelated facets (acceptance, defusion, present moment, values, committed actions and self as context; see table 1 for the definition of each facet) all working together to increase PF, improve the quality of life, and decrease avoidance. It does so by fertilizing an open and aware posture to unwanted experiences via acceptance, mindfulness, and defusion processes, promoting vital behavioral changes via the use of values clarification and committed actions processes, and decreasing inflexible way of coping with pain responses via the use of exposure-based processes (Hayes et al., 2011).

ACT is a very active form of behavior therapy. Specific ACT therapeutic goals can be delivered through various practices, including metaphors, illustrations, stories and behavioral activation techniques. Metaphors, stories, and illustrations are utilized to increase awareness of sufferers' experiences with a more flexible and experiential rather than didactic way. Behavioral activation and committed action processes are employed to assist individuals in achieving their short and long-term behavioral goals. The brief presentation of ACT for chronic pain is followed by an illustration of applying ACT for headache sufferers and a presentation of a brief practical guide for clinicians on how to deliver an ACT-based intervention for this population.

Applying and Delivering ACT for Headache Sufferers

The application of ACT in headache management requires an understanding of how sufferers interact with their headache triggers (internal and external), in the presence of pain, and how they cope with them. Sufferers should recognize how they cope with head pain responses, and whether these responses assist them in reaching their long-term goals. It is argued that the recognition of psychological inflexible responses and their impact these responses have on functioning, as well as; the acquisition of skills, such as pain acceptance, value-based actions, and cognitive defusion, can expand the range of behavioral repertoires. Expanding the range of psychological flexible responses, sufferers can learn to behave in a way that assists them in achieving their long-term goals, particularly when these goals have been interrupted as a result of pain and avoidance. Utilizing psychological flexible responses to head pain sufferers can diminish needless suffering, headache-related disability, and increases quality of life, even in the presence of pain.

Another aim of ACT for head pain is to bring awareness of the barriers that obstruct headache sufferers' from reaching their goal-congruent behaviors (i.e. behaviors that increase the possibility of reaching verbally constructed goals). Barriers are recognized as obstacles that stand against one's goals, and usually represent unwanted internal experiences (e.g., head pain triggers, the fear of pain, etc.) that individuals try to avoid (Hayes et al., 1999). The recognition that unwanted internal experience are not always within the direct control of individuals (Dahl, Wilson, Luciano & Hayes, 2005), and that a narrow set of responding to pain (e.g., by preventing headaches with avoidance) obstructs sufferers from reaching their goals or in some cases becomes counterproductive (e.g., increase needless suffering, etc.), can motivate sufferers to obtain a more psychological flexible pain agenda. The focus on this agenda should be on changing the relationship of individuals with their pain symptoms and other unwanted experiences without attempts to control or change their frequency or form (Hayes et al., 2011). Thus, specific aims of this agenda include the development of an "open" (comprised of acceptance and cognitive defusion), "Centered" (comprised of present moment awareness and self-as-context), and "Engaged" (comprised of values clarification and committed action) stance to unwanted experiences. Enhancing psychological flexibility (comprised of the open, centered, and engaged components of the ACT approach) sufferers can improve their functioning and quality of life, even if the experience of head pain itself remains relatively stable (Foote et al., 2015). For a schematic representation of this suggestion see figure 1.

Further, given the multifactorial cause of headaches and the fact that headaches are associated with other conditions which make them comorbid (Jette, Patten, Becker, & Wiebe, 2008), an ACT approach can help sufferers generalize the newly acquired skills from one context (e.g., dealing with headache triggers) to another (e.g., dealing with frustration or low mood due to headache). By implementing ACT processes in dealing with conditions that increase the risk of various headache-related comorbidities (e.g., depression, anxiety, obesity, etc.), sufferers can significantly lower the burden of headaches that extends well beyond the severity of pain itself. An example of this is when acceptance (i.e., willingness to have pain) is not only applied to the unwanted pain sensation per se, but is also employed in other conditions and contexts that the sufferer find challenging to deal with (e.g., reactions to a stressful situation, daily worries, etc.). Another example of this is when values-based actions (e.g., following a healthy dietary or a good sleep hygiene) facilitate behavior changes (e.g., weight lost, better quality of sleep), especially when doing so diminishes the risk of activating headaches.

Evidence from the broad area of behavioral medicine (see Dindo, 2015 for a review) demonstrates that ACT can substantially reduce the distress or comorbidities that frequently accompany numerous medical illnesses, such as tinnitus (Westin, Hayes, & Andersson, 2008), diabetes (Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007), vascular diseases (Dindo, Marchman, Grindes, & Fiedorowicz, 2015), epilepsy (Lundgren, Dahl, & Hayes, 2008), weight loss (Lillis, Hayes, Bunting, & Masuda, 2009) and irritable bowel syndrome (Ljotsson, Hesser, Andersson, Lindfors, Hursti, Ruck et al., 2013). Teaching a set of flexible behavioral repertoires (e.g., acceptance, committed actions, values clarification, etc.), ACT aims to assist individuals in achieving a better adjustment with their illnesses, and evidence from the headache literature also shows that ACT can facilitate better head pain adjustment for headache sufferers with comorbidities (Dindo et al., 2012).

An ACT approach for headache management can be practically delivered in a group or face-to-face format. A novel ACT intervention, as proposed here, is organized into four phases in order to reflect specific therapeutic goals. As per the PF model suggestions, the new intervention was divided into four phases so as to represent the "*open, centered, and engaged*" approach (Hayes et al., 2013). . As table 2 illustrates, in the first phase, "*setting the premises for a change*," a detailed analysis of the pathophysiology of pain, medication adherence, and lifestyle factors can inform sufferers about the role of modifiable lifestyle risk factors that increase susceptibility to headache episodes (e.g., overuse of rescued medication, skipping meals, gaining weight, insomnia, etc.). The

emphasis here is to increase awareness of the factors that sufferers can flexibly deal with, in order to better prevent or manage their headaches. By examining these factors, and whether they really reduce or prevent headaches, sufferers are encouraged to adopt more flexible responses to pain and increase behaviors that are more consistent with their personal values, rather than with reaching short-term goals such as pain reduction, especially when doing so cannot be achieved (e.g., during a migraine episode, in daily persistent headaches, etc.).

An "*engaged approach*" (phase two) consists of processes that encourage sufferers to clarify their values and commitment actions. The link between values and committed actions serves to illustrate the possibility of increasing functioning and facilitating long-lived behavioral changes, not by primarily controlling head pain, but by having valued life. A third phase, "*a centered approach*", teaches a series of practical skills that help individuals promote valued living and confront the barriers (e.g., thoughts, emotions, sensations, etc.) that show up when individuals try to achieve their values. Promoting a moment-to-moment mindfully decision making (e.g., choosing to act on what is most important in the present moment considering all available behavioral choices), learning to defuse from pain related thoughts (e.g., separating oneself from one's thoughts, learning to not take one's thoughts so literal true, etc.), and implementing exposures procedures (e.g., moving toward previously avoided committed actions even when pain is present), are all employed to enhance a flexible response to pain. At the final phase, "*the open approach*," sufferers are encouraged to willingly open up and without defense accept unavoidable experiences, such as pain or other unwanted internal events. Maintaining and further enhancing the newly acquired set of skills is the final goal of the treatment.

Overall, an ACT approach for head pain management, as table 2 illustrates, is driven by the PF model, and it appears to make conceptual sense, although, variations in terms of different treatment methods are likely to occur (e.g., acceptance-based interventions, value-based intervention, etc.). There is currently no empirical evidence demonstrating that ACT provides beneficial outcomes beyond that of the first and second waves of behavioral headache treatments. Yet, there is some promising evidence supporting the efficacy of ACT in headache, and more yet to come (Smitherman, 2016).

Empirical Evidence of ACT Studies for Head Pain Management

Currently, ACT has been classified as an empirically supported treatment with "*strong research support*" for general chronic pain conditions (Society of Clinical Psychology, Division 12; APA, 2015). However, to date, there have been only two small-

scale ACT-based trials for headaches: one controlled (Mo'tamedi et al., 2012), and one uncontrolled (Dindo et al., 2012). Also, there are three cross-sectional studies examining the role of acceptance and value-based actions in headache adjustment (Chiros & o'Brien, 2011; Dindo et al., 2015; Foote al., 2013).

The first study examined an 8-sessions acceptance-based intervention vs. a Medical Treatment as Usual group of Iranian women with recurrent headaches (N = 30 per group). Results yielded a significant reduction in headache-related disability (d = .93), emotional functioning (d = 1.35) and psychological distress (d = 2.54). Yet, there were no reductions in headache activity for the treatment group at 3-month follow-up (Mo'tamedi et al., 2012). Next, a dismantling study utilizing 1–day ACT-based workshop with Migraine education for MIs with co-morbid depression vs. a Wait-list control group showed that the ACT group presented with significant improvements in depressive symptoms (d = .87), MI-related disability (d = .98), and quality of life (d = .69) at 3-month follow-up, when compared to the control group.

Additional support for the ACT approach comes from three cross-sectional studies. In one study, pain acceptance and value-based actions accounted for significant improvements in depression and headache-related disability among 93 patients with a migraine and depressive symptoms (15- 37% for pain acceptance and 3-7% for values; Dindo et al., 2015). Two other studies have further demonstrated, that pain acceptance along with values-based action accounted for a 10% of unique variance in headache severity, 20% in headache-related disability (Foote et al., 2015), and were significantly related to lower levels of catastrophizing, less pain-related interference, and a better control of behavioral expression of MIs (Chiros & o'Brien, 2011). Despite these positive findings and the growing empirical support of ACT for headache, there are numerous limitations that warrant attention, and future suggestions that call for more ACT research.

Limitations, Future Directions, and Conclusions

Larger-scale studies with more power samples and longitudinal examination of the effects of ACT could ascertain generalizability before making conclusions as to the effectiveness of ACT for headaches. Also, evaluating the effectiveness of ACT in headache-related outcomes utilizing different treatment packages (e.g., pragmatic or dismantling studies), settings (e.g., multidisciplinary headache units, outpatients departments, etc.), and formats (e.g., group/ web-based, limited contact, etc.), can shed more light on the utility of ACT in clinical practice. It can also guide therapies on how to

combine ACT with other behavioral headache approaches in order to maximize treatment effects for sufferers with recurrent headaches. Relatedly, research on the ACT processes of change may provide a better understanding of the mechanism of action that lead to better head pain adjustment, and highlight which ACT components account for therapeutic changes.

Further, the development of psychometrically sound ACT measures for head pain populations can better reflect the six processes encompassing the ACT approach. For example, the idea of radical pain acceptance as it is theorized in chronic pain literature may sound incompatible or even misleading for headache sufferers that manage to achieve pain alleviation to a certain degree. Hence, a more functional definition of head pain acceptance should be proposed. Relatedly, new measures assessing specific moment-to-moment mindfully decision making rather than general mindfulness levels (e.g., a non-judgmental and on purpose awareness in the present moment) can better reflect the function of this process. For example, a specific to headache measure of mindfulness should assess whether mindfulness help sufferers decide to respond to their pain based on what is most flexible in the present moment, rather than to respond to their pain with an automatic way. There are currently no such methods available to evaluate pain acceptance, mindfulness or other PF processes in this sort of context, thus future research is needed.

Additionally, given the multifactorial cause of headaches, an examination of specific moderators found to be comorbid with headaches (e.g., medical or psychiatric co-morbidity) or other pertaining to the treatment issues (e.g., treatment expectations, personality traits etc.), and whether they contribute to treatment effects or failures, can improve treatment methods leading to more personalized interventions, particularly for complex sufferers with comorbidities or other difficulties.

Finally, provided that the primary aim of ACT is to increase functioning and not to eliminate the experience of pain per se, it is important for the wider research headache community to consider examining the effectiveness of ACT on headache-related outcomes based on its aims, such as functioning and quality of life, rather on the reported outcomes of pain reduction only. This suggestion does not oppose the internationally applied core outcome domains of pain trials that propose the always desirable and in many cases achievable reduction of pain (Dworkin et al., 2005; Penzien et al., 2005; Turk, Dworkin, Revicki, Harding, Burke, Cella, et al. 2005). Yet, it raises questions as for the aims of the existing cognitive-behavioral headache interventions to increase functioning by primarily teaching sufferers to avoid headache triggers. By evaluating both ACT-related outcomes and outcomes specific to pain, researchers can better examine how different treatments

work, and whether the emerging behavioral therapies reduce the burden of headaches with the same way as previous therapies do. Perhaps, a refine in what constitutes effective behavioral headache treatment may be needed in order to better fit with the aims of emerging behavioral therapies.

In conclusion, it is argued that the effects of the first and second wave of behavior headache therapies in reducing the burden of headaches may not be universal for all headache sufferers. New interventions stemming from emerging behavioral headache treatments, such as ACT, provide an alternative to the avoidance of headache approach. Recent findings are promising, particularly for the effects of ACT in improving headache-disability, avoidance, and headache-specific quality of life. Whether ACT can be classified as an effective and efficacious treatment for headache sufferers is a matter of further studies, particularly RCTs trials and mechanism of action research.

Study 2: ACCEPTANCE AND COMMITMENT THERAPY FOR PRIMARY HEADACHE SUFFERERS: A RANDOMIZED CONTROLLED TRIAL

Abstract

The main behavioral treatment suggestion today for headache management is the prevention of headaches mostly via avoidance of external and internal headache triggers. Despite the wide use of avoidance in headache management, very little empirical evidence exists to support its effectiveness. Attempts at avoiding headache triggers or other internal private experiences associated with a headache, may increase trigger potency, restrict lifestyle, decrease internal locus of control, and exacerbate and maintain pain perception. New treatment approaches, such as Acceptance and Commitment Therapy (ACT), emphasize acceptance and valued living as alternatives to avoidance. Though APA characterizes ACT as an empirically supported treatment for chronic pain, there is limited evidence for its effectiveness for head pain, and this evidence is afflicted with methodological limitations that need to be overcome before making conclusions as to the effectiveness of ACT for headaches. The purpose of the present study was to examine in a Randomized Controlled Trial (RCT) whether an ACT-based intervention for headache sufferers, added to Medical Treatment as Usual, decreases disability and improves the quality of life, compared to only Wait List Control (WL). 94 headache sufferers (90% diagnosed with migraines and 9.1 % with tension-type headaches) mostly women (84%), averaged 43 years old, married (72%) with a higher or vocational school diploma (34%), were randomized to each group. Headache-related disability and quality of life (primary outcomes); headache severity, medical utilization and psychological distress (secondary outcomes); and ACT process measures (e.g., assessing acceptance, defusion, values, mindfulness etc.) were assessed before-treatment, at treatment-end, and at 3 and 6-month follow-up. Results demonstrated substantial improvement in favor of ACT compared to the WL group on primary outcomes. No significant groups by time differences were noted for secondary outcomes, except for depression where ACT demonstrated significant reductions when compared to the control group. At 6-month follow-up ACT resulted in significant effects of time for disability, quality of life, pain severity, frequency of medical utilization, and depression. For process measures, the ACT group, compared to the control group, presented improvements in pain acceptance, avoidance of pain, cognitive fusion, and value obstructions at treatment-end, and at 3-month follow-up. Findings from this study offer new evidence for the utility and efficacy of ACT in the management of primary headaches.

Keywords: Headaches; Acceptance and Commitment Therapy; Randomized-Controlled Trial; Efficacy Study.

Introduction

Headaches are universal phenomena with 90% of adults having experienced headaches at some point during their lives (Rasmussen, Jensen, Schroll, & Olesen, 1991). Primary headaches, such as migraine (MI) or tension-type headache (TTH), are associated with major functional impairment, disability, economic costs (e.g., increased medical utilization) and consequences for the sufferers' lives (e.g., decreased quality of life, sickness absence or reduced efficiency at work; Buse, Rupnow, & Lipton, 2009; Leonardi, Steiner, Scher, & Lipton, 2005). The burden of headaches on individuals' lives, their families, and on societies, is a major public health concern (Jensen & Stovner, 2008).

Despite the efficacy of behavioral therapies (e.g., relaxation, biofeedback, cognitive-behavioral stress-management) and pharmacotherapy (e.g., prophylactic) in reducing the burden caused by headaches, of those offered treatment, only 35% to 50% are considered responders at treatment end (Rains, Penzien, Douglas, McCrory, & Gray, 2005). Numerous sufferers continue to experience serious headache-related disability and low quality of life as a result of uncontrollable and excessive head pain. This recognition has called for more research, particularly on how inflexible utilization of coping with headaches, results in increased disability and more suffering (Martin & MacLeod, 2009). Empirical evidence demonstrates that avoiding external and internal triggers, the two head pain responses most utilized by headache sufferers (Stronks, Tulen, Bussman, Mulder, & Passchier, 2004), lead to an increased in trigger potency (Ford, Calhoon, Kahn, & Mann, 2008), a restricted lifestyle (Kelman, 2007), a decrease in internal locus of control (Marlowe, 1998), and an exacerbated and maintained pain perception (Chiros & o'Brien, 2011; Foote, Harmer, Roland, Landy, & Smitherman, 2015), when inflexibly applied to all headache triggers.

Inflexible use of external headache trigger avoidance, known as behavioral avoidance (BA), refers to the avoidance of external triggers (e.g., visual stimuli, noise) that activate headaches, when attempts at avoiding these triggers occur at the expense of valued living (Kolotylo & Broome, 2000; Martin, 2009; 2010). Studies indicate that avoiding external triggers is an effective technique for dealing with some short-lived hazardous situations or known triggers activating a headache (Blau & Thavapalan, 1988; Grant, 1979; O'Banion, 1981; Radnitz, Blanchard, & Bylina, 1990). However, in the long run, excessively and inflexibly applied BA to all headaches triggers becomes counterproductive resulting, instead of fewer headaches for individuals, more needless suffering (Martin, 2010). Given that not all headache triggers can be avoided (e.g., weather, stress,

menstruation, odors, etc.), and attempts at avoiding them result in restricting life (Kelman, 2007), the effects of BA can be really detrimental to sufferers' lives (Martin & MacLeod, 2009).

The problem with inflexible trigger avoidance is further highlighted when one considers that the major headache triggers are internal in nature (e.g., stress and negative emotions; Andress-Rothrock, King, & Rothrock, 2010; Karli, Zarifoglu, Calisir, & Akgoz, 2005). Attempts at altering internal triggers (e.g., unwanted internal experiences, such as pain, thoughts, fear, etc.), result in more problems and difficulties through a mechanism known as experiential avoidance (Hayes, Strosahl, Wilson, Bissett, Pistorello, Toarmino et al., 2004). Experiential avoidance (EA) is an inflexibly applied and context incongruent process of deliberate control, purposeful avoidance, or unwillingness to experience private events, such as negative thoughts, sensations and images, and the situations in which they occur (Hayes, Strosahl, & Wilson, 1999; Hayes & Wilson, 1994; Karekla, Forsyth, & Kelly, 2004). Empirical evidence shows that pain suffering does not occur as a result of the aversive experience of pain severity per se, but it is the consequence of individuals' efforts to suppress, avoid or in any way control pain and any unwanted internal experience following at pain sensation (Crombez, Vlaeyen, Heuts, & Lysens, 1999; Esteve & Ramizer-Maestre, 2013; McCracken & Vowles, 2006). Repeated utilization of EA paradoxically leads to increases in the experiences one is trying to avoid (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996), decreases in pain tolerance (Feldner, Zvolensky, Stickle, Bonn-Miller, & Leen-Feldner, 2006; Hayes, Bissett, Korn, & Zettle, 1999; Nedeltchev, Amold, Schwerzmann, Nirkko, Lagger, Mattle et al., 2004; Zettle, Barner, Gird, Boone, Renollet, & Burdsal, 2012), reductions in internal locus of control over the head pain (Marlowe, 1998), and restrictions in the way of living (Kelman, 2007).

The problematic role of avoiding external and internal triggers has led researchers to examine alternative interventions. New behavioral interventions emphasize pain acceptance, aimed to increase sufferers' ability to behave effectively in their lives even if pain is experienced, instead of focusing on preventing headache through avoidance (McCracken & Vowles, 2014; Stonnington, Kothari, & Davis, 2016). Recent findings demonstrate that higher pain acceptance (considered the opposite of EA) and an increase in values-based actions (considered the opposite of BA) are associated with lower headache-related disability and better daily functioning (Chiros & o'Brien, 2011; Dindo, Recober, Marchman, O'Hara, & Turvey, 2015; Foote et al., 2015). Given that numerous sufferers with intractable headaches may never succeed in achieving a pain-free life, approaches cultivating acceptance-related responses appear to provide the necessary solutions to

dealing with headaches. Acceptance & Commitment Therapy (ACT; Hayes et al., 2012) is one such, behavioral approach, proposed to alleviate pain-related suffering (Smitherman, Wells, & Ford, 2015).

ACT is an empirically supported treatment that helps sufferers engage in values-based behaviors while remaining in contact with unwanted experiences, especially, when efforts to control or reduce these experiences via avoidance, have repeatedly failed or contribute to further suffering in the long run (McCracken, 2005). To increase sufferers' functioning, ACT proposes increases in psychological flexibility (PF; Hayes, Strosahl, & Wilson, 2011). PF represents an open and conscious stance to experience pain without trying to control or avoid it, when doing so in the service of one's values and goals (McCracken & Morley, 2014). PF includes six interrelated processes: acceptance, cognitive defusion, present moment, values, committed actions, and self as context (see table 1 for a brief explanation of each process). When these processes work synergistically, for example, when acceptance and cognitive defusion lower experiential avoidance and diminish the believability of pain-related thoughts (e.g., "headaches make me handicapped"), then increases committed actions and valued living result in better functioning (Vowles, Witzkietwitz, Sowden, & Asworth, 2014; Vasiliou, Karekla, Michaelides, & Kasinopoulos, under review).

Currently, the American Psychological Association (Society of Clinical Psychology, Division 12 http://www.div12org/PsychologicalTreatmnts/treatmnts/chronicpain_act.html; APA, 2011) characterizes ACT as an approach with "strong research support" for general chronic pain conditions, including headache. Yet, there are only two studies that have evaluated acceptance-based interventions for headaches (Dindo, Recober, Marchman, Turvey, & O'Hara, 2012; Mo'tamedi, Rezaiemaram, & Tavallaie, 2012). Thus, it is not yet clear whether the empirically supported guidelines for general chronic pain are also applied for head pain. Therefore, more research is needed in evaluating ACT for headache conditions.

Further, the two studies evaluating acceptance-based protocols to date for head pain are afflicted with some methodological limitations that need to be overcome before making conclusions as to the effectiveness of ACT for headaches. Mo'tamedi and Colleagues' (2012) study examined the effectiveness of a group-based Acceptance and Commitment additive to medical treatment therapy for individuals with MIs, however, the protocol utilized was developed for chronic pain patients (see Vowles, Wetherell, & Sorrell, 2009). Given the unique characteristics of the head pain experience (i.e., unique set of triggers, the intermittent nature of headache episodes, the unpredictability of attacks, lifestyle changes

etc.), the utilization of non-specific to head pain protocols, may limit the generalizability of findings. The second study evaluated an acceptance and values-based intervention (i.e., included only two of the six ACT processes) for headaches (Dindo et al., 2012), and also presents with methodological shortcomings, such as (a) comorbid sample comprised of patients with MIs and depression; (b) non- randomization assignment of the sample to the two conditions (treatment and control); and (c) absence of medical and psychological evaluations of participants (i.e., they were evaluated based on their previous medical records). All these limit the generalizability of findings for patients who only present with headaches, and may inflate errors in terms of the validity of treatment outcomes. Given these limitations and coupled with an absence of studies evaluating the efficacy of an ACT intervention for headache management, further research is warranted.

To our knowledge, there have been no RCTs that have recruited community-based headache samples, provided official headache diagnoses for participants, and evaluated the efficacy of an ACT-based intervention exclusively developed to address the difficulties of headache sufferers. Further, no studies have examined the effects of an ACT intervention that includes all six proposed components for headache sufferers. Also, no previous studies have examined the long-term efficacy of ACT by including a 6-month follow-up.

The purpose of the present study was to examine in a Randomized Controlled Trial (RCT) design the efficacy of an ACT-based 9-session group intervention for patients diagnosed with primary headaches, added to the medical treatment already being prescribed and used by clients, compared to a Wait-list Control Group (WL). Based on preliminary empirical findings pointing to the efficacy of ACT for head pain, the hypotheses of the study were:

1. The ACT group would demonstrate improvements in primary outcomes (i.e., psycho-social functioning, disability, and quality of life), when compared with the WL at post-treatment and 3-month follow-up, and when the data examined in both completer and intent to treat analyses.

2. The ACT group would result in reductions in secondary outcomes (i.e., headache severity, headache-related medical utilization, and psychological distress), when compared with the WL at post-treatment and at 3-month follow-up periods, and when the data examined in both completer and intent to treat analyses.

3. The ACT group, compared to the control, would present significant changes in the ACT processes (i.e., increases in pain acceptance, committed actions, values progress, and mindfulness, and decreases in cognitive fusion, avoidance of pain, and obstruction in

pursuing valued living), when compared with the WL at post-treatment, and at 3- month follow- up, and when the data examined in both completer and intent to treat analyses.

4. The ACT group would demonstrate continued improvements in all outcomes and processes assessed, at 6-month follow-up, when the data examined in both completer and intent to treat analyses. Given that the control group entered treatment at 3-month, no group comparisons were made at the 6-month follow-up point.

The study received approval from the Cyprus National Bioethics Committee (reference: ΕΕΒΚ/ΕΠ/2013/05), and the Cypriot office of the Commissioner for personal data protection (reference: 2.0.18/II). Also, the current study was conducted in compliance with the Helsinki Declaration of ethical principles for medical research involving human subjects, and has been registered with the clinical trials.gov registry (NCT02734992).

Method

Participants

Headache sufferers were recruited through a variety of sources in the island of Cyprus: via mailings to private-care Neurologists; e-mails, newsletter adverts, and fliers distributed at various locations (e.g., municipalities, libraries, outpatients' waiting rooms, etc.); articles published in local newspapers; referrals resulting from previous ALGEA studies[1] (Karekla, Karademas, Vasiliou, Kasinopoulos, Flouri, Christou et al., in press); and through the facebook page of the Algea project The recruitment was conducted over a six month period (from Sept. 2013- February 2014) and more than half of the participants came from self-referrals from the general community. 87% of potential interests came from the district of Nicosia, 6% from the district of Larnaca, and 7% from the district of Limassol.164 individuals were screened via telephone and of those, 94 were invited to participate in the study. Table 3 illustrates the demographics and headache history of the sample. Given that research demonstrates no differences in terms of the way Migraine and Tension-type Headache sufferers utilize avoidance (Karli, Zarifoglu, Callsir, & Akgoz, 2005), a mixed headache sample was employed in this study. 79.8% of the total sample was diagnosed with Migraines and 11.7% with Tension-Type headaches. Figure 2 presents the study CONSORT flow diagram.

Inclusion & Exclusion Criteria

Selection criteria included: a) meeting the diagnostic criteria for the Primary Headache of the Classification Committee of The International Headache Society (International Classification of Headache Disorders-II [ICHD-II]; HIS, 2013); b) being at

least 18 years; c) sufficient reading ability in Greek; d) and stable pharmacotherapy (i.e., remained unchanged for at least four weeks before treatment and remained unchanged over the course of treatment), especially prophylactic, abortive, psychotropic, analgesic or other headache medications. Participants completed a daily headache self-monitoring comprising of a Likert-type scale from 0 = not at all to 10 = extreme level assessing: daily headache activity, disability, levels of stress, quality and quantity of sleep amount. Also, participants were requested to keep a record of any extra medications taken over their standard prescription in order to prevent or alleviate headache and whether they visit a physician due to a headache. The diary was distributed three weeks before the beginning of the trial to ensure stability of the headache experience and remained throughout the trial's period.

Participants were excluded if a) they had an active psychotic spectrum condition or manic episode, suicidal ideation/ intent or substance use problems within 6 months prior to recruitment; b) there was a history of seizure, facial neuralgia or other secondary headache diagnoses, as these conditions might preclude the accuracy of primary headache diagnosis; c) there was evidence of significant cognitive impairment as assessed using the Mini-mental Status Examination (MMSE score < 20); d) they were living in nursing homes; e) they had multiple pain sides (pain experienced in multiple body sides or groups of muscles) excluding headaches; f) they took part in other psychological interventions or counseling (particularly for managing headache) over the last two years; and g) they were pregnant or lactating, as hormonal imbalances may cause unpredictable headache episodes that need special treatment. All criteria were assessed based on two structured clinical interviews (one medical and one psychological).

Assessment Procedures

164 interested individuals were initially screened for eligibility via a brief telephone interview by a study researcher. After being informed that they would participate in a study assessing the efficacy of a treatment that may not be a larger-scale study, and signing a consent form, candidates received both a medical examination by the study neurologist and a psychological evaluation by a-doctoral-level- clinical psychology trainee. 70 individuals were excluded for various reasons (see Figure 2), and referred to local medical or mental health providers if necessary. Two individuals were diagnosed with secondary headaches rather than primary and were excluded. The neurologist conducted a neurological examination, requested lab tests, ordered an MRI scan, and established an official headache diagnosis using the diagnostic criteria of the ICDH-II (IHS, 2013). The psychological evaluation consisted of a psychosocial history/interview intake form that

was based on an adapted version of Smitherman et al.s' (2014) headache assessment (permission granted).

Randomization Procedures

Following assessment procedures, eligible participants were randomly assigned to either Acceptance Commitment Therapy with Medical Treatment as Usual (ACT) or Wait-list Control Group (WL). This group was purely a wait-list and no new medication was added. Participants in this group were receiving their medication as usual (i.e., rescued or prophylactic). A simple within-sample randomization technique was used with participants being randomized in a single block. This technique requires that a person randomly matches codes (e.g., "F"= ACT or "A"= WL) next to participants I.Ds' in a single block workbook. First, all eligible participants were passed into an excel file (a single block workbook). Second, an independent to the study person received instructions to randomize each participant into one of the two conditions. Third, the person conducted the randomization created two lists with participants: one including the I.Ds of the 47 participants allocated in the ACT group and another (47 participants) for those allocated in the WL group (see Wicksell, Melin, Lekander, & Olsson, 2009, for a similar randomization procedure). Individuals allocated to the WL group did not receive medication as part of the study aims but were asked to continue their medications as prescribed by their medical provider. This within-sample randomization technique (a single block) was considered appropriate for examining the hypotheses of this study because it: (a) maximizes the possibility that the two groups are equivalent (e.g., participants have 50% chance of being randomly allocated to either condition; Rains et al., 2005), (b) limits the risk of increased variance in the two groups, and (c) increases the validity power of treatment outcomes (Penzien et al. 2005). Altough the use of a non-active treatment control group inflates treatment errors (e.g., inability to blind both therapist and participants; Rains & Penzien, 2005), it was chosen because it represents a standard of proof and a valid comparison group for trials assessing treatment efficacy (Arian, Campell,Cooper, & Lancaster, 2010; Nathan, Stuart, & Dolan, 2000).

Assessment Procedures Post-randomization

Participants in both groups (ACT vs. WL) completed the same package of questionnaires at three different assessment points: pre-treatment, post-treatment, and at 3-month follow-up. Given that the control group entered treatment at 3-month, only the ACT completed the same package at 6-month follow-up.

Participants randomized to the wait-list condition were informed from the beginning that they would receive the intervention with a 4-month delay, but were asked to continue their medical treatment as prescribed by the treating physician. During the waiting period, participants in WL groups were contacted four times by telephone so as to maintain contact, answer any questions, and ensure the stable continuation of headache pharmacotherapy. Upon completion of the ACT 3-month follow-up, the WL group was enrolled to receive the ACT intervention.

Treatment Protocol

The new full ACT treatment protocol, was developed for the aims of this study, , and consisted of a therapist's manual, a complementary participants' Action Plan (AP) workbook, and two CDs with mindfulness exercises. The new protocol (Vasiliou & Karekla, 2015), which was part of a multilevel collaborative European funded research project named "Algea" investigating critical factors in pain adjustment and testing novel psychological treatments in chronic pain (Karekla et al., in press), was developed based on: (a) previous ACT-related tested protocols (e.g., Dahl & Lundgren, 2006; Dahl, Wilson, Luciano, & Hayes, 2005; Forsyth, & Eifert, 2007; Hayes & Strosahl, 2004; Hayes et al., 2011; Karekla, 2010; McCracken, 2005; Turk & Winter, 2006; Vowles & Sorrell, 2009), (b) recent ACT-related material retrieved by the ACBS website (https://contextualscience.org/; Association for Contextual & Behavioral Sciences[ACBS]), and (c) findings from an Algea's study investigating psychosocial needs of Greek-speaking chronic pain patients (Karademas, Karekla, Flouri, Vasiliou, Kasinopoulos, & Papacostas, under review; Stavrinaki, Paraskeva-Siamata, Vasiliou, kasinopoulos, Karekla, Karademas et al., 2014; Vasiliou, Flouri, Karademas, Kasinopoulos, & Karekla, 2015).

The primary purpose of this protocol was to alter participants' responses to head pain, with the aim to decrease disability, increase physical and psychological functioning, and improve quality of life. The protocol was developed to be consistent with the ACT approach, thus exercises and illustrations facilitating the development of the six ACT processes were intergraded, and the main aim was to address daily head pain problems (e.g., avoidance, functioning, sleeping difficulties, disability, etc.). The protocol comprised of the following goals that trained therapist should specify: (a) building awareness on the futile effects of head pain control (i.e., pain cannot be controlled, may get worse in the long-run, & control attempts limits valued living); (b) learning to recognize headache-related thoughts, emotions and sensations for what they are (i.e., detachment for the literal

meaning of them- cognitive defusion); (c) increasing willingness (acceptance) to head pain; (d) establishing effective responses to pain such that responses increase values-based actions; (e) cultivating the ability to adopt a perspective taking over physical sensations (i.e., perspective of an observer self over the head pain); (e) clarifying values and promoting meaningful activities even in the presence of head pain; and (f) increasing healthy behavioral patterns (e.g., sleep hygiene, healthy diet habits, exercise, activity pacing) with the aim of improving functioning even if pain remains relative stable. Material was presented using a variety of methods including metaphors, experiential exercises, illustrations and behavioral activation techniques. Session-by-session outlines with objectives are presented in table 2.

Although each session had specific objectives, therapists within the time frame, were allowed to accommodate discussion or other group dynamic issues as needed. All participants received the Participants Action Plan Workbook which included: an outline of each session, the activity plan assignments, a weekly headache diary, and two CDs with mindfulness recorded exercises. Participants were encouraged to attend all sessions. Individuals missing more than two consecutive sessions or more than four sessions out of the nine (not consecutive), were dropped out of the treatment.

The nine, weekly, 1.5-hour treatment sessions were conducted in groups of approximately 8-10 participants and two co-therapists. Therapists were doctoral Clinical Psychology Trainees (2^{nd} or 3^{rd} year of their training at the University of Cyprus) who participated in a comprehensive training program (> 35 hours training) in the ACT approach and received instructions on how to deliver the specific protocol, by a peer-reviewed trainer/expert in ACT and two international ACT consultants. Treatment sessions were carried out at the Cyprus Institute of Neurology and Genetics (CING), the University of Cyprus (UCY), and municipal community social centers in private classrooms at specific pre-arranged days and times. Finally, weekly peer and individual supervision meetings lead by a licensed Clinical Psychologist were carried out.

Follow-up Assessment

For the follow-up assessments, participants in both groups were invited to attend a follow-up meeting. Those in the wait-list group completed the questionnaires and then entered the ACT treatment. Those in the ACT met as a group, completed the questionnaires, and briefly discussed any difficulties pertaining to implementing the material taught in their daily lives. For those participants who were not able to attend follow-up meetings, but were willing to complete the assessment, researchers either mailed

the questionnaire to participants or e-mailed the questionnaires to a corresponding e-mail address, with directions to complete and send back within a week. Self-addressed and posted-paid envelopes were provided for the return of the questionnaires via mail.

Treatment Outcomes and Process Measures

All measures were selected with regard to recommendations given by the Initiative on Methods, Measurements, and Pain assessment in Clinical Trials group (IMMPACT; Dworkin et al., 2005), and the guidelines for the design of clinical trials evaluating behavioral headache treatments (Penzien, Andrasik, Freidenberg, Hoole, Lake, Lipchik, et al., 2005). Participants at the end of each session assessed the therapists' competence, the treatment satisfaction, and the therapeutic alliance (see appendix C for relevant forms). Measures that were not available in the Greek language (i.e., b-HDI, MSQ v 2.1., EQ, CAQ, VQ) were translated using standard front and back-translation procedures. Any inconsistencies were corrected in order to reflect the same item content as the original version. Prior to the statistical analyses, psychometric properties for all non-validated measures were examined [e.g., confirmatory factor analyses (CFA), convergent validity, internal consistency]. None of the non-validated scales appeared with different structure when compared to their original counterparts, except for the process measure of Experience Questionnaire (EQ; Fresco, Moore, van Dulmen, Segal, Teasdale, Ma et al., 2007) which presented with psychometrically poor characteristics (e.g., factors were not confirmed with its English counterpart, low reliability in each of its sub-scale, etc.), and thus, it was excluded from further analyses.

Primary Outcomes

As per IMMPACT's and Penzien's et al (2005) recommendations, primary outcomes included measures of physical and emotional functioning, headache-related disability, and the quality of life.

The Henry Ford Hospital Headache Disability Inventory (b-HDI; Jacobson, Ramadan, Aggarwal & Newman, 1994) is a 25-item measure, divided into two sub-group scales: Functional (HDI- Func; 13 items) and Emotional (HDI- Em; 12 items) disability, and evaluates the effect of a headache on daily activities (e.g., 'Because of my headache I am less likely to socialize'). Answer choices are "yes" = 4 points, "sometimes" = 2 points, and "no" = 0 points. Points in each subscale are summed and higher scores indicate greater disability caused by headaches (a general disability score; HDI). b-HDI has demonstrated high reliability (Cronbach's alpha = .84), and sufficient validity with theoretically-related

scales. Cronbach's alpha for this study were: .93 for the total score, .88 for functional and .87 for emotional subscales.

The Migraine-Specific Quality of Life Questionnaire version 2.1 (MSQ v 2.1; Martin, Pathak, Sharfman, Adelman, Taylor, Kwong et al., 2000; use permission received from GlaxoSmithKline; GSK USMA health outcome group) is a 14-item scale assessing the impact of headaches on patients' quality of lives over the past four weeks on a 6-point frequency-type scale, with 1 = none of the time and 6 = all of the time. Prior to using the scale, some items were slightly modified (the word "migraines" was substituted with the word "headache") in order to be more broadly applicable for all primary headache diagnoses, not only MIs (i.e., no differences in reliability were found between patients with migraines and other primary headache diagnoses). The scale is comprised to reflect three dimensions: (a) Role Restrictive (MSQ-RR; 7 items); assesses the degree to which performance of daily activities is limited by headaches, (b) Role Preventive (MSQ-RP; 4 items); assesses the amount of normal activities interrupted by headaches, and (c) Emotional Function (MSQ-EF; 3 items); assesses the degree to which emotional reactions (e.g., frustration) affect headaches. Each of the three dimensions is scored following a two-step approach. First, all items are reversed so as higher scores indicate a higher quality of life. Second, raw scores for each dimension are computed by multiplying the raw score of each dimension subtracting it from the number of items, and then dividing it by a corresponding algebraic value (i.e., 35 for RR; 20 for RP; 15 for EF). Each dimension is converted to a 0-100 scale in order to reflect the percentage of the total possible score achieved by participants. MSQ presents adequate psychometric validity and reliability (Cronbach's alphas = .86-.96) across different headache groups (Cole, Lin & Rupnow, 2007; Rendas- Baum, Bloudek, Maglinte & Varon, 2013). Cronbach's alphas for the current study were .93 for MSQ-RR, .87 for MSQ-RP, and .83 for MSQ-EF.

Secondary Outcomes

Secondary outcomes included variables of interest that, albeit important, were not the main focus for improvement within this trial.

Greek Brief Pain Inventory (G-BPI; Mystakidou, Mendoza, Tsilika, Befon, Parpa et al., 2001; Original version: Cleeland, 1994) is an 11-item measure of pain intensity (4 items) and pain interferences (7-items). For the purpose of this study, only the pain intensity subscale was used as pain interference was measured with the MSQ-RP subscale. Pain intensity items (e.g., please rate your pain by marking the number that best describes your pain on average), rated on a scale from 0 = "no pain" to 10 = "pain as bad as you can

imagine". The G-BPI has shown good reliability test scores, cronbach's alpha test score for interference was .85 and intensity .88 (Mystakidou et al., 2001). Cronbach's alpha for this study was .78 (pain severity).

Medical Utilization (use permission received by Vowles & McCracken, 2008), four items assess medical visits in relevance to headache and its treatment. Participants record the total number of headache-related medical visits they had over the last two months in four areas: (a) Number of #headache-related visits to different physicians, (b) Number of #primary care visits for headache, (c) Number of #Emergency department visits for headache, and (d) Number of #hospitalizations due to headache. Numbers of #headache-related visits to different physicians are summed and a total score of visits is calculated. The other three types of medical visits are added, composing an overall index of headache-related medical utilization.

The Hospital Anxiety and Depression Scale- Greek version (HADS; Mitsopoulos, Douzenis, Kalkavoura, Christodoulou, Michalopoulou, Kalemi et al., 2007; Original version: Zigmond & Snaith, 1983) is a 14-item questionnaire assessing levels of Depression (HADS-dep) and Anxiety (HADS-anx) symptomatology, considered unbiased by coexisting medical conditions (Snaith, 1987). Each subscale consists of 7 items rated on a 4-point scale (0-3). Higher scores indicate greater anxiety and depression. The Greek version presents with high reliability (Cronbach's alpha = .88) and validity. Cronbach's alpha for this study was a = .75 for depression, and a = .84 for anxiety.

Process Measures

Process measures assessed mechanisms of treatment effects as proposed by the ACT approach (Hans & McCracken, 2014).

The Greek Chronic Pain Acceptance Questionnaire (G-CPAQ; Vasiliou, Karekla, Kasinopoulos, & Michaelides, under review; Original version: McCracken, Vowles, & Eccleston, 2004) assesses pain acceptance using two sub-factors: Activity Engagement (G-CPAQ-AE;4 items), indicating the degree to which participants engage in meaningful activity even in the presence of pain; and Pain Willingness (G-CPAQ-PW;4 items), assessing the degree to which individuals experience pain without trying to change, control, or struggle with it. The G-CPAQ is rated on a 7-point frequency-type scale (1 = "never true" to 6 = "always true") and yields a total sum. Higher scores denote greater AE and PW. The G-CPAQ presents with high reliability (alpha = .80) and adequate construct validity with theoretically related constructs. Cronbach's alpha for this study was .78 for the total score, .83 for G-CPAQ-AE and .63 for G-CPAQ-PW.

*The Greek Psychological Inflexibility in Pain Scale (*G-PIPS-II; Vasiliou, Karekla, Michaelides, & Kasinopoulos, in preparation; Original Swedish version: Wicksell, Lekander, Sorjonen, & Olsson, 2010*)* contains 12 items assessing psychological inflexibility in two subscales: a) Avoidance of pain (G-PIPS-avoid; 8 items), examining behaviors that lead to avoidance of pain and related distress; and b) Cognitive Fusion (G-PIPS-fus; 4 items), assessing how patients' thoughts about an event can lead to avoidance of pain or distress. Items are rated on a 7-point frequency-type scale, with 1 = "never true" and 7 = "always true". The scale shows good psychometric properties in its Greek version (Vasiliou et al., in preparation). Cronbach's alpha for this study was .90 for the total score, .90 for the G-PIPS-avoidance and .68 for the G-PIPS-fusion subscale, which is similar with the original version (.89 for the total scale, .90 for avoidance, and .75 for cognitive fusion).

Committed Action Questionnaire (CAQ; McCracken et al., 2014), is an 8-item scale assessing goal- directed behaviors (McCracken, 2013) in two sub-scales: a) 4 positively worded items ("I prefer to change how I approach a goal rather than quit"), and b) 4 negatively worded items ("If I cannot do something my way, I will not do it at all) of committed actions. Items are rated on a likert-type scale from 0 = never true to 6 = always true. Negatively worded items are reversed so as to reflect higher levels of committed actions. A total score from the two subscales reflects an individual's tendency to persist in value-driven behaviors. CAQ presents with high reliability (alpha = .87) and sufficient validity with other related instruments, including pain acceptance, depression, and functioning (McCracken et al., 2015). Cronbach's alpha for this study was .80 for the total score, .92 for the positively worded committed action items and .71 for the negatively worded items

The Valuing Questionnaire (VQ; Smout, Davies, Burns, & Christie, 2014), is a 10-item instrument assessing the extent to which individuals acted based on personal values during the past week in two dimensions: progress in identified values (VQ-Pr; 5 items, e.g., "I worked toward my goals even if I didn't feel motivated to do so"), and obstruction of valued living (VQ-Ob; 5 items, e.g., "When things didn't go according to plan, I gave up easily"). Items are rated on a 7-point Likert scale with 0 = not at all true and 6 = completely true. Higher scores in the progress subscale represent pursuing valued living, whereas higher scores on the obstruction subscale indicate psychological barriers (e.g., disturbing thoughts, emotions, sensations, etc.) in pursuing valued living. VQ demonstrates good convergent validity and high reliability (alpha = .87 for each subscale; Smoot et al., 2014). Cronbach's alpha for this study was .62 for VQ-obstruction and .87 for VQ-progress. The low variability in obstruction subscales warrants further psychometric

examination of the VQ. Thus, any conclusion derived from the VQ-obstruction subscale should be interpreted with caution.

The Cognitive Affective Mindfulness Scale-Revised (CAMS-R; Feldman, Hayes, Kumar, Greeson, & Laurenceau, 2007) is a 12-item self-report questionnaire assessing affective and cognitive components of mindfulness. Items are rated on a 4-point Likert scale from 1 = "rarely" to 4 = "almost always". CAMS-R yields four factors, however, the authors suggest the use of its total score assessing a general mindfulness level (Feldman et al., 2007). CAMS-R presents with high reliability (alpha = .81) and adequate construct validity. The Greek version presents with similar to original unitary factor structure, high reliability (alpha = .88) and adequate construct validity with other scales. Cronbach's alpha for this study was .86.

Satisfaction with treatment

Satisfaction with treatment components were assessed with the Session rating scale version 3 (SRS V.3.0; Duncan, Miller, Sparks, Claud, Reynolds, Brown et al., 2003). Participants were rated their responses regarding the therapeutic alliance on a 10-cm visual analog scale making a harsh mark on a continuum line representing on the left site the least satisfaction, and on the right site the most satisfaction. Results were calculated by summing the marks given by participants measured to the nearest centimeter on each of the four lines. The four lines represented four items assessing therapeutic alliance: (a) relationship (e.g., «I did not feel heard, understood, and respected" or "I felt heard, understood, and respected"; (b) goals and topics (e.g., "We did not work or talk about what I wanted to work on or talk about" or "We worked on or talked about what I wanted to work on or talk about"); (c) approach or method (e.g., "The therapist's approach is not a good fit for me" or "The therapist's approach is a good fit for me"); and (d) overall session perception (e.g., "There was something missing in the session today" or "Overall, today's session was right for me"). Reliability presents high (alpha = .88) and concurrent validity with similar measures, such as the helping alliance questionnaire (HAQ-II; Luborsky, Barber, Siqueland, Johnson, Najavits, Frank et al., 1996) appears sufficient (Dunca et al., 2003). Cronbach's alpha for this study was .87.

Therapists' Adherence and Treatment Fidelity

For the purpose of this study, a manualization of the treatment components and a blinded session rating system (i.e., both are available upon request from the author) were developed to examine therapists' competence and overall treatment adherence. At least two

sessions for each group were videotaped at random for adherence checks and supervision purposes. An independent to the study registered Clinical Psychologist rated a sample of 14 ACT tapes to assess therapist competence and treatment fidelity. The rating system comprised of four parts: (a) protocol adherence (i.e., a completion of a checklist during sessions about components covered); (b) therapist competence (i.e., a completion of a checklist during sessions about therapist actions and components covered); (c) anti-ACT therapeutic responses (e.g., two items assessing how much the therapist encourages participants to change or modify the content of their thoughts and feelings and how much the therapist encourages participants to use avoidance of internal experiences as a way to cope with their difficult experiences); and (d), and an overall session approach with three items assessing: overall therapist adherence to the ACT approach, adherence to the aims of the sessions, and general adherence to the sessions. The rating system consisted of a Likert-type scale ranged from 0 = indicating very bad adherence, competence, etc. to 10 = excellent adherence, competence, etc. A mean score for each of the four scale's parts was calculated based on the ratings of a clinician who analyzed the recorded videotaped sessions for each group.

Data Analyses

Power Analysis & Preliminary Analyses

A G* power 3 software calculation (Faul, Erdfelder, Lang, & Buchner, 2007) was employed to compute statistical power for the multilevel analyses or the probability of rejecting the null hypothesis when the alternative is true. In order to compare means assuming equal size groups, an *F* test for repeated measures, within-between interaction tests was requested for estimating an a priori sample size, an error probability, and effect size. Findings showed that a relatively stable group proportion of individuals that could provide reliable effect size estimates would be a sample size of 72 individuals (36 in each condition), and effect size $\eta_p^2 = 0.25$ for $p < .05$.

Before running parametric tests, the data set was analyzed to detect possible violation of assumptions (i.e., homogeneity of variance, normal distribution; as assessed by the visual inspection of histograms, stem-and-leaf and normality plots, kurtosis and skewness). None of the examined variables were transformed. To ascertain that data set were randomly absent, missing values were analyzed with Little's MCAR test in the Missing Values analysis module. Given the amount of missing data (10.5% at Post), and their random nature of missing cases (as assessed both via visual inspection of the missing

data patterns and the non-significant MCAR testing; Little's MCAR test, x^2= 55.802, DF = 5, Sig = .63), it was decided that any form of imputation is unwarranted.

Statistical Analyses

In order to examine the study main hypotheses, first, a series of *t*-tests for independent samples with Bonferroni corrections or x^2 (for categorical data) were executed so as to evaluate the comparability of the two groups on socio-demographic and pre-treatment assessment of primary and secondary outcomes, and process variables. Second, the effects for each group (ACT vs. WL) across time on primary and secondary outcomes, and on process measures was examined, using a 2X3 Repeated measures analysis of variance (ANOVA: 2 Group: ACT vs. WL by 3 Time points: pre, post, and 3-month follow-up). Also, One-way Analysis of variance (ANOVAs) were executed to examine the main effect of Time, from pre-treatment to the 6-month follow-up, for the treatment group only (the WL began the treatment at the end of the 3-month follow-up of the ACT group, and thus there were no available 6-month follow-up data for this group). Statistical correction adjustments were chosen in case of any violation of assumptions for parametric statistics (e.g., in ANOVAs in a case of sphericity assumption violation, degrees of freedom were adjusted using Greenhouse- Geisser correction; Field, 2005). Further, in those outcomes and process measures where pre-treatment differences between the groups were detected, a 2X3 Repeated measures analysis of covariance (ANCOVAs) with pre-treatment data used as covariate and the outcome/process measures as dependent variables was employed to test for within-group error variance (Van Breukelen, 2006; Vickers, 2004). Effect sizes were assessed using partial eta squared (η_p^2) as follow: η_p^2 = 0.01 (small effect), η_p^2= 0.09 (medium effect), and η_p^2 = 0.25 (large effect; Cohen, 1988).

Third, to examine bias in findings as a result of individuals who prematurely terminated treatment or those who did not respond to post measures, intention-to-treat (ITT) analyses following the last-value-carried- forward procedure (LCFP) were executed. In this case, the last value that the participants gave (the pre-treatment scores) across all variables for those considered drop-outs, were carried forward to post-treatment and follow-up assessments.

Finally, an estimation of the percentage of the participants in the ACT showed reliable changes after treatment was calculated utilizing the Jacobson's reliable change index formulae (RCI; Jacobson & Trau, 1991). RCI serves one aspect of clinical significance (the other two include "normal" and "recovered" changes) and involves the calculation of how much change has occurred during the course of the treatment that could

not be accounted for by measurement errors (Jacobson, Roberts, Berns, & McGlinchey, 1999). The RCI estimates the range of individuals whose scores extend two standard deviations beyond the mean for that population, following the completion of treatment (2 SD equates 1.94 for 90% Confidence Intervals; CI). Using the Jacobson's formula, it was examined whether participants' scores in primary outcome variables change to a degree that can be described as reliably improved. The S_{diff}, as described by Jacobson & Truax (1991), is provided by the following formulae:

$SEM_1 = SDpre\sqrt{1-r_{12}}$ (standard deviation from Pre- treatment assessment multiplied by the square root of 1 minus the test-retest coefficient).

$SEM_2 = SDfup6\sqrt{1-r_{12}}$ (standard deviation from Follow-up 6 months assessment multiplied by the square root of 1 minus the test-retest coefficient).

$S_{diff} = \sqrt{SEM_1^2 + SEM_2^2}$ (Square root of the sum of the test-retest squared SEMs)

If the RCI (i.e., required change) for each participant is 1.94 or greater, then the difference is statistically significant (1.94 equates to the 90% CI). If the RCI is less than 1.94 then the difference is not significant. Reliable change analyses were executed for the two primary outcomes (HDI and MSQ) and the analyses were done for the 3- and 6-month follow-up. Test-retest coefficient (r_{12}) for each scale was also calculated, as it was considered necessary to estimate the S_{diff}. Given that there are no available norms from the general population to estimate the other two aspects of clinical significant change (i.e., those considered moved from a "clinical" to a "normal" and "recovered" distribution; see Jacobson et al., 1999), that require non-clinical norms only the RCI was calculated.

All statistical analyses were executed with the Statistical Package for Social Science version 22.0 (SPSS, Inc., Chicago, IL).

Results

Participants Characteristics

Table 3 presents basic demographics and headache characteristics of participants. The majority of participants in both treatment groups were women (84%), averaged 43.9 years of age (*SD* = 10.35), held a high or vocational school diploma (34%), were married (72 %), and had an average monthly income around 1000 euro (37%). For both groups, time since headache suffering onset varied between 1 to 46 years (*M* = 18.42 years, *SD* =

10.81) and mean headache duration per month was 9.40 days (*SD* = 7.28; ranged 4 to 30 days/month). Also, most of the participants in both groups, at the time they were asked, received prescribed medication for their headaches (71%).

Preliminary Analyses

Independent *t*-test analyses of differences between the two conditions at pretreatment scores showed that participants in both groups were comparable on demographics, primary, secondary and process outcomes. For each series of *t*- tests or x^2 for categorical variables (i.e., demographics, primary, secondary, and process) a modified Bonferroni procedure was employed in order to control for bias when running multiple analyses. Specifically, the following *p* values were calculated and used for judging significance across all analyses executed: for the demographics the cut off for significant was $p < .008$ (.05 divided by 6 demographics variables for x^2), $p < .007$ (.05 divided by 7 demographics variables for t-tests; for the primary measures, $p <. 008$ (.05 divided by the 6 outcome variables); for the secondary, $p <.01$ (.05 divided by the 5 outcomes); and for the process, $p <.005$ (.05 divided by the 10 process variables). Comparisons using independent *t*-tests or x^2 for categorical variables with Bonferonni corrections between the two groups on demographic variables suggest that the ACT and WL groups did not differ on any demographic variable (gender, age, educational level, family status, monthly income, occupations, time since headache onset, headache index, medical prescription, headache diagnosis, or cognitive abilities) , as assessed at pre-treatment.

For outcome and process variables, the mean scores of the two groups were found to not differ on any of the variables, except for the primary outcome of emotional role (MSQ-EM: $t_{90} = 2.51$, $p = .04$), with those in the ACT group presenting with slightly higher quality of life (*M* = 27.47, *SD* = 5.16) in the dimension assessing emotional role, than the WL group (*N* = 24.96, *SD* = 7.14). Also, there was a mean score difference in the process variable assessing avoidance of pain (G-PIPS-av.;$t_{87} = 6.35$, $p = .01$), with those in the ACT group demonstrating lower avoidance of pain (*N* = 28.16, *SD* = 9.21) than the WL control group (*M* = 34.05, *SD* = 12.53). Therefore, for these two variables, any findings should be interpreted with caution.

Treatment Outcomes and Process Effects (Intention to Treat Analyses; ITT)

Given that they were no differences in findings on the primary, secondary, and process variables when the data examined in terms of treatment completers and intention-to-treat analyses[2], the results presented here are based on the intention-to-treat analyses

(ITT) using the Last Carried Forward Procedure (LCFP). Table 4 illustrates the results from primary and secondary outcomes, and table 5 illustrates the results from the process measures as they were assessed in the two groups on pre-, post- and 3-month follow-up assessments, when the data for those considered drop-outs were carried forward to post-treatment and 3-month follow-up. For comparison purposes, Appendix A-1 presents the results from treatment completers (Tables A-1 and A-2 correspond to the tables 4 and 5 illustrated in the main text).

ITT: 2X3 Repeated Measures ANOVA of Group (ACT vs. WL) by Time (pre, post, follow-up) for Primary Outcome Measures

A repeated measures ANOVA was used to examine the effects of Group by Time (pre, post & FU-3M) on the primary outcome measures, when the data for those considered drop out were carried forward to post-treatment and 3-month follow-up. The ACT vs. WL groups did not differ at pre-treatment on all primary outcomes. There was a significant interaction effect of Group by Time on general disability scores [F (1.59, 120) = 6.22, $p <$ .01, η_p^2 =.09] (see table 4 and figure 3). There were also significant main effect of time [F (1.59, 120) = 27.84, $p < .001$, η_p^2 = .32], with general disability decreasing across the three treatment time points, and a main effect of group [F (1, 60) = 5.99, $p < .01$, η_p^2 = .09] with the ACT group presenting with lower general disability (M = 38.92)[3] than the WL group (M = 52.80). Single degree of freedom interaction contrasts showed that the two groups differed at post-treatment [F (1, 60) = 6.99, $p < .01$, η_p^2 = .10] and at 3-month follow-up [F (1, 60) = 9.09, $p < .01$, η_p^2 = .13] with those in the ACT group presenting with lower disability when compared to the WL group.

Additionally, there was a significant interaction of Group by Time on functional disability scores [HDI-Func; F (1.63, 120) = 8.87, $p < .001$, η_p^2 = .13], and significant main effect of time [F (1.63, 120) = 31.93, $p < .001$, η_p^2 = .35], with functional disability decreasing across time. There was a main effect of group [F (1, 60) = 5.03, $p < .05$, η_p^2 = .08], with the ACT group demonstrating lower functional disability (M = 20.35) than the control (M = 26.91). Single degree of freedom interaction contrasts showed that the two groups differed at post-treatment [F (1, 60) = 7.29, $p < .01$, η_p^2 = .11] and at 3-month follow-up [F (1, 60) = 7.96, $p < .01$, η_p^2 = .12], with those in the ACT group presenting with lower functional disability compared to the WL group.

There was a significant interaction of Group by Time on emotional disability scores [HDI-Em; F (1.52, 120) = 3.02, $p < .05$, η_p^2 = .05] (see table 4). Significant main effect of time [F (1.52, 120) = 23.16, $p< .001$, η_p^2 = .28] were found with emotional disability scores

decreasing across the three time points, and a significant main effect of group [F (1, 60) = 6.12, $p < .01$, $\eta_p^2 = .09$], with the ACT showing lower emotional disability (M = 18.17) than the control group (M = 25.29). Single degree of freedom interaction contrasts showed that the two groups differed at post-treatment [F (1, 60) = 5.76, $p < .01$, $\eta_p^2 = .09$] and at 3-month follow-up [F (1, 60) = 8.87, $p < .01$, $\eta_p^2 = .13$], with those in the ACT group presenting with lower emotional disability compared to the WL group.

For headache-specific quality of life, results demonstrated a significant Group by Time interaction on the role restrictive dimension of the quality of life scale [MSQ-RR; F (1.42, 120) = 5.53, $p < .01$, $\eta_p^2 = .08$] (see table 4 and figure 4). There was also a significant main effect of time [F (1.42, 120) = 30.11, $p < .001$, $\eta_p^2 = .33$], with role restrictive quality of life increasing across the three time points, and a main effect of group [F (1, 60) = 12.51, $p < .001$, $\eta_p^2 = .17$], with the ACT group presenting with higher quality of life in terms of improving the performance of previously limited daily roles (e.g., family, professional, social, etc.; M = 69.74) than the control group (M = 54.87). Single degree of freedom interaction contrasts showed that the ACT group presented with higher quality of life at post-treatment [F (1, 60) = 12.15, $p < .001$, $\eta_p^2 = .17$] and at 3-month follow-up [F (1, 60) = 17.96, $p < .001$, $\eta_p^2 = .23$], when compared to the WL group.

A significant interaction effect of group by time for the role preventive dimension of the quality of life scale was also found [RP-MSQ; F (1.68, 120) = 3.74, $p < .05$, $\eta_p^2 = .06$] (see table 4). There was also a significant main effect of time [F (1.68, 120) = 9.09, $p < .001$, $\eta_p^2 = .13$] with increasing scores of the role preventive dimension across the three time points, and a significant main effect of group [F (1, 60) = 10.87, $p < .001$, $\eta_p^2 = .15$], with the ACT group demonstrating higher levels of previously interrupted daily activities due to headache (N = 82.74; e.g., routine tasks, job demands, social activities, etc.), compared to the control group (N = 68.23). Single degree of freedom interaction contrasts showed that the two groups differed at post-treatment [F (1, 60) = 10.63, $p < .001$, $\eta_p^2 = .15$], and at 3-month follow-up [F (1, 60) = 13.87, $p < .001$, $\eta_p^2 = .18$], with those in the ACT group presenting with higher improvements in the role preventive dimension of the quality of life scale, when compare to the WL.

Finally, contrary to our hypotheses, there was no significant interaction effect of Group by Time on the emotional functioning dimension of the quality of life scale (EM-MSQ; [F (1.58, 120) = 1.46, $p = .23$, $\eta_p^2 = .02$]. Given that the two groups differed at pre-treatment on their levels of emotional functioning scale, where the ACT group presented with higher emotional functioning than the control group, the data were examined by controlling for the influence of pre-treatment scores. There were significant group by time

interaction effects for the emotional role [F (1, 72) = 3.39, $p < .05$, $\eta_p^2 = .04$]. An examination of the single degree of freedom interaction contrasts (controlling for the pre-treatment scores) showed that the two groups differed at post-treatment [F (1, 72) = 3.39, $p < .05$, $\eta_p^2 = .04$] and at 3-month follow-up [F (1, 59) = 7.47, $p < .01$, $\eta_p^2 = .11$], with those in the ACT group presenting with higher improvements in the emotional role dimension of the quality of life (e.g., less frustration, anger, etc.) when compared to the WL.

ITT: One-way *Repeated Measures ANOVA of Time (pre, post, follow up-3, & 6 months) for Primary Outcome Measures of ACT Group only*

One-way Repeated Measures ANOVAs were examined to compare scores on the primary outcomes for the ACT group only, at pre, post-treatment, at 3-, and 6-month follow-up. This analysis is limited only to the ACT group as the WL group received the intervention following the completion of the 3-month follow-up assessment of the ACT group. Figure 5 illustrates the results of headache disability change scores across time. Significant effects of Time for general headache-related disability [HDI; F (2.08, 57) = 19.15, $p < .001$, $\eta_p^2 = .50$], functional disability [HDI-Func.; F (2.06, 57) = 21.71, $p < .001$, $\eta_p^2 = .53$], and emotional disability [HDI-Em.; F (2.11, 57) = 13.62, $p < .001$, $\eta_p^2 = .42$] were noted, with those in the ACT group presenting with marked reductions in disability scores across the four-time points.

Similar analyses were reported for the three dimensions of the quality of life scale (MSQ). Figure 6 illustrates the results of the three dimensions of the headache-specific quality of life scale. Results demonstrated significant effects of time on the three dimensions of the quality of life scale, including role restrictive [MSQ-RR; F (1.88, 60) = 8.43, $p < .001$, $\eta_p^2 = .30$], role preventive [MSQ-RP; F (1.62, 57) = 3.01, $p< .05$, $\eta_p^2 = .14$], and emotional functioning [MSQ-Em; F (1.85, 54) = 6.44, $p < .01$, $\eta_p^2 = .26$]. The quality of life was consistently improved across the four-time points for two of the three dimensions of the MSQ scale (RR & EM indicating a marked improvement in functioning, but for the MSQ-RP, there was a slight reduction for the treatment group. Overall, changes in headache-related disability were larger than changes in quality of life across time, with the overall average effect size across all primary outcomes to be high, $\eta_p^2 = .35$ (range: .14 -.53).

ITT: 2X3 Repeated Measures ANOVA of Group (ACT vs. WL) by Time (pre, post, follow up) for Secondary Outcome Measures

A (2 by 3) repeated measures ANOVA examined the effects of Group by Time (pre, post, & FUP-3M) on the secondary outcomes. There were no significant differences in any of the secondary outcomes at pre-treatment. Results showed no significant

interaction effects of Group by Time on the secondary outcomes, except for depression [HADS-dep; F (1.78, 112) = 2.75 $p < .05$, $\eta_p^2 = .05$]. There was a significant main effect of time [F (1.78, 112) = 58.78, $p < .001$, $\eta_p^2 = .51$], with depression decreasing across the two time point, and main effect of group [F (1, 56) = 6.08, $p < .01$, $\eta_p^2 = .10$], with the ACT group presenting with lower depression levels (M = 4.18) when compared with the WL group (M = 5.80). Single degree of freedom interaction contrasts showed that the two groups differed at the levels of depression at post-treatment only [F (1, 56) = 5.51, $p < .05$, $\eta_p^2 = .09$], with those at the ACT group presenting with lower depression when compared with the WL group (see table 4).

Given recent findings demonstrating continued improvements in pain severity and psychological distress following an ACT-based approaches for pain (Veehof, Trompetter, Bohlmeijer, & Schreurs, 2016; Vowles, Witkiewitz, Levell, Sowden, & Ashworth, 2016), we proceeded to examine the single degree of freedom interaction contrasts to investigate any possible differences on the secondary outcomes of the groups at post-treatment and 3-month follow-up. Results showed that the two groups differed at pain severity scale, with those in the ACT group presenting with lower pain severity at post-treatment [F (1, 56) = 16.41, $p < .001$, $\eta_p^2 = .23$] and at 3-month follow-up [F (1, 56) = 15.36, $p < .001$, $\eta_p^2 = .21$] compared to the WL group. No other differences in secondary outcomes of the groups were observed.

ITT: One-way Repeated Measures ANOVA of Time (pre, post, follow up-3, & 6 months) for Secondary Outcome Measures of ACT Group only

One-way repeated measures ANOVAs of time showed significant effects of time on pain intensity [GBPI; F (2.09, 57) = 3.14, $p < .05$, $\eta_p^2 = .14$], frequency of medical utilization [F (1.86, 48) = 3.51, $p < .05$, $\eta_p^2 = .18$], and depression [HADS-dep; F (1.93, 54) = 7.56, $p < .001$, $\eta_p^2 = .30$] with significant reductions across the four time points for all these measures. The overall average effect size across all secondary outcomes was medium, $\eta_p^2 = .16$ (range: .03 -.30).

ITT: 2X3 Repeated Measures ANOVA Group (ACT vs. WL) by Time (pre, post, follow-up) for Process Measures

A (2 by 3) repeated measures ANOVA examined the effects of Group by Time (pre, post & FU-3M) on process measures. Figure 7 illustrates the effect sizes for all process measures. The two groups did not differ at pre-treatment on all process measures except for the avoidance of pain, where the ACT presented with lower avoidance of pain than the control group.

There was a significant interaction of Group by Time on pain acceptance [G-CPAQ; F (2, 56) = 4.49, $p < .01$, $\eta_p^2 = .14$] (see table 5). There were also significant main effect of time [F (2, 56) = 7.54, $p < .001$, $\eta_p^2 = .22$], with an increased level of pain acceptance across time, and a main effect of group [F (1, 57) = 9.49, $p < .001$, $\eta_p^2 = .15$], with the ACT group presenting with higher pain acceptance (M = 28.63) than the control group (M = 22.26). Single degree of freedom interaction contrasts showed that the two groups differed at post-treatment [F (1, 57) = 8.95, $p < .001$, $\eta_p^2 = .14$], and at 3-month follow-up [F (1, 57) = 13.52, $p < .001$, $\eta_p^2 = .19$], with those in the ACT group presenting with higher pain acceptance compared to the WL.

Similarly, there was a significant interaction effect of Group by Time on the activity engagement levels [G-CPAQ-AE; F (2, 56) = 4.10, $p < .05$, $\eta_p^2 = .13$] (see table 5). There were also significant main effect of time [F (2, 56) = 3.17, $p < .05$, $\eta_p^2 = .10$], with those in the ACT demonstrating an increased in activity engagement across time, and a main effect of group [F (1, 56) = 6.54, $p < .01$, $\eta_p^2 = .10$], with the ACT group presenting with higher levels of activity engagement (M = 16.92) compared to the control group (M = 13.31). Single degree of freedom interaction contrasts showed that the two groups differed at post-treatment [F (1, 57) = 7.90, $p < .01$, $\eta_p^2 = .12$], and at 3-month follow-up [F (1, 57) = 9.22, $p < .001$, $\eta_p^2 = .14$], with those in the ACT group presenting with a mark improvement in activity engagement compared to the WL group. Contrary to our hypotheses, there was no significant interaction of Group by Time on pain willingness [G-CPAQ-PW; F (1.68, 114) = 1.33, $p = .26$, $\eta_p^2 = .03$]. Given the significant attention in the protocol for enhancing pain willingness (as part of the process of pain acceptance), we proceeded to the examination of single degree of freedom interaction contrasts to investigate any possible differences of the groups at post-treatment and 3-month follow-up. Results demonstrated that the ACT group significantly differed at post-treatment [F (1, 57) = 4.10, $p < .05$, $\eta_p^2 = .07$] and at 3-month follow-up [F (1, 57) = 8.01, $p < .01$, $\eta_p^2 = .12$], with those in the ACT group presenting with higher levels of pain willingness when compared with the WL group.

Further, significant interaction effect of Group by Time were observed for the psychological inflexibility in pain scale [G-PIPS; F (1.31, 104) = 10.72, $p < .001$, $\eta_p^2 = .17$] (see table 5).There was also a significant main effect of time [G-PIPS; F (1.31, 104) = 24.72, $p < .001$, $\eta_p^2 = .32$], with the psychological inflexibility in pain levels decreasing across time, and a main effect of group [G-PIPS; F (1, 52) = 10.21, $p < .001$, $\eta_p^2 = .16$], with the ACT group presenting with lower psychological inflexibility levels (M = 42.68), compared to the WL control group (M = 55.63). Single degree of freedom interaction

contrasts showed that the two groups differed at post-treatment [F (1, 52) = 15.04, p < .001, η_p^2 = .22], and at 3-month follow-up [F (1, 52) = 12.92, p < .001, η_p^2 = .20], with those in the ACT group presenting with lower psychological inflexibility in pain when compared with the WL group.

Accordingly, significant interaction effect of Group by Time on the cognitive fusion subscale was also observed [PIPS-fus.; F (1.38, 112) = 8.32, p < .001, η_p^2 = .13] (see table 5). There was a significant main effect of time [G-PIPS-fu.; F (1.38, 112) = 17.72, p < .001, η_p^2 = .24], with decreasing scores on the cognitive fusion subscale on time, and significant main effect of group [G-PIPS-fu; F (1, 56) = 6.55, p < .01, η_p^2 = .10], with the ACT group presenting with lower fusion with pain-related thoughts (M = 18.90) than the control group (N = 23.98). Single degree of freedom interaction contrasts showed that the two groups differed at post-treatment [G-PIPS-fus.; F (1, 56) = 10.19, p < .001, η_p^2 = .15], and at 3-month follow-up [G-PIPS-fus.; F (1, 56) = 8.70, p < .01, η_p^2 = .13], with those in the ACT group presenting with lower levels of fusion with pain-related thoughts when compared with the WL group.

Regarding the avoidance of pain subscale, there was also a significant interaction of Group by Time [PIPS-av.; F (1.28, 104) = 6.92, p < .01, η_p^2 = .12] (see table 5). There was also a significant main effect of time [G-PIPS-av.; F (1.28, 104) = 17.35, p < .001, η_p^2 = .25], with avoidance of pain decreasing across the two time points and a main effect of group [G-PIPS-av.; F (1, 52) = 10.26, p < .001, η_p^2 = .16], with the ACT group presenting with lower avoidance of pain (N = 23.98), compared to the control group (N = 33.61). Single degree of freedom interaction contrasts showed that the two groups differed at post-treatment [G-PIPS-av.; F (1, 52) = 14.07, p < .001, η_p^2 = .21], and at 3-month follow-up [G-PIPS-av.; F (1, 52) = 12.24, p < .001, η_p^2 = .19], with those in the ACT group presenting with substantially lower avoidance of pain compared to the WL group. Given that the two groups significantly differed at pre-treatment scores, where the ACT group presented with lower avoidance of pain than the control group, findings were examined controlling for the pre-treatment scores. Results demonstrated a significant group by time interaction effect of the pain avoidance scale [G-PIPS-av.; F (1, 64) = 11.93, p < .001, η_p^2 = .16], with those in the ACT group presenting with lower avoidance than the control group.

Contrary to our hypotheses, there was no significant interaction effects of Group by Time for committed actions (CAQ: F (2, 1.52) = .73, p > .05 , η_p^2 = .01, value progress (VQ-pr.; F (2, 1.63) = .28, p > .05, η_p^2 = .00), values obstruction (VQ-ob.; F (1, 1.53) = 2.43, p > .05, η_p^2 = .04), and mindfulness (CAMS-R; F (2, 1.56) = .31, p > .05, η_p^2 = .02].

Given the inclusion of numerous sections in the protocol with material covering these processes, we proceeded to investigate the single degree of freedom interaction contrasts in order to explore any possible differences of the groups at post-treatment and 3-month follow-up. Results showed that the two groups differed in their levels of committed action (CAQ) at post-treatment [F (1, 56) = 6.39, $p < .01$, $\eta_p^2 = .10$] and at 3-month follow-up [F (1, 56) = 10.98, $p < .001$, $\eta_p^2 = .16$], with those in the ACT group presenting with higher levels of committed actions on time. Further, single degree of freedom interaction contrasts also demonstrated that there was a significant improvement in values-based actions (VQ-Pr.) for the ACT group when compared with the WL group at 3-month follow-up [F (1, 56) = 4.13, $p < .05$, $\eta_p^2 = .06$]. Accordingly, significant single degree of freedom interaction contrasts were also found for the values obstruction scale (VQ-ob.) at post-treatment [F (1, 57) = 4.05, $p < .05$, $\eta_p^2 = .07$] and at 3-month follow-up [F (1, 57) = 5.03, $p < .05$, $\eta_p^2 = .08$], with those in the ACT group presenting with marked improvements in values obstructions when compared with the WL group.

ITT: One-Way Repeated Measures ANOVA of Time (pre, post, follow-up 3, & 6-month) for Process Measures of ACT Group only

One-way Repeated Measures ANOVAs were examined to compare scores on the process measures for the ACT group, at pre, post- treatment, and at 3, and 6-month follow-up. Significant effects of Time were found for pain acceptance [G-CPAQ; F (1.67, 57) = 10.37, $p < .001$, $\eta_p^2 = .35$], activity engagement [G-CPAQ-A.E.; F (1.97, 57) = 4.99, $p < .01$, $\eta_p^2 = .21$], and pain willingness [G-CPAQ-P.W.; F (2.07, 54) = 11.04, $p < .001$, $\eta_p^2 = .38$], with those in the ACT group presenting with marked improvements in pain acceptance across the four time points. Further, significant effect of time were also found for psychological inflexibility in pain [G-PIPS; F (1.96, 45) = 14.88, $p < .001$, $\eta_p^2 = .50$], cognitive fusion with pain-related thoughts [PIPS-Fu.; F (1.98, 48) = 12.98, $p < .001$, $\eta_p^2 = .45$], and avoidance of pain [PIPS-av.; F (2.03,45) = 10.37, $p < .001$, $\eta_p^2 = .41$], with those in the ACT group demonstrating a substantial reduction in psychologically inflexible responses to pain across time. Also, there was a significant effect of time for value obstruction [VQ-Ob; F (1.70, 60) = 3.49, $p < .05$, $\eta_p^2 = .15$], with those in the ACT group presenting with lower obstructions in pursuing values-based actions across time. The overall average effect size across all process measures was high, $\eta_p^2 = .26$ (range: .03 -.50).

Provided that the two groups demonstrated low variability for some of the outcome and process measures at pre-treatment (e.g., EM-MSQ, medical utilization, G-CPAQ-PW), an examination of all outcome and process measures controlling for their pre-treatment scores (ANCOVA) was executed. Results demonstrated a similar pattern of findings as

presented with the repeated measures ANOVA of group by time analyses. In each outcome and process measure, when the pre-treatment scores were controlled for, all the measures presented findings that they were in the expected directions.

Reliable Change Analyses

Table 6 and Figure 8 illustrate the results of the reliable change analyses from pre-treatment to 3, and 6-month follow-up outcome scores. In general there was a 63.18% reliable improvement for all treatment outcomes, which was continued at 6-month follow-up (79.35%). More than half of those participants in the ACT group provided data at 3-month follow-up, presented with reliable improvements in general (68% for HDI-T) and functional disability (68% for HDI-Func.) scales, with those presenting reliable improvements at 3-month to continue improve at 6-month follow-up (90.90% for HDI-T and 90.90% for HDI-Func.). Also, half of the participants who provided data at 3-month follow-up showed improvements in the emotional disability subscale (53% for HDI-Em.). Those participants presenting improvements at 3-month follow-up, presented with substantial improvements at 6-month follow-up for this scale (90.48% for HDI-Em). A small amount of individuals exhibited a decline in disability at 3-month follow-up, on average for the three HDI subscales 6.53% of participants. None of the participants who provided data showed declined at 6-month follow-up scores for general headache-related disability and functional disability scores. However, 5% of the participants exhibited reliable change in the emotional disability subscale (HDI-em) at 3-month follow-up demonstrated a reliable decline at 6-month follow-up.

For quality of life, at 3-month follow-up 71% of participants reported a reliable improvement in previously avoided roles due to headache (MSQ-RR), 68% reported improvement in previously restricted roles due to headache (MSQ-RP), and half of the participants showed improvement in emotional reactions (e.g., frustration) affecting headaches (52% for MSQ-EM). At 6-month follow-up, participants noted further increase in two of the three quality of life dimensions (80% for MSQ-RR and 71% for MSQ-EM). However, for the role preventive dimension of the quality of life scale there was a 15.36% reduction of participants classified as reliable improved (i.e., was 67.74% at 3-month and 53% at 6-month follow-up for MSQ-RP). Finally, few participants demonstrated a reliable decline in quality of life dimensions at 3-month follow-up, on average 10.7%, and 14% at 6-month follow-up. Given the low test-retest correlations observed for the three dimensions of the quality of life scale, findings of the MSQ for the reliable change analysis should be interpreted with caution.

Satisfaction with Treatment, Therapists' Competence & Treatment Adherence

More than half of the participants in the treatment group (56.70% *M* = 59.96, *SD* = 21.80, range 6–90) reported that they were generally satisfied with the overall treatment. Also, more than half of the participants (55.16%; M = 61.63, *SD* = 21.53, range = 8–90) reported satisfaction with the therapists' interpersonal styles across sessions (e.g., "how heard, understood, and respected you felt"), and 60% (M = 58.20 (*SD* = 58.20, range = 5–90) reported satisfied with the goals and topics of each session. Further, 57% (M = 60.42, *SD* = 22.07, range = 5–90) reported satisfied with the therapists' approach (e.g., "how appropriate the therapists' approach was for their needs"), and the same percentage of participants evaluated their experience from the treatment as positive (M = 59.58, *SD* = 22.08, range 5–90; "how positive the overall experience from the program was"). A blind rate of sessions, examining therapists' competence and overall treatment adherence, was executed by an independent to the study Registered Clinical Psychologist. Ratings were made separately for each of the four parts comprised of protocol adherence and overall session's competency. Mean overall therapists' adherence to the protocol scores was 4.02 (ranged from 2 to 6) on a frequency-type scale (0-6) across ACT therapists, and mean therapists competence scores was 4.03 (ranged from 2 to 5) on a frequency-type scale (0-6). The anti-ACT therapeutic responses yielded a mean score of 1.21 (ranged from 0 to 2) on a frequency-type scale (0 = not at all use to 10 = very frequent use). Mean therapists' adherence to the ACT therapeutic style was 5.36 (ranged from 2.67 to 7.33), and mean score of a global assessment of sessions was 7.67 (ranged from 4 to 10), as both assessed on a frequency-type scale (0-10).

Discussion

The primary aim of this study was to evaluate the outcome and process effects of an ACT-based 9-sessions group intervention of a community-recruited sample of patients diagnosed with primary headache disorders, and in comparison to a WL group. Given that the avoidance of internal and external triggers approach is considered a problematic coping way of managing pain or other experiences associated with headache difficulties (Martin & McLeod, 2009; Kelman, 2007), an alternative to the avoidance/ control approach was examined. It was hypothesized that by emphasizing acceptance and valued living (ACT; Hayes et al., 2012), sufferers would result in significant improvements in their daily functioning and disability. In sum, our hypotheses were mainly supported, and findings from this study suggest ACT as an efficacious approach in head pain management. Results

are discussed based on the ITT analysis, which is considered a more stringent analysis. Findings demonstrated that there was still evidence of significant changes both in treatment outcomes and process effects, even when the "worst cases" (drop-outs) participants with no improvements whatsoever were counted on.

Findings from this study showed that at the end of treatment and at 3-month follow-up participants in the ACT group, compared to the WL group, achieved significant declines in general, functional and emotional headache- related disability levels, and demonstrated marked improvements in headache-specific quality of life dimensions. Medium effect sizes were evident for all primary outcomes both following treatment completion, and at 3-month follow-up. Notably, the effect sizes at 3-month follow-up for two dimensions of the headache-specific quality of life scale (i.e., role preventive; MSQ-RR and role restrictive; MSQ-RP) were the highest among the outcomes examined (.23 and .19, respectively), indicating that the suggested intervention increased participants' performance of previously interrupted daily activities due to headache (e.g., exercise, social life, other leisure time activities, etc.).

Findings from the reliable change analyses are promising, if we consider that more than the half of treatment completers demonstrated reliable improvements in disability and quality of life at 3-month follow-up, and almost two-thirds of treatment completers showed further improvements on these variables at 6-month follow-up. Given the protracted and extensive pain chronicity and treatment failures (i.e., more than 18 years since the onset of suffering and, on average, 9 days of headache/month) of individuals participating in this study, the findings from reliable change analyses are indeed noteworthy, and provide further support for the efficacy of ACT in sufferers with recurrent headaches.

The effect of treatment across time from pre to 6 month follow-up was examined only for the ACT group. Results demonstrated significant improvements in time for the following outcomes: headache-related disability, quality of life, head pain intensity, the frequency of medical utilization, and levels of depressions. Notably, in almost all of the findings (except for the preventive role of quality of life dimension; RR-MSQ), the effects sizes at 6-month follow-up were large (ranging from .26 to .53) indicating that an ACT-based intervention is an effective approach for reducing the burden that headaches cause to sufferers. The significant effects of ACT in lowering medical utilization imply that ACT may also be a cost-effective approach for headache sufferers, but large-scale RCTs, including individuals with medication-overuse headaches, can shed more light on this issue.

With regard to process effects, to our knowledge, this is the first ACT RCT study in head pain that reports the effects of an ACT intervention including all six proposed components for headache sufferers, and for over a longer than a 6-month follow-up period. Results demonstrated significant improvements in pain acceptance, goal-directed behaviors, and value-based actions; and substantial reductions in pain avoidance, fusion with pain-related thoughts, and values obstruction at pre- to a 6-month follow-up. Effect sizes across all process variables were uniformly large. Notably, two key factors that have been repeatedly associated with pain-related disability, avoidance of pain and fusion with pain-related thoughts (Crombez, Vlaeyen, Heuts, & Lysens, 1999; Vlaeyen & Linton, 2000; Vasiliou et al., in preparation; Wicksell, Ahlqvist, Bring, Melin, & Olsson, 2008), marked the highest levels of effect sizes across all ACT process variables (e.g., .41 and .45, respectively), providing further support for the theoretical underpinnings of ACT that deemphasize control and avoidance of internal experiences, and emphasize increases in pain acceptance and valued living.

Overall, treatment outcomes from this trial are in line with previous studies assessing ACT for head pain sufferers (Dindo et al., 2012; Mo'tamedi et al., 2012), and offer new evidence for the efficacy of ACT in this population. For example, findings from the effects of ACT in process measures indicate that inflexible and context incongruent responding to pain (e.g., avoidance and fusion) can become more problematic than pain itself, leading to needless suffering. In turn, adopting a more flexible way of coping with pain experiences (e.g., an open and acceptance response) and doing so in service of valued living, the result are increases in daily functioning and quality of life, even in the absence of head pain reductions (Crombez et al., 1999; Dindo, Recober, Marchman, Turvey, & O'Hara, 2013; Esteve & Ramizer-Maestre, 2013; McCracken & Gutierrez-Martinez, 2011; Wicksell, Melin, Lekander, & Olsson, 2009; Vowles & McCracken, 2008; Vowles, Witkiewitz, Levell, Sowden, & Ashworth, 2016). Study findings provide support to a new stream of research proposing that the reduction of pain severity may not helpful in promoting psychosocial functioning, particularly for many unavoidable pain conditions, such as migraines, where direct control of pain cannot be entirely achieved. Thus, focusing exclusively on alleviating pain may be impractical or in some cases counterproductive (Ballantyne, 2016; Dindo, 2016; Vowles et al., 2016).

No significant group by time effects were found for pain severity, frequency of physicians' visits for headaches and anxiety levels. These variables constitute secondary outcomes, and were not specifically targeted in the intervention. An absence in symptom reduction (i.e., severity of pain and anxiety levels) is not surprising given that the main

focus of ACT is on acceptance of all unwanted experiences even in the presence of head pain.

As noted earlier, interventions for head pain that focus on the alleviation of pain do not achieve enhancement of functioning and reduction in pain disability, at least for many sufferers that experiencing continuous pain. Findings from this and other studies put into question whether pain reduction should be the outcome of interest when the goal is to improve pain-related functioning and disability. In fact, there is a stream of new research questioning the added utility of head pain reduction, particularly for numerous sufferers that reducing pain cannot be ultimately achieved (e.g., during a MI episode), and instead promotes new interventions emphasizing pain adjustment even if head pain remains relatively stable (Chiappedi, Mensi, Termine, & Balottin, 2016; Dindo et al., 2012; Ford et al., 2015; Mo'tamedi et al., 2012; Martin, Reece, Callan, MacLeod, Kaur, Gregg, et al., 2014; Stonnington et al., 2016; Smitherman et al., 2015). A larger scale RCT is needed in order to further demonstrate whether the null Group by Time interaction effect of pain severity was due to a small sample size or due to the ACT approach that deemphasizes pain reduction.

Lack of treatment effects in relation to headache sufferers' frequency of visits to physician and anxiety levels may be an artifact of the sample utilized. This sample, although appeared dysfunctional in terms of pain chronicity, it was, generally, a psychologically healthy group of community-based headache sufferers with relatively low levels of distress and medical utilization. Given that the frequency of medical utilization and visits to physicians represent a complex pattern of behaviors to capture with self-reports, the present finding awaits further research. It may be argued that our methods of assessing medical utilization with retrospective self-reports are not sensitive enough to demonstrate changes. Utilizing more sensitive methods to measure medication use (e.g., ecologically momentary assessment methodologies that capture behaviors close to the time of occurrence in participants' environment), recruiting a more disabled sample of headache sufferers (e.g., patient with medication-overuse headaches), and targeting the reduction of medication more directly, one can examine whether and to what extent continued medication influences treatment outcomes. Finally, the low group variance in medical utilization and psychological distress may be partially attributed to environmental factors, including the latitude and climatological factors that individuals reside in. Research supports that individuals residing in areas with high mean temperatures, as in this case, are less likely to suffer from intractable headaches requiring systematic medical care (Mitsikostas, Tsaklakidou, Athanasiadis, & Thomas, 1996). Therefore, the pattern of

findings may be directly related to this population, yet, it is possible that other samples with more intractable headaches or environmental conditions, will demonstrate different findings. Future work should further examine this issue.

Present study findings should be considered in light of some limitations. First, the sole dependence on retrospective self-reports in assessing treatment effects, and the absence of inclusion of any behavioral, recordable measures (e.g., physiological modifications, physical improvements, etc.), may limit the interpretation of findings. Second, participants in the groups may be differed in various characteristics, such as motivation, treatment expectations, adherence to their medication, and previous learning experiences etc. It is unclear how these variables may have impacted the present study findings. Next, the majority of the study participants were community-based headache sufferers exhibiting higher levels of functionality, compared to patients seen in tertiary neurology clinics that present with complex headaches conditions and comorbidities (Meskunas, Tepper, Rapoport, Sheftell, & Bigal, 2006). Thus, present study findings may not be generalized to these patients seeking specialized treatments. Final, participants' prophylactic or other headache medications were not disallowed during the trial's period, and this may have inflated the present study findings.

Coupled with limitations, the present study has a number of notable strengths. First, findings of this study provide support for the emerging behavioral therapies in head pain management, such as ACT and Mindfulness-based interventions, which challenge the conventional idea that by avoiding headache-related experiences (e.g., stress, triggers, etc.) sufferers can reduce headache activity and increase their functioning in the long-run (Smitherman et al., 2015). Instead, these interventions support that by increasing willingness to have pain and diminishing the influence that avoidance poses on daily functioning, sufferers may not achieve to reduce their pain per se, but adopt new behavioral repertoires, and enhance learning experiences that facilitate more effective responses to pain (e.g., acceptance). Second the positive findings in terms of treatment adherence and therapists' fidelity and the participation of individual from the general community provide evidence for the sound ecological validity of the newly developed protocol for headache sufferers. This means that the protocol can be used in real-world settings, such as tertiary clinics or in primary care centers, where the majority of headache sufferers are being treated. Finally, clinical implications of these findings could be the more targeted personalization of treatment component delivery. For example, targeting at pain acceptance may assist highly avoidant sufferers in better managing their long lasting headache episodes and benefit in terms of emotional well-being and psychological

functioning. On the contrary, focusing on committed-based behaviors may be useful for sufferers exhibiting significant reductions of valued activities and vitality, and benefit in terms of headache-related disability and physical functioning.

Future studies should extend the findings from this efficacious study with large-scale effectiveness trials, including active control groups receiving an established psychological treatment (e.g., biofeedback, relaxation) and recruiting more homogeneous groups of headache participants (i.e., only MI or TTH sufferers). This allows the examination of how different headache categories respond to the ACT treatment or other effective behavioral headache therapies, and whether different headache categories (e.g., chronic daily persistent headaches) are more benefit from this approach than others. Also, future trials should compare ACT with established behavioral therapies (e.g., relaxation, biofeedback) and pharmacotherapy, and examine the potential efficacy of ACT in different settings (e.g., multidisciplinary headache units, outpatient departments, etc.), and formats (e.g., group/ web-based, limited contact, etc.). This can optimizing effective behavioral components used in behavioral headache treatments, and create progress in the field of behavioral headache management. Further, a comprehensive examination of several ACT processes in predicting changes in treatment outcomes through mediation analyses, and session-by-session mechanism of ACT action research through advanced statistical analyses (e.g., latent growth models and multilevel mediation models; Cheong, MacKinnon, & Khoo, 2003), can improve treatment methods, maximize outcomes, and highlight the therapeutic components that are responsible for treatment changes (Dindo et al., 2013; Kazdin, 2007; Smitherman et al., 2015). Process of change research can also shed more light on variables that were found to fade out at 6-month follow-up (e.g., reduction in the role restrictive dimension of the quality of life scale). Finally, although an attempt was made to monitor pharmacotherapy in both groups and thus examine the impact of pharmacotherapy on treatment's outcomes, this was not executed in a standardized way by the study physicians. Future research should more explicitly attempt to monitor preventive or rescue pharmacotherapy in order to better assess whether and to what extend pharmacotherapy enhances the effects of ACT treatment on outcomes.

In conclusion, this study examined the efficacy of ACT among a group of community-based headache sufferers randomly assigned to either ACT or to WL. Findings yielded promising results in support of the ACT for head pain management, particularly on improving headache-related disability and quality of life. To the extent that improvements can be achieved by having sufferers' approaching their pain and headache triggers with a more flexible and open way is a matter of further research. Collectively, this study may

have practical and translational value as it provides new evidence for the effects of ACT in headaches.

Study 3: TREATMENT MEDIATORS IN ACCEPTANCE AND COMMITMENT THERAPY FOR PRIMARY HEADACHE SUFFERERS

Abstract

Though improvements in headache-related treatment outcomes are considered to result from changes in CBT process of change variables, such as increases in self-efficacy, positive coping skills, locus of control, and reductions in self-regulation of physiological responses, there is no research to determine which of these processes are more important for long-standing therapeutic effects in headache management. Thus, more research is needed to examine the mechanism by which CBT exerts its influence on headaches. Acceptance and Commitment Therapy (ACT) is an emerging behavioral headache therapy that organizes their treatment methods into six processes. The examination of the six processes, and whether they really mediate the effect of an ACT-based approach in treatment outcomes, creates progress in behavioral research for headaches. It does so by highlighting which process of change variables are more related with treatment effects. The present study explored the mediating effects of an ACT-based intervention on headache-related disability and quality of life outcomes, through ACT-theoretically-based mediators (pain acceptance, psychological inflexibility in pain, avoidance of pain, fusion with pain-related thoughts, committed actions, value obstruction-progress, and mindfulness). 94 primary headache sufferers (*M* = 43 yrs; 84% females; *M* headache frequency/month = 9.30) were randomized to either an ACT-based intervention for headache sufferers, added to Medical Treatment as Usual (ACT; *N* = 47), or to only Wait List Control (WL; N = 47). Participants completed questionnaires related to their headache experience and ACT processes at pre- (T1), post-treatment (T2) and 3-month follow-up (T3). Mediation analysis, using a non-parametric cross product of the coefficient approach, was utilized to examine whether improvements in these processes mediated the effect of ACT on pre to post-treatment (T1-T2) and pre to 3-month follow-up (T1-T3) change scores on outcomes for the two groups. Results demonstrated mediating effects of treatment for the ACT group when compared with the WL group, on headache-related disability and quality of life, through changes in pain acceptance, value progress, psychological inflexibility in pain and avoidance of pain at post treatment and 3-month follow-up. Changes in headache-related disability and quality of life through improvements in pain acceptance, values-based actions, and psychological inflexibility in pain appear to be important treatment mediators for headache sufferers. Therefore, targeting at these processes, sufferers can increase their functioning and reduce headache-related disability, even in head pain is relatively stable.

Keywords: Headaches; Mediation Analysis; Mechanism of Change; Acceptance and Commitment Therapy

Introduction

Primary headaches, such as migraines or tension-type headaches are prevalent conditions affecting around 47% of the general population within the span of a year (Jensen & Stovner, 2008). Although headaches are not related to high mortality risks (Leonardi, Steiner, Scher, & Lipton, 2005), they are comorbid with other conditions (e.g., strokes, hypertension, obesity, diabetes, chronic pain other than headaches, depression, and anxiety). They are also associated with increased economic costs (e.g., medical utilization) and indirect consequences (e.g., decreased quality of life, sickness absence or reduced work efficiency; Buse, Rupnow, & Lipton, 2009; Leonardi et al., 2005). The burden of headaches on individuals' lives and their families is considered a major public health issue with significant clinical, economic, and societal consequences (Jensen & Stovner, 2008).

Behavioral headache interventions (e.g., relaxation, biofeedback, cognitive-behavioral stress-management therapies) and pharmacotherapy can significantly reduce the burden of headaches in an individual's life (see Penzien, Irby, Smitherman, Rain, & Hoole, 2015; Rains, Penzien, Douglas, McCrory, & Gray, 2005 for reviews), and are considered effective in lowering head pain severity (Kropp, Meyer, Landgraf, Ruscheweyh, Ebinger, & Strauber, 2013; Starling & Dodick, 2015). However, exactly how the mechanism of behavioral therapy works is not yet clear (Penzien & Irby, 2014). In fact, there are very few studies focusing on the specific processes of change as potential active treatment mechanisms (i.e., mediators) that account for therapeutic improvements (Holroyd, Labus, & Carlson, 2009; Seng & Holroyd, 2014).

While behavioral headache therapies (e.g., biofeedback and relaxation) attribute their treatment effects to processes aiming to reduce muscle tension (e.g., self-regulation of physiological responses; Rains et al., 2005), the mechanism of change is still unknown for the most frequently utilized approach to headache management, cognitive-behavioral stress- therapy (CBT; Penzien, Irby, Smithermann, Rains, & Hoole, 2015). Self-efficacy is one of the processes of change that has been examined in terms of its contribution to CBT for headache outcomes (Blanchard, Kim, Hermann, & Steffek, 1993; French, Holroyd, Pinell, Malinoski, O'donnell, & Hill, 2000; Holroyd, Penzien, Hursey, Tobin, Rogers, Holm et al., 1984; Marlowe, 1998; Rokicki, Holroyd, France, Lipchik, France, & Kvaal, 1997). Additional processes proposed to act as mediators in CBT for headaches include the reduction of catastrophizing, and increases in positive coping skills (e.g., recognizing and avoiding triggers, better adherence to medication, etc.; Seng & Holroyd, 2014; Holroyd, Cottrell, O'Donnell, Cordingley, Drew, Carlson, et al., 2010). Although improvements in

these processes as a result of CBT have all been found to significantly predict changes in headache outcomes, they cannot fully explain what accounts for the therapeutic effects of CBT on headache outcomes (Seng & Penzien, 2014).

The reason behind this may lie a lack of empirical evidence as for the processes responsible for therapeutic changes in headaches, and a lack of knowledge about how these processes are related to headache treatment outcomes. Most psychological treatments for headaches utilize a wide variety of CBT components, such as self-efficacy, problem-solving, stress reduction, prevention of headaches via avoidance of triggers, and others. However, it is argued that CBT components are neither universally suitable for all headache sufferers, nor always effective in reducing the burden of headaches to individuals (Seng & Penzien, 2014; Holroyd et al., 2009). For example, although the short-term use of avoidance in managing headache triggers reduces headaches, an excessive and inflexible use of avoidance in the long-run leads to more needless suffering, instead of fewer headaches (Martin & MacLeod, 2009). Thus, it is not yet clear how the processes underlying CBT lead to improvements in headache-related outcomes.

Further, the few studies that have examined how CBT processes of change variables are related to treatment effects have been criticized for their methodological weaknesses. Very few studies have gathered headache sufferers' data on what is really done in the therapeutic sessions and how this is associated with reported therapeutic processes (Penzien & Irby, 2014). For example, in a research study examining the effects of a CBT in reducing catastrophizing among individuals with migraines, catastrophizing was found to decrease migraine-related disability, and thus it was proposed as a potential mechanism of action for those received the treatment. However, researchers employed a construct assessing coping skills (i.e., a simple count of positive and palliative coping strategies used) rather than a construct of catastrophizing (Seng & Holroyd, 2014). Further, researchers have mostly utilized traditional data analytic approaches (e.g., multiple regressions or analysis of variance; ANOVA) that examine pre-post changes and group mean differences for error variance (Nicholson, Hursey, & Nash, 2005) or investigate moderators that found to be comorbid with headaches (e.g., psychiatric comorbidity; Holroyd, Lobus, & Carlson, 2009), rather than examining the effect of CBT putative mediators on treatment outcomes. By examining mediations, one expects that specific processes of change variables would reflect the indirect, otherwise mediating effects, between the treatment offered to patients (X), and the outcomes (Y) expected of this treatment (Preacher & Hayes, 2008). There is yet no study to examine the putative processes underlying CBT for headaches. Thus, more research is warranted.

Acceptance and Commitment therapy (ACT; Hayes, Strosahl, & Wilson, 2011), an emerging behavioral approach for headaches (Smitherman, Wells, & Ford, 2015), is a form of CBT that, in contrast to its previous predecessors (e.g., cognitive-behavioral stress management therapy), organizes its treatment methods into six putative processes (acceptance, cognitive defusion, present moment, values, committed actions, and self as context; McCracken & Morley, 2014; see table for an explanation of each process). ACT has developed and validated measures to assess these constructs (Scoot & McCracken, 2015). Thus, processes stemming from the ACT approach can be tested in randomized controlled trials, and then examined with mediation methods (Wicksell et al., 2010). This allows for a comprehensive examination of the putative processes that the treatment is designed to target. Therefore, an examination of several ACT processes in predicting changes on treatment outcomes through mediation analyses, can improve treatment methods, maximize outcomes, and highlight the therapeutic components that are responsible for treatment changes (Dindo, 2015; Kazdin, 2007; Smitherman et al., 2015).

ACT proposes increases in psychological flexibility as the primary process by which it achieves its effects (PF; Hayes, Strosahl, & Wilson, 2011). PF is a behavioral pattern, which in the context of chronic pain consists of a willingness to experience pain when attempts at controlling or avoiding pain lead to exacerbating suffering, reduce valued-based actions, and lower moment-to-moment attention in the present moment (Vowles & Thompson, 2011). PF is associated with the six interrelated processes encompassing the ACT approach (McCracken & Vowles, 2014). When these processes work synergistically, for example when acceptance and cognitive defusion lower avoidance and diminish the believability of pain-related thoughts (e.g., "pain makes me handicapped"), then increases in committed actions and valued living result in improving functioning (Thompson & McCracken, 2011; Vowles, Witzkietwitz, Sowden, & Asworth, 2014; Vasiliou, Karekla, Michaelides, & Kasinopoulos, under review). Given that treatment mediator analyses require theoretically driven a priori hypotheses (Vlaeyen & Morley, 2005), it is considered plausible that the theoretically related to the ACT approach processes of changes variables (e.g., acceptance, cognitive defusion, values-based actions, mindfulness, and committed actions etc.), would be a priori treatment mediators to be tested.

To date, several studies in chronic pain demonstrate the effects of ACT-based interventions in mediating functioning, life satisfaction, pain interference and psychological distress, through the ACT processes, such as pain acceptance, psychological inflexibility, and values-based actions (McCracken & Gutierrez-Martinez, 2011; Wicksell,

Olsson, & Hayes, 2011; Wicksell, Olsson, & Hayes, 2010; Vowles, McCracken, & Eccleston, 2007; Vowles, Sowden, & Ashworth, 2014). In headache, there are three cross-sectional studies indicating that higher pain acceptance and values-based actions are associated with lower depression, less headache-related disability and interference, and fewer catastrophizing (Chiros & o'Brien, 2011; Dindo, Recober, Marchman, O'Hara, & Turvey, 2015; Foote, Hamer, Roland, Landy, & Smitherman, 2015). However, no studies have yet examined how the processes encompassing the ACT approach mediate treatment outcomes in headache sufferers. An examination utilizing formal test of mediation is thus warranted.

The aim of the present study was to examine the potential mediating effects of the ACT processes following a feasible ACT RCT trial for community-based sufferers with primary headache diagnoses (see chapter 2). Specific research questions of this study were to:

(1) explore the effects of an ACT-based intervention on headache-related disability and quality of life outcomes through possible treatment mediators associated with the ACT approach (pain acceptance, psychological inflexibility in pain, values obstruction and progress, committed actions, and mindfulness),

(2) examine whether changes in these mediators would predict subsequent changes in headache-related disability and headache-specific quality of life at two-time points: post-treatment and 3-month follow-up.

Method

Participants, Recruitment, and Settings

A full description of participants' recruitment procedures is described in chapter 2. Briefly, 164 individuals with headaches were recruited through postings, announcements, advertisements, and referrals from Neurologists. 94 of them were scheduled for a medical and psychological examination in order to evaluate the inclusion criteria. 61 participants provided data at post-treatment and follow-up 3 months (31 from the ACT and 30 from the WL group). The majority of participants in both treatment groups were women (84%), averaged 43.9 years of age (SD = *10.35*), married (72 %), with an average monthly income around 1000 euro (37%) and held a high or vocational school diploma (37%). For both groups, time since headache suffering onset varied between 1 to 46 years (mean 18.42, *SD* = 10.81) and mean headache duration per month was 9.40/month (*SD* = 7.28; ranged 4 to 30 days/month). Also, most of the participants in both groups, at the time they were asked, received prescribed medication for their headache (83.5%). The study approved by the

Cyprus National Bioethics Committee (reference: ΕΕΒΚ/ΕΠ/2013/05), and the Cypriot office of the Commissioner for personal data protection (reference: 2.0.18/II).

Treatment Protocol

The ACT group received 9 sessions based on an ACT protocol developed for the aims of this study. The full ACT treatment protocol consisted of a therapist manual, a complementary participants Action Plan (AP) workbook and two CDs with mindfulness exercises (Vasiliou & Karekla, 2015). The primary purpose of this protocol focused at altering responses to head pain, with the aim to decrease disability, increase physical and psychological functioning, and improve the quality of life of headache sufferers. The new protocol was developed to be consistent with the ACT approach and with the aim to increase functioning and reduce headache-related disability. The 1 ½ hours, weekly treatment sessions were conducted in groups of approximately 8-10 participants and two co-therapists. Therapists were doctoral Clinical Psychology Trainees who were trained (> 25 hours training) in the ACT approach. Therapists' adherence and treatment fidelity were ensured by manualization of the treatment components and with fidelity checks, in which an independent to the study registered Clinical Psychologist rated a sample of 14 ACT tapes to assess whether therapists completing the material covered in each session.

Participants randomized to the WL group did not receive any medication as part of the study aims, and were informed from the beginning that they would receive the intervention with a 4–month delay. During the waiting period, participants in the WL group were asked to continue their medical treatment as prescribed by the treating physician and to report to the researchers if any changes to the medications needed to be made. Also, participants in the WL group were contacted four times by telephone so as to maintain contact, answer any questions, and ensure the stable continuation of headache pharmacotherapy. Upon completion of the ACT group 3-month follow-up, the WL group was enrolled to receive the ACT intervention.

Assessment Procedures and Measures

Both groups completed the same assessments across three-time points: pre-treatment (assessment session; Time [T1]), post-treatment [T2], and at 3-month follow-up [T3]. All measures were selected with regard to the recommendations given by the Initiative on Methods, Measurements, and Pain assessment in Clinical Trials group (IMMPACT; Dworkin et al., 2005), and the guidelines for the design of clinical trials evaluating behavioral headache treatments (Penzien et al., 2005). The primary outcomes

included scales assessing headache-related disability and headache-specific quality of life dimensions.

Treatment Outcomes

The Henry Ford Hospital Headache Disability Inventory (b-HDI; Jacobson, Ramadan, Aggarwal & Newman, 1994) is a 25-item measure, divided into two scales: functional (HDI- Func; 13 items) and emotional (HDI- Em; 12 items) disability, and evaluates the effect of a headache on daily activities (e.g., 'Because of my headache I am less likely to socialize'). Answer choices are "yes" = 4 points, "sometimes" = 2 points, and "no" = 0 points. Higher scores indicate greater disability. b-HDI has demonstrated high reliability (Cronbach's alpha = .84), and sufficient validity with theoretically-related scales. Cronbach's alpha for this study were: .93 for the total score, .88 for the functional and .87 for the emotional subscales.

The Migraine-Specific Quality of Life Questionnaire version 2.1 (MSQ v 2.1; Martin, Pathak, Sharfman, Adelman, Taylor, Kwong et al., 2000; use permission received from GlaxoSmithKline; GSK USMA health outcome group) is a 14-item scale assessing the impact of migraine on patients' quality of lives over the past four weeks on a 6-point Frequency-type scale, with 1 = none of the time and 6 = all of the time. Prior to the use of this scale, some items were slightly modified (i.e., the word "migraine" was substituted with the word "headache") in order to be more broadly applicable for all primary headache diagnoses, not only migraines (no differences in reliability were found between migraineurs and other primary headache diagnoses). The scale primarily assess the subjective reaction of sufferers to their head pain experience through three dimensions: (a) Role Restrictive (MSQ-RR; 7 items), assesses the degree to which performance of daily activities are limited by headaches, (b) Role Preventive (MSQ-RP; 4 items), assesses the amount of normal activities interrupted by headaches, and (c) Emotional Function (MSQ-EF; 3 items), assesses the degree to which emotional reactions (e.g., frustration) affect headaches. Each of the three dimensions is scored following a two-step approach. First, all items are reversed so that higher scores indicate a higher quality of life. Raw scores are converted to a 0-100 scale so that each dimension score reflects the percentage of the total possible score achieved by participants. MSQ presents with adequate psychometric validity and reliability (Cronbach's alphas = .86-.96) across different headache groups (Cole, Lin & Rupnow, 2007; Rendas- Baum, Bloudek, Maglinte & Varon, 2013). Cronbach's alphas for the current study were .93 for the MSQ-RR, .87 for the MSQ-RP, and .83 for the MSQ-EF.

Hypothesized Mediators

Potential mediators included the following variables: pain acceptance (CPAQ), psychological inflexibility in pain (PIPS), committed actions (CAQ), values-based actions (VQ), and mindfulness (CAMS-R). The selection of CPAQ and PIPS-II was based on previous research proposing that these measures are psychometrically sound for use with head pain populations (e.g., Dindo et al., 2015; Foote et al., 2015; Vasiliou et al., in preparation). All the other measures were selected based on prior psychometric research conducted in chronic pain populations (Scott & McCracken, 2015).

The Greek Chronic Pain Acceptance Questionnaire (G-CPAQ; Vasiliou, Karekla, Kasinopoulos, & Michaelides, under review; Original: McCracken, Vowles, & Eccleston, 2004) assesses pain acceptance in two sub-factors: activity engagement (G-CPAQ-AE;4 items), indicating the degree to which participants engage in meaningful activity even in the presence of pain; and pain willingness (G-CPAQ-PW;4 items), assessing the degree to which individuals experience pain without trying to change, control, or struggle with it. The G-CPAQ is rated on a 7-point frequency-type scale (1 = "never true" to 6 = "always true") and yields a total sum. Higher scores denote greater AE and PW. The G-CPAQ presents with high reliability (alpha = .80) and adequate construct validity with theoretically related constructs. Cronbach's alpha for this study was .78 for the total score, .83 for AE and .63 for PW, which is similar to the original scale (.78 for the total score, .82 for AE, and .78 for PW).

*The Greek Psychological Inflexibility in Pain Scale (*G-PIPS-II; Vasiliou, Karekla, Michaelides, & Kasinopoulos, in preparation; Original: Wicksell, Lekander, Sorjonen, & Olsson, 2010*)* contains 12 items assessing psychological inflexibility in two subscales: a) avoidance of pain (G-PIPS-avoid; 8 items), examining behaviors that lead to avoidance of pain and related distress; and b) cognitive fusion (G-PIPS-fus;4 items), assessing how patients' thoughts about an event can lead to avoidance of pain or distress. Items are rated on a 7-point frequency-type scale, with 1 = "never true" and 7 = "always true". The scale shows good psychometric properties (Wicksell et al. 2010). Also, PIPS-II yielded a similar factorial structure in its Greek version (G-PIPS-II), and showed signs of group invariance when examined with different chronic pain populations (headaches; Vasiliou et al, in preparation). Cronbach's alpha for this study was .90 for the total score, .90 for avoidance and .68 for the Fusion subscales, which is similar with the original version (.89 for the total scale, .90 for avoidance, and .75 for cognitive fusion).

Committed Action Questionnaire (CAQ; McCracken et al., 2014), is an 8-item scale assessing goal- directed behaviors (McCracken, 2013) in two sub-scales: a) 4 positively worded items (e.g., "I prefer to change how I approach a goal rather than quit"), and b) 4 negatively worded items (e.g., "If I cannot do something my way, I will not do it at all) of committed actions. Items are rated on a frequency-type scale from 0 = never true to 6 = always true. Negatively word items are reversed so as to reflect higher levels of committed actions. A total score from the two subscales reflects an individual's tendency to persist in values-driven behaviors. CAQ presents with high reliability (alpha = .87) and sufficient validity with other related instruments, including pain acceptance, depression, and functioning (McCracken et al., 2014). Cronbach's alpha for this study was .80 for the total score, .92 for the positively worded committed action items and .71 for the negatively committed action items.

The Valuing Questionnaire (VQ; Smout, Davies, Burns, & Christie, 2014), is a 10-item instrument assessing the extent to which individuals acted based on personal values during the past week in two dimensions: progress in identified values (VQ-Pr; 5 items, e.g., "I worked toward my goals even if I didn't feel motivated to do so"), and obstruction of valued living (VQ-Ob; 5 items, e.g., "When things didn't go according to plan, I gave up easily"). Items are rated on a 7-point Likert scale with 0 = not at all true and 6 = completely true. Higher scores in the progress sub-scale represent pursuing valued living, whereas higher scores on the obstruction subscale indicate psychological barriers (e.g., disturbing thoughts, emotions, sensations, etc.) in pursuing valued living. VQ demonstrate good convergent validity and high reliability (alpha = .87 for each subscale; Smoot et al., 2014). Cronbach's alpha for this study was .62 for obstruction and .87 for progress. The low variability in obstruction subscales warrants further research, thus any conclusion derived from this factor should be interpreted with caution.

The Cognitive Affective Mindfulness Scale Revised (CAMS-R; Feldman, Hayes, Kumar, Greeson, & Laurenceau, 2007) is a 12-item self-report questionnaire assessing affective and cognitive components of mindfulness. Items are rated on a 4-point Likert scale from 1 = "rarely" to 4 = "almost always". CAMS-R yields four factors, however, the authors suggest the use of its total score that assesses a general mindfulness level (Feldman et al., 2007). CAMS-R presents with high reliability (alpha = .81) and adequate construct validity. The Greek version presents with similar to original unitary factor structure, high reliability (alpha = .88) and adequate construct validity with other scales. Cronbach's alpha for this study was .86.

Data Analyses Plan and Statistical Procedures

Mediation Analysis

Mediators have been traditionally examined using the Baron & Kenny (1986) casual step method. New methods, however, such as the cross-product of the coefficients approach, are now widely used in behavioral research therapy (Donaldson, 2001). These methods are more robust than the traditional Baron & Kenny (1986) four casual steps, particularly in RCT designs examining processes related to treatment effects (see MacKinnon, Fairchild, & Fritz, 2007 for a review). In examining indirect effects, one expects that targeted mediating variables (M) will exert an effect on a relation between an independent (X) and a dependent (Y) variable (Kazdin & Nock, 2003). Thus, mediation represents the addition of a third variable to this X→ Y relation, in which X impacts the mediator (M), and M impacts Y, so X→M→ Y. Figure 8 depicts the classical mediation model (adapted from Baron & Kenny, 1986).

Overview of Statistical Analyses

First, a series of *t*-tests for independent samples with Bonferroni corrections were executed so as to evaluate the comparability of the two groups on primary outcomes and process variables. Then, bivariate Pearson correlations coefficients between primary outcomes (dependent variables) and hypothesized mediators were estimated to explore the interrelated pattern of correlation and to examine multicollinearity. Third, mediation analyses using the simple mediation model of Preacher & Hayes (2004) were executed to examine whether treatment effects on primary outcomes would occur through targeted mediators.

The simple mediation analysis of Preacher & Hayes (2004) method utilizes the cross- product of the coefficient approach. According to this approach, the coefficient value derived from the differential impact of the two interventions (coded as ACT = 0 vs. WL = 1) on the mediator (the a path; see figure 9), is multiplied (bootstrapped) by the coefficient value derived from the relation between the mediator and the primary outcome (the b path), but controlling for X (the c' direct path when a mediator has been added to the model). Mediation is also entitled indirect effect, and it is thought to occur if the strength of the relation between the predictor and outcomes (this is the c path) is reduced by including the mediator. In mediation analysis the c equals with the c'+ ab. The indirect effect (ab) is the measure of the amount of mediation and represents the targeted value of the analysis. Figure 10 depicts the hypothesized mediation model.

Indirect effects of mediators were examined with a non-parametric bootstrap approach to the cross product coefficient test across all analyses. There are two reasons explaining why a non-parametric approach was chosen. First, the a*b distribution frequently violates the assumption of normality, thus a non-parametric approach controls for the a*b deviation from normality (Baron & Kenny, 1986; MacKinnon, Lockwood, Hofmman, West, & Sheet, 2002). Second, given the small sample size of this study, a non-parametric bias corrected bootstrap approach increases statistical power, and warrants the validity of findings (Hayes & Scharkow, 2013).

For the aims of this study, a cross product of the coefficients with 5000 bootstrap resampling was used to evaluate the mean value for the a*b product (and the obtained score distribution) across the conditions (ACT vs. WL). Given that the mean of the bootstrap distribution does not equate the mean of the indirect effect (the function of the a and b), corrections for bias are estimated. The a*b product calculates a point estimate of the indirect effect and the confidence intervals of these effects at BCa; 95% CI (Bootstrap distribution in adjusted for bias and skewness at ninety-five percentage confidence interval equates $p < .05$; Preacher & Hayes, 2008). If lower and upper bounds of these confidence intervals do not include zero, then the indirect effects are significant at the level values indicated in analyses (at BCa 95%). Given that mediating indirect effects are generally interpreted not by their significant levels at specific *p* values, as this interpretation warrants cautious (Falk, & Biesanz, 2016), the interpretation of these findings was based on the BCa 95%.Finally, normal theory (Sobel) test was also examined (*z* scores), but the interpretation of indirect effects was based on confidence intervals not containing zero, rather than the formal tests of significance (Shrout & Bolger, 2002).

In the present study, the hypothesized mediators were selected based on the timeline criterion (i.e., mediators always come between what they mediate and the outcome; Kraemer, Wilson, Fairburn, & Agras, 2002). Operationalizing the timeline criterion, one can be more confident that mediators were not arbitrarily chosen based on researchers' preferences and biases, but they were selected based on a-prior-decisions relevant to the underlying theoretical rationale (Kraemer et al., 2002). Thus, post-treatment scores were used as mediators and change scores for the outcomes. Although many studies utilize change scores to assess treatment mediators, in this study post-treatments scores were chosen instead (see Wicksell et al., 2011 for a similar approach). The argument for selecting post instead of change scores to assess the mediators lies on the ACT approach which is interested in examining more how flexible individuals become (i.e., ACT assumes that individuals have different levels of flexibility to facilitate), rather examining how

individuals change on their levels of psychological flexibility from pre-to post assessment periods. Indeed, ACT researchers study individuals' patterns of behaving and how these patterns result in specific outcomes (e.g., adaptive functioning etc.), rather than differences in the six ACT processes from pre to post-treatment levels (Ciarrochi, Bilich, & Godsell, 2010). For example, low pain acceptance does not direct link with low disability. Rather, disability results due to ineffective response to headache that promotes low acceptance toward head pain. Hence, the ACT approach seeks to predict and influence individuals' levels of the six processes (e.g., committed actions) in way that that this prediction and influence facilitate individuals' psychological flexibility (i.e., how individuals' behaviors lead them to promote valued-based actions, rather than reduce the pain), not merely increases individuals' levels of the ACT processes per se.

For these reasons, the use of post- instead of change scores for the putative mediators was thought to more succinctly represent the aim of the ACT approach, and thus post-treatment scores were used. . Also, utilizing post-treatment scores ones can increase clarity of the results. Prior to running the main simple mediation analyses, a set of preliminary analyses were conducted to ascertain that this choice of utilizing post-treatment instead of change scores for mediators did not result in different pattern of results. In these set of analyses, instead of utilizing pre to post outcomes' change scores, the post-treatment (T2) and 3-month follow-up (not change) scores (T3) were used, but controlling for the pre-treatment outcome scores [T1]. In these analyses, the T2 scores of the following variables: pain acceptance (G-CPAQ), psychological inflexibility in pain (G-PIPS-Total), avoidance of pain (G-PIPS-av), fusion with pain-related thoughts (G-PIPS-fus.), committed actions (CAM), values progress (VQ-Pr), values obstruction (VQ-Ob.), and mindfulness (CAMS-R) were used as mediators; the T2 and T3 headache-related disability (HDI) and quality of life (MSQ) (not pre to post or pre to follow-up change) scores as outcomes; and the T1 scores of HDI and MSQ as covariates. Mediators were examined one at a time, and with, and without, the T1 scores of HDI as covariate.

For the main mediation analyses, the hypothesized mediators included the post-treatments' (T2) mean scores of the following variables, reflecting the six processes of the ACT approach: pain acceptance (G-CPAQ); psychological inflexibility in pain total (G-PIPS); avoidance of pain (G-PIPS-avoid); pain fusion (G-PIPS-fus); committed actions (CAQ), values progress (VQ-Pr.), values obstructions (VQ-Ob), and mindfulness (CAMS-R)[1]. For the outcomes, pre to post- outcomes' (T1-T2) change scores, and pre- to 3-month follow-up outcomes' (T1-T3) scores were calculated. Running multiple mediations was unwarranted due to a small number of participants in each group. Thus, simple mediations

were executed separately for each putative mediator. To reduce the possibility of statistical errors in running multiple simple mediation analyses, a stricter 95%, instead of 90%, BCa CI was set for interpreting the indirect effects. Analyses were examined in two ways: (a) in terms of the effects of treatment on outcomes' (HDI and MSQ) pre to post change scores (T1-T2) through all the possible mediators, and (b) in terms of the effects of treatment on outcomes' pre to 3-month follow-up change scores (T1-T3) through the same possible mediators (see figure 10).

All analyses were performed with SPSS version 22, utilizing the macros for bootstrapping procedures downloaded from http://www.afhayes.com/spps-sas-and-mplus-macros-and-code.html. Missing values were not manipulated in any way, as any form of imputation was unwarranted. Interpretation of findings was executed setting the statistically significant change at $p < .05$ = significant. The exact p values were reported to allow examination of results with a critical interpretation (Greenwald, Gonzales, Harris, & Guthrie, 1996).

Results

Initial Analyses

Independent t-test & Pearson's Coefficient Correlation Analyses

Given that demographics and main findings from the ACT RCT for primary headache sufferers were presented in chapter 2, this information is not presented here. First, *t*-tests for independent samples were executed so as to evaluate the comparability of the two groups on primary outcomes and mediators. For each series of *t*- tests (i.e., primary outcomes and mediators) a modified Bonferroni procedure was employed in order to control for bias of running multiple analyses; for the treatment outcomes, $p <$. 004 (.05 divided by the 12 outcome variables), and for the mediators, $p < .006$ (.05 divided by the 8 process variables). As table 7 presents, there were significant differences of ACT, compared to WL group in headache general disability and functional disability variables at T1-T2 and T1-T3 change scores. All the other variables were not statistically significant when the data examined with Bonferroni corrections at p < 004 cut off point. The effect sizes for the majority of headache-related outcomes were medium to large (Cohen *ds* ranging from .36 to .83)..

For the three dimensions assessing headache-specific quality of life (MSQ), when the ACT was compared with the WL group, there were no significant findings at T1-T2 or T1-T3 change scores for any of the quality of life dimensions (Bonferroni corrections at p

< .004 cut off point). However, when the data examined without the Bonferroni cut off point, significant findings were found for the emotional dimension of the quality of life (MSQ-EM, p < .03) at T1-T3 change scores, the role restrictive dimension (MSQ-RR, p < .008) and role preventive dimension (MSQ-RP, p < .02) at T1-T3 change scores. The effect sizes for the significant dimensions were medium Cohen *ds* ranging from .21 to .70*)*.

Significant group differences with large effect sizes (medium for values obstructions), based on Bonferroni corrections, were also observed for five mediators at T2 (see table 7; pain acceptance, psychological inflexibility, avoidance of pain, fusion with pain-related thoughts, values obstruction). For three mediators (committed actions, value progress, and mindfulness), results were significant, thought, they did not reach the cut-off point of $p < .006$. Notably, pain acceptance and psychological inflexibility in pain marked the largest effect sizes (Cohen $d = 1.17$ and $d = 1.05$, respectively).

To examine the pattern of interrelations between mediators (T2) and dependent variables (T1-T2 and T1-T3 change scores in outcomes), Pearson's coefficient correlation analyses were executed. Table 8 presents the results of correlation analyses. Overall, correlations were in the expected directions, and mutlicollinearity was not found to be the case for any correlation among the examined variables. Pain acceptance, psychological inflexibility in pain, avoidance of pain, and values progress significantly correlated with all headache-related disability at T1-T2 change scores (*r* ranging from .24 to -.39) and at T1-T3 change scores (*r* ranging from .24 to -.38). Fusion with pain-related thoughts also significantly correlated with the headache-related disability scales. (*r* ranging from -.24 to .27), and so did values obstruction (*r* ranging from -.25 to .30, $p < .01$) Finally, no significant correlations between headache-related disability and mindfulness were observed.

For the quality of life scale (MSQ), pain acceptance, psychological inflexibility in pain, and avoidance of pain correlated significantly with the role restrictive dimension (RR-MSQ) of the headache-specific quality of life scale at T1-T2 change scores (*r* ranging from .28 to .38). Also, pain acceptance correlated with the emotional role dimension (EM-MSQ) of the headache-specific quality of life scale at T1-T3 ($r = .23$, $p < .05$). Committed actions, values progress, and values obstruction correlated with the role restrictive dimension (RR-MSQ) of the quality of life scale at T1-T3 (*rs* =.-.27,-.27, and .28, *ps* < 05). Values obstruction and mindfulness did not correlate with any of the headache-specific quality of life outcomes.

Effects of Mediators on Outcomes Controlling for Pre-treatment Outcomes

Before running the simple mediation analyses, a series of preliminary analyses were executed to examine whether utilizing instead of change scores of outcomes, the post and 3-month follow-up scores controlling for the pre-treatment scores. These preliminary analyses were then compared with the main simple mediation analyses, in order to ascertain whether the researchers' choice of utilizing post-treatment for mediators, instead of change scores present similar findings with the ones from the main simple mediation analyses.

Effects of Mediators on Post-treatment (not change) Scores [T2] of the Headache-related Disability Scale (HDI), Controlling for the Effects of [T1] HDI Scores

Findings demonstrated that when T1 HDI scores were controlled for (entered as covariates), pain acceptance, psychological inflexibility in pain, avoidance of pain, pain fusion, committed actions, and values obstruction, all mediated the effects of treatment on headache-related disability at T2 (HDI-Total; HDI-Func.; HDI-Em; BCa 95% CI). Additionally, values progress mediated the effects of treatment on general headache-related disability at T2 (BCa 95% CI). When the mediations examined without controlling for the T1 HDI scores, there was a similar pattern of mediation as previously described.

Effects of Mediators on 3-month Follow-up (not change) Scores [T3] of the Headache-related Disability Scale (HDI), Controlling for the Effects of [T1] HDI Scores

Findings demonstrated that when T1 HDI scores were controlled for (entered as covariates), pain acceptance, psychological inflexibility in pain, avoidance of pain, and committed actions mediated the effects of treatment on headache-related disability at T3 (HDI-Total; HDI-Func.; HDI-Em; BCa 95% CI). Further, fusion with pain-related thoughts mediated the effects of treatment on emotional headache-related disability at T3 (HDI-Em.; BCa 95% CI). When the mediating variables were examined without controlling for the T1 HDI scores, there was a similar pattern of mediations, as previously presented, including also the mediating effects of values obstructions on headache general and functional disability.

Effects of Mediators on Post-treatment (not change) Scores [T2] of the Headache-specific Quality of Life Scale (MSQ), Controlling for the Effects of [T1] MSQ Scores

Findings demonstrated that when the T1 MSQ scores were controlled for (entered as covariates), pain acceptance, psychological inflexibility in pain, avoidance of pain, and committed actions, mediated the treatment effects on the three headache-specific quality of

life dimensions at T2 (MSQ-RR; MSQ-RP; MSQ-EM; BCa 95% CI). When the data examined without controlling for T1 MSQ scores, results showed a similar pattern of findings, as previously presented, including the mediating effects of pain fusion, and values obstruction on the three quality of life dimensions of the MSQ scale at T2 scores (at BCa 95% CI).

Effects of Mediators on 3-month Follow-up (not change) scores [T3] of the Headache-specific Quality of Life Scale (MSQ), Controlling for the effects of [T1] MSQ Scores

Findings present that when the T1 MSQ scores were controlled for (entered as covariates), pain acceptance, psychological inflexibility in pain, avoidance of pain, and committed actions mediated the treatment effects on the role preventive dimension of the quality of life scale (MSQ-RP; BCa 95% CI). Also, avoidance of pain, fusion with pain-related thoughts, and committed actions mediated the effects of treatment on the role preventive dimension of the quality of life scale (MSQ-RP; BCa 95% CI). Finally, psychological inflexibility in pain, avoidance of pain, committed actions, and values obstruction mediated the effects of treatment on the role emotional dimension of the quality of life scale (MSQ-EM; BCa 95% CI).

When the data examined without controlling for T1 MSQ scores, results showed mediating effects of treatment on the role restrictive dimension of the quality of life (RR-MSQ; BCa 95% CI), through all the mediators, expect for values progress and mindfulness. Next, mediating effects of treatment on the role preventive dimension of the quality of life scale (RP-MSQ; BCa 95% CI), through psychological inflexibility in pain, avoidance of pain, and committed actions were observed. Finally, mediating effects of treatment on the emotional role dimension of the quality of life scale (EM-MSQ; BCa 95% CI), through psychological flexibility in pain, avoidance of pain, fusion with pain-related thoughts, and committed actions were also noted.

Examining Indirect Effects (Mediation Analyses)

Tables 9 and 10 present the indirect effects of treatment (ACT vs. WL) on the headache-related disability scale and its subfactors (HDI), through the examined mediators (CPAQ, PIPS-Total, PIPS-Av, PIPS-Fus, CAQ, VQ-Pr., VQ-ob., and CAMS-R). Likewise, table 11 and 12 illustrate the indirect effects of treatment on the headache-specific quality of life dimensions (MSQ), through the same possible mediators as previously presented. The mediating effects were examined at T1-T2 and T1-T3 change scores for the two headache-related outcomes.

Effects of Mediators on Pre and Post Change Scores [T1-T2] of the Headache-related Disability Outcome

Pain acceptance, psychological inflexibility in pain, avoidance of pain, and values progress, all significantly mediated the effects of treatment on general headache-related disability and functional disability (HDI- Func.) at BCa 95% CI (see table 9). Also, treatment mediated the effects of functional disability levels through values obstruction. No mediating effects of treatment were found for mindfulness. Figure 11 and figure 12 illustrate the mediation paths.

Further mediating effects of treatment on emotional headache-related disability (HD-Em) were found for pain acceptance, psychological inflexibility in pain, and avoidance of pain at BCa 95% CI. No mediating effects were observed for pain fusion, committed actions, values progress, values obstruction, and mindfulness. Table 9 presents the results from the mediation analyses, and figure 13 illustrates the mediation paths.

Effects of Mediators on Pre and 3-month follow-up Change Scores [T1-T3] of the Headache-related Disability Scale

As for the effects of the putative ACT mediators on headache-related disability at 3-month follow-up, only values progress was found to mediate the effects of treatment on headache-related functional disability scale (HDI-Func.) at BCa 95% CI. All the other mediators did not mediate the effects of treatment on headache-related disability (in the three subscales) at T1-T3 change scores. Table 10 presents the results from the mediation analyses, and figure 14 illustrates the mediation path.

Effects of Mediators on Pre to Post-treatment Change Scores [T1-T2] on Headache-Specific Quality of Life Outcomes (MSQ)

There were mediating effects of treatment on the role-restrictive dimension of the quality of life scale (MSQ-RR) at T1-T2 change scores, through pain acceptance, avoidance of pain, and values progress at BCa 95% CI. Also, mediating effects of treatment on emotional role dimension of the quality of life scale (MSQ-EM) were observed through values progress at BCa 95% CI. There were no other mediating effects of treatment on headache-specific quality of life scale. Table 11 presents the indirect effects, and figure 15 illustrates the mediation paths.

Effects of Mediators on Pre to 3 Months Follow-up Change Scores [T1-T3] on Headache-Specific Quality of Life (MSQ)

There were mediating effects of treatment on the role restrictive dimension of the quality of life scale (RR-MSQ) at T1-T3 change scores, through psychological inflexibility in pain, and pain avoidance at BCa 95% CI. Also, at T1-T3 change scores mediating

effects of treatment on emotional role dimension of the quality of life (EM-MSQ) through value progress and value obstruction at 95% CI were also observed. There were no other mediating effects of treatment on the quality of life scale, through any of the mediators examined. Table 12 presents the indirect effects and figure 16 & 17 illustrate the mediation paths. In sum, findings from both the preliminary analyses and the main simple mediation analyses demonstrate a similar pattern of results. This provides additional support for the mediating effects of the ACT treatment on headache-related outcomes. Also, results from these mediating effects strengthen the theoretical argument of ACT for using post-instead of change scores for mediators.

Discussion

Studies examining treatment mediators in relation to the ACT approach and head pain adjustment variables are of crucial theoretical and clinical importance. These studies can provide a better understanding of how the mechanism underlies the ACT approach facilitates head pain adjustment. This can also inform researchers and clinicians about therapeutic processes (e.g., values, acceptance, etc.) that can effectively influence behavioral outcomes (e.g., patients' functioning). To date, there are few clinical trials examining the efficacy of ACT for headache sufferers, and no studies exploring how ACT for head pain achieves its effects on headache-related outcomes through ACT-theoretically-based mediators. Following a previous reported RCT examining the efficacy of ACT for primary headache sufferers (chapter 2), a set of separate analyses were conducted to evaluate the effects of ACT on headache treatment outcomes through hypothesized mediators. This study examined whether changes in the ACT processes (e.g., increases in acceptance and values-based actions, reductions in avoidance of pain in fusion with pain-related thoughts, etc.) predicted lower disability, increased functioning, and improved quality of life at pre to post-treatment outcomes change scores and pre to 3-month follow-up outcome change scores. In sum, findings provide support for the study hypotheses.

In terms of treatment outcomes, the ACT group demonstrated significant improvements in headache-related disability and headache-specific quality of life compared to the WL group at post-treatment, and at 3-month follow-up. In regard to treatment mediators, findings show that improvements in the ACT processes were unanimously mediated by the effects of treatment on headache-disability for the ACT group when compared to the WL group. Higher pain acceptance, lower psychological inflexibility in pain, less pain avoidance, and increases in values-based actions all mediated

headache-related general, functional, and emotional disability subscales at post-treatment and at 3-month follow-up. Cognitive fusion, values obstruction, and mindfulness did not mediate the effects of the ACT treatment on any headache-related disability scale.

Differential effects of treatment on ACT group, compared to the WL group on headache-specific quality of life outcomes, were also mediated by several ACT-theoretically-based processes. Results demonstrate mediating effects of treatment on quality of life outcomes through changes in pain acceptance, psychological inflexibility, avoidance of pain, and values-based action for the ACT group compared to the WL group. For instance, improvements in psychosocial functioning (e.g., increases in daily activities that had been previously restricted due to headaches) and emotional functioning (e.g., reductions in frustration, hopelessness, guilt etc.) occurred due to changes in pain acceptance, values-based actions, and avoidance of pain. Of note is that at 3 month follow-up, value progress and obstruction were both mediated the effect of treatment on emotional dimension of the quality of life scale supporting that the ACT treatment increases emotional functioning by making sufferers pursue their values. Contrary to our hypotheses, there were no mediating effects of treatment on headache-specific quality of life dimensions at post-treatment and 3-month follow-up through changes in fusion with pain–related thoughts, committed actions, and mindfulness.

Given the results presented here, this study proposes three sets of findings that are noteworthy. First, reducing avoidance and inflexibility in pain may be particularly helpful processes in situations where the performance of daily activities (e.g., leisure activities, hobbies, professional tasks, daily errands) is restricted due to headaches. Second, increasing head pain acceptance and promoting values-based actions may be useful therapeutic aims in situations where headaches cause significant impairments on sufferers' emotional functioning (e.g., the emotional effects of headaches, such as distress and frustration). Third, given that pain acceptance mediated the effects of treatment on headache-related disability and quality of life mostly at post-treatment assessment, and valued-based action at 3-month follow-up, a treatment component delivery can be proposed. For example, targeting pain acceptance early as treatment unfolds, when sufferers present with strong avoidance patterns, may increase their psycho-social functioning and motivate them to pursue their value-based actions in the long-run. Overall, the current findings add to the existing scarce literature, and highlight key functional pathways that are responsible for improvements in headache-related outcomes.

To our knowledge, this is the first study to explore the mediating effects of ACT processes on headache sufferers' disability and quality of life. Findings are consistent with

the theoretical underpinnings of ACT for headaches that postulate that inflexible way of coping with headaches and headache triggers (e.g., avoidance) may not be helpful in promoting psychosocial functioning, and may result in restricting life and diminish value-based actions. On the contrary, when responding to head pain with flexibility, valued living, and with an open and conscious stance to experience pain without trying to control or avoid it (Hayes et al., 2013), sufferers results in better head pain adjustment even when the experience of head pain remains relative stable (Dindo, Recober, Marchman, O'Hara, & Turvey, 2014; Foote et al., 2015). Providing that numerous headache sufferers may never succeed in becoming permanently pain-free, maximizing acceptance and values-based actions and minimizing head pain avoidance and inflexibility appear to provide the necessary solutions to dealing with headaches. Acceptance & Commitment Therapy interventions, indeed, target these processes in treatment, and evidence from this study adds to previous findings providing support for the use of ACT in alleviating pain-related suffering (see Smitherman et al., 2015 for a review).

Findings of this study should be interpreted in light of a few limitations. First, the sample size was relatively small, and this limits the power of findings and the possibility of running multiple mediation analyses. Thus, exploratory mediation analyses were executed investigating the effect of treatment on outcomes through separated models for each process. Second, given the community-based sample used in this study, the generalizability of these findings to other headache populations with comorbidities or other medical complexities should be considered with caution. Third, the use of retrospective self-reports and the overlapping content in some of their items used in this study (e.g., G-CPAQ, G-PIPS-II and HDI) may have inflated the relations among the examined mediators with the outcomes. This may be a result of a shared method variance in the examined constructs and not due to true responses of individuals in each construct. Finally, even though efforts were made to investigate temporal relations between the ACT putative processes and treatment outcomes, a method which is rarely met in mediation studies assessing therapeutic processes (Kazdin, 2007); the exploratory nature of this study does not allow conclusions about causality.

Coupled with these limitations, this study has notable strengths. For the first time in headache literature functional paths from treatment to outcomes are specified. This can have translational value as specific therapeutic paths can be suggested. One such functional path highlights that psychological inflexibility acted as mediator of treatment outcomes for sufferers who scored high in disability and low in role restrictive dimension of the quality of life scale before treatment. This finding is in accordance with findings from multiple

open trials that demonstrate mediating effects of ACT processes of change variables between ACT-based interventions and treatment outcomes. Findings from chronic pain (McCracken & Gutierrez-Martinez, 2011; Wicksell et al., 2009; 2010), and other conditions in behavioral medicine, such as tinnitus (Westin, Hayes, & Andersson, 2008), diabetes (Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007), vascular diseases (Dindo, Marchman, Grindes, & Fiedorowicz, 2015), epilepsy (Lundgren, Dahl, & Hayes, 2008), weight loss (Lillis, Hayes, Bunting, & Masuda, 2009), and irritable bowel syndrome (Ljotsson, Hesser, Andersson, Lindfors, Hursti, Ruck et al., 2013) all consistently show that increases in psychological flexibility are associated with better illness adjustment. Accordingly, findings from this study also demonstrated that psychological inflexibility mediated treatment effects in headache sufferers.

The central role of psychological inflexibility in pain and its contribution to disability among headache sufferers highlights the need for a better understanding of the ACT processes impacting headache-related outcomes. Notably, the ACT theoretical framework is interested in making sufferers more psychologically flexible in pain, rather than make them change pain-related outcomes (e.g., catastrophizing, locus of control, etc.). Recognizing how psychological inflexible in pain sufferers become, may assist practitioners in targeting more explicitly on processes appear to be problematic (e.g., cognitive fusion, pain avoidance, lack of value clarification), and then assist sufferers in reaching an optimal, long-lived, head pain adjustment, even when pain is present.

Specific pathways, as the ones presented here, may guide headache practitioners to help sufferers become more psychological flexible with their pain. From an ACT perspective, goals reflect behavioral repertoires (i.e., what individuals do with their pain) facilitating willingness to experience pain when attempts at controlling or avoiding pain lead to exacerbate suffering, reduce valued-based actions, and lower moment-to-moment attention in the present moment (Vowles & Thompson, 2011). Thus, findings from mediation analyses can have a high practical value for clinicians as they guide them in an empirically supported way to enhance specific paths that increase effective behavioral repertoires (e.g., pain acceptance, values-based actions) that lead to better daily functioning. Finally, given that the findings from the mediation analyses were identical, when the mediating paths examined utilizing change scores and post/follow-up scores; an incremental support to the issue of temporarily can be credited. It is possible that headache-related disability and quality of life outcomes to be functionally related with pain acceptance and psychological inflexibility, and that change in these mediators to be a plausible mechanism of change,

Future studies should replicate and extend these findings with higher powered sample sizes to ascertain generalizability and validity of the ACT putative processes of change for head pain management. Also, research may examine mediators at multiple time points during treatment, and then investigate how those improvements may be related to headache outcomes over time (e.g., at 3 or 12-months follow-up). Next, the examination of the effects of moderators found to co-occur with headaches (e.g. psychiatric comorbidity, high body mass index; BMI; Chai, Peterlin, Scher, & Sacco, 2017) or other moderators related to treatment (e.g., treatment expectations, therapists' competence etc.;Rief & Glombiewski, 2016) may result in more personalized treatment components for certain subgroups of headache sufferers. Likewise, an examination of other mediators not examined in this study (e.g., catastrophizing, self-efficacy, etc) can ascertain whether the findings are accounted exclusively due to the proposed mediators or other mechanisms. Findings from mediation and moderation analyses, can provide a better understanding of how behavioral headache treatment works, and guide future research on how better head pain adjustment is achieved through a flexible responding to pain.

In conclusion, results from this study provide strong support for the proposed mechanism of psychological flexibility in pain that aims to reduce avoidance and fusion with pain-related thoughts through, pain acceptance, and engagement in personally meaningful actions. Findings from the present study demonstrate that improvement in disability, functioning, and quality of life for headache sufferers was primarily carried out due to the mediating effects of pain acceptance, psychological inflexibility, and values progress. These findings add to the existing evidence providing support for the theoretical underpinning of the ACT approach, which postulates that by focusing on optimizing head pain adjustment, instead of preventing or controlling the experience of pain, sufferers can better manage the degree to which headaches interfere with their daily functioning.

Footnotes:

Study 2

1. A multilevel collaborative European funded research project named "Algea" investigating critical factors in pain adjustment, and testing novel psychological treatments in chronic pain (Karekla et al., accepted).
2. The only difference between the completers and ITT data analyses was found on HADS-anxiety (secondary outcome) wherein single degree of freedom interaction contrasts at completers for the ACT group showed lower anxiety [HADS-Anx; F (1, 54) = 8.78, p< .01, η_{p2} =.14] at post-treatment, and at 3-month follow-up [HADS-Anx; F (1, 54) = 7.46, p< .01, η_{p2} =.12] compared to the WL. No other differences between the completers vs. the ITT dataset were observed.
3. A series of post hoc analyses, including ANCOVAS with pre-treatment data used as covariates (Van Breukelen, 2006; Vickers, 2004) and the outcomes at post-treatment and 3-month follow-up as the dependent variables (controlling for pain severity), demonstrated that the ACT group, when compared with the WL presented with significant time by group interaction effects for general (HDI; F (1,73) = 7.79, p < .01), emotional (HDI- Em; F (1,73) = 4.83, p < .05) and functional (HDI-Func; F (1,73) = 10.55, p <.001) disability scales. Also, when the effects of pain severity were controlled for, there were significant time by group changes in role restrictive (MSQ-RR; F (1,73) = 6.09, p <.05), role preventive (MSQ- RP; F(1,73) = 6.71, p < .05), and role emotional (MSQ- EF; F(1,72) = 3.39, p <.05).
4. Mean scores here represent differences in groups only. Mean scores in tables 4 and 5 represent interaction effects.

Study 3

1. The scale assessing the ACT process of self-as-context (Experiences Questionnaire; EQ; Fresco, Moore, van Dulmen, Segal, Ma, Teasdale, et al., 2007) was excluded from these analyses due to its poor psychometric properties.

2. The issue of directionality in mediation, an important criterion for assessing mediating effects, was examined here. However, due to the numerous disagreements among methodologists as for the use of this "rather ambiguous method" (Kenny, 2016), results from these analyses were not reported. In these supplementary set of analyses, the timeline criterion, which postulates that because both mediators and outcomes are not manipulated in any way, they must relate each other even if their roles are reversed, was explored (Kenny, 2007). In order to examine this criterion, mediators demonstrated indirect effects were reversely assessed as outcomes, and the changes scores (i.e., pre to post and pre to 3 months follow-up) as mediators (Baron & Kenny, 1986). It was assumed that once treatment effects of headache disability and quality of life outcomes were functionally mediated by the proposal mediators, the same pattern of results would exist by reversing this pattern. In sum, findings from these analyses provide similar with the original results, though, the effects of treatment on outcomes were not supported on BCa 95% CI, but on 90% CI. It is possible that headache-related disability and quality of life outcomes to be functionally related with pain acceptance and psychological inflexibility, and vice versa, however more studies are needed to examine this hypothesis.

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FIGURES

Figure 1

The Dyad of the Three Response Styles: Open, Centered, Engaged Underpinning Psychological Flexibility.

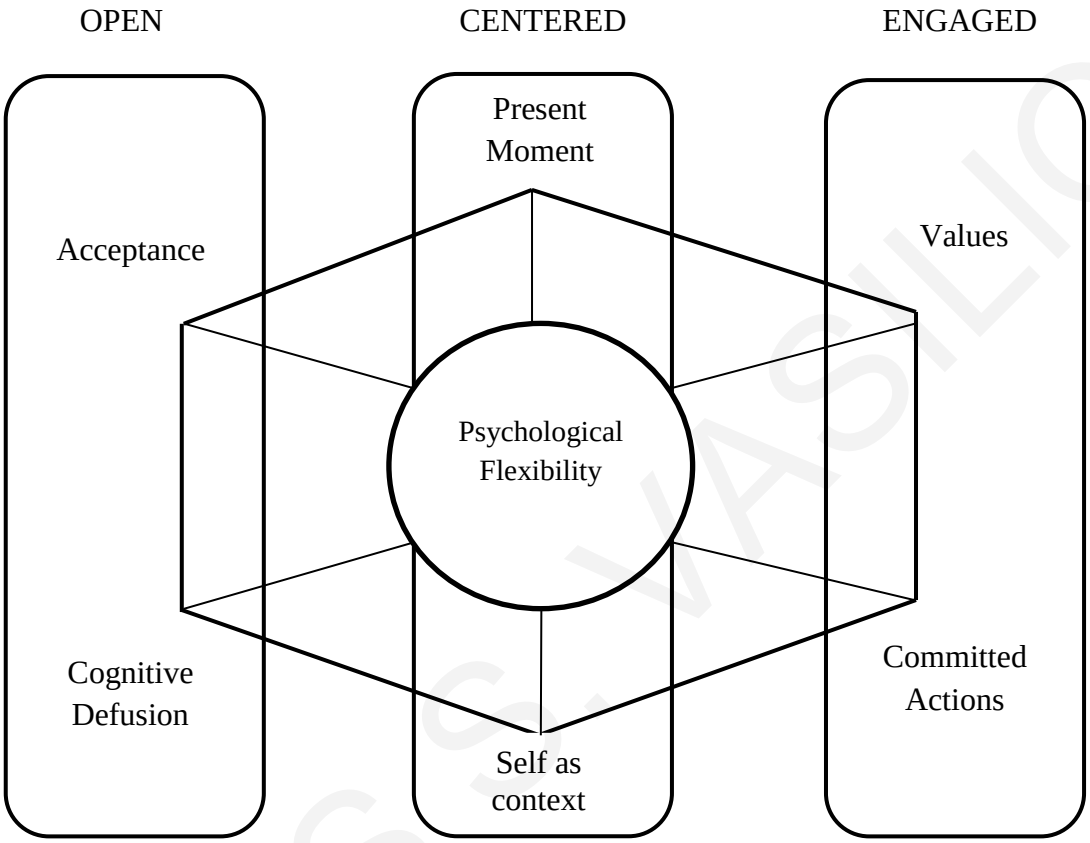
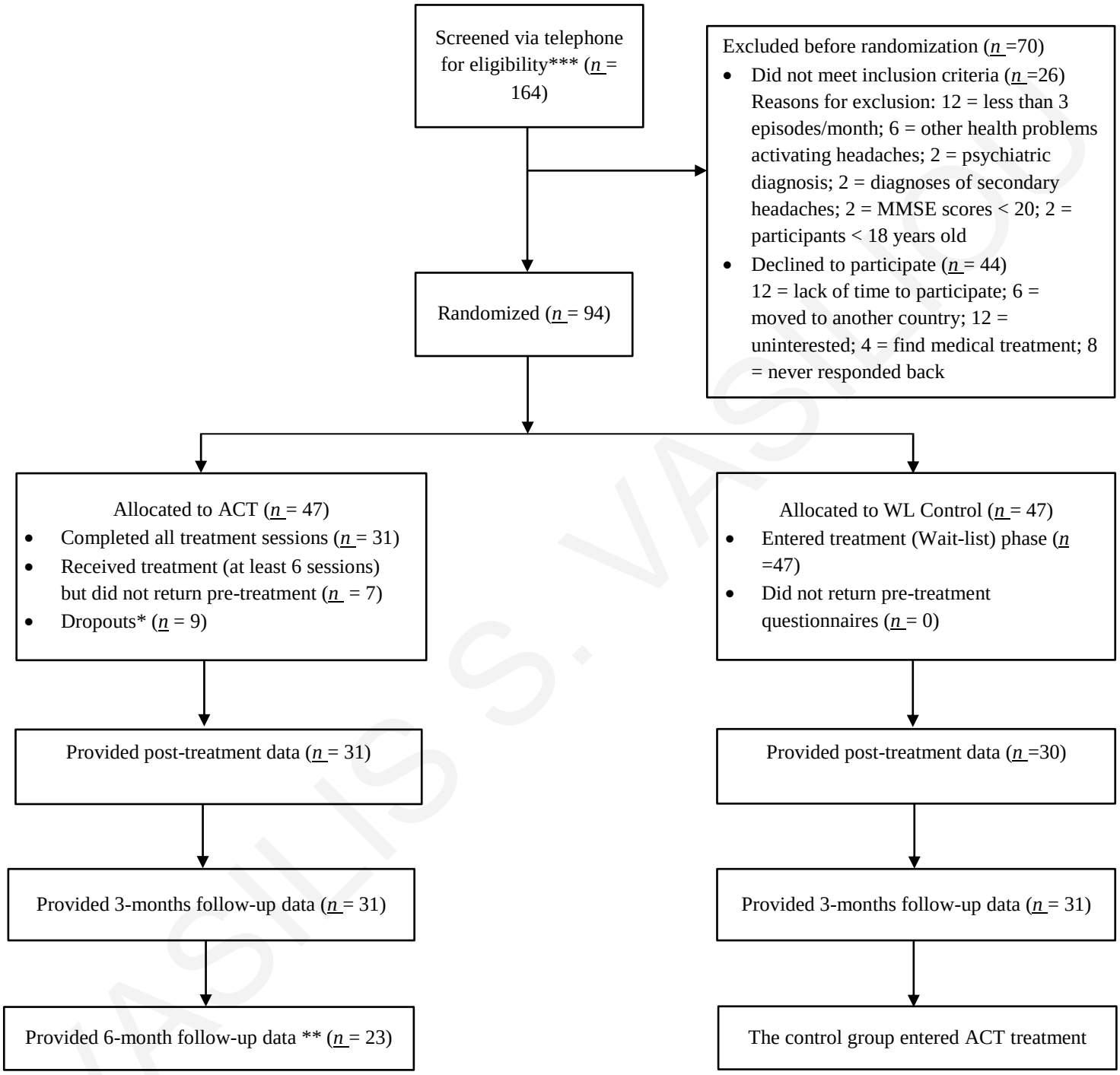


Figure 2

CONSORT Flow Diagram of Study.



Note1* : Individuals missing more than two consecutive sessions were considered as dropouts.
Note2** : Only the ACT group completed 6 month follow up.
Note 3*** : Recruitment sources: the Cyprus Institute of Neurology and Genetics (CING), private-care Neurologists; self-referrals

Figure 3

Changes in Headache Disability Levels Following Treatment and at 3-month Follow-up (Error Bars Represent Std. Error).

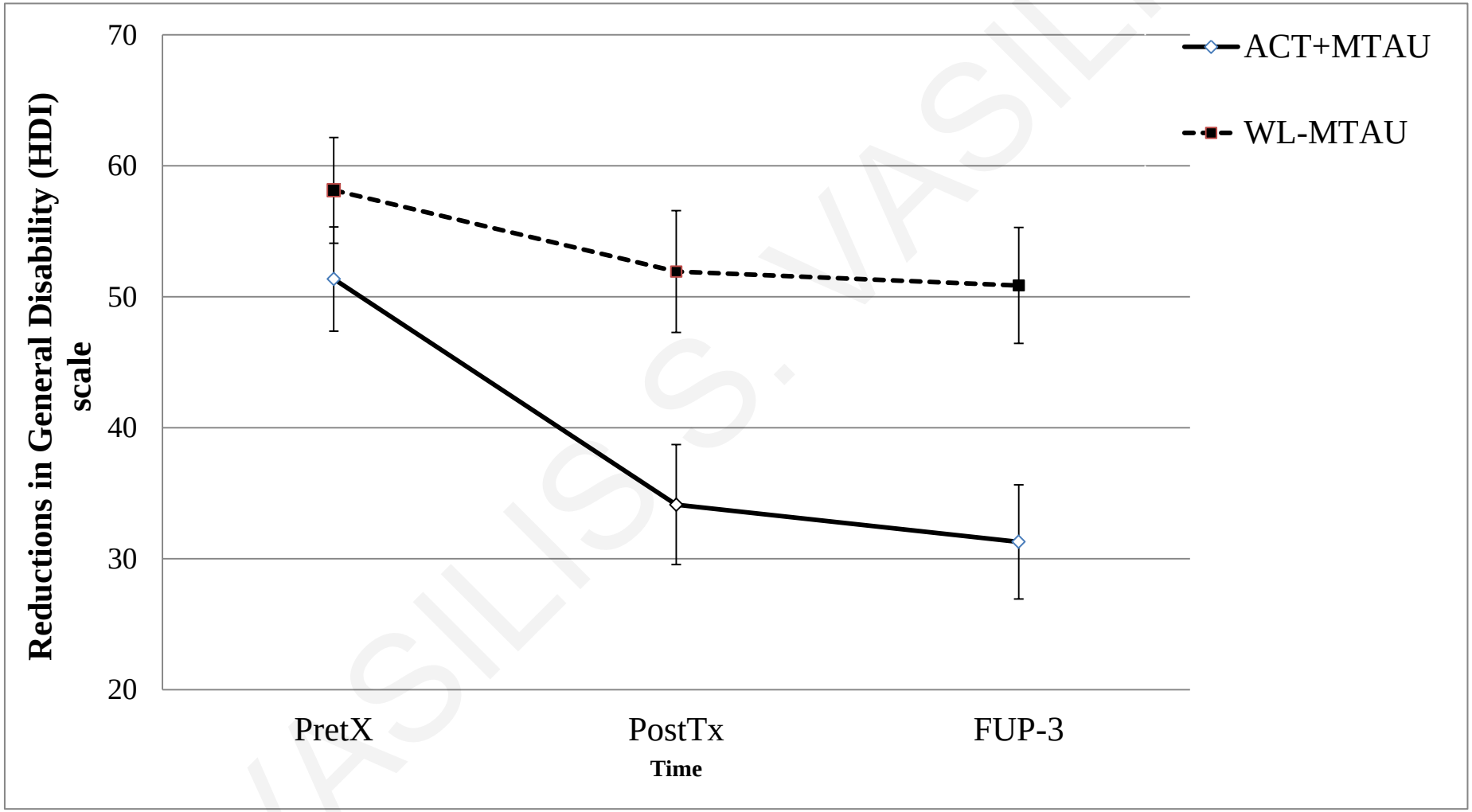


Figure 4

Changes in Quality of Life (MSQ) Levels for each Treatment (Error Bars Represent Std. Error).

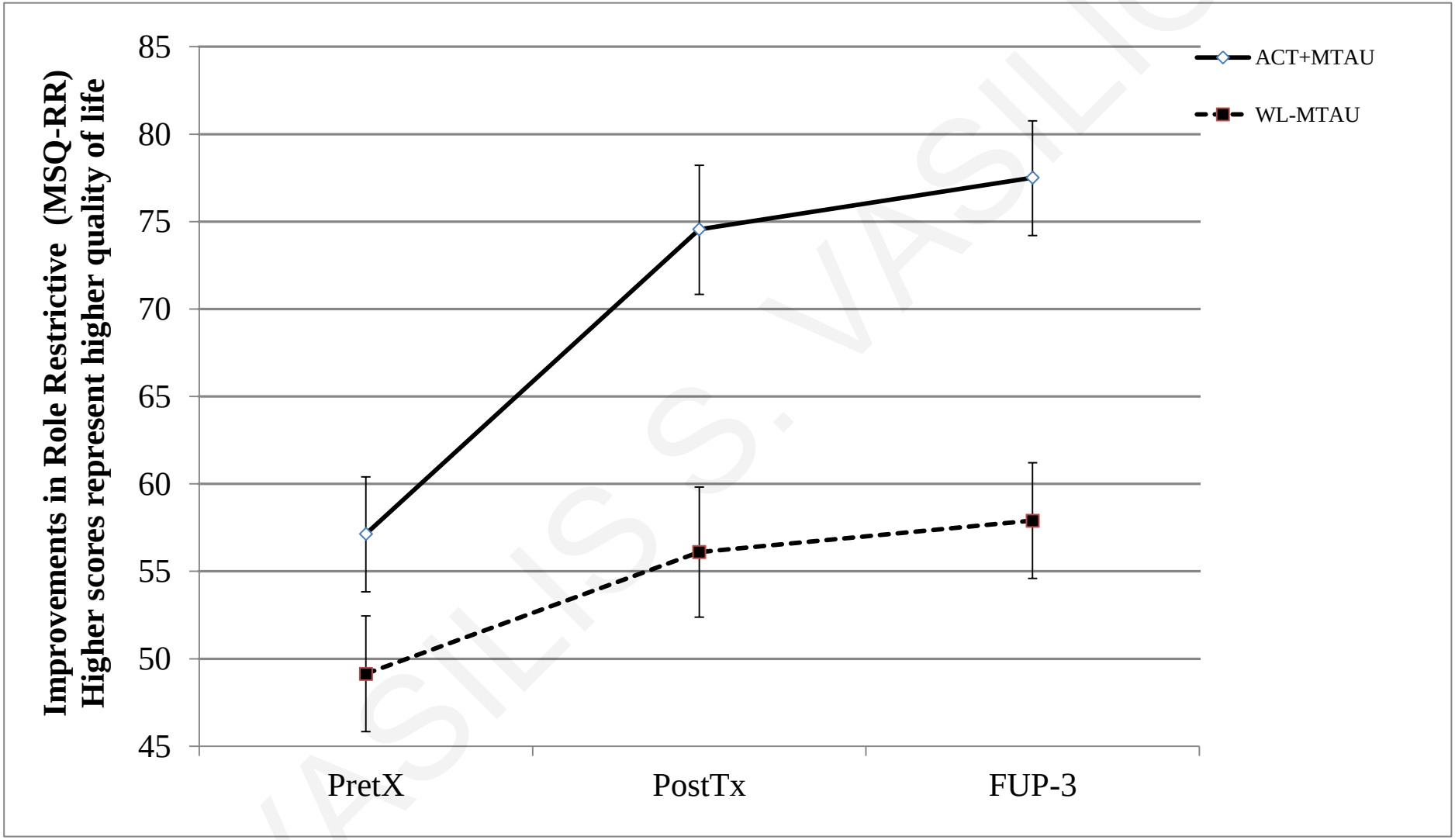


Figure 5

Changes in Headache-related Disability Levels for the ACT at Pre, Post- treatment, 3, and 6- Months Follow-up (Error Bars Represent Std. Error).

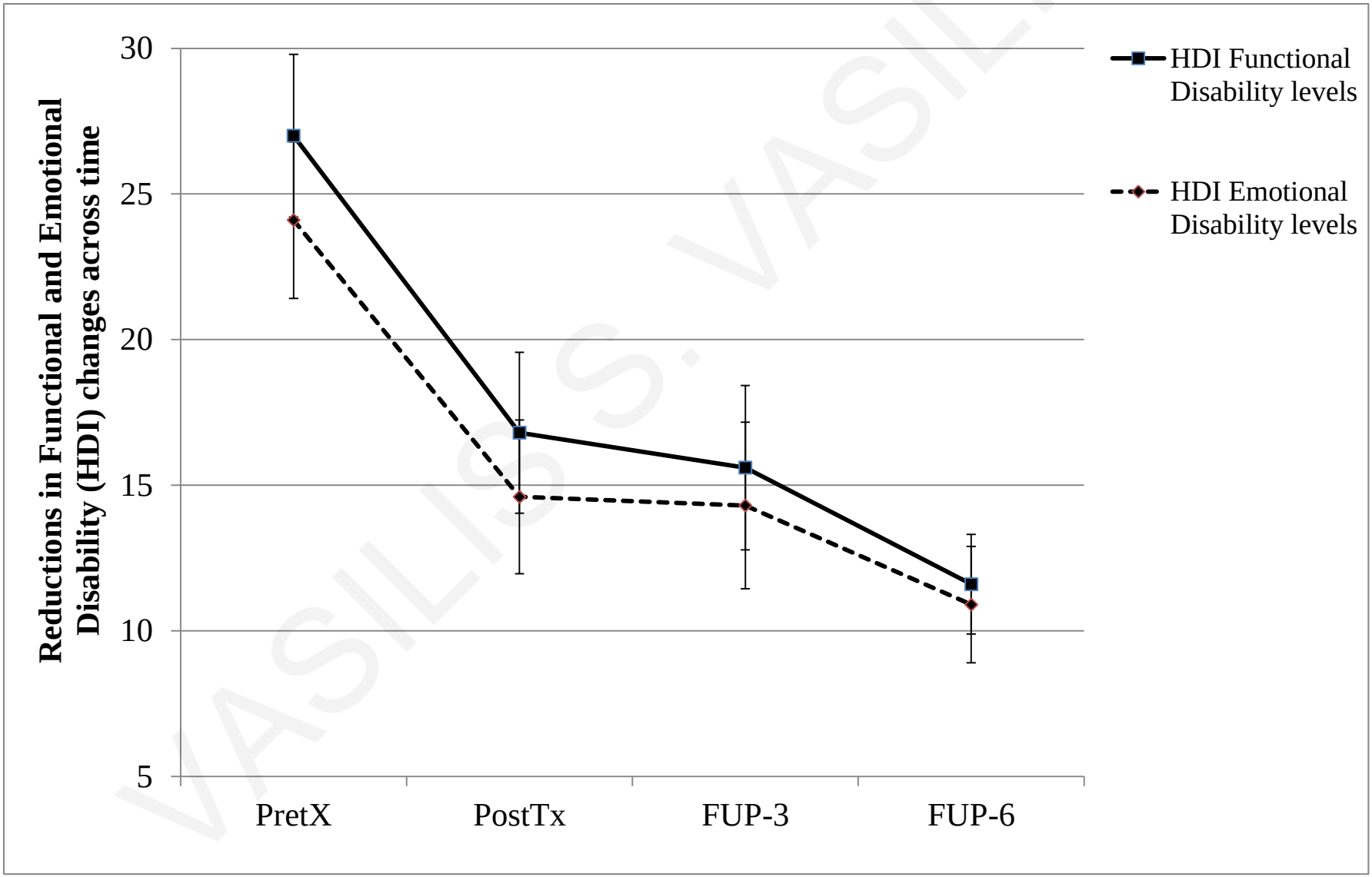


Figure 6

Changes in the Three Dimensions of the Headache Specific Quality of life Scale for the ACT at Pre, Post- treatment, 3, and 6- Months Follow-up (Error Bars Represent Std. Errors).

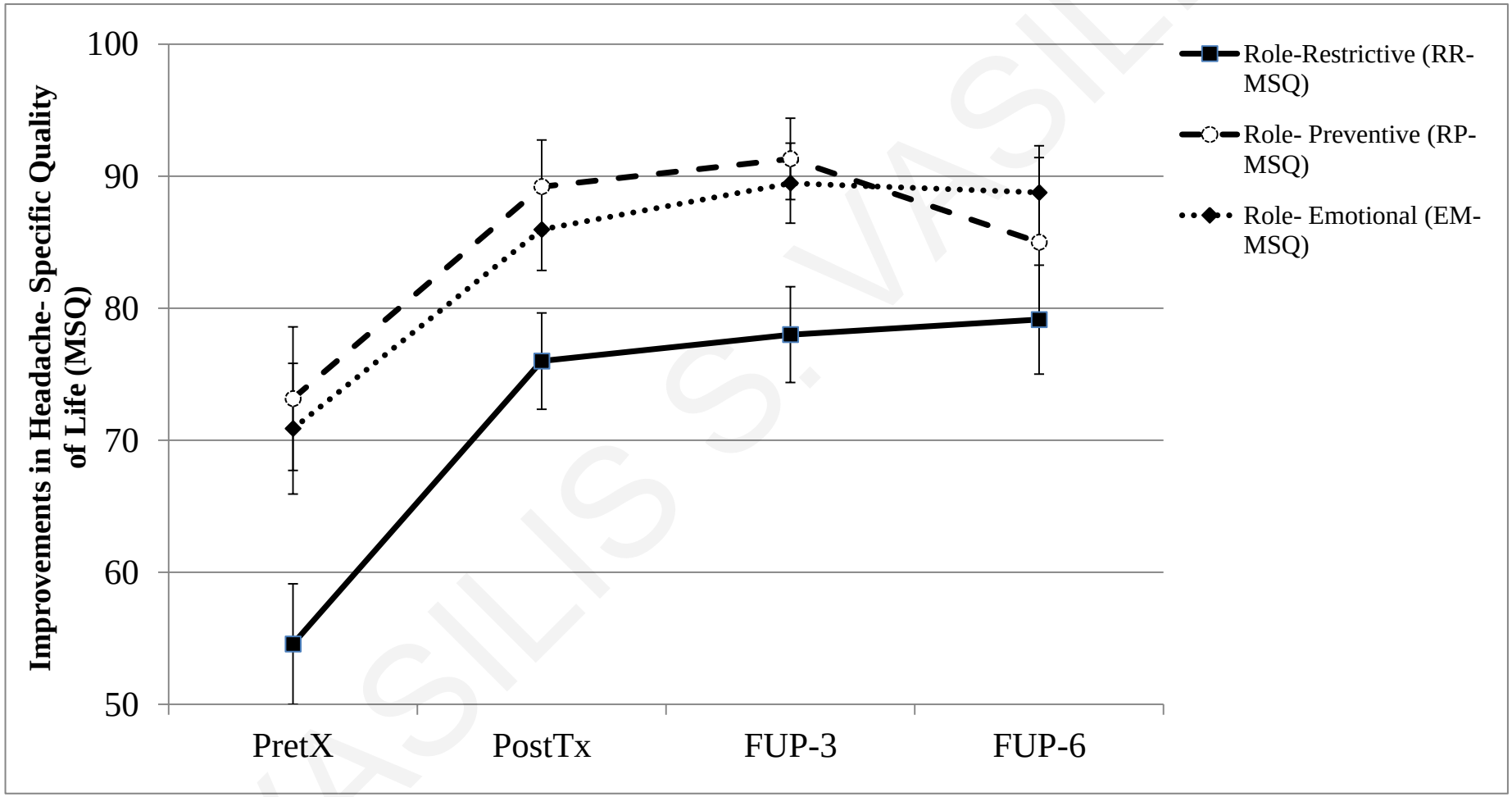


Figure 7

Within-Subject Effect Sizes (η_p^2) for All Process Measures. Effect Sizes Represents: η_p^2= 0.01 (small effect), η_p^2 = 0.09 (medium effect), and η_p^2= 0.25 (large effect; Cohen, 1988).

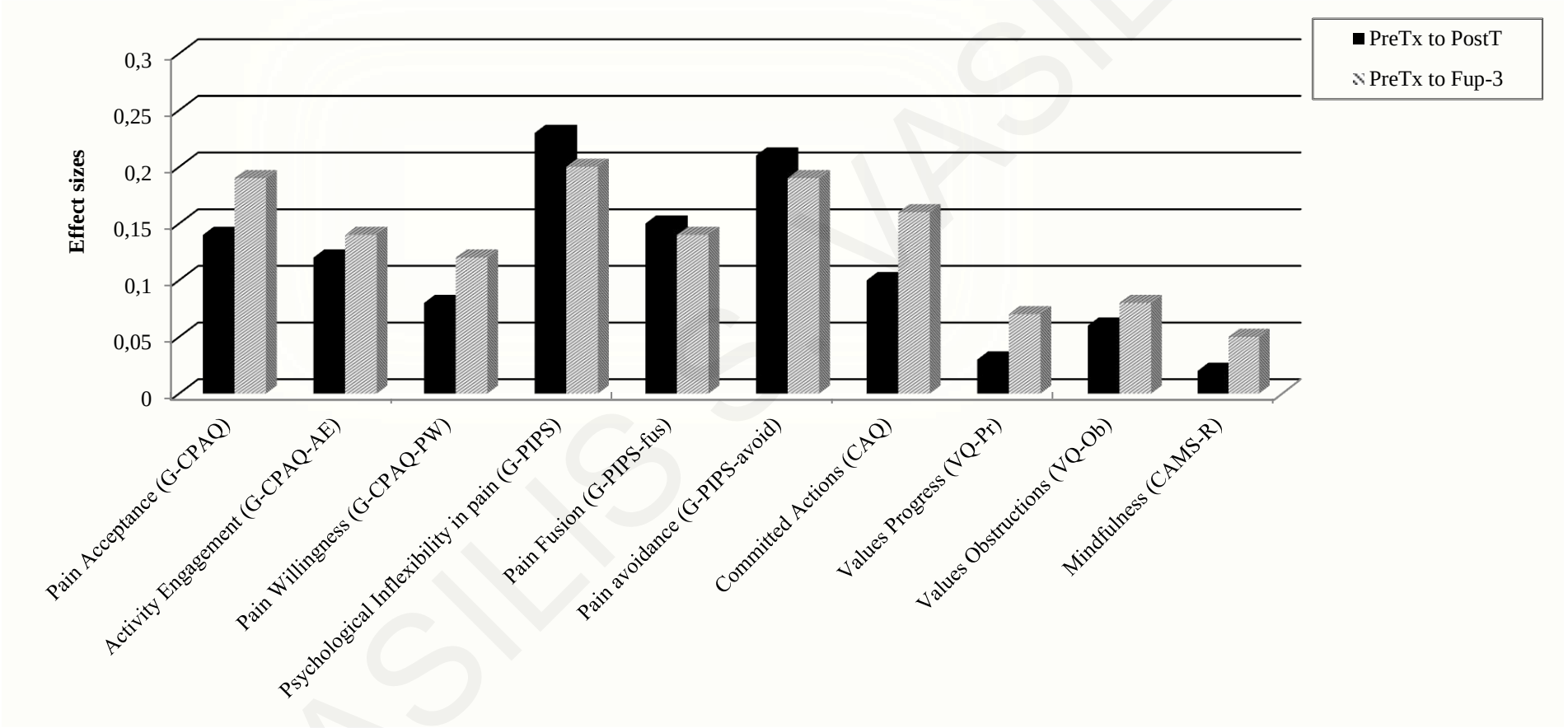


Figure 8

Reliable Change Analyses for Primary Outcomes: Pre to 3 and Pre to 6 months Follow-up for ACT group only.

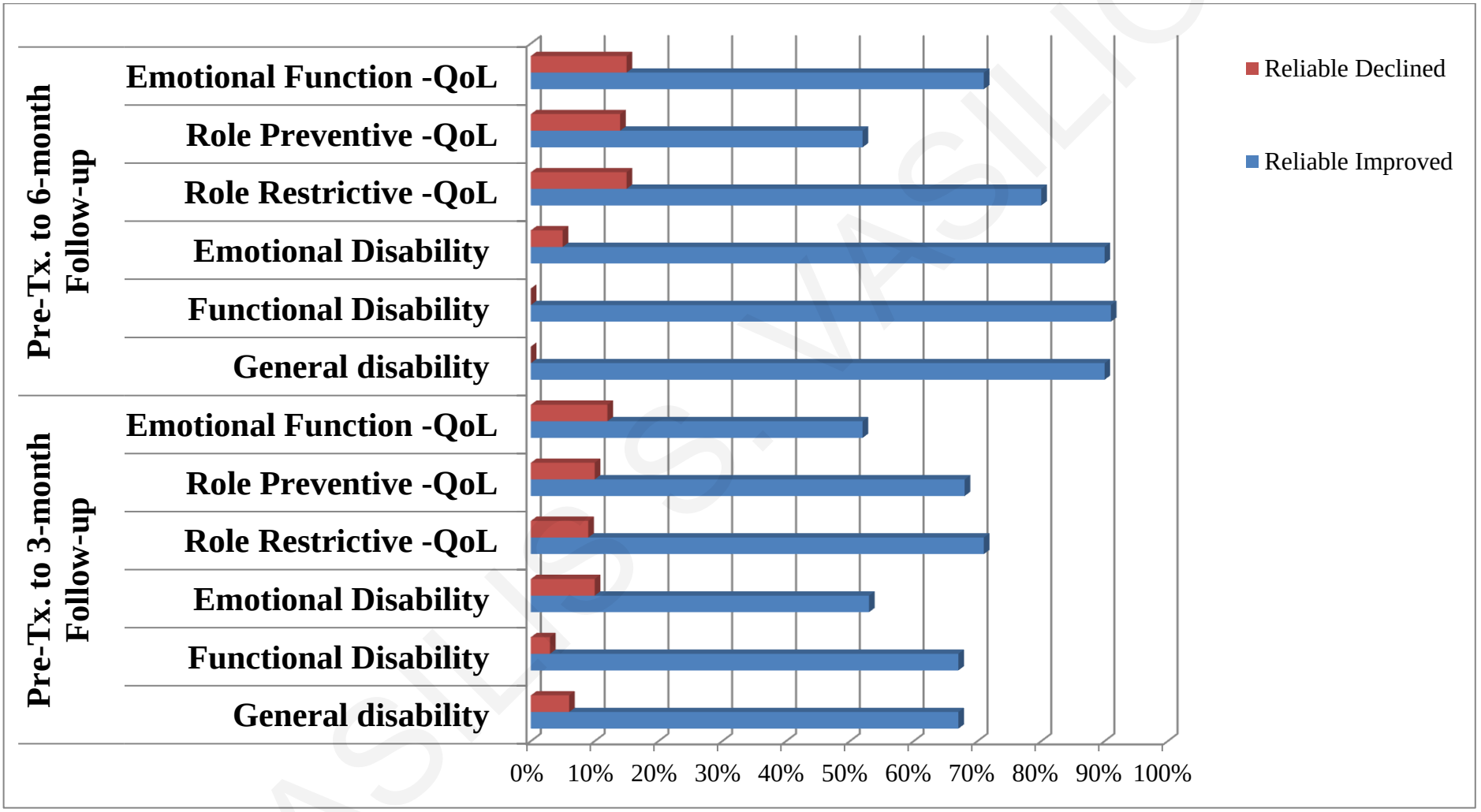


Figure 9

Conceptual Diagram of Classical Mediation Model

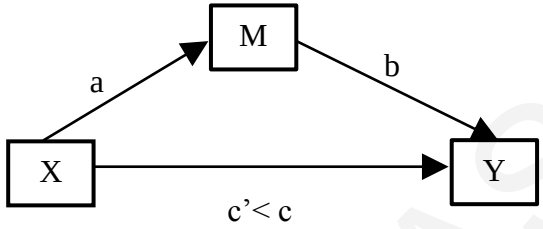


Figure 10

Schematic Representation of Mediator Effects on Direct and Indirect Relations of Treatment Groups to Primary Outcomes (Mediators Entered One at a Time).

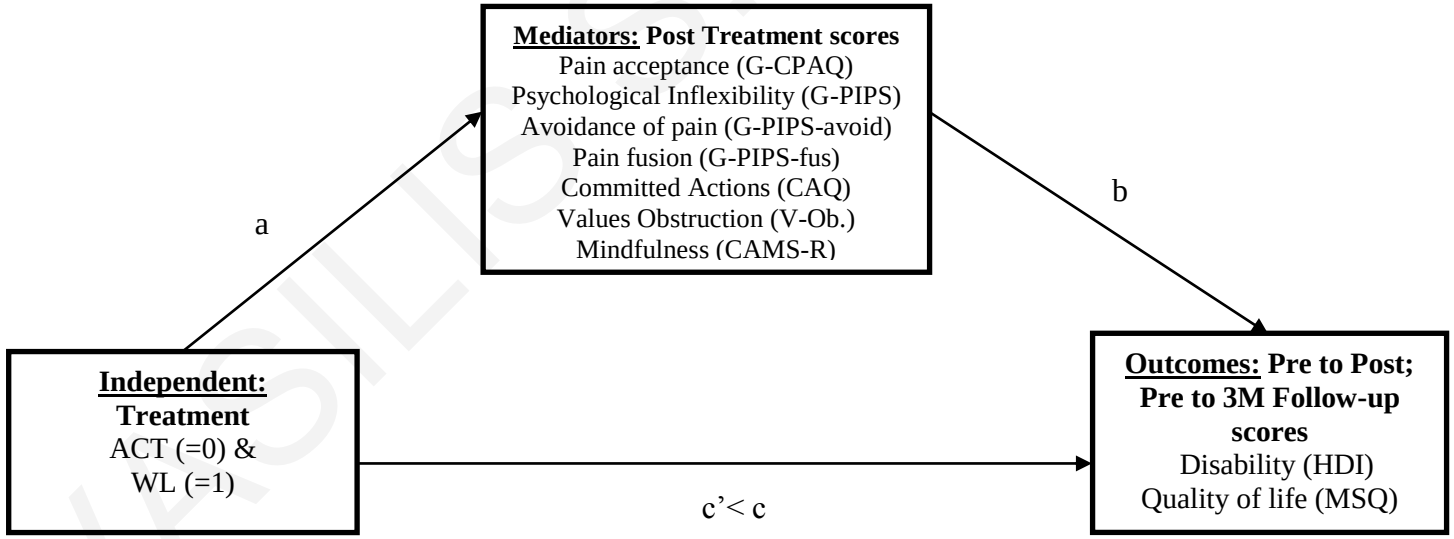


Figure 11

Schematic Representations of the Indirect Effect of Treatment on the HDI –Total T1-T2 Change Scores through Mediators

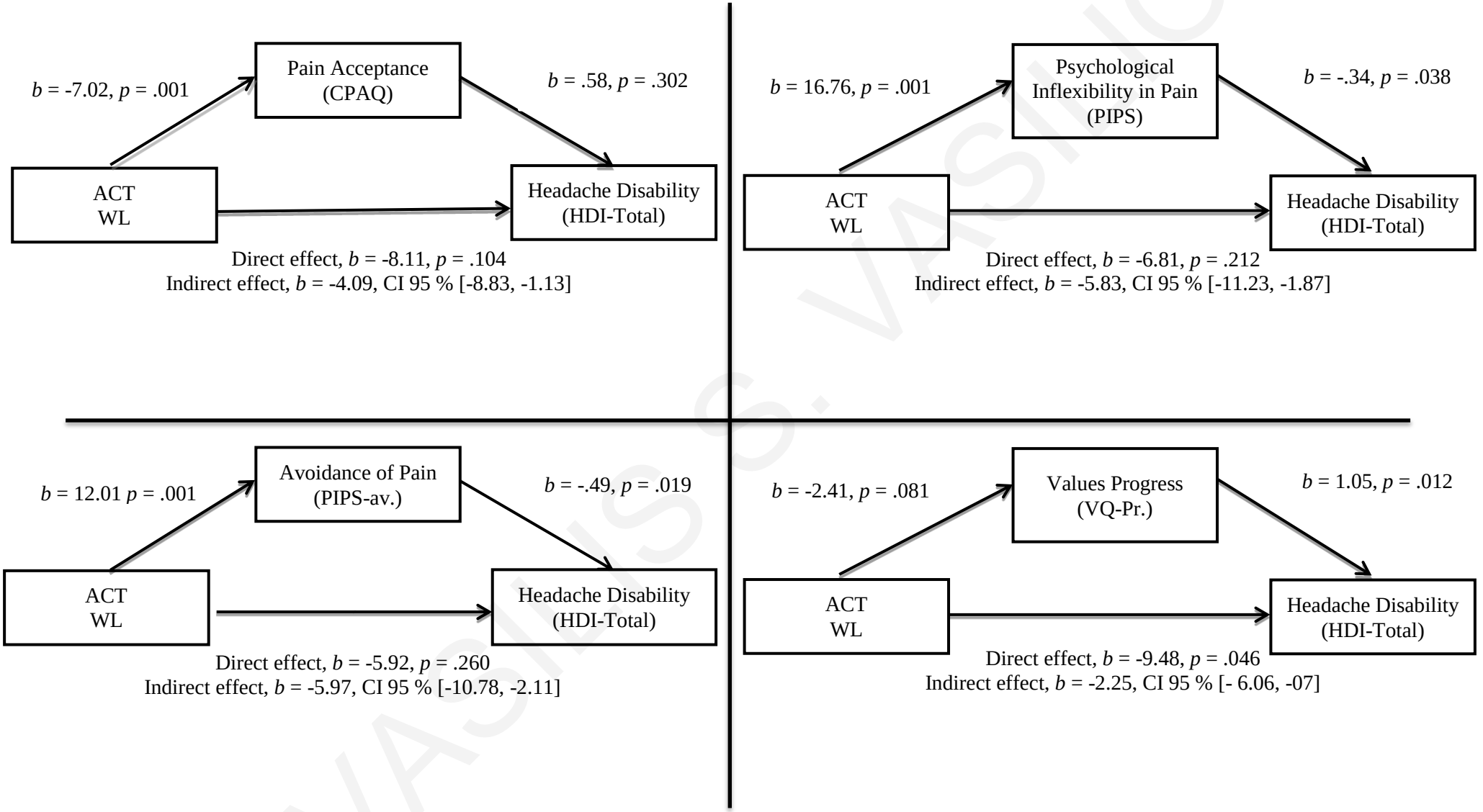


Figure 12

Schematic Representations of the Indirect Effect of Treatment on the HDI Functional Disability T1-T2 Change Scores Through Mediators

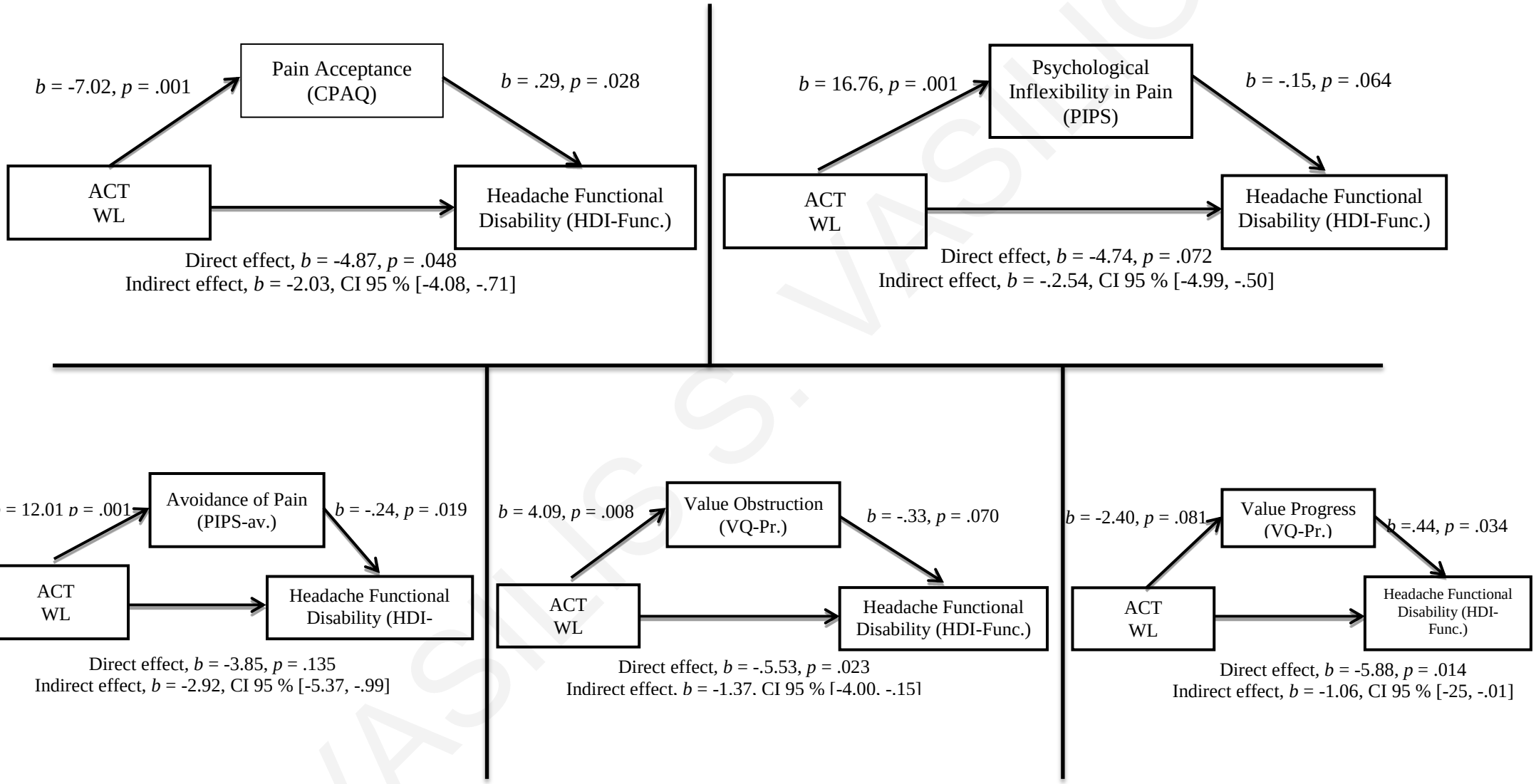


Figure 13

Schematic Representations of the Indirect Effect of Treatment on the HDI Emotional Disability T1-T2 Change Scores Through Mediators

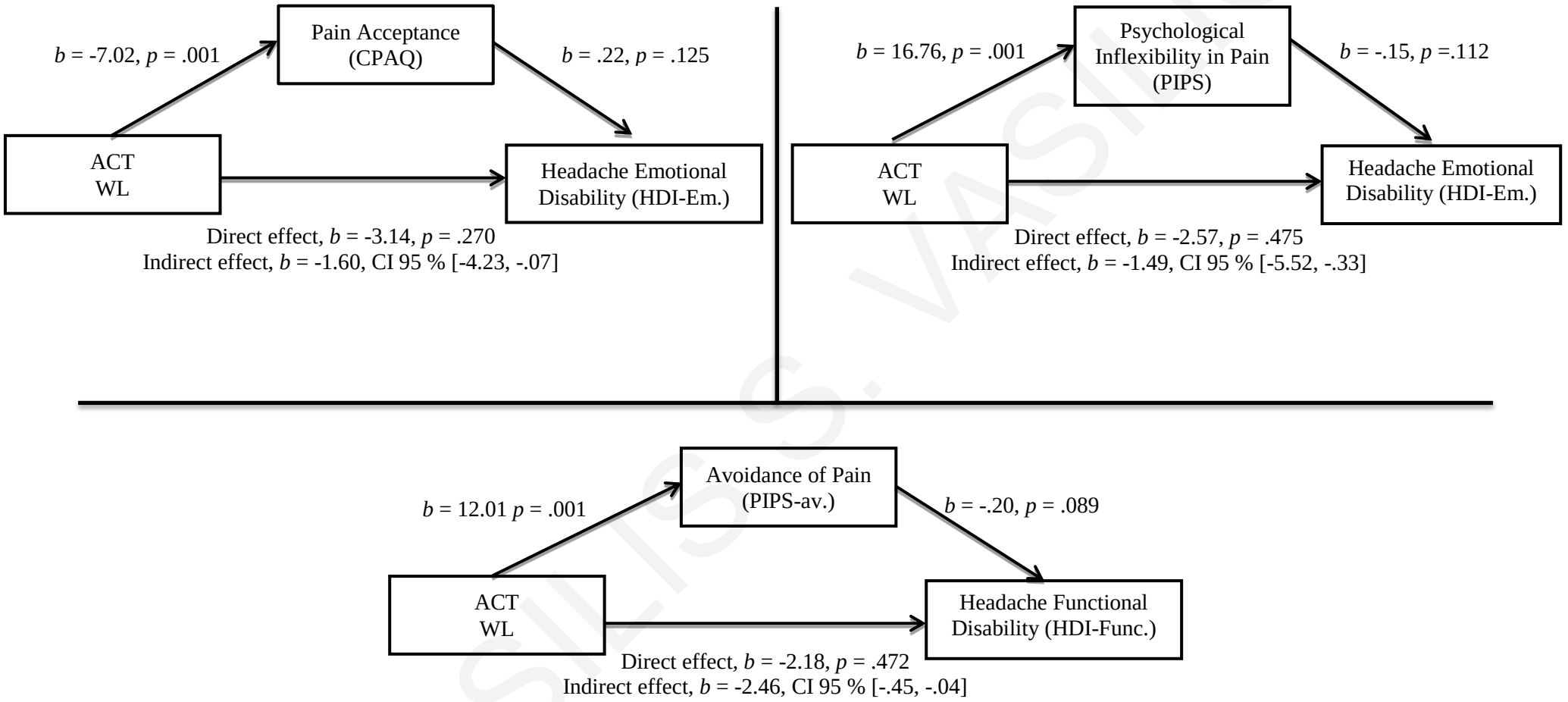


Figure 14

Schematic Representations of the Indirect Effect of Treatment on the HDI T1-T3 Change Scores through Mediators

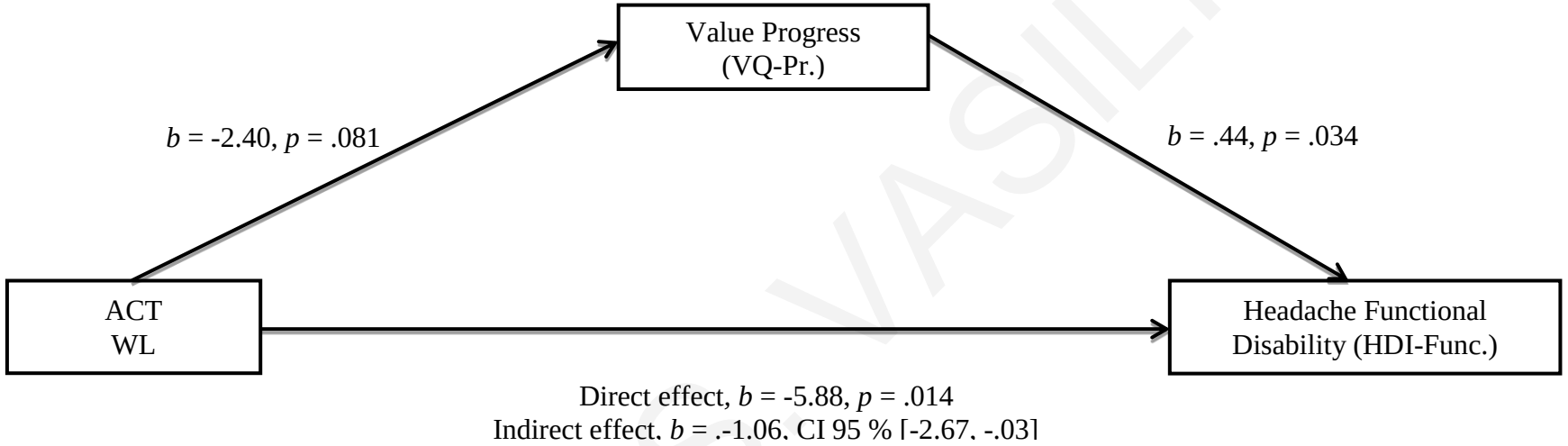


Figure 15

Schematic Representations of the Indirect Effect of Treatment on Quality of Life Dimension (MSQ) at T1-T2 Follow-up Change Scores through Mediators

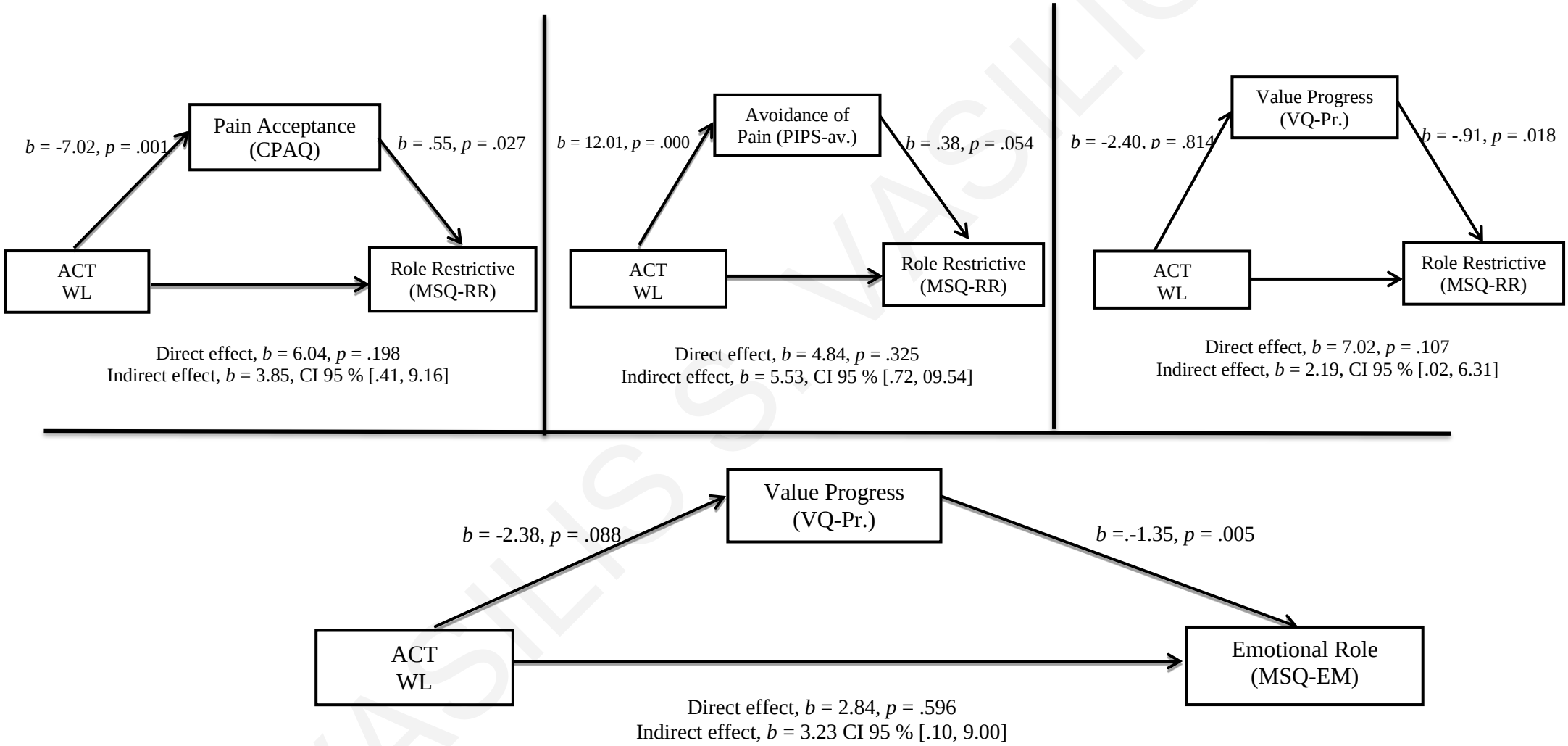


Figure 16

Schematic Representations of the Indirect Effect of Treatment on Quality of Life Dimension (MSQ) at T1-T3 Follow-up Change Scores through Mediators

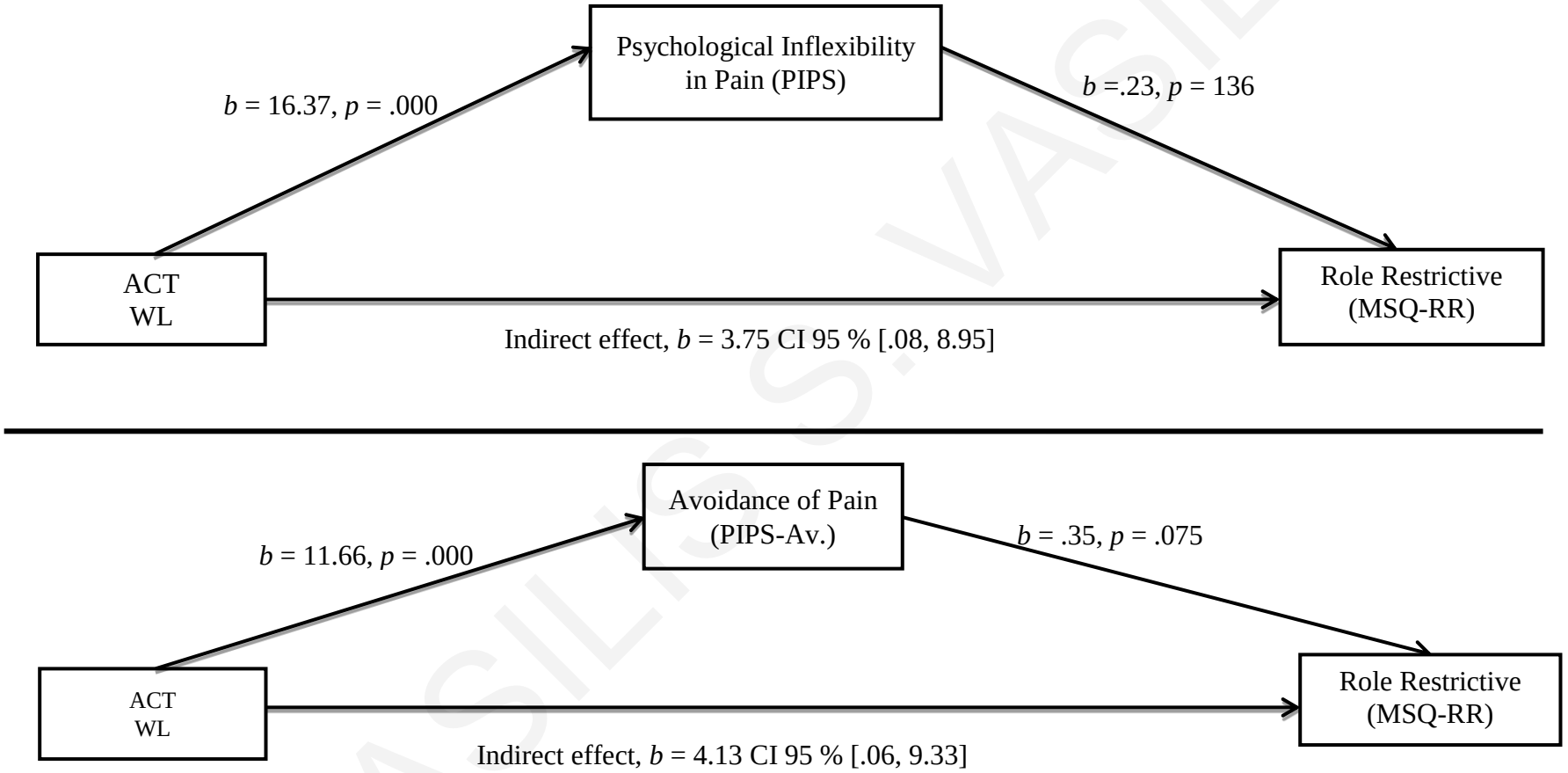
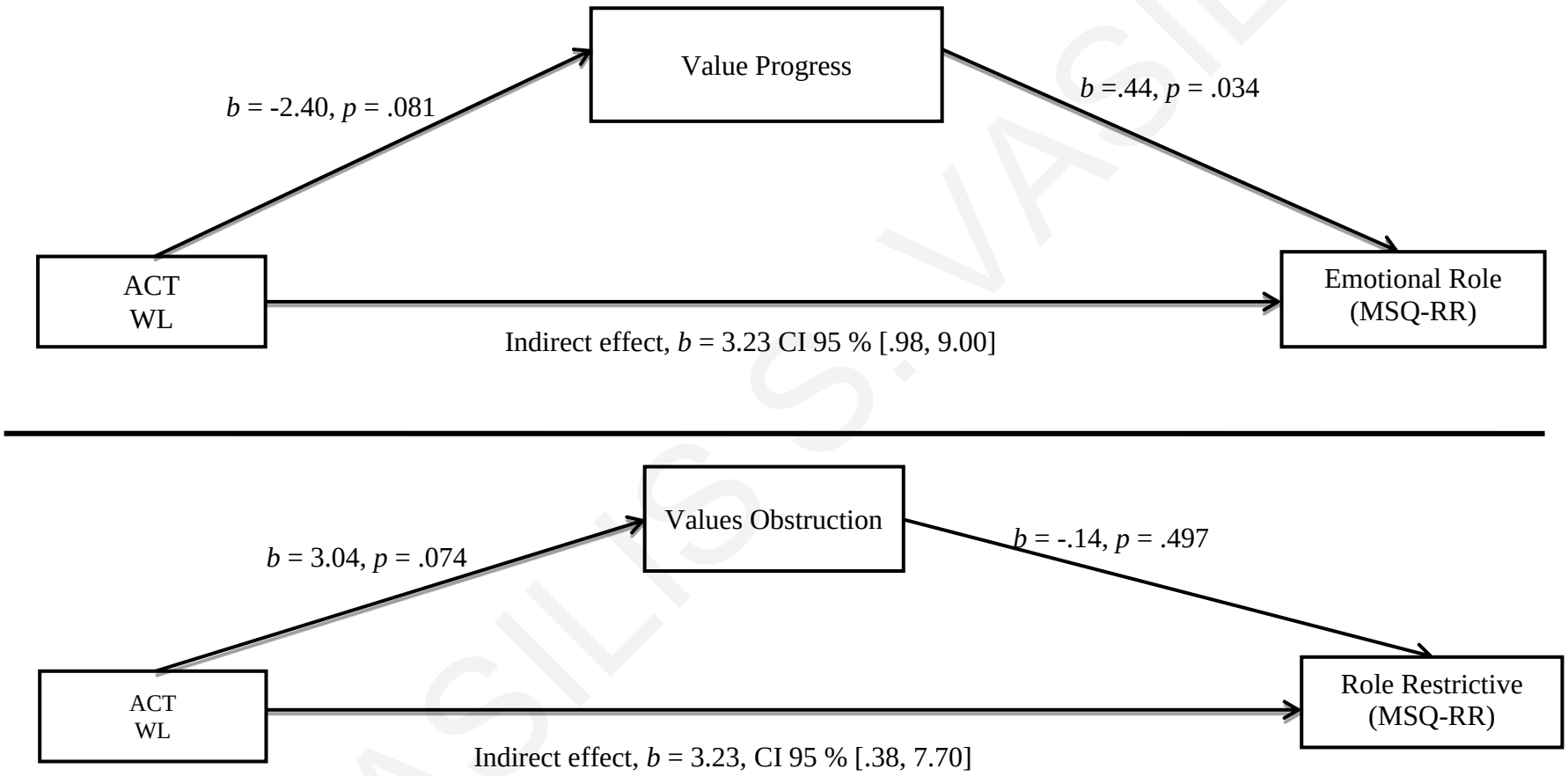


Figure 17

Schematic Representations of the Indirect Effect of Treatment on Quality of Life Dimension (EM-MSQ) at T1-T3 Follow-up Change Scores through Mediators



TABLES

Table 1

6 Processes of PF Which ACT Aims to Cultivate in Relation to Head Pain

PF Process	Brief Definition
Acceptance	An open, non-defensive embrace of unwanted or difficult experiences (e.g., head pain) without attempts to control or change their frequency or form, especially when doing so leads to further suffering.
Cognitive Defusion	A process of diminishing the impact of thoughts on behavior by viewing thoughts as what they are, a stream of words, symbols, or internal phenomena, rather than literally true entities that should drive behaviors.
Being Present (mindfulness)	Taking a flexible and open stance in the here and now where attention is brought to the present moment, whereas thoughts, emotions, and bodily sensations are allowed to come and go without attempts at altering them in any way. Mindfulness also encompasses regarding all available behavioral choices and choosing to act on what is most important in the present moment.
Self-as-context	Is the process of flexible perspective taking; the ability of individuals to distinguish between a self as a continuous perspective. From a self-as-context perspective an individual becomes aware of his/her flow of experiences without caught up to them.
Values	Represent chosen qualities of behaviors that can never be achieved as terminated goals but can be pursued in a moment-to-moment basis.
Committed Actions	A process of behaving in a particular way based on ones identified values

Table 2

An Illustration of Delivering an ACT Intervention For Headache Management

Phases	Treatment Goals[1]	ACT-related Material to Achieve Treatment Goals[2]	Participants Action Plans
1. Setting the premises for a change	a. Introducing the therapy; building rapport; getting to know each other b. Patients' education about the pathophysiology of headache, lifestyle factors c. Building awareness that the direct attempts to control head pain is problematic d. Introducing a short mindfulness practice (5') and its usefulness in managing headaches e. Recognizing that attempts to control internal experiences (including bodily sensations) can become problematic when it is excessively and irrespective of context applied f. Head pain agenda vs. valued living g. Head pain vs. suffering	- Creative hopelessness, - The room full of adhesive tape metaphor , - ACT matrix for headache - Control metaphors: the polygraph & chocolate cake; - Experiential exercises: A battle with a headache monster - Metaphor: my choice and action - Pain vs. Suffering	- Psycho-education about headache development & life-style choices - A brief mindfulness exercise (CD track) - An illustrated Metaphor: experimenting with the exhaustive battle with the headache monster - Mindfulness exercise (CD track)
2. An engaged response style	a. Identifying values, value compass, and values incongruent actions b. Recognizing values vs. goals, shaping behaviors with effective values-based actions and the SMART approach c. Potential barriers in valued living life and ways to deal with them d. The dominance of verbal processes and the way they impact behaviors e. The auto-pilot mode and how to shift toward the being-present mode (how to choose an adaptive pain response)	- Experiential exercise: the funeral exercise Value compass worksheet - Committed Action worksheet (using SMART approach) - Experiential exercises : fused thoughts - Breathing exercise - Experiential exercise : decentering from thoughts - More cognitive defusion techniques and how to react to mind products and rules	- Values vs. goals - Expanding behavioral repertoires: values-based actions & personal barriers (internal & external) - Fighting chronic fatigue - Body scan exercise (CD track) - Values-based actions and barriers - Simple ways to be present (Part A') - Cognitive defusion practice - Activity pacing worksheet - Defusion exercise: you are more than your pain (CD track)

3. A centered response style	a. The observing self (self-as-context and the observing self) b. Discovering the self-as-context c. Using the observing self to build awareness of pain behaviors d. Cultivating willingness toward discomfort when doing so serves valued living e. Fostering acceptance and willingness of head pain and other unwanted experiences f. Turning avoidance of pain behaviors into willingness g. Learning to cope with trigger (exposures as experiments to headache triggers)	- Experiential exercise: thinking vs. observing self - The shadow and bottle metaphor, - Self-as-context mindfulness exercise - Mindfulness and acceptance exercise - Experiential metaphors: TV metaphor, and acceptance as a choice vs. passivity - Basic ABCs in identifying triggers	- Chosen values-based action and barriers - Simple ways to be present (Part A') - Decentering exercise - Using Self-as-context to deal with headache-related "guiltiness" - Fostering the self-as-context (leaves on the stream exercise, CD track) - Acceptance and willingness exercises - Simple ways to be present (Part B') - Triggers, food, and headaches - Cultivating acceptance (CD track)
4. An open response style	a. Cultivating willingness and committed actions: Part I & II b. Mindfulness practice c. Learning to move on when thinks go awry d. Values, head pain, and significant others e. Long-term maintenance of the acquired skills	- Experiential metaphors: Passenger on the bus metaphor, committed parade exercise - Metaphor: the gardening metaphor - Experiential metaphor: the staying still exercise - The "finding meaning" exercise	- Dealing with barriers: a plan for action - Sleep hygiene: a guide to better sleep - Body awareness exercise (CD track) - The two pain cycles (avoidance/ control vs. willingness and committed actions) - Having choices in moments of headache crises: Practical suggestions for severe headache episodes - Recognizing relapses and planning steps to overcome barriers

Notes:
1. The full ACT treatment protocol described here consists of a therapist manual, a complementary participants Action Plan (AP) workbook, and two CDs with mindfulness exercises. The protocol was tested (registered with the clinical trials.gov registry: NCT02734992), and it is available upon request from the author of this manuscript. Also, the therapists' adherence and treatment fidelity protocol accompanied this protocol, are available upon request from the author.
2. Metaphors, experiential exercises, and illustrations utilized in this protocol were found from various resources (e.g., Dahl & Lundgren, 2006; Dahl, et al., 2005; Forsyth, & Eifert, 2007; Hayes & Strosahl, 2004; Hayes et al., 2012; McCracken, 2005; Turk & Winter, 2006; Vowles & Sorrell, 2009; ACT-related material available from the ACBS (Association for Contextual & Behavioral Sciences[ACBS]).

Table 3

Baseline Comparisons Between the Groups on Demographics and Headache Characteristics.

Variable	Groups			Total
	ACT (*N*= 47)	WL (*N* = 47)	values (*p*)[2]	*N =94*
Age (Mean/SD)	42.89 (10.27)	44.92 (10.43)	2.50 (*.01*)	43.97 (10.35)
Gender (female %)	74.5%	92.5%	5.99 (*.01*)	84%
Educational level completed %			6.50 (*.17)*	
Primary education (6 years of education)	3.2%	1.9%		2%
Middle school (9 years)	3.2%	11.5%		7%
High or vocational school (12 years)	34.8%	34.6%		34%
College/ University degree (16 years)	26.2%	34.6%		32%
Postgraduate degree (>16 years)	35.8%	17.4%		25%
Family Status			8.48 (*.13*)	
Single	10.6%	22.6%		17%
Separated	2.1%	9.4%		6%
Married	85.1%	60.4%		72%
Widowed	0%	2.9%		1%
Cohabiting/ single	2.2%	4.7%		4%
Monthly income			12.86 (*.02*)	
< 1000 euros	25.6%	55.3%		37%
1000-1500 euros	27.9%	21.3%		22%
1500-2000 euros	11.6%	12.8%		17%
2000-2500 euros	18.6%	8.5%		15%
2500-3000 euros	11.6%	0%		6%
>3000 euros	4.7%	2.1%		3%
Occupation			19.63 (*.01*)	
Managers	0%	4.3%		2%
Professionals	6.7%	8.5%		7%
Office work	15.6%	6.4%		11%
C.S. & I.W.	15.6%	27.6%		20%
Clerical and P.A.P.	28.9%	8.5%		21%
SW, L., C.,G.A.P.	24.4%	17%		20%
Unemployed	6.5%	6.3%		6%
Students/ H.K.	2.2%	21.4%		14%
Years since Headache problem onset (Mean/ SD)	18.09 (10.71)	18.72 (10.99)	-.29 (*.78*)	18.42 (10.81)
General measure index of headache rating				

Pain Severity (GBPI)	4.20 (1.91)	5.08 (2.05)	-2.14 (*.03*)	4.63 (11.05)
HDI-Func (0-48)	26.34 (10.46)	28.08 (11.61)	-.77 (*.44*)	27.24 (11.05)
Average headache frequency/month (Mean/ SD)	7.87 (5.73)	10.55 (8.25)	-1.85 (*.06*)	9.30 (7.28)
Currently taking medication for headache (% yes)	82.2%	85%	-.34 (*.49*)	83.5%
Headache Diagnosis (H.I.S. Criteria)[3]			1.02 (*.31*)	
Migraine	90.9%	83.3%		76%
Tension-type headache	9.1%	16.7%		11%
Other Primary Headaches	5.5%	7.5%	-.12 (*.92*)	13%
MMSE (Mean/SD)	29.00 (.91)	29.00 (.89)		29.01 (.90)

Note1. ACT = Acceptance and Commitment Therapy; WL = Wait list control; Occupation categories were adapted based on Martin et al. (2014) study and included: C.S. & I.W.P=Community service & Independent working positions; P.A.P.= Public Administration Positions; SW, L., C.,G.A.P.= Sales Workers, Cleaners, General Assistance Positions; H.K.= Home Keepers; GBPI= Greek Brief Pain Inventory; HIS= Headache International Society; MMSE=Mini Mental Status Examination.

Note2. Mean comparisons between groups were executed with Independent *t*-tests for continuous variables and x^2 for categorical variables.

Note3. Based on Penzien's et al., (2005) guidelines for Trials of behavioral headache research, every trial should report a general "measure index of headache rating" that includes headache intensity, activity, and frequency. For the purpose of this study the G-BPI, the functional subscale of the Headache Disability Inventory (HDI- Func), and the frequency of headaches item (single item) were employed to assess the three parameters of headaches.

.

Table 4

ITT: 2X3 Repeated Measures ANOVA of Group (ACT vs. WL) by Time (pre, post, follow-up) for Outcomes

Variables	Groups	Means (*SD*)[1]			Interaction effects of Group by Time (pre, post, fup-3)	Effect Sizes : η_p^2
		Pre	Post	FUP-3	F (*df*)[2]	η_p^2
			Primary Outcomes			
General Disability (HDI; 0-100)	ACT	51.35 (*21.28*)	34.13 (*21.20*)	31.29 (*21.32*)	6.22** (*1.59, 120*)	.09
	WL	57.23 (*23.12*)	51.23 (*29.07*)	49.94 (*27.03*)		
Functional Disability (HDI- Func; 0-48)	ACT	24.06 (*11.59*)	15.48 (*10.68*)	14.97 (*11.30*)	8.87*** (*1.63, 120*)	.13
	WL	28.19 (*12.48*)	23.16 (*14.25*)	24.52 (*13.81*)		
Emotional Disability (HDI- Em; 0-52)	ACT	27.29 (*10.84*)	17.42 (*11.40*)	16.32 (*11.39*)	3.02* (*1.52, 120*)	.05
	WL	29.03 (*12.03*)	26.26 (*14.21*)	25.42 (*13.87*)		
Role Restrictive (MSQ-RR;0-100)	ACT	57.14 (*17.30*)	74.56 (*16.74*)	77.51 (*14.95*)	5.05** (*1.42, 120*)	.08
	WL	49.86 (*19.06*)	56.59 (*23.31*)	58.16 (*20.57*)		
Role Preventive (MSQ-RP;0-100)	ACT	73.23 (*19.52*)	85.97 (*16.90*)	89.03 (*13.25*)	3.74* (*1.68, 120*)	.06
	WL	66.13 (*21.08*)	69.03 (*23.47*)	69.52 (*25.99*)		
Role Emotional (MSQ-EF ;0-100)	ACT	71.83 (*20.20*)	83.01 (*18.61*)	86.45 (*15.82*)	1.46 (*1.58, 120*)	.02
	WL	63.01 (*24.21*)	67.53 (*25.69*)	67.53 (*30.00*)		
			Secondary Outcomes			
Pain Severity (GBPI; 0-10)	ACT	4.01 (*1.94*)	3.23 (*1.58*)	3.03 (*1.62*)	2.37 (1.49, 112)	.04

	WL	5.04 (*2.16*)	5.13 (*1.98*)	5.05 (*2.28*)		
Headache medical visits (last 2 months)	ACT	.39 (*.66*)	.39 (*.58*)	.30 (*.47*)	.28 (1.71, 80)	.01
	WL	.53 (*1.13*)	.63 (*.89*)	.58 (*1.02*)		
Headache Medical use (last 2 months)	ACT	1.04 (*1.48*)	.60 (*.82*)	.60 (*.87*)	.83 (1.61, 94)	.02
	WL	.83 (*1.76*)	.83 (*1.43*)	.63 (*1.38*)		
Anxiety (HADS;0-21)	ACT	7.13 (*3.92*)	6.23 (*3.50*)	6.47 (*3.55*)	.20 (1.20, 110)	<.01
	WL	9.81 (*3.83*)	9.26 (*3.84*)	9.19 (*3.57*)		
Depression (HADS;0-21)	ACT	5.35 (*3.19*)	4.71 (*3.13*)	2.48 (*1.50*)	2.75* (1.78, 112)	.05
	WL	7.44 (*3.73*)	6.81 (*3.70*)	3.15 (*1.54*)		

Note 1: Means and Standard Deviations are presented without controlling for pre-treatment scores as covariates. When assumption of sphericity was violated, the Greenhouse-Geisser criterion (corrections for degrees of freedom with Greenhouse-Geisser value greater than .75), were adjusted accordingly (*F*- and *p*- values).
Note 2: Pair-wise comparisons among the observed means (contrast).
Note 3: Effect sizes were assessed using partial eta squared (η_p^2) as follow: η_p^2= 0.01 (small effect), η_p^2 = 0.09 (medium effect), and η_p^2= 0.25 (large effect; Cohen, 1988).
****p* <.001; ***p* <.01; * *p* <.05.

Table 5

ITT: 2X3 Repeated Measures ANOVA Group (ACT vs. WL) by Time (pre, post, follow-up) for Process Measures

Variables	Groups	Means (*SD*)[1]			Interaction effects of Group by Time (pre, post, fup-3)	Effect Sizes : $\eta_p^{2,3}$
		Pre	Post	FUP-3	F (*df*)[2]	η_p^2
Pain Acceptance (G-CPAQ; 0-47)	ACT	25.35 (*5.71*)	29.71 (*7.39*)	30.84 (*6.92*)	4.49** (*2,56*)	.14
	WL	21.79 (*9.51*)	22.36 (*11.26*)	22.64 (*10.05*)		
Activity Engagement (G-CPAQ-AE; 0-24)	ACT	15.26 (*4.43*)	17.55 (*4.54*)	17.97 (*4.13*)	4.10* (*2,56*)	.13
	WL	13.57 (*6.57*)	12.89 (*7.89*)	13.46 (*7.03*)		
Pain Willingness (G-CPAQ-PW; 0-24)	ACT	10.10 (*3.88*)	12.16 (*4.63*)	12.87 (*4.76*)	1.33 (*1.68, 114*)	.03
	WL	8.21 (*5.94*)	9.46 (*5.59*)	9.18 (*5.26*)		
Psychological Inflexibility in pain (G-PIPS; 10-70)	ACT	50.60 (*13.88*)	39.07 (*13.43*)	38.40 (*15.16*)	10.72*** (*1.31, 104*)	.17
	WL	57.21 (*16.82*)	55.04 (*16.85*)	54.67 (*18.09*)		
Pain Fusion (G-PIPS-fus; 7-42)	ACT	21.87 (*5.30*)	17.71 (*5.78*)	17.13 (*6.56*)	8.32*** (*1.38, 112*)	.13
	WL	22.74 (*4.46*)	22.07 (*4.42*)	21.78 (*5.25*)		
Pain avoidance (G-PIPS-avoid; 10-70)	ACT	28.83 (*9.95*)	21.57 (*9.65*)	21.53 (*10.27*)	6.92** (*1.28, 104*)	.12
	WL	34.71 (*13.26*)	33.21 (*13.15*)	32.92 (*13.64*)		
Committed Actions (CAQ;1-45)	ACT	30.68 (*6.32*)	32.84 (*6.83*)	32.52 (*6.74*)	.76 (1.53, 112)	.01
	WL	25.78 (*7.55*)	27.70 (*8.63*)	26.19 (*7.80*)		
Values Progress (VQ;0-30)	ACT	20.35 (*4.87*)	21.00 (*4.22*)	21.45 (*4.01*)	.15 (1.66, 112)	.01

	WL	18.33 (*7.01*)	19.04 (*7.12*)	18.89 (*5.55*)		
Values Obstructions (VQ;0-30)	ACT	13.16 (*6.38*)	10.03 (*6.29*)	10.90 (*6.82*)	2.25 (1.50, 114)	.04
	WL	14.32 (*5.44*)	13.39 (*6.52*)	14.79 (*6.43*)		
Mindfulness (CAMS-R;20-50)	ACT	33.77 (*6.12*)	35.26 (*6.74*)	35.06 (*6.82*)	1.15 (1.51, 110)	.02
	WL	31.56 (*7.15*)	33.30 (*6.90*)	31.81 (*7.11*)		

Note 1: Means and Standard Deviations are presented without controlling for pre-treatment scores as covariates. When assumption of sphericity was violated, the Greenhouse-Geisser criterion (corrections for degrees of freedom with Greenhouse-Geisser value greater than .75), were adjusted accordingly (*F*- and *p*- values).
Note 2: Pair-wise comparisons among the observed means (contrast).
Note 3: Effect sizes were assessed using partial eta squared (η_p^2) as follow: η_p^2= 0.01 (small effect), η_p^2 = 0.09 (medium effect), and η_p^2= 0.25 (large effect; Cohen, 1988).
***p <.001; **p <.01; * p <.05.

Table 6

Results from the Reliable Change Analyses of the Treatment Completers (90% CI)

Primary Outcome	Test-Retest (r_{12})	Pre-Treatment to 3-month Follow-up (N= 31)[1]			Pre-Treatment to 6-month Follow-up (N = 22)		
		Required Change[2]	Reliable Improvement[3]	Reliable Decline	Required Change	Reliable Improvement	Reliable Decline
General disability (HDI-T)	.57	5.17	67.74%	6.40%	4.82	90.90%	0%
Functional Disability (HDI- Func.)	.67	3.54	67.74%	3.20%	3.49	90.90%	0%
Emotional Disability (HDI- Em.)	.48	5.21	53.30%	10.00%	3.61	90.48%	5%
Role Restrictive -Quality of Life (MSQ-RR)	.26	5.26	70.96%	9.60%	5.65	80.00%	15%
Role Preventive -Quality of Life (MSQ-RP)	.26	5.17	67.74%	9.60%	5.65	52.38%	14%
Emotional Function -Quality of Life (MSQ-EF)	.30	5.41	51.61%	12.90%	5.27	71.43%	14%
Mean	-	-	63.18%	8.61%	-	79.35%	8%

Note 1: Only observed data were utilized for this set of analyses.

Note 2: Required change = the observed changes from pre-treatment to 3 and 6-month follow-up must equate or exceed this value in order for a participant to be defined as a reliably change case (Jacobson & Traux, 1991).

Note 3: the percentage of participants provided data at 3 and 6-month follow-up time points whose scores are defined as reliably change (> 1.94 for 90% CI) or reliable declined (< 1.94 for 90% CI). The remaining percentage represents participants exhibiting no change.

Table 7

Between Group Comparisons for the Outcomes (Dependent variables) and Mediators at T1-T2 and T1-T3 Change Scores

	Group	M (*SD*)	t	*p*-value	Effect sizes (*d*)[1]
Outcome Variables (change scores)					
HDI: T1-T2	ACT	16.65 (*19.89*)	2.40	.001	.55
	WL	5.90 (*19.02*)			
HDI: T1-T3	ACT	20.06 (*19.69*)	2.85	.006	.72
	WL	7.29 (*15.28*)			
HDI-Func: T1-T2	ACT	9.35 (*9.34*)	2.86	.005	.66
	WL	3.05 (*9.72*)			
HDI-Func: T1-T3	ACT	10.97 (*9.12*)	3.27	.002	.83
	WL	3.61 (*8.60*)			
HDI-Em: T1-T2	ACT	8.53 (*11.42*)	1.57	.120	.36
	WL	4.57 (*10.46*)			
HDI-Em: T1-T3	ACT	9.10 (*11.66*)	2.11	.039	.54
	WL	3.68 (*8.26*)			
MSQ-RR: T1-T2	ACT	-16.72 (*20.80*)	-1.45	.152	.33
	WL	-10.27 (*18.02*)			
MSQ-RR: T1-T3	ACT	-20.37 (*19.78*)	-2.75	.008	.70
	WL	-8.29 (*14.33*)			
MSQ-RP: T1-T2	ACT	-11.62 (*22.59*)	-.1.04	.303	.24
	WL	-6.55 (*19.95*)			
MSQ-RP: T1-T3	ACT	-15.81 (20.58)	-2.34	.022	.60
	WL	-3.39 (*21.11*)			

MSQ-EF: T1-T2	ACT	-11.57 (*24.08*)	-.917	.362	.21
	WL	-6.67 (*22.16*)			
MSQ-EF: T1-T3	ACT	-.14.62 (*21.60*)	-1.40	.168	.35
	WL	-4.52 (*34.01*)			
Mediators (post-treatment scores)					
Pain Acceptance (G-CPAQ)	ACT	29.88 (*7.08*)	3.47	.001	.82
	WL	22.79 (*9.95*)			
Psychological Inflexibility in Pain (G-PIPS)	ACT	34.44 (*12.77*)	-4.88	<.001	1.17
	WL	56.11 (*15.46*)			
Pain Fusion (G-PIPS-fus.)	ACT	17.97 (*5.62*)	-3.88	<.001	.92
	WL	22.47 (*3.97*)			
Avoidance of Pain (G-PIPS-avoid)	ACT	21.47 (*9.13*)	-4.40	<.001	1.05
	WL	33.28 (*12.90*)			
Committed Actions (CAQ)	ACT	32.59 (*7.01*)	2.33	.02	.55
	WL	28.38 (*8.13*)			
Values Progress (VQ-Pr.)	ACT	21.21 (*4.15*)	1.79	.07	.43
	WL	18.81 (*6.69*)			
Values Obstructions (VQ-Ob)	ACT	10.21 (*6.13*)	-2.83	.006	.67
	WL	14.46 (*6.47*)			
Mindfulness (CAMS-R)	ACT	34.85 (*6.64*)	1.31	.19	.31
	WL	32.78 (*6.64*)			

Note 1. Effect sizes were assessed using Cohen's *d* as follow: *d* = 0.2 (small effect), *d* = 0.5 (medium effect), and *d* = 0.8 (large effect; Cohen, 1988).

Table 8

Descriptive Statistics and Correlations between Treatment Outcomes at T1-T2, T1-T3 Change Scores and Mediators.

	Variables	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1	HDI-T (T1-T2)	-																			
2	HDI-T (T1-T3)	.82***	-																		
3	HDI-Func. (T1-T2)	.92***	.77***	-																	
4	HDI-Func. (T1-T3)	.74***	.93***	.82***	-																
5	HDI-EM (T1-T2)	.93***	.75***	.74***	56***	-															
6	HDI-EM (T1-T3)	.80***	.94***	.63***	.75***	.83***	-														
7	MSQ-RR (T1-T2)	-.40***	-.56***	-.44***	-.58***	-.32**	-.46***	-													
8	MSQ-RR (T1-T3)	-.42***	-.58***	-.47***	-.62***	-.31**	-.48***	.87***	-												
9	MSQ-RP (T1-T2)	-.30**	-.48***	-.30**	-.47***	-.25*	-.43***	.70***	.62***	-											
10	MSQ-RP (T1-T3)	-.46***	-.64***	-.48**	-.62***	-.40***	-.59***	.65***	.73***	.78***	-										
11	MSQ-EM (T1-T2)	-.47***	-.42***	-.38***	-.39***	-.49***	.40***	.63***	.57***	.57***	.59***	-									
12	MSQ-EM (T1-T3)	-.40***	-.50***	-.36**	-.46***	-.39***	-.49***	.60***	.61***	.47***	.67***	.84***	-								
13	G-CPAQ	.34**	.27*	.36**	.36**	.24*	.24*	-.34**	-.30*	-.17	-.09	.23*	-.05	-							
14	G-PIPS-T	-.36**	-.36**	-.37**	-.36**	-.27*	-.32**	.28*	.36**	.08	.13	.15	.13	-.80***	-						
15	G-PIPS-av.	-.38***	-.37**	-.39***	-.38**	-.27*	-.31*	.32**	.38**	.08	.16	.16	.15	-.81***	.96***	-					
16	G-PIPS-Fus.	-.27*	-.26*	-.24*	-.23	-21	-.26*	.17	.20	.05	.03	.10	.03	-.60***	.79***	.61***	-				

17	CAQ	.20	.26*	.17	.24	.16	.24	-.21	-.27*	-.11	-.19	-.23*	-.23	.51***	-.52***	-.47***	-.43***	-		
18	VQ-Pr.	.34**	.37**	.31**	.37**	.31**	.31**	-.32**	-.27*	-.17	-.29*	-.36**	-.35**	.52***	-.39***	-.40***	-.26*	.69***	.56***	-
19	VQ-Ob.	-.25*	-.22	-.30*	-.26*	-.16	-.16	.18	.28*	.06	.22	.06	.07	-.46**	.52***	.51***	.36**	-.57***	-.63***	-.57***	-
20	CAMS-R	.20	.15	.18	.15	.16	.13	-.10	-.18	-.03	-.08	-.06	-.11	.32*	-.31**	-.30*	-.23*	.62***	-.57***	.56***	-.63***
	M	10.71	13.68	5.87	7.29	6.34	6.39	-13.16	-14.33	-8.82	-9.60	-8.89	-9.57	26.14	47.90	27.54	20.29	30.39	19.97	12.42	33.77
	SD	20.02	18.63	9.99	9.54	11.01	10.38	19.45	18.17	21.18	21.60	23.02	28.71	9.36	16.41	12.63	5.31	7.85	5.69	6.62	6.67

Notes:T1-T2 = Pre and Post change scores; T1-T3 = Pre to 3-month follow-up change scores; M= HDI-T = Headache Disability Inventory- Total; HDI-Func. = Headache Disability Inventory- Functional; HDI-EM = Headache Disability Inventory- Emotional; MSQ-RR = Migraine-specific Quality of Life-Role Restrictive; MSQ-RP = Migraine-specific Quality of Life-Role Preventive; MSQ-EM = Migraine-specific Quality of Life- Emotional Role; G-CPAQ = Greek Chronic Pain Acceptance Questionnaire; G-PIPS-T = Greek Psychological Inflexibility in Pain Scale- Total; G-PIPS-av. = Greek Psychological Inflexibility in Pain Scale- avoidance; G-PIPS-fus. = Greek Psychological Inflexibility in Pain Scale-Fusion; CAQ = Committed Action Questionnaire; VQ-Pr. = Values Questionnaire Progress; VQ-Ob. = Values Questionnaire Obstruction; CAMS-R = Cognitive and Affective Mindfulness Scale-Revised; Mean, SD= standard Deviation,
***$p < .000$, ** $p < .01$, * $p < .05$.

Table 9

Results from Mediation Analyses with Disability Total Scale and its Subscales (HDI; T1-T2 Change Scores) as Outcomes

							Bootstrap results for indirect effects : bias corrected & accelerated confidence internals (BCa) (95% CI)[2]	
Mediators		Paths	Coefficient	SE	*t*	*p*	Lower	Upper
			General Disability (HDI)					
	Pain Acceptance	*a*	-7.02	2.11	-3.33	.0014		
		b	.58	.26	2.21	.0302		
		Total (*c*)	-12.20	4.70	-2.59	.0115		
		Direct (*c'*)	-8.11	4.93	-1.64	.1046		
		a * *b*					-8.83	-1.13
PIPS	Psychological Inflexibility in pain	*a*	16.76	3.46	4.83	<.0001		
		b	-.34	.16	-2.11	.0388		
		Total (*c*)	-12.64	4.76	-3.65	.0100		
		Direct (*c'*)	-6.81	5.40	-1.26	.2120		
		a * *b*					-11.23	-1.87
PIPS-Avoid.	Avoidance of pain	*a*	12.01	2.71	4.42	<.0000		
		b	-.49	.20	-2.41	.0190		
		Total (*c*)	-11.90	4.75	-2.50	.0148		

		Direct (*c'*)	-5.92	5.22	-1.13	.2606		
		a * *b*					-10.78	-2.11
PIPS-Fus.	Fusion with pain	*a*	4.37	1.17	3.75	.0004		
		b	-.63	.49	-1.28	.2020		
		Total (c)	-12.93	4.70	-2.74	.0077		
		Direct (*c'*)	-10.16	5.15	-1.97	.0525		
		a * *b*					-.38	.043
CAQ	Committed Actions	*a*	-4.33	1.83	-2.37	.0205		
		b	.33	.31	1.05	.2935		
		Total (c)	-12.20	4.70	-2.59	.0115		
		Direct (*c'*)	-10.77	4.88	-2.21	.0309		
		a * *b*					-5.25	.95
VQ-Pr.	Values Progress	*a*	-2.41	1.36	-1.76	.0814		
		b	1.05	4.11	2.56	.0127		
		Total (c)	-12.01	4.76	-2.52	.0140		
		Direct (*c'*)	-9.48	4.68	-2.02	.0469		
		a * *b*					-6.06	-.07
VQ-Ob.	Values Obstruction	*a*	4.09	1.51	2.71	.0084		
		b	-.54	.37	-1.46	.1482		
		Total (c)	-12.20	4.69	-2.59	.0115		
		Direct (*c'*)	-9.95	4.91	-2.03	.0463		
		a * *b*					-7.05	.14

CAMS-R	Mindfulness	*a*	-2.24	1.58	-1.41	.1628		
		b	.48	.35	1.35	.1819		
		Total (c)	-12.20	4.70	-2.59	.0115		
		Direct (*c'*)	-11.12	4.74	-2.34	.0219		
		a * *b*					-5.57	.33
		Functional Disability (HDI-Func)						
G-CPAQ	Pain Acceptance	*a*	-7.02	2.11	-3.33	<.0000		
		b	.29	.13	-2.01	.0282		
		Total (c)	-6.91	2.31	-2.98	.0039		
		Direct (*c'*)	-4.87	2.42	-2.02	.0483		
		a * *b*					-4.08	-.71
G-PIPS	Psychological Inflexibility in Pain	*a*	16.76	3.47	4.83	<.0000		
		b	-.15	.08	-1.88	.0641		
		Total (c)	-7.29	2.32	-3.14	.0025		
		Direct (*c'*)	-4.74	2.64	-1.79	.0722		
		a * *b*					-4.99	-.50
G-PIPS-Av.	Avoidance of Pain	*a*	12.01	2.72	4.42	<.0000		
		b	-.24	.10	-2.39	.0196		
		Total (c)	-6.78	2.34	-2.90	.0051		
		Direct (*c'*)	-3.85	2.57	-1.49	.1385		
		a * *b*					-5.37	-.99

G-PIPS-Fus.	Fusion with Pain	*a*	4.37	1.17	3.75	.0004		
		b	-.20	.24	-.87	.3846		
		Total (c)	-7.41	2.28	-3.24	.0018		
		Direct (*c'*)	-6.49	2.52	-2.57	.0121		
		a * *b*					-3.14	.95
VQ- Pr.	Value Progress	*a*	-2.40	1.36	-1.76	.0814		
		b	.44	.20	2.16	.0342		
		Total (c)	-6.95	2.34	-2.96	.0042		
		Direct (*c'*)	-5.88	2.33	-2.52	.0141		
		a * *b*					-.25	-.01
VQ-Ob.	Value Obstruction	*a*	4.09	1.51	2.71	.0084		
		b	-.33	.18	-1.83	.0709		
		Total (c)	-6.90	2.31	-2.98	.0039		
		Direct (*c'*)	-5.53	2.39	-2.31	.0237		
		a * *b*	-1.37	.90	-1.45	.1460	-4.00	-.15
CAMS-R	Mindfulness	*a*	-2.24	1.58	-1.41	.1628		
		b	.20	.17	1.13	.2625		
		Total (c)	-6.90	2.31	-2.98	.0039		
		Direct (*c'*)	-6.46	2.33	-2.76	.0074		
		a * *b*					-2.29	.21
			Emotional Disability (HDI-Em)					
G-CPAQ	Pain Acceptance	*a*	-7.02	2.11	-3.33	.0014		

		b	.22	.15	1.51	.1257		
		Total (c)	-4.75	2.65	-1.79	.0076		
		Direct (*c'*)	-3.14	2.83	-1.11	.2706		
		a * *b*					-4.23	-.07
G-PIPS	Psychological Inflexibility in Pain	*a*	16.76	3.47	4.83	<.0000		
		b	-.15	.09	-1.61	.1122		
		Total (c)	-4.82	2.72	-1.77	.0809		
		Direct (*c'*)	-2.57	3.12	-.71	.4750		
		a * *b*					-5.52	-.33
G-PIPS-Avoid.	Avoidance of Pain	*a*	12.01	2.71	4.42	<.0000		
		b	-.20	.11	-1.72	.0898		
		Total (c)	-4.64	2.68	-1.73	.0886		
		Direct (*c'*)	-2.18	3.01	-.72	.4719		
		a * *b*					-.45	-.04
G-PIPS-Fus.	Fusion with pain	*a*	4.37	1.16	3.75	.0004		
		b	-.29	.28	-1.04	.2986		
		Total (c)	-4.92	2.68	-1.84	.0707		
		Direct (*c'*)	-3.64	2.94	-1.23	.2211		
		a * *b*					-4.06	.60
CAQ	Committed Actions	*a*	-4.92	2.02	-2.42	.0184		
		b	.13	.15	.85	.4001		
		Total (c)	-8.67	2.29	-3.79	.0004		
		Direct (*c'*)	-8.04	2.41	-3.33	.0015		
		a * *b*					-2.82	.88

VQ-Prog.	Values Progress	*a*	-1.58	1.50	-1.05	.2975		
		b	.52	.19	2.70	.0091		
		Total (c)	-8.04	2.25	-3.56	.0008		
		Direct (*c'*)	-7.22	2.16	-3.35	.0015		
		a * *b*					-.27	.07
VQ-Obstr.	Values Obstruction	*a*	4.09	1.51	2.71	.0084		
		b	-.18	.21	-.83	.4069		
		Total (c)	-4.75	2.65	-1.79	.0776		
		Direct (*c'*)	-4.02	2.80	-1.44	.1552		
		a * *b*					-3.30	.65
CAMS-R	Mindfulness	*a*	-1.81	1.77	-1.02	.3111		
		b	.12	.17	.72	.4754		
		Total (c)	-8.67	2.28	-3.78	.0004		
		Direct (*c'*)	-8.44	2.32	-3.63	.0006		
		a * *b*					-1.70	.30

Note 1: T1-T2 = pre to post treatment change scores
Note 2: Bootstrap distribution in adjusted for bias and skewness at ninety five percentage confidence interval equates $p < .05$ (BCa; 95% CI).

Table 10

Results from Mediation Analyses with Disability Total and its Sub-scales (HDI; T1-T3 change scores) as Outcomes

							Bootstrap results for indirect effects :bias corrected & accelerated confidence internals (BCa) (95% CI)[2]	
Mediators		Paths	Coefficient	SE	t^1	*p*	Lower	Upper
		General Headache Disability (HDI)						
G-CPAQ	Pain Acceptance	*a*	*-7.49*	2.50	-2.99	-2.99		
		b	.25	.24	1.03	.3036		
		Total (*c*)	-15.39	4.54	-3.39	.0013		
		Direct (*c'*)	-13.51	4.88	-2.76	.0078		
		a * *b*					-7.74	1.51
G-PIPS	Psychological Inflexibility in pain	*a*	16.37	3.94	4.15	.0001		
		b	-.23	.16	-1.52	.1329		
		Total (*c*)	-15.68	4.63	-3.39	.0013		
		Direct (*c'*)	-11.78	5.23	-2.25	.0258		
		a * *b*					-9.72.	.37
G-PIPS-Avoid.	Avoidance of pain	*a*	11.66	3.03	3.85	.0003		
		b	-.33	.20	-1.63	.1096		
		Total (*c*)	-15.68	4.63	-3.39	.0013		
		Direct (*c'*)	-11.83	5.13	-2.30	.0251		
		a * *b*					-9.37	.39

G-PIPS-Fus.	Fusion with pain	*a*	4.92	1.34	3.66	.0005		
		b	-.33	.45	-2.70	.0091		
		Total (*c*)	-15.40	4.54	-3.39	.0013		
		Direct (*c'*)	-13.74	5.10	-2.70	.0091		
		a * *b*					-7.17	2.69
CAQ	Committed Actions	*a*	-4.91	2.03	-2.42	.0184		
		b	.33	.29	1.11	.2684		
		Total (*c*)	-15.40	4.54	-3.39	.0013		
		Direct (*c'*)	-13.75	4.76	-2.99	.0056		
		a * *b*					-6.59	.57
VQ-Prog.	Values Progress	*a*	-1.58	1.49	-1.05	.2957		
		b	1.02	.38	2.67	.0100		
		Total (*c*)	-14.21	4.30	-2.92	.0025		
		Direct (*c'*)	-12.60	4.30	-2.92	.0050		
		a * *b*					-5.50	1.30
VQ-Ob.	Values Obstruction	*a*	3.04	1.67	1.82	.0742		
		b	-.38	.36	-1.06	.2921		
		Total (*c*)	-15.40	4.54	-3.39	.0013		
		Direct (*c'*)	-14.22	4.66	-3.04	.0036		
		a * *b*					-5.67	.78
CAMS-R	Mindfulness	*a*	-1.81	1.77	-1.02	.3111		
		b	.26	.34	.77	.4441		
		Total (*c*)	-15.40	4.54	-3.39	.0013		
		Direct (*c'*)	-14.92	4.60	-3.24	.0020		
		a * *b*					-3.46	.52
			Functional Disability (HDI-Func.)					
G-CPAQ	Pain Acceptance	*a*	-7.48	2.50	-2.99	.0041		
		b	.10	.12	.83	.4079		

		Total (*c*)	-8.67	2.29	-3.78	.0004		
		Direct (*c'*)	-7.90	2.47	-3.19	.0023		
		a * *b*					-3.40	1.15
G-PIPS-	Psychological Inflexibility in pain	*a*	16.37	3.94	4.15	.0001		
		b	-7.16	2.64	-2.70	.0090		
		Total (*c*)	-8.89	2.32	-3.82	.0003		
		Direct (*c'*)	-7.16	2.64	-2.70	.0090		
		a * *b*					-.50	.06
G-PIPS-Avoid.	Avoidance of pain	*a*	11.66	3.02	3.85	.0003		
		b	-.16	.10	-1.59	.117		
		Total (*c*)	-8.89	2.32	-3.82	.0003		
		Direct (*c'*)	-6.99	2.58	-2.70	.0091		
		a * *b*					-4.75	.22
G-PIPS-Fus.	Fusion with pain	*a*	4.92	1.34	3.66	.0005		
		b	-.06	.23	-.26	.7927		
		Total (*c*)	-8.37	2.57	-3.26	.0019		
		Direct (*c'*)	-8.37	2.57	-3.25	.0019		
		a * *b*					-2.75	1.98
VQ-Pr.	Value Progress	*a*	-2.40	1.36	-1.77	.0814		
		b	.44	.20	2.16	.0342		

		Total (*c*)	-6.95	2.34	-2.96	.0042		
		Direct (*c'*)	-5.88	2.33	-2.52	.0141		
		a * *b*					-2.67	-.03
VQ-Obs.	Values Obstruction	*a*	3.04	1.67	1.82	.0742		
		b	-.24	.18	-1.33	.1894		
		Total (*c*)	-8.67	2.28	-3.78	.0004		
		Direct (*c'*)	-7.93	2.34	-3.39	.0013		
		a * *b*					-3.00	.29
CAMS-R	Mindfulness	*a*	-2.24	1.58	-1.41	.1628		
		b	.20	.17	1.13	.2625		
		Total (*c*)	-6.90	2.31	-2.98	.0039		
		Direct (*c'*)	-6.46	2.33	-2.76	.0074		
		a * *b*					-.20	.02
		Emotional Disability (HDI-Em.)						
G-CPAQ	Pain Acceptance	*a*	-7.48	2.50	-2.99	.0041		
		b	.14	.14	1.06	.2917		
		Total (*c*)	-6.72	2.63	-2.55	.0133		
		Direct (*c'*)	-5.60	2.83	-1.98	.0527		
		a * *b*					-4.48	.65
G-PIPS	Psychological Inflexibility in pain	*a*	16.37	3.94	4.15	<.0000		
		b	-.13	.09	-1.46	.1497		

		Total (*c*)	-6.78	2.68	-2.53	.0143		
		Direct (*c'*)	-4.61	3.04	-1.51	.1349		
		a * *b*					-5.65	.34
G-PIPS-Avoid.	Avoidance of pain	*a*	11.66	3.03	3.85	.0003		
		b	-.16	.12	-1.41	.1627		
		Total (*c*)	-6.79	2.68	-2.53	.0143		
		Direct (*c'*)	-4.83	2.99	-1.61	.1124		
		a * *b*					-.51	.03
G-PIPS-Fus.	Fusion with pain	*a*	4.92	1.34	3.66	.0005		
		b	-.28	.26	-1.05	.2954		
		Total (*c*)	-6.72	2.63	-2.55	.0133		
		Direct (*c'*)	-5.36	2.92	-1.83	.0723		
		a * *b*					-4.80	1.04
VQ-Pr.	Value Progress	*a*	-2.40	1.36	-1.77	.0814		
		b	.44	.20	2.16	.0342		
		Total (*c*)	-6.95	2.34	-2.96	.0042		
		Direct (*c'*)	-5.88	2.33	-2.52	.0141		
		a * *b*					-2.67	-.03
VQ-Obs.	Values Obstruction	*a*	3.04	1.67	1.82	.0742		
		b	-.14	.21	-.68	.4979		
		Total (*c*)	-6.72	2.63	-2.55	.0133		
		Direct (*c'*)	-6.28	2.72	-2.31	.0247		
		a * *b*					-2.58	.69
CAMS-R	Mindfulness	*a*	-1.81	1.77	-1.02	.3111		
		b	.14	.19	.70	.4843		
		Total (*c*)	-6.72	2.63	-2.55	.0133		
		Direct (*c'*)	-6.47	2.66	-2.42	.0186		

*a * b*	-2.16	.35

Note 1: T1-T3 = pre to three months follow-up change scores
Note 2: Bootstrap distribution in adjusted for bias and skewness at ninety five percentage confidence interval equates $p < .05$ (BCa; 95% CI).

Table 11

Results from Mediation Analyses with Quality of Life Dimensions (MSQ; T1-T2 change scores) as Outcome Measures

							Bootstrap results for indirect effects :bias corrected & accelerated confidence internals (BCa) (95% CI)[2]	
Mediators		Paths	Coefficient	SE	t^1	*p*	Lower	Upper
			Role Restrictive (MSQ-RR)					
G-CPAQ	Pain Acceptance	*a*	-7.02	2.10	-3.33	.0014		
		b	-.55	.24	-2.25	.0275		
		Total (*c*)	9.90	4.35	2.27	.0262		
		Direct (*c'*)	6.04	4.56	1.32	.1986		
		a * *b*					.41	9.16
G-PIPS	Psychological Inflexibility in pain	*a*	16.76	3.46	4.83	.0001		
		b	.21	.15	1.37	.1732		
		Total (*c*)	10.33	4.33	2.38	.0200		
		Direct (*c'*)	6.81	5.01	1.35	.1790		
		a * *b*					-.35	8.81
G-PIPS-Avoid.	Avoidance of Pain	*a*	12.01	2.72	4.42	<.0000		
		b	.38	.19	1.95	.0548		
		Total (*c*)	9.37	4.38	2.13	.0361		
		Direct (*c'*)	4.84	4.88	.99	.3250		

		*a * b*					.72	9.54
G-PIPS-Fus.	Fusion with pain	*a*	4.37	1.16	3.74	.0004		
		b	.21	.45	.48	.6298		
		Total (*c*)	10.84	4.30	2.51	.0141		
		Direct (*c'*)	9.88	4.76	2.07	.0418		
		*a * b*					-3.71	6.07
CAQ	Committed Actions	*a*	-4.33	1.82	-2.37	.0205		
		b	-.34	.28	-1.19	.2375		
		Total (*c*)	9.89	4.35	2.27	.0262		
		Direct (*c'*)	8.41	4.51	1.86	.0670		
		*a * b*					-.40	5.29
VQ-Pr	Values Progress	*a*	-2.40	1.36	-1.76	.0814		
		b	-.91	.37	-2.41	.0188		
		Total (*c*)	9.21	4.35	2.11	.0383		
		Direct (*c'*)	7.02	4.30	1.63	.1078		
		*a * b*					.02	6.31
VQ-Ob.	Values Obstruction	*a*	4.09	1.51	2.71	.0084		
		b	.29	4.59	1.89	.0627		
		Total (*c*)	9.89	4.35	2.27	.0262		
		Direct (*c'*)	8.69	4.59	1.89	.0627		

		*a * b*					-.10	.29
CAMS-R	Mindfulness	*a*	-1.81	1.77	-1.02	.3111		
		b	-.34	.33	-1.04	.2991		
		Total (*c*)	14.01	4.41	3.17	.0024		
		Direct (*c'*)	13.38	4.45	3.00	.0040		
		*a * b*					-.57	4.34
		Role Preventive (MSQ-RP)						
G-CPAQ	Pain Acceptance	*a*	-7.02	2.10	-3.33	.0014		
		b	-.25	.27	-.91	.3611		
		Total (*c*)	7.86	4.73	1.66	.1015		
		Direct (*c'*)	6.10	5.11	1.19	.2372		
		*a * b*					-.05	.28
G-PIPS	Psychological Inflexibility in pain	*a*	16.76	3.46	4.83	.0000		
		b	-.04	.17	-.26	.7903		
		Total (*c*)	8.23	4.86	1.69	.0953		
		Direct (*c'*)	9.01	5.70	1.58	.1188		
		*a * b*					-6.00	3.25
G-PIPS-Fus.	Fusion with pain	*a*	4.37	1.16	3.74	.0004		
		b	-.17	.50	-.34	.7301		
		Total (*c*)	8.18	4.79	1.70	.0923		
		Direct (*c'*)	8.95	5.30	1.68	.0964		

		*a * b*					-6.01	3.05
G-PIPS-Avoid.	Avoidance of pain	*a*	12.01	2.71	4.42	.0000		
		b	-.01	.21	-.07	.9376		
		Total (*c*)	7.90	4.80	1.644	.1048		
		Direct (*c'*)	8.10	5.50	1.47	.1455		
		*a * b*					-4.93	3.61
CAQ	Committed Actions	*a*	-4.33	1.82	-2.37	.0205		
		b	-.14	.3161	-.46	.6438		
		Total (*c*)	7.86	4.73	1.66	.1015		
		Direct (*c'*)	7.23	4.96	1.45	.1496		
		*a * b*					-1.54	4.14
VQ-Pr.	Values Progress	*a*	-2.40	1.36	-1.76	.0814		
		b	-.48	.43	-1.12	.2648		
		Total (*c*)	7.76	4.80	1.61	.1111		
		Direct (*c'*)	6.59	4.90	1.34	.1836		
		*a * b*					-.07	4.85
VQ-Ob.	Values Obstruction	*a*	4.09	1.51	2.71	.0084		
		b	.012	.38	.03	.9751		
		Total (*c*)	7.86	4.73	1.66	.1015		
		Direct (*c'*)	7.81	5.02	1.55	.1245		
		*a * b*					-3.92	4.05

CAMS-R	Mindfulness	*a*	-2.24	1.58	-1.41	.1628		
		b	.00	.36	.02	.9786		
		Total (*c*)	7.86	4.73	1.66	.1015		
		Direct (*c'*)	7.88	4.84	1.62	.1080		
		*a * b*					-2.51	1.75
			Emotional Role (MSQ-EM)					
G-CPAQ	Pain Acceptance	*a*	-6.99	2.13	-3.27	.0017		
		b	-.48	.31	-1.51	.1341		
		Total (*c*)	7.37	5.59	1.31	.1920		
		Direct (*c'*)	4.01	5.97	.67	.5038		
		*a * b*					-.52	9.87
G-PIPS	Psychological Inflexibility in Pain	*a*	16.52	3.51	4.70	.0000		
		b	.14	.20	.70	.4831		
		Total (*c*)	6.92	5.74	1.20	.2324		
		Direct (*c'*)	4.54	6.67	.68	.4979		
		*a * b*					-2.13	7.68
G-PIPS-Fus.	Fusion with pain	*a*	4.32	1.18	3.65	.0005		
		b	.20	.59	.344	.7307		
		Total (*c*)	7.45	5.68	1.31	.1942		
		Direct (*c'*)	6.56	6.27	1.04	.2993		
		*a * b*					-2.97	5.48

G-PIPS-Avoid.	Avoidance of pain	*a*	11.82	2.74	4.30	.0001		
		b	.20	.25	.81	.4205		
		Total (*c*)	6.86	5.65	1.21	.2293		
		Direct (*c'*)	4.42	6.41	.69	.4925		
		*a * b*					-.06	.31
CAQ	Committed Actions	*a*	-4.33	1.82	-2.37	.0205		
		b	-.14	.3161	-.46	.6438		
		Total (*c*)	7.86	4.73	1.66	.1015		
		Direct (*c'*)	7.23	4.96	1.45	.1496		
		*a * b*					-1.54	4.14
VQ-Ob.	Value Obstruction	*a*	3.87	1.51	2.55	.0127		
		b	.06	.45	.13	.8904		
		Total (*c*)	7.37	5.59	1.31	.1920		
		Direct (*c'*)	7.13	5.90	1.20	.2316		
		*a * b*					-2.45	4.27
VQ-Pr.	Value Progress	*a*	-2.38	1.38	-1.73	.0889		
		b	-1.35	.47	-2.90	.0050		
		Total (*c*)	6.08	5.52	1.10	.2749		
		Direct (*c'*)	2.84	5.35	.5319	.5966	.10	9.00
		*a * b*						

CAMS-R	Mindfulness	*a*	-2.24	1.58	-1.41	.1628		
		b	.00	.36	.02	.9786		
		Total (*c*)	7.86	4.73	1.66	.1015		
		Direct (*c'*)	7.88	4.84	1.62	.1080		
		a * *b*					-2.51	1.75

Note 1: T1-T2 = pre to post treatment change scores
Note 2: Bootstrap distribution in adjusted for bias and skewness at ninety five percentage confidence interval equates $p < .05$ (BCa; 95% CI).

Table 12

Results from Mediation Analyses with Quality of Life Dimensions (MSQ; T1-T3 change scores) as Outcomes

							Bootstrap results for indirect effects :bias corrected & accelerated confidence internals (BCa) (95% CI)[2]	
Mediators		Paths	Coefficient	SE	*t*	*p*	Lower	Upper
			Role Restrictive Dimension (RR-MSQ)					
G-CPAQ	Pain Acceptance	*a*	-7.48	2.50	-2.99	.0041		
		b	-.31	.23	-1.33	.1879		
		Total (*c*)	14.01	4.41	3.17	.0024		
		Direct (*c'*)	11.67	4.72	2.47	.0166		
		a * *b*					-.01	7.86
G-PIPS	Psychological Inflexibility in Pain	*a*	16.37	3.95	4.15	<.0000		
		b	.23	.15	1.51	.1361		
		Total (*c*)	14.43	4.48	3.22	.0022		
		Direct (*c'*)	10.57	5.08	2.10	.0403		
		a * *b*					.08	8.95
G-PIPS- Av.	Avoidance of Pain	*a*	11.66	3.03	3.85	.0003		
		b	.35	.19	1.81	.0755		
		Total (*c*)	14.43	4.49	3.22	.0022		

		Direct (*c'*)	10.29	4.95	2.08	.0424		
		a * *b*					.06	9.33
G-PIPS-Fus.	Pain Fusion	*a*	4.92	1.34	3.66	.0005		
		b	.12	.44	.29	.7725		
		Total (*c*)	14.01	4.42	3.17	.0024		
		Direct (*c'*)	13.38	4.96	2.69	.0092		
		a * *b*					-5.22	6.06
CAQ	Committed Actions	*a*	4.92	1.34	3.66	.0005		
		b	.13	.44	.29	.7725		
		Total (*c*)	14.01	4.42	3.17	.0024		
		Direct (*c'*)	13.38	4.96	2.69	.0092		
		a * *b*					-5.22	6.06
VQ-Pr.	Values Progress	*a*	-1.57	1.49	-1.05	.2975		
		b	-.70	.39	-1.78	.0802		
		Total (*c*)	13.66	4.49	3.04	.0036		
		Direct (*c'*)	12.55	4.44	2.82	.0067		
		a * *b*					-.62	5.19
VQ-Ob.	Values Obstructions	*a*	3.04	1.67	1.81	.0742		
		b	.56	.34	1.61	.1128		
		Total (*c*)	14.01	4.42	3.17	.0024		
		Direct (*c'*)	12.32	4.48	2.74	.0081		
		a * *b*					-.32	7.81
CAMS-R	Mindfulness	*a*	-1.82	1.77	-1.02	.3111		
		b	-.35	.33	-1.04	.2991		
		Total (*c*)	14.01	4.41	3.17	.0024		
		Direct (*c'*)	13.38	4.45	3.00	.0040		
		a * *b*					-.57	4.34
		Role Preventive Dimension (RP-MSQ)						
G-CPAQ	Pain Acceptance	*a*	-7.48	2.50	-2.99	.0041		
		b	.10	.27	.39	.6927		

		Total (*c*)	15.06	5.10	2.94	.0046		
		Direct (*c'*)	15.88	5.54	2.86	.0059		
		a * *b*					-6.35	2.56
G-PIPS	Psychological Inflexibility in pain	*a*	16.37	3.94	4.19	.0001		
		b	-.08	.17	-.44	.6577		
		Total (*c*)	15.61	5.18	3.01	.0039		
		Direct (*c'*)	16.91	5.98	2.82	.0066		
		a * *b*					-8.22	3.16
G-PIPS-Fus.	Pain Fusion	*a*	4.92	1.34	3.66	.0005		
		b	-.57	.50	-1.13	.2603		
		Total (*c*)	15.06	5.10	2.94	.0046		
		Direct (*c'*)	17.90	5.67	3.15	.0026		
		a * *b*					-10.48	1.64
G-PIPS-Avoid.	Avoidance of pain	*a*	11.66	3.02	3.85	.0003		
		b	-.03	.23	-.13	.9034		
		Total (*c*)	15.61	5.18	3.01	.0039		
		Direct (*c'*)	15.94	5.89	2.70	.0091		
		a * *b*					-6.83	3.95
CAQ	Committed Actions	*a*	-4.91	2.02	-2.42	.0184		
		b	-.22	.33	-.67	.5007		
		Total (*c*)	15.06	5.10	2.94	.0046		
		Direct (*c'*)	13.93	5.39	2.58	.0125		
		a * *b*					-.07	.24
VQ-Pr.	Value Progress	*a*	-1.57	1.49	-1.05	.2975		
		b	-.88	.45	-1.93	.0132		
		Total (*c*)	14.46	5.17	2.79	.0072		
		Direct (*c'*)	13.07	5.10	2.56	.0132		
		a * *b*					-.93	5.97
VQ-Ob.	Value Obstructions	*a*	3.04	1.67	1.81	.0742		
		b	.44	.41	1.08	.2811		

		Total (*c*)	15.06	5.10	2.94	.0046		
		Direct (*c'*)	13.72	5.24	2.61	.0115		
		a * *b*					-.57	6.94
CAMS-R	Mindfulness	*a*	-1.82	1.77	-1.02	.3111		
		b	-.09	.38	-.25	.8052		
		Total (*c*)	15.06	5.11	2.94	.0046		
		Direct (*c'*)	14.89	5.20	2.86	.0059		
		a * *b*					-1.02	3.08
		Emotional Role (MSQ-EM)						
G-CPAQ	Pain Acceptance	*a*	-7.48	2.50	-2.99	.0041		
		b	.09	.35	.26	.7916		
		Total (*c*)	11.16	6.58	1.69	.0953		
		Direct (*c'*)	11.87	7.15	1.66	.1024		
		a * *b*					-9.03	7.05
G-PIPS	Psychological Inflexibility in pain	*a*	16.37	3.94	4.14	.0001		
		b	.02	.23	.10	.9163		
		Total (*c*)	11.80	6.68	1.76	.0829		
		Direct (*c'*)	11.40	7.72	1.47	.1457		
		a * *b*					-7.60	7.38
G-PIPS-Avoid.	Avoidance of pain	*a*	11.66	3.02	3.85	.0003		
		b	.10	.30	.33	.7394		
		Total (*c*)	11.80	6.68	1.76	.0829		
		Direct (*c'*)	10.63	7.59	1.40	.1670		
		a * *b*					-.22	.37
G-PIPS-Fus.	Fusion with pain	*a*	4.92	1.35	3.66	.0005		
		b	-.35	.65	-.53	.5952		
		Total (*c*)	11.17	6.58	1.69	.0953		
		Direct (*c'*)	12.90	7.37	1.74	.0859		
		a * *b*					-9.08	3.93
CAQ	Committed Action	*a*	-4.42	1.85	-2.38	.0200		

		b	-.59	.36	-1.62	.1102		
		Total (*c*)	7.37	5.59	1.32	.1920		
		Direct (*c'*)	4.77	5.76	.82	.4106		
		a * *b*					-.01	.35
VQ-Ob.	Values Obstruction	*a*	-2.38	1.38	-1.72	.0889		
		b	-1.35	.46	-2.90	.0050		
		Total (*c*)	6.07	5.52	1.10	.2749		
		Direct (*c'*)	2.84	5.35	.53	.5966		
		a * *b*					.38	7.70
VQ-Pr.	Values Progress	*a*	-2.84	5.35	.53	.5966		
		b	-1.35	.46	-2.90	.0050		
		Total (*c*)	6.07	5.52	1.11	.2749		
		Direct (*c'*)	2.84	5.35	1.11	.2749		
		a * *b*					.09	9.00
CAMS-R	Mindfulness	*a*	-1.99	1.59	-1.25	.2140		
		b	-.12	.43	-.28	.7777		
		Total (*c*)	7.37	5.59	1.31	.1920		
		Direct (*c'*)	7.13	5.70	1.25	.2154		
		a * *b*					-1.23	3.50

Note 1: T1-T3 = pre to three months follow-up change scores

Note 2: Bootstrap distribution in adjusted for bias and skewness at ninety five percentage confidence interval equates $p < .05$ (BCa; 95% CI).

APPENDICES

Appendix A

Table A-1

Treatment Completers: 2X3 Repeated Measures ANOVA of Group (ACT vs. WL) by Time (pre, post, follow-up) for Treatment Outcomes

Variables	Groups	Means (*SD*)[1]			Interaction effects of Group by Time (pre, post, fup-3)	Effect Sizes : η_p^2
		Pre	Post	FUP-3	F (*df*)[2]	η_p^2
			Primary Outcomes			
General Disability (HDI; 0-100)	ACT	51.35 (*21.28*)	34.13 (*21.20*)	31.29 (*21.32*)	5.96 ** (*1.58, 118*)	.09
	WL	58.13 (*22.95*)	51.93 (*29.30*)	50.87 (*26.98*)		
Functional Disability (HDI- Func; 0-48)	ACT	27.29 (*10.84*)	17.42 (*11.40*)	16.32 (*11.39*)	8.51*** (*1.63, 118*)	.13
	WL	29.60 (*11.81*)	26.73 (*14.20*)	26.00 (*13.72*)		
Emotional Disability (HDI- Em; 0-52)	ACT	24.06 (*11.59*)	15.48 (*10.68*)	14.97 (*11.30*)	2.91* (*1.52, 118*)	.05
	WL	28.53 (*12.55*)	23.33 (*14.46*)	24.87 (*13.91*)		
Role Restrictive (MSQ-RR;0-100)	ACT	57.14 (*17.30*)	74.56 (*16.74*)	77.51 (*14.95*)	5.05** (*1.42, 118*)	.08
	WL	49.14 (*18.95*)	56.10 (*23.54*)	57.90 (*20.87*)		
Role Preventive (MSQ-RP;0-100)	ACT	73.23 (*19.52*)	85.97 (*16.90*)	89.03 (*13.25*)	3.43* (*1.68, 118*)	.06
	WL	65.17 (*20.74*)	68.17 (*23.36*)	69.00 (*26.27*)		

Role Emotional (MSQ-EF ;0-100)	ACT	71.83 (*20.20*)	83.01 (*18.60*)	86.45 (*15.82*)	.99 (*1.47, 118*)	.02
	WL	61.78 (*23.61*)	66.44 (*25.40*)	69.11 (*29.16*)		
			Secondary Outcomes			
Pain Severity (GBPI; 0-10)	ACT	4.01 (*1.94*)	3.23 (*1.58*)	3.03 (*1.62*)	2.27 (1.49, 110)	.04
	WL	5.10 (*2.17*)	5.19 (*1.98*)	5.11 (*2.30*)		
Headache medical visits (last 2 months)	ACT	.39 (*.66*)	.39 (*.58*)	.30 (*.47*)	.28 (1.71, 80)	.01
	WL	.53 (*1.13*)	.63 (*.89*)	.58 (*1.02*)		
Headache Medical use (last 2 months)	ACT	1.04 (*1.48*)	.60 (*.82*)	.60 (*.87*)	.79 (1.61, 92)	.01
	WL	.87 (*1.79*)	.87 (*1.46*)	.65 (*1.40*)		
Anxiety (HADS;0-21)	ACT	7.13 (*3.92*)	6.23 (*3.50*)	6.47 (*3.55*)	.72 (1.20, 108)	<.01
	WL	9.73 (*3.88*)	9.15 (*3.87*)	9.08 (*3.59*)		
Depression (HADS;0-21)	ACT	5.35 (*3.19*)	4.71 (*3.13*)	2.48 (*1.50*)	2.07 (1.79, 110)	.04
	WL	7.23 (*3.64*)	6.58 (*3.56*)	3.12 (*1.55*)		

Note 1: Means and Standard Deviations are presented without controlling for pre-treatment scores as covariates. When assumption of sphericity was violated, the Greenhouse-Geisser criterion (corrections for degrees of freedom with Greenhouse-Geisser value greater than .75), were adjusted accordingly (*F*- and *p*- values).
Note 2: Pair-wise comparisons among the observed means (contrast).
Note 3: Effect sizes were assessed using partial eta squared (η_p^2) as follow: η_p^2= 0.01 (small effect), η_p^2 = 0.09 (medium effect), and η_p^2= 0.25 (large effect; Cohen, 1988).
***p <.001; **p <.01; * p <.05.

Table A-2

Treatment Completers: 2X3 Repeated Measures ANOVA Group (ACT vs. WL) by Time (pre, post, follow-up) for Process Measures.

Variables	Groups	Means (*SD*)[1]			Interaction effects of Group by Time (pre, post, fup-3)	Effect Sizes : $\eta_p^{2,3}$
		Pre	Post	FUP-3	F (*df*)[2]	η_p^2
Pain Acceptance (G-CPAQ; 0-47)	ACT	25.35 (*5.71*)	29.71 (*7.39*)	30.84 (*6.92*)	4.42** (*2,55*)	.14
	WL	21.63 (*9.65*)	22.22 (*11.45*)	22.33 (*10.11*)		
Activity Engagement (G-CPAQ-AE; 0-24)	ACT	15.26 (*4.43*)	17.55 (*4.54*)	17.97 (*4.13*)	3.98* (*2,55*)	.13
	WL	13.33 (*6.57*)	12.63 (*7.92*)	13.22 (*7.04*)		
Pain Willingness (G-CPAQ-PW; 0-24)	ACT	10.10 (*3.88*)	12.16 (*4.63*)	12.87 (*4.76*)	1.54 (*1.67, 112*)	.03
	WL	8.30 (*6.04*)	9.59 (*5.65*)	9.11 (*5.35*)		
Psychological Inflexibility in pain (G-PIPS; 10-70)	ACT	50.60 (*13.88*)	39.07 (*13.43*)	38.40 (*15.16*)	10.46*** (*1.30, 102*)	.17
	WL	58.39 (*16.15*)	56.13 (*16.34*)	56.04 (*17.16*)		
Pain Fusion (G-PIPS-fus; 7-42)	ACT	21.87 (*5.30*)	17.71 (*5.78*)	17.13 (*6.56*)	8.48*** (*1.36, 110*)	.13
	WL	23.12 (*4.10*)	22.42 (*4.11*)	22.31 (*4.56*)		
Pain avoidance (G-PIPS-avoid; 10-70)	ACT	28.83 (*9.95*)	21.57 (*9.65*)	21.53 (*10.27*)	6.56** (*1.28, 102*)	.11
	WL	35.48 (*12.97*)	33.91 (*12.97*)	33.70 (*13.39*)		

Committed Actions (CAQ;1-45)	ACT	30.68 (*6.32*)	32.84 (*6.83*)	32.52 (*6.74*)	.73 (1.53, 110)	.01
	WL	26.04 (*7.57*)	27.88 (*8.74*)	26.42 (*7.86*)		
Values Progress (VQ;0-30)	ACT	20.35 (*4.87*)	21.00 (*4.22*)	21.45 (*4.01*)	.27(1.63, 110)	.01
	WL	18.69 (*6.88*)	19.22 (*.82*)	19.64 (*.78*)		
Values Obstructions (VQ;0-30)	ACT	13.16 (*6.38*)	10.03 (*6.29*)	10.90 (*6.82*)	2.43 (1.47, 112)	.04
	WL	14.04 (*5.33*)	13.07 (*6.42*)	14.70 (*6.54*)		
Mindfulness (CAMS-R;20-50)	ACT	33.77 (*6.11*)	35.65*(6.78*)	35.06 (6.81)	1.15 (1.51, 110)	.02
	WL	31.85 (*7.13*)	33.65 *(6.78*)	32.08 (*7.12*)		

Note 1: Means and Standard Deviations are presented without controlling for pre-treatment scores as covariates. When assumption of sphericity was violated, the Greenhouse-Geisser criterion (corrections for degrees of freedom with Greenhouse-Geisser value greater than .75), were adjusted accordingly (*F*- and *p*- values).
Note 2: Pair-wise comparisons among the observed means (contrast).
Note 3: Effect sizes were assessed using partial eta squared (η_p^2) as follow: η_p^2= 0.01 (small effect), η_p^2 = 0.09 (medium effect), and η_p^2= 0.25 (large effect; Cohen, 1988).
****p* <.001; ***p* <.01; * *p* <.05

Appendix B

Consent Forms and Questionnaires/ Forms Completed by Participants

Τίτλος μελέτης: **«Άλγεα»: Καινοτόμο Πρόγραμμα Ψυχοκοινωνικής Παρέμβασης για την Αντιμετώπιση των Χρόνιων Πόνων στους ασθενείς και τις οικογένειές τους**

Γραπτές πληροφορίες και έγγραφο συγκατάθεσης για Ασθενείς με Πονοκεφάλους – Συμμετοχή σε Πρόγραμμα Ψυχολογικής Παρέμβασης

Αγαπητέ συμμετέχοντα,

Έχετε κληθεί να συμμετάσχετε σε μια ερευνητική μελέτη με στόχο την αναγνώριση των ψυχοκοινωνικών συνθηκών που σχετίζονται με τον πονοκέφαλο σε ασθενείς στη Κύπρο και τη Κρήτη, έτσι ώστε να αναγνωρισθούν οι παράγοντες που θα τους βοηθούσαν στην διαχείριση των πονοκεφάλων. Η μελέτη διεξάγεται από το Πανεπιστήμιο Κύπρου, το Πανεπιστήμιο Κρήτης και το Ινστιτούτο Νευρολογίας και Γενετικής Κύπρου, με χρηματοδότηση από την Ευρωπαϊκή Ένωση (ΕΤΠΑ) και από τους Εθνικούς Πόρους της Ελλάδας και της Κύπρου.

Συγκεκριμένα, έχετε κληθεί να συμμετάσχετε σε μια ερευνητική ψυχολογική παρέμβαση που απευθύνετε σε άτομα που υποφέρουν από κάποια μορφή πονοκεφάλων. Με τον όρο «ερευνητική παρέμβαση» εννοούμε τη συμμετοχή σας σε μια ψυχολογική παρέμβαση που θα έχει ως στόχο την βελτίωση της ποιότητας της ζωής σας σε σχέση με τον πονοκέφαλο. Η παρέμβαση αυτή, αν και έχει στηριχθεί σε προηγούμενες παρόμοιες προσπάθειες και βασίζεται σε ισχυρές θεωρητικές αρχές, δεν έχει δοκιμαστεί στο παρελθόν. Έτσι, τώρα δοκιμάζουμε την αποτελεσματικότητα της παρέμβασης αυτής σε σχέση με τον πονοκέφαλο. Οι πιθανότητες να ωφεληθείτε από τη συμμετοχή σας στην παρέμβαση είναι σημαντικές, ενώ οι πιθανότητες να υπάρξει για εσάς κάποια βλάβη ή σημαντική ταλαιπωρία είναι σχεδόν μηδενικές, από όσο μας έχει δείξει πληθώρα παλιότερων σχετικών ερευνών.

Στόχος, βέβαια, της μελέτης της αποτελεσματικότητας της παρέμβασης στην οποία σας καλούμε να λάβετε μέρος, είναι να δούμε πόσο πραγματικά βοηθά, ποια σημεία της

θέλουν αλλαγές και τροποποιήσεις, καθώς και τι μπορούμε να κάνουμε με βάση τα σχόλια που εσείς θα μας κάνετε για την όλη διαδικασία, έτσι ώστε να μπορεί να χρησιμοποιηθεί στο μέλλον για να ενισχύσει ψυχολογικά και άλλους ανθρώπους που πάσχουν από πονοκεφάλους. Έτσι, εσείς βοηθάτε να φτιαχτεί ένα πρόγραμμα που αργότερα θα βοηθήσει άλλους ανθρώπους που πάσχουν. Τέλος, στόχος μας είναι να εκπαιδεύσουμε και άλλους επαγγελματίες στην τελική μορφή της παρέμβασης, αλλά και να τη γνωστοποιήσουμε μέσω του διαδικτύου, ώστε να είναι διαθέσιμη σε όσο το δυνατόν περισσότερα άτομα που αντιμετωπίζουν προβλήματα πονοκεφάλων.

Η διαδικασία θα είναι περίπου ως εξής: Μετά από μια αρχική ατομική συνάντηση με τους υπεύθυνους της παρέμβασης, θα ξεκινήσει μια σειρά 9 θεραπευτικές συναντήσεων. Οι συναντήσεις θα είναι ομαδικές. Θα συμμετάσχουν, δηλαδή, περίπου 10 ασθενείς με πονοκεφάλους και 1-2 Ψυχολόγοι. Στην τελευταία συνάντηση ($9^{η}$ κατά σειρά) θα κληθούν να συμμετάσχουν και οι σημαντικοί άλλοι των ασθενών (π.χ. σύζυγοι, συγγενείς ή άνθρωποι που ζουν καθημερινά με εσάς). Οι συναντήσεις θα διαρκούν περίπου μία ώρα και μισή, θα έχουν συχνότητα περίπου μία ανά 7-8 μέρες, και θα γίνονται απογεύματα, σε ημέρα και ώρα που θα συμφωνήσει η ομάδα. Σε κάθε συνάντηση θα συζητάει όλη η ομάδα ζητήματα που σχετίζονται με τον πονοκέφαλο, θα γίνεται μια σειρά από «ψυχολογικές» ασκήσεις, και θα ανατίθεται ένα ελαφρύ έργο για το σπίτι που θα συζητιέται στην επόμενη συνάντηση. Επίσης, πριν την έναρξη της παρέμβασης και μετά το τέλος της θα σας ζητήσουμε να συμπληρώσετε μερικά ερωτηματολόγια για να διαπιστώσουμε τις αλλαγές που έγιναν κατά το χρονικό διάστημα της παρέμβασης.

Σας προσκαλούμε, λοιπόν, να συμμετάσχετε στην ερευνητική μας παρέμβαση. Η συμμετοχή είναι απολύτως εθελοντική αλλά πολύ σημαντική για τους σκοπούς της έρευνας. Σημειώνουμε ότι τα δεδομένα που θα συγκεντρωθούν είναι απολύτως εμπιστευτικά και θα χρησιμοποιηθούν μόνο από τους ερευνητές για αυστηρά επιστημονικούς σκοπούς. Μόλις συμπεριληφθείτε στη μελέτη, θα σας αποδοθεί ένας προσωπικός αναγνωριστικός κωδικός, ο οποίος δε θα περιλαμβάνει κανένα δεδομένο που να σχετίζεται με το όνομά σας ή άλλες πληροφορίες που μπορεί να οδηγήσουν στην ταυτοποίησή σας.

Μπορείτε να αρνηθείτε να συμμετέχετε στη μελέτη οποιαδήποτε στιγμή της διαδικασίας, ακόμα και αν έχετε συγκατατεθεί αρχικά, για οποιοδήποτε λόγο και χωρίς κανένα κόστος. Σε αυτήν την περίπτωση, όλα τα δεδομένα σας και το υπογεγραμμένο έγγραφο συγκατάθεσης θα καταστραφούν παρουσία σας.

Εάν έχετε οποιαδήποτε ερώτημα, ένσταση ή παράπονο παρακαλούμε επικοινωνήστε με την Δρ Μαρία Καρεκλά, με ένα από τους παρακάτω τρόπους: Τηλέφωνο: (357) 22892100, Email: algea@ucy.ac.cy ή τον Αντιπρύτανη Ακαδημαϊκών Υποθέσεων του Πανεπιστημίου Κύπρου, Δρ. Α. Γαγάτσης, τηλ. 22894000.

Περισσότερες πληροφορίες για την μελέτη, θα μπορέσετε να βρείτε στο αναλυτικό φυλλάδιο συγκατάθεσης που θα σας δοθεί στην 1η συνάντηση.

Αν συμφωνείτε να συμμετέχετε, σημαίνει ότι έχετε διαβάσει και συμφωνείτε με όλα όσα περιγράφονται στο έγγραφο συγκατάθεσης που σας δόθηκε.

Σας ευχαριστούμε πολύ για το χρόνο σας!

Ονοματεπώνυμο_____

ΜΕΛΕΤΗ «ΑΛΓΕΑ»

ΕΓΓΡΑΦΟ ΓΡΑΠΤΗΣ ΣΥΓΚΑΤΑΘΕΣΗΣ ΓΙΑ ΑΣΘΕΝΕΙΣ ΜΕ ΠΟΝΟΚΕΦΑΛΟΥΣ – ΣΥΜΜΕΤΟΧΗΣ ΣΕ ΠΡΟΓΡΑΜΜΑ ΨΥΧΟΛΟΓΙΚΗΣ ΠΑΡΕΜΒΑΣΗΣ

Αριθμός Συμμετέχοντα- Συμπληρώνεται από την ερευνητική ομάδα

	⓪	①	②	③	④	⑤	⑥	⑦	⑧	⑨
	⓪	①	②	③	④	⑤	⑥	⑦	⑧	⑨
	⓪	①	②	③	④	⑤	⑥	⑦	⑧	⑨
	⓪	①	②	③	④	⑤	⑥	⑦	⑧	⑨
	⓪	①	②	③	④	⑤	⑥	⑦	⑧	⑨

Αγαπητέ συμμετέχοντα. Προσπάθησε να απαντήσεις σε ΟΛΕΣ τις ερωτήσεις σημειώνοντας ΜΟΝΟ με *ένα ευδιάκριτο Χ* στην κάθε απάντηση που εσύ επιλέγεις.

Παρακαλώ, συμπληρώστε τα παρακάτω στοιχεία ή σημειώστε με ένα " Χ " όπου χρειάζεται :

1) Φύλο

① Άντρας
② Γυναίκα

2) Ηλικία (σε χρόνια): _____

3) Σημειώστε με 'Χ' στην εκπαίδευση που έχετε αποκτήσει μέχρι τώρα:

① Μερικές Τάξεις δημοτικού (Πρωτοβάθμια)
② Ολοκλήρωσα το Δημοτικό (Πρωτοβάθμια)
③ Γυμνάσιο (Δευτεροβάθμια)
④ Λύκειο/ Τεχνική σχολή (Δευτεροβάθμια)
⑤ Κολλέγιο/ Πανεπιστήμιο (Πρώτο πτυχίο)
⑥ Μεταπτυχιακό/ Διδακτορικό

4) Σημειώστε με 'Χ' στην οικογενειακή σας κατάσταση:

① Άγαμος /η

② Διαζευγμένος /η

③ Έγγαμος /η

④ Χήρος /α

⑤ Σε διάσταση

⑥ Συγκατοίκηση

5) Παρακαλώ δηλώστε το μηνιαίο εισόδημά σας με βάση την παρακάτω κλίμακα:

① μέχρι 1000 ευρώ

② 1000- 1500 ευρώ

③ 1500- 2000 ευρώ

④ 2000-2500 ευρώ

⑤ 2500- 3000 ευρώ

⑥ περισσότερα από 3000 ευρώ

6) Ποια διάγνωση πονοκεφάλου έχετε ή σας είπε ο γιατρός σας ότι έχετε; (π.χ. ημικρανία, κεφαλαλγία κλπ: _____

7) Πόσες φορές έχετε πονοκέφαλο μέσα στον μήνα; (π.χ. 2 ή 3 ή 10 φορές κλπ.)

_____

8) Πόσα χρόνια υποφέρετε από πονοκεφάλους (βάλτε χρόνια, όχι ημερομηνία);

_____

9) Φαρμακευτική αγωγή που λαμβάνετε για τον πονοκέφαλο; (εάν δεν παίρνετε κάτι, βάλτε όχι. Εάν δεν θυμάστε, συμβουλευτείτε το βιβλιάριο υγείας σας αντιγράφοντας τα φάρμακα που σας έχει γράψει ο Γιατρός σας)

_____

_____

_____

_____

10) Επάγγελμα (εάν είστε φοιτητής, δεν εργάζεστε, είστε άνεργος, ή συνταξιούχος, παρακαλώ δηλώστε το):

_____

_____

_____

Παρακαλούμε απαντήστε στα επόμενα ερωτηματολόγια σε όλες τις ερωτήσεις.

ΠΡΟΣΠΑΘΗΣΤΕ ΝΑ <u>ΜΗΝ ΑΦΗΝΕΤΕ ΚΕΝΑ</u> στις ΑΠΑΝΤΗΣΕΙΣ ΣΑΣ!!!!

Ερωτηματολόγιο 1

Παρακαλώ διαβάστε προσεκτικά: Ο σκοπός αυτής της κλίμακας είναι να αναγνωρίσει δυσκολίες που πιθανών να βιώνετε εξ αιτίας των πονοκεφάλων σας. Βάλτε ένα Χ πάνω στον κύκλο, σε κάθε μία από τις προτάσεις, ανάλογα με το τι ισχύει. Απαντήστε κάθε ερώτηση μόνο αναφορικά με τους πονοκεφάλου σας.

		ΝΑΙ	ΜΕΡΙΚΕΣ ΦΟΡΕΣ	ΟΧΙ
1.E	Εξ αιτίας των πονοκεφάλων μου αισθάνομαι ανάπηρος.	①	②	③
2.F	Εξ αιτίας των πονοκεφάλων μου αισθάνομαι περιορισμένος στο να εκτελέσω τις καθημερινές μου δραστηριότητες.	①	②	③
3.E	Κανένας δεν κατανοεί την επίδραση που έχουν οι πονοκέφαλοι στη ζωή μου.	①	②	③
4.F	Περιορίζω τις ψυχαγωγικές δραστηριότητες μου (π.χ. αθλήματα, hobbies), εξ αιτίας των πονοκεφάλων μου.	①	②	③
5.E	Οι πονοκέφαλοι μου, με θυμώνουν.	①	②	③
6.E	Μερικές φορές, νιώθω, ότι θα χάσω τον έλεγχο εξ αιτίας των πονοκεφάλων μου.	①	②	③
7.F	Εξ αιτίας των πονοκεφάλων μου είναι λιγότερο πιθανό να κοινωνικοποιηθώ.	①	②	③
8.E	Οι συγγενείς μου (σημαντικοί άλλοι), ή η οικογένεια μου και οι φίλοι μου, δεν έχουν ιδέα τη περνώ, εξ' αιτίας των πονοκεφάλων μου.	①	②	③
9.E	Οι πονοκέφαλοι μου είναι τόσο άσχημοι που νιώθω ότι θα τρελαθώ.	①	②	③
10.E	Ο τρόπος που βλέπω τον κόσμο επηρεάζεται από τους πονοκεφάλους μου.	①	②	③
11.E	Φοβάμαι να βγω έξω όταν πάει να με πιάσει πονοκέφαλος.	①	②	③

12.E	Νιώθω απόγνωση εξ αιτίας των πονοκεφάλων μου.	①	②	③
13.E	Ανησυχώ για το τι μου κοστίζουν οι πονοκέφαλοι μου στη δουλειά ή στο σπίτι **.**	①	②	③
14.E	Οι πονοκέφαλοι, μου προκαλούν στρες στις σχέσεις μου με την οικογένεια και τους φίλους μου.	①	②	③
15.F	Αποφεύγω να είμαι γύρω από ανθρώπους όταν έχω πονοκέφαλο.	①	②	③
16.F	Πιστεύω ότι οι πονοκέφαλοι μου, κάνουν δύσκολο να πετύχω τους στόχους μου στη ζωή.	①	②	③
17.F	Δεν είμαι σε θέση να σκεφτώ καθαρά εξ' αιτίας των πονοκεφάλων μου.	①	②	③
18.F	Μου προκαλείται ένταση (π.χ. στου μύες) εξ αιτίας των πονοκεφάλων μου .	①	②	③
19.F	Δεν απολαμβάνω κοινωνικές συγκεντρώσεις εξ αιτίας των πονοκεφάλων μου.	①	②	③
20.F	Νιώθω ευερέθιστος εξ αιτίας των πονοκεφάλων μου.	①	②	③
21.F	Αποφεύγω να ταξιδεύω εξ αιτίας των πονοκεφάλων μου.	①	②	③
22.E	Οι πονοκέφαλοι μου, με κάνουν να νιώθω μπερδεμένος.	①	②	③
23.E	Οι πονοκέφαλοι μου, με κάνουν να νιώθω απογοητευμένος.	①	②	③
24.F	Μου είναι δύσκολο να διαβάζω εξ αιτίας των πονοκεφάλων μου.	①	②	③
25.F	Μου είναι δύσκολο να επικεντρωθώ μακριά από τους πονοκεφάλους, σε άλλα πράγματα.	①	②	③

Ερωτηματολόγιο 2

Παρακαλώ, απαντήστε στις παρακάτω ερωτήσεις όπως εσείς νιώθετε την εμπειρία του πόνου που βιώνετε **βάζοντας ένα Χ πάνω στο κύκλο με τον αριθμό.**

1. Κατά την διάρκεια της ζωής μας, οι περισσότεροι από εμάς, έχουμε πόνο κατά διαστήματα (π.χ. πονόδοντους). Πέρα από αυτούς τους καθημερινούς πόνους, είχατε κάποιου άλλου είδους πόνο σήμερα;

① Ναι

2. Παρακαλώ, βαθμολογήστε τον πονοκέφαλο σας σημειώνοντας με **'Χ' στο κύκλο με τον αριθμό** που περιγράφει καλύτερα **τον χειρότερο πονοκέφαλο σας**, τις τελευταίες 24 ώρες.

⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩

Καθόλου Πονοκέφαλο

Αφάνταστα μεγάλος πονοκέφαλος

3. Παρακαλώ βαθμολογήστε τον πονοκέφαλο σας σημειώνοντας με **'Χ' στο κύκλο με τον αριθμό** που περιγράφει καλύτερα **τον λιγότερο πονοκέφαλο σας**, τις τελευταίες 24 ώρες

.

⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩

Καθόλου Πονοκέφαλο

Αφάνταστα μεγάλος πονοκέφαλος

4. Παρακαλώ βαθμολογήστε σημειώνοντας με **'Χ' στο κύκλο με τον αριθμό** που περιγράφει καλύτερα την ένταση του πονοκεφάλου που νιώθετε **γενικά.**

⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩

Καθόλου Πονοκέφαλο

Αφάνταστα μεγάλος πονοκέφαλος

5. Παρακαλώ βαθμολογήστε σημειώνοντας με **‘Χ’ στο κύκλο με τον αριθμό** που περιγράφει καλύτερα την ένταση του πονοκεφάλου που νιώθετε **αυτή τη στιγμή.**

⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩

Καθόλου Πονοκέφαλο

Αφάνταστα μεγάλος πονοκέφαλος

⓪ Όχι

Ερωτηματολόγιο 3

Παρακαλώ, συμπληρώστε το ερωτηματολόγιο. Θα μας βοηθήσει να καταλάβουμε την επίδραση των πονοκεφάλων στις καθημερινές σας δραστηριότητες .

Το ερωτηματολόγιο έχει σχεδιαστεί έτσι ώστε να μπορεί να συμπληρωθεί γρήγορα και εύκολα. Θα πρέπει να απαντήσετε σε κάθε ερώτηση. Παρακαλώ, σημειώστε μόνο μια (1) απάντηση για κάθε ερώτηση.

Καθώς απαντάς τις παρακάτω ερωτήσεις, σκέψου όλα τα επεισόδια πονοκεφάλων που είχες τις **τελευταίες 4 εβδομάδες.**

1. Τις τελευταίες 4 εβδομάδες, πόσο συχνά οι πονοκέφαλοι **παρενέβησαν** στο πόσο καλά αντιμετώπισες την οικογένεια, τους φίλους και άλλους που είναι κοντά σου; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή

② Λίγες στιγμές

③ Μερικές στιγμές

④ Αρκετές στιγμές

⑤ Τις περισσότερες στιγμές

⑥ Όλη την ώρα

2. Τις τελευταίες 4 εβδομάδες, πόσο συχνά οι πονοκέφαλοι **παρενέβησαν** στις ψυχαγωγικές σου δραστηριότητες, όπως το διάβασμα ή η άσκηση; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή

② Λίγες στιγμές

③ Μερικές στιγμές

④ Αρκετές στιγμές

⑤ Τις περισσότερες στιγμές

⑥ Όλη την ώρα

3. Τις τελευταίες 4 εβδομάδες, πόσο συχνά είχες **δυσκολίες** στο να εκτελέσεις τη δουλειά ή τις καθημερινές δραστηριότητες σου, εξ αιτίας των συμπτωμάτων του πονοκέφαλου; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

4. Τις τελευταίες 4 εβδομάδες, πόσο συχνά οι πονοκέφαλοι **σε κράτησαν πίσω** από το να κάνεις όση δουλειά ήθελες στην εργασία ή στο σπίτι; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

5. Τις τελευταίες 4 εβδομάδες, πόσο συχνά οι πονοκέφαλοι, **περιόρισαν** την προσοχή σου στην εργασία ή σε καθημερινές δραστηριότητες; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

6. Τις τελευταίες 4 εβδομάδες, πόσο συχνά οι πονοκέφαλοι, **σε κούρασαν** στο σημείο να μην μπορείς να κάνεις τις εργασίας και καθημερινές δραστηριότητες σου; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

7. Τις τελευταίες 4 εβδομάδες, πόσο συχνά οι πονοκέφαλοι, **περιόρισαν** τον αριθμό των ημερών που ήσουν δραστήριος (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

8. Τις τελευταίες 4 εβδομάδες, πόσο συχνά έπρεπε **να ακυρώσεις** εργασία ή καθημερινή δραστηριότητα επειδή είχες πονοκέφαλο; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

9. Τις τελευταίες 4 εβδομάδες, πόσο συχνά **χρειάστηκες βοήθεια** στο να χειριστείς καθημερινές δραστηριότητες όπως δουλειές του σπιτιού, απαραίτητες εργασίες, ψώνια, ή να φροντίσεις τους άλλους, όταν είχες πονοκέφαλο; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

10. Τις τελευταίες 4 εβδομάδες, πόσο συχνά έπρεπε **να σταματήσεις** την εργασία ή καθημερινές δραστηριότητες για να διαχειριστείς τα συμπτώματα των πονοκεφάλων; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

11. Τις τελευταίες 4 εβδομάδες, ποσο συχνα **δεν ησουν ικανος** να πας σε κοινωνικές δραστηριότητες, όπως πάρτι ή δείπνο με φίλους, επειδή είχες πονοκέφαλο; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

12. Τις τελευταίες 4 εβδομάδες, πόσο συχνά είχες αισθανθεί **αγανακτισμένος ή απογοητευμένος**, εξ αιτίας των πονοκεφάλων; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

13. Τις τελευταίες 4 εβδομάδες, πόσο συχνά αισθάνθηκες σαν να ήσουν βάρος στους άλλους επειδή είχες πονοκέφαλο; (επέλεξε μόνο **μία** απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές
⑤ Τις περισσότερες στιγμές
⑥ Όλη την ώρα

14. Τις τελευταίες 4 εβδομάδες, πόσο συχνά φοβήθηκες ότι **απογοητεύεις** τους άλλους εξ αιτίας των πονοκεφάλων σου; (επέλεξε μόνο μία απάντηση).

① Καμιά στιγμή
② Λίγες στιγμές
③ Μερικές στιγμές
④ Αρκετές στιγμές,
⑤ Τις περισσότερες στιγμές,
⑥ Όλη την ώρα

Ερωτηματολόγιο 4

Παρακάτω, ακολουθούν ορισμένες ερωτήσεις για το πόσες φορές λαμβάνετε φάρμακα για τους πονοκεφάλους, καθώς και πόσες φορές επισκεφθήκατε Ιατρούς γι αυτό το θέμα, **τους τελευταίους δύο μήνες από σήμερα**. Παρακαλώ, βάλτε τον **αντίστοιχο αριθμό** στο κουτάκι που βρίσκεται δεξιά της κάθε ερώτησης. Π.χ. για την ερώτηση 1, εάν είδατε 4 διαφορετικές Γιατρούς τους τελευταίους δύο μήνες μέχρι και σήμερα, τότε θα βάλετε στο κουτί δεξιά τον αριθμό 4.

1. Πόσους διαφορετικούς Γιατρούς έχεις επισκεφτεί τους τελευταίους δύο μήνες μέχρι και σήμερα για τους πονοκεφάλους σου;	
2. Πόσες φορές, τους τελευταίες δύο μήνες μέχρι και σήμερα, έχεις επισκεφτεί τον Γιατρό (π.χ. Νευρολόγο, Παθολόγο, Οικογενειακό Ιατρό) που σε παρακολουθεί για τους πονοκεφάλους σου;	
3. Πόσες φορές, τους τελευταίους δύο μήνες μέχρι και σήμερα, επισκέφθηκες τα επείγοντα ενός Νοσοκομείου εξ αιτίας των πονοκεφάλων σου (π.χ. κρίση ημικρανίας ή αβάσταχτος πονοκέφαλος που σε ανάγκασε να πας έκτακτα στο Νοσοκομείο. Εάν δεν επισκέφθηκες, τους τελευταίους δύο μήνες, βάλε στο κουτί 0).	
4. Πόσες φορές, τους τελευταίους δύο μήνες, έχεις νοσηλευτεί εξ αιτίας των πονοκεφάλων σου (εάν δεν έχεις νοσηλευτεί, τους τελευταίους δύο μήνες, βάλε στο κουτί 0).	

Ερωτηματολόγιο 5

Παρακάτω θα βρείτε μια λίστα με δηλώσεις. Παρακαλώ όπως βαθμολογήστε πόσο αληθεύει για σας η κάθε δήλωση. Χρησιμοποιήστε την παρακάτω κλίμακα για να κάνετε την επιλογή σας. Παραδείγματος χάριν αν πιστεύετε ότι μια δήλωση «*Πάντα αληθεύει*» τότε σημειώστε με ένα "Χ" στον αριθμό 6 δίπλα από την δήλωση.

		Ποτέ δεν αληθεύει	**Πολύ σπάνια αληθεύει**	**Σπάνια αληθεύει**	**Αληθεύει μερικές φορές**	**Αληθεύει Συχνά**	**Αληθεύει σχεδόν πάντα**	**Πάντα αληθεύει**
1	Συνεχίζω κανονικά τη ζωή μου ανεξάρτητα από το επίπεδο του πόνου μου	⓪	①	②	③	④	⑤	⑥
2	Παρόλο που τα πράγματα έχουν αλλάξει, ζω μια φυσιολογική ζωή ανεξάρτητα από το πόνο μου	⓪	①	②	③	④	⑤	⑥
3	Ζω μια ζωή γεμάτη έστω και αν έχω χρόνιο πόνο	⓪	①	②	③	④	⑤	⑥
4	Είναι προτεραιότητα όταν κάνω κάτι, να έχω τον πόνο μου υπό έλεγχο	⓪	①	②	③	④	⑤	⑥
5	Πριν να κάνω οποιαδήποτε σημαντικά σχέδια, πρέπει να ελέγξω τον πόνο μου	⓪	①	②	③	④	⑤	⑥
6	Ακόμα και όταν αυξηθεί ο πόνος μου, μπορώ να ολοκληρώνω τις υποχρεώσεις μου	⓪	①	②	③	④	⑤	⑥
7	Αποφεύγω να βάζω τον εαυτό μου σε καταστάσεις όπου μπορεί να αυξηθεί ο πόνος μου	⓪	①	②	③	④	⑤	⑥
8	Οι ανησυχίες και οι φόβοι μου σχετικά με το τι μπορεί να μου κάνει ο πόνος είναι αληθινοί	⓪	①	②	③	④	⑤	⑥

Ερωτηματολόγιο 6

Παρακάτω, θα βρείτε μια λίστα από δηλώσεις. Παρακαλώ, βαθμολογήστε πόσο αληθινή αυτή τη στιγμή είναι για εσάς η κάθε δήλωση, βάζοντας **'Χ' πάνω στον κύκλο με τον αριθμό** που σας αντιπροσωπεύει δίπλα από τη κάθε πρόταση.

	Ποτέ αλήθεια	**Πολύ σπάνια αλήθεια**	**Σπάνια αλήθεια**	**Μερικές φορές αλήθεια**	**Συχνά αλήθεια**	**Σχεδόν Πάντα αλήθεια**	**Πάντα αλήθεια**
1. Ακυρώνω προγραμματισμένες δραστηριότητες όταν πονώ.	①	②	③	④	⑤	⑥	⑦
2. Λέω πράγματα όπως «Δεν έχω καθόλου ενέργεια», « Δεν είμαι αρκετά καλά», «Δεν έχω χρόνο», «Δε με νοιάζει», «Έχω τόσο πολύ πόνο», «Νιώθω τόσο άσχημα», ή «Δε θέλω να νιώθω έτσι».	①	②	③	④	⑤	⑥	⑦
3. Χρειάζεται να καταλάβω τι μου συμβαίνει προκειμένου να συνεχίσω τη ζωή μου.	①	②	③	④	⑤	⑥	⑦
4. Εξ' αιτίας του πόνου μου, δε προγραμματίζω πια για το μέλλον.	①	②	③	④	⑤	⑥	⑦
5. Αποφεύγω να κάνω πράγματα που μπορεί να μου προκαλέσουν πόνο ή να χειροτερεύσουν την κατάσταση.	①	②	③	④	⑤	⑥	⑦
6. Είναι σημαντικό να κατανοήσω τι προκαλεί το πόνο μου .	①	②	③	④	⑤	⑥	⑦
7. Για να αποφύγω το πόνο, δεν κάνω πράγματα που είναι σημαντικά για εμένα.	①	②	③	④	⑤	⑥	⑦

8. Αναβάλλω πράγματα εξ' αιτίας του πόνου μου.	①	②	③	④	⑤	⑥	⑦
9. Θα έκανα σχεδόν τα πάντα για να αποφύγω το πόνο μου.	①	②	③	④	⑤	⑥	⑦
10. Δεν είμαι εγώ που ελέγχω τη ζωή μου, αλλά ο πόνος μου.	①	②	③	④	⑤	⑥	⑦
11. Αποφεύγω να σχεδιάσω δραστηριότητες εξ' αιτίας του πόνου μου.	①	②	③	④	⑤	⑥	⑦
12. Είναι σημαντικό να μάθω να ελέγχω το πόνο μου.	①	②	③	④	⑤	⑥	⑦

Ερωτηματολόγιο 7

Οδηγίες: Ενδιαφερόμαστε για τις πρόσφατες εμπειρίες σας. Παρακάτω, υπάρχει μια λίστα με πράγματα που βιώνουν, μερικές φορές, οι άνθρωποι. Δίπλα από κάθε ερώτημα, υπάρχουν 5 επιλογές «Ποτέ». «Σπάνια», «Μερικές φορές», «Συχνά», «Όλη την ώρα». Παρακαλώ, βάλτε ένα Χ στον κύκλο με την αντίστοιχη απάντηση έτσι ώστε να δηλώσετε πόσο πολύ βιώνετε, στην παρούσα φάση, παρόμοιες εμπειρίες όπως αυτές που περιγράφονται παρακάτω.

Παρακαλώ, μην ξοδεύετε πολύ χρόνο σε κάθε πρόταση. Η πρώτη απάντηση που έρχεται στο μυαλό σας, είναι αυτή που μας ενδιαφέρει. Σιγουρευτείτε ότι απαντάτε σε όλες τις προτάσεις.

		Ποτέ	Σπάνια	Μερικές φορές	Συχνά	Όλη την ώρα
1	Σκέφτομαι τι θα συμβεί στο μέλλον.	①	②	③	④	⑤
2	Υπενθυμίζω στον εαυτό μου ότι οι σκέψεις δεν είναι γεγονότα.	①	②	③	④	⑤
3	Είμαι περισσότερο ικανός να αποδέχομαι τον εαυτό μου όπως είναι.	①	②	③	④	⑤
4	Παρατηρώ όλων των ειδών τα μικροπράγματα και τις λεπτομέρειες στον κόσμο γύρω μου.	①	②	③	④	⑤
5	Είμαι πιο καλός προς τον εαυτό μου, όταν κάτι πάει λάθος.	①	②	③	④	⑤
6	Μπορώ να επιβραδύνω τη σκέψη μου σε στιγμές στρες.	①	②	③	④	⑤
7	Αναρωτιέμαι τι είδους άνθρωπος είμαι πραγματικά.	①	②	③	④	⑤
8	Δεν παρασύρομαι τόσο εύκολα από τις σκέψεις και τα συναισθήματα μου.	①	②	③	④	⑤
9	Παρατηρώ ότι δεν παίρνω τις δυσκολίες τόσο προσωπικά.	①	②	③	④	⑤

10	Μπορώ να διαχωρίσω τον εαυτό μου από τις σκέψεις και τα συναισθήματα μου.	①	②	③	④	⑤
11	Αναλύω γιατί τα πράγματα καταλήγουν με τον τρόπο που καταλήγουν.	①	②	③	④	⑤
12	Παίρνω τον χρόνο μου να ανταποκριθώ στις δυσκολίες.	①	②	③	④	⑤
13	Σκέφτομαι ξανά και ξανά τι μου έχουν πει οι άλλοι.	①	②	③	④	⑤
14	Μπορώ να φερθώ στον εαυτό με καλοσύνη.	①	②	③	④	⑤
15	Μπορώ να παρατηρώ δυσάρεστα συναισθήματα χωρίς να απορροφώμαι από αυτά.	①	②	③	④	⑤
16	Νιώθω ότι αντιλαμβάνομαι πλήρως τι γίνεται γύρω μου και μέσα μου.	①	②	③	④	⑤
17	Μπορώ πραγματικά να δω ότι εγώ δεν είμαι οι σκέψεις μου.	①	②	③	④	⑤
18	Συνειδητά αντιλαμβάνομαι το σώμα μου ως ένα σύνολο.	①	②	③	④	⑤
19	Σκέφτομαι τους τρόπους που διαφέρω από άλλους ανθρώπους.	①	②	③	④	⑤
20	Βλέπω τα πράγματα από μια ευρύτερη οπτική.	①	②	③	④	⑤

Ερωτηματολόγιο 8

Οδηγίες: Παρακάτω υπάρχει μια λίστα από δηλώσεις. Αξιολογήστε, πόσο αληθής είναι η κάθε δήλωση για σας, τοποθετώντας ένα «Χ» μέσα στον κύκλο με τον αντίστοιχο αριθμό. Χρησιμοποιήστε την ακόλουθη κλίμακα βαθμολόγησης για τις επιλογές σας. Για παράδειγμα, αν πιστεύετε ότι μια δήλωση είναι «Πάντα Αληθεύει», τοποθετήστε ένα «Χ» πάνω στο κύκλο με τον αριθμό 6 που βρίσκεται δίπλα από τη συγκεκριμένη δήλωση.

	Ποτέ δεν αληθεύει	**Πολύ σπάνια αληθεύει**	**Σπάνια Αληθεύει**	**Αληθεύει μερικές φορές**	**Αληθεύει συχνά**	**Αληθεύει σχεδόν πάντα**	**Πάντα αληθεύει**
1 Μπορώ να μείνω δεσμευμένος με τους στόχους μου ακόμη και όταν υπάρχουν στιγμές που αποτυγχάνω να τους πετύχω.	⓪	①	②	③	④	⑤	⑥
2 Όταν ένας στόχος είναι δύσκολο να επιτευχθεί, είμαι ικανός να κάνω μικρά βήματα για να τον επιτύχω.	⓪	①	②	③	④	⑤	⑥
3 Προτιμώ να αλλάζω το πώς προσεγγίζω κάποιο στόχο από το να σταματήσω.	⓪	①	②	③	④	⑤	⑥
4 Είμαι ικανός να ακολουθώ τα μακροπρόθεσμά μου σχέδια, ακόμα και σε περιόδους που η πρόοδος είναι αργή.	⓪	①	②	③	④	⑤	⑥
5 Το βρίσκω δύσκολο να συνεχίζω μια δραστηριότητα εκτός και αν νιώσω ότι πετυχαίνει.	⓪	①	②	③	④	⑤	⑥
6 Αν νιώσω στεναχωρημένος ή αποθαρρημένος, εγκαταλείπω τις δεσμεύσεις	⓪	①	②	③	④	⑤	⑥

	μου.							
7	Κατακλύζομαι τόσο πολύ από αυτά που σκέφτομαι ή αισθάνομαι, που δεν μπορώ να κάνω τα πράγματα που αξίζουν για μένα.	⓪	①	②	③	④	⑤	⑥
8	Αν δεν μπορώ να κάνω κάτι με το δικό μου τρόπο, δεν θα το κάνω καθόλου.	⓪	①	②	③	④	⑤	⑥

<u>Ερωτηματολόγιο 9</u>

Παρακαλώ, απαντήστε στις επόμενες ερωτήσεις σημειώνοντας με ένα **<u>ευδιάκριτο Χ</u> <u>πάνω στο κύκλο</u>** με τον αριθμό που αντιπροσωπεύει την καταλληλότερη για εσάς απάντηση**.**

1. Αισθάνομαι ένταση.

⓪ Τον περισσότερο καιρό

① Πολλές φορές

② Από καιρού εις καιρόν, περιστασιακά

③ Καθόλου

2. Τα πράγματα που συνήθως με ευχαριστούσαν, εξακολουθούν να με ευχαριστούν.

⓪ Σίγουρα τόσο όσο και παλαιότερα

① Όχι τόσο όσο παλαιότερα

② Μόνο λίγο

③ Σχεδόν καθόλου

3. Έχω ένα άσχημο προαίσθημα, σα να πρόκειται να συμβεί κάτι κακό.

⓪ Σίγουρα έχω ένα πολύ άσχημο προαίσθημα

① Ναι έχω, αλλά δεν είναι τόσο άσχημο

② Λίγο, αλλά δεν με ανησυχεί

③ Καθόλου

4. Μπορώ να γελάω και να βλέπω την αστεία πλευρά των πραγμάτων.

⓪ Τόσο πολύ όσο πάντα μπορούσα

① Όχι τόσο πολύ τώρα όσο παλαιότερα

② Σίγουρα λιγότερο τώρα

③ Καθόλου

5. Ανησυχητικές σκέψεις περνούν από το μυαλό μου.

⓪ Συνέχεια

① Συχνά

② Από καιρού εις καιρόν, αλλά όχι πολύ συχνά

③ Μόνο περιστασιακά

6. Αισθάνομαι χαρούμενος.

⓪ Καθόλου

① Σπάνια

② Μερικές φορές

③ Τον περισσότερο καιρό

7. Μπορώ να κάτσω ήρεμα και να χαλαρώσω.

⓪ Σίγουρα

① Συνήθως

② Σπάνια

③ Καθόλου

8. Αισθάνομαι σα να επιβραδύνω (σα να κινούμαι αργά).

⓪ Σχεδόν όλη την ώρα

① Πολύ συχνά

② Μερικές φορές

③ Καθόλου

9. Με πιάνει ένα είδος φόβου, μια αγωνία.

⓪ Καθόλου

① Περιστασιακά

② Αρκετά συχνά

③ Πολύ συχνά

10. Δεν με ενδιαφέρει η εμφάνισή μου.

⓪ Σίγουρα

① Δεν φροντίζω τόσο τον εαυτό μου όσο θα έπρεπε

② Μπορεί να μην φροντίζω πολύ τον εαυτό μου

③ Φροντίζω τόσο τον εαυτό μου όσο πάντα

11. Είμαι ανήσυχος, σαν να πρέπει να βρίσκομαι σε διαρκή κίνηση.

⓪ Πραγματικά πολύ

① Αρκετά

② Λίγο

③ Καθόλου

12. Περιμένω να συμβούν ευχάριστα πράγματα.

⓪ Τόσο όσο πάντα

① Μάλλον λιγότερο από όσο συνήθιζα

② Σίγουρα λιγότερο από όσο συνήθιζα

③ Σχεδόν καθόλου

13. Με πιάνει μια ξαφνική αίσθηση πανικού.

⓪ Πραγματικά πολύ συχνά

① Αρκετά συχνά

② Σπάνια

③ Καθόλου

14. Μπορώ να απολαύσω ένα καλό βιβλίο ή ένα πρόγραμμα στην τηλεόραση ή το ράδιο.

⓪ Συχνά

① Μερικές φορές

② Λίγες φορές

③ Πολύ σπάνια

Ερωτηματολόγιο 10

Οι άνθρωποι έχουν διάφορους τρόπους να σχετίζονται με τις σκέψεις και τα συναισθήματα τους. Για κάθε μια από τις παρακάτω ερωτήσεις, σημειώστε με ένα 'Χ' πάνω στον αριθμό ανάλογα με το πόσο πολύ κάθε ένας από αυτούς τους τρόπους ταιριάζει *σε εσάς*, **ΚΑΤΑ ΤΗΝ ΠΡΟΗΓΟΥΜΕΝΗ ΕΒΔΟΜΑΔΑ.**

		Σπάνια/ Καθόλου	**Μερικές φορές**	**Συχνά**	**Σχεδόν πάντα**
1	Είναι εύκολο για εμένα να συγκεντρώνομαι σε οτιδήποτε κάνω.	①	②	③	④
2	Είμαι τελείως απορροφημένος με τις σκέψεις μου για το μέλλον.	①	②	③	④
3	Μπορώ να αντέξω το συναισθηματικό πόνο.	①	②	③	④
4	Μπορώ να αποδεχτώ πράγματα που δεν μπορώ να αλλάξω.	①	②	③	④
5	Συνήθως μπορώ να περιγράψω με σημαντική λεπτομέρεια πως νιώθω κάθε στιγμή.	①	②	③	④
6	Αποσπώμαι εύκολα.	①	②	③	④
7	Είμαι τελείως απορροφημένος με τις σκέψεις μου για το παρελθόν.	①	②	③	④
8	Είναι εύκολο για μένα να ακολουθώ τις σκέψεις και τα συναισθήματα μου.	①	②	③	④
9	Προσπαθώ να παρατηρώ τις σκέψεις μου χωρίς να τις κρίνω.	①	②	③	④
10	Είμαι ικανός να αποδέχομαι τις σκέψεις και τα συναισθήματα που έχω.	①	②	③	④
11	Είμαι σε θέση να επικεντρώνομαι στη παρούσα στιγμή.	①	②	③	④
12	Είμαι σε θέση να δίνω ιδιαίτερη προσοχή σε ένα πράγμα για μεγάλο χρονικό διάστημα.	①	②	③	④

Ερωτηματολόγιο 11

Παρακαλώ, διαβάστε προσεκτικά κάθε δήλωση και μετά κυκλώστε τον αριθμό που περιγράφει καλύτερα, ποσό πολύ αυτή η δήλωση σας αντιπροσώπευε **ΚΑΤΑ ΤΗΝ ΔΙΑΡΚΕΙΑ ΤΗΣ ΠΡΟΗΓΟΥΜΕΝΗΣ ΕΒΔΟΜΑΔΑΣ, ΣΥΜΠΕΡΙΛΑΜΒΑΝΟΜΕΝΗΣ ΚΑΙ ΤΗΣ ΣΗΜΕΡΙΝΗΣ ΗΜΕΡΑΣ:**

		Καθόλου δεν αληθεύει						**Απόλυτα Αληθεύει**
1	Ξοδεύω πολύ χρόνο σκεφτόμενος/η σχετικά με το παρελθόν ή μέλλον, αντί να εμπλέκομαι σε δραστηριότητες που αξίζουν.	⓪	①	②	③	④	⑤	⑥
2.	Βασικά, ήμουν στον «αυτόματο πιλότο», τον περισσότερο καιρό ανεξάρτητα από το πόνο μου.	⓪	①	②	③	④	⑤	⑥
3.	Δούλεψα προς τους στόχους μου, ακόμη κι αν δεν ένιωσα κινητοποιημένος.	⓪	①	②	③	④	⑤	⑥
4.	Ήμουν περήφανος σχετικά με το πως έζησα την ζωή μου.	⓪	①	②	③	④	⑤	⑥
5.	Έκανα πρόοδο σε περιοχές της ζωής μου που με νοιάζουν.	⓪	①	②	③	④	⑤	⑥
6.	Δύσκολες σκέψεις, συναισθήματα ή μνήμες παρενέβησαν σε αυτό που πραγματικά ήθελα να κάνω.	⓪	①	②	③	④	⑤	⑥
7.	Συνέχιζα να τα πηγαίνω καλύτερα (βελτιώνομαι), έτσι ώστε να γίνομαι ο τύπος του ανθρώπου που θέλω να είμαι.	⓪	①	②	③	④	⑤	⑥
8.	Όταν τα πράγματα δεν πήγαν σύμφωνα με τα πλάνα μου, τα παράτησα εύκολα.	⓪	①	②	③	④	⑤	⑥

9.	Ένιωσα σαν να είχα ένα σκοπό στη ζωή.	⓪	①	②	③	④	⑤	⑥
10.	Φαίνονταν σαν να « έκανα τα πράγματα μηχανικά», παρά να εστιάζομαι στο τι ήταν σημαντικό για μένα.	⓪	①	②	③	④	⑤	⑥

Η ομάδα εργασίας ΑΛΓΕΑ, σας ευχαριστεί για την συμπλήρωση αυτού του ερωτηματολογίου. Πριν το παραδώσετε στην πρώτη συνάντηση της ομάδας:

α) βεβαιωθείτε ότι έχετε απαντήσει σε όλες τις ερωτήσεις,

β) εάν έχετε κάποια απορία με ένα ή περισσότερα ερωτηματολόγια, ενημερώστε έναν από τους συνεργάτες του έργου στην πρώτη σας συνάντηση.

ΑΛΓΕΑ, Γιατί η ζωή, μπορεί να είναι ωραία και με τον πονοκέφαλο!!

Είστε έτοιμοι να ξεκινήσουμε το ταξίδι μας;

Appendix C

Questionnaires completed by Participants before and after each session

Ονοματοεπώνυμο:_____, Κωδικός Συμμετέχοντα_____
Ημερομηνία_____

Ερωτηματολόγιο ΠΡΙΝ-2 την συνάντηση

1. Βαθμολόγηση την ένταση του πονοκεφάλου σου την εβδομάδα που μας πέρασε:

Καθόλου ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Η μεγαλύτερη που είχα ποτέ

2. Βαθμολόγησε, πόσο διατεθειμένος ήσουν να έχεις πονοκέφαλο την εβδομάδα που μας πέρασε:

Καθόλου διατεθειμένος ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Υπερβολικά διατεθειμένος

3. Βαθμολόγησε πόση προσπάθεια κατέβαλες να διώξεις τον πονοκέφαλο, ή τις ανησυχητικές σκέψεις, συναισθήματα, ή μνήμες, την εβδομάδα που μας πέρασε:

Καθόλου προσπάθεια ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Υπερβολική προσπάθεια

4. Βαθμολόγησε, πόσο αποτελεσματικός ήσουν κατά την τελευταία εβδομάδα, στο να κάνεις πράγματα για μια καλύτερη, πιο ενεργή και πιο ποιοτική ζωή:

Καθόλου προσπάθεια ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Υπερβολική προσπάθεια

5. Βαθμολόγησε πόσο αποτελεσματικός ήσουν την εβδομάδα που μας πέρασε, στο να βελτιώσεις τομείς της ζωής σου που είναι σημαντικοί για εσένα:

Καθόλου αποτελεσματικός ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Πάρα πολύ Αποτελεσματικός

6. Κατά την τελευταία εβδομάδα, πόσο αποτελεσματικός ήσουν στο να διαχειριστείς τα πράγματα που έκανες, ανεξάρτητα από τον πονοκέφαλο σου:

Καθόλου αποτελεσματικός ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Πάρα πολύ Αποτελεσματικός

7. Κατά την τελευταία εβδομάδα, πόσο ικανός ήσουν στο να διαχειριστείς τα πράγματα που έκανες, ανεξάρτητα από τον πονοκέφαλο σου:

Καθόλου ικανός ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Υπερβολικά ικανός

Ερωτηματολόγιο ΜΕΤΑ-2 την συνάντηση

Βαθμολογήστε τη σημερινή συνάντηση βάζοντας ένα 'Χ' μέσα στον κύκλο με τον αριθμό που να ταιριάζει καλύτερα με την εμπειρία σας από την σημερινή συνάντηση

Σχέση

Δεν ένιωσα ότι με ακούν, με καταλαμβάνουν, & με σέβονται.

Ένιωσα ότι με ακούν, με καταλαμβάνουν, & με σέβονται.

⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩

Στόχοι και θέματα

Δεν δουλέψαμε ούτε μιλήσαμε για αυτά που ήθελα να δουλέψουμε και να μιλήσουμε.

Δουλέψαμε και μιλήσαμε για αυτά που ήθελα να μιλήσουμε και να δουλέψουμε.

⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩

Προσέγγιση και μέθοδος

Η προσέγγιση των θεραπευτών δεν ταίριαζε καλά σε εμένα.

Η προσέγγιση των θεραπευτών ταίριαζε καλά σε εμένα.

⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩

Γενικά

Υπήρχε κάτι που έλλειπε από την σημερινή συνεδρία.

Γενικά, η σημερινή συνεδρία ήταν εντάξη για εμένα.

⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩

Detailed Self-Monitoring form filled out by Participants between Sessions

Οδηγίες για τη συμπλήρωση του φυλλαδίου καταγραφής πονοκεφάλων

Αυτό το φυλλάδιο σχεδιάστηκε για να σε βοηθήσει να κρατάς ένα λεπτομερές ιστορικό των: α) επιπέδων έντασης του πονοκέφαλου, β) ανικανότητας, γ) στρες, και δ) ποσότητα και ποιότητα ύπνου. Συμπλήρωσε για κάθε μέρα της εβδομάδας τον πίνακα που βρίσκεται κάτω αναλόγως με τους πέντε τομείς αξιολόγησης. Μπορείς να το έχεις δίπλα από το κρεβάτι σου, ώστε να το συμπληρώνεις λίγο πριν κοιμηθείς. Για κάθε τομέα αξιολόγησης (π.χ. ένταση πονοκεφάλου, ανικανότητα κλπ), υπάρχει μια κλίμακα από το 0 έως το 10 που μπορείς να χρησιμοποιείς για να βαθμολογήσεις, κατά μέσο όρο για όλη την ημέρα την ένταση των πονοκεφάλων, την ανικανότητα που σας προκαλούν στην καθημερινότητα, τα επίπεδα του στρες που έχετε, καθώς και την ποσότητα και ποιότητα του ύπνου.

Κάτω αριστερά υπάρχει ένα μέρος που θα θέλαμε να συμπληρώσεις στην περίπτωση που κατανάλωσες εξτρά φάρμακα εξαιτίας των πονοκεφάλων (π.χ. συμπλήρωση το μόνο αν πήρες κάποιο εξτρά φάρμακο, π.χ. ένα Panadol, όχι αυτά που παίρνεις συνήθως). Κάτω δεξιά, θέλουμε να συμπληρώσετε, εάν επισκεφθήκατε κάποιον Ιατρό την εβδομάδα που συμπληρώνεις το φυλλάδιο.

Οι περισσότεροι άνθρωποι βρίσκουν πιο εύκολο να συμπληρώνουν αυτό το φυλλάδιο περίπου τις ίδιες ώρες κάθε μέρα. Επίσης, πολλοί βρίσκουν βοηθητικό να συνδυάζουν τη συμπλήρωση του φυλλαδίου με κάποια άλλη δραστηριότητα, έτσι ώστε να το θυμούνται. Για παράδειγμα, μπορείς να συμπληρώνεις το φυλλάδιο (1) κατά τη διάρκεια του βραδινού, (2) ή πριν κοιμηθείς, έτσι ώστε να μπορείς να δώσεις μία κατά προσέγγιση καλή εκτίμηση του πως κινήθηκε η μέρα με τον πονοκέφαλο. Εάν ξεχάσεις να καταγράψεις το φυλλάδιο τη συνηθισμένη ώρα, παρακαλώ συμπλήρωσε το, μόλις το θυμηθείς.

Για την ένταση των πονοκεφάλων θα βάλεις έναν αριθμό από 0 (ΚΑΘΟΛΟΥ ΠΟΝΟΚΕΦΑΛΟ) έως 10 (ΥΠΕΡΒΟΛΙΚΑ ΕΠΙΠΟΝΟ ΠΟΝΟΚΕΦΑΛΟ), για τα επίπεδα της ανικανότητας που σου προκαλεί ο πονοκέφαλος θα βάλεις έναν αριθμό από 0 (ΚΑΘΟΛΟΥ ΑΝΙΚΑΝΟΤΗΤΑ) έως 10 (ΑΠΟΛΥΤΗ ΑΝΙΚΑΝΟΤΗΤΑ), και για το στρες θα βάλεις έναν αριθμό από 0 (ΚΑΘΟΛΟΥ ΣΤΡΕΣ) έως 10 (ΥΠΕΡΒΟΛΙΚΟ ΣΤΡΕΣ). Μη σε πολυανησυχεί για το πώς θα βαθμολογήσεις τα παραπάνω, ο πρώτος αριθμός που σου έρχεται στο μυαλό είναι πιθανόν η καλύτερη εκτίμηση. **Ακόμη και αν δεν έχετε καθόλου πονοκέφαλο κάποια μέρα, σημειώστε και πάλι τα παραπάνω** (π.χ. βάζοντας 0 ή 1, αναλόγως).

Βεβαιώσου ότι έχεις βάλει το όνομά σας και την ημερομηνία. Ένα συμπληρωμένο φυλλάδιο (το όνομα δεν είναι πραγματικό) από συμμετέχοντα σας παρέχεται στο τέλος αυτών των οδηγιών. Εάν έχετε οποιεσδήποτε ερωτήσεις σχετικά με τη συμπλήρωση του φυλλαδίου, καλέστε στο 22892024 ή στείλε e-mail στο algea@ucy.ac.cy

ΛΕΠΤΟΜΕΡΗΣ ΚΑΤΑΓΡΑΦΗ ΤΩΝ ΠΟΝΟΚΕΦΑΛΩΝ

ΟΝΟΜΑΤΕΠΩΝΥΜΟ	ΗΜΕΡΟΜΗΝΙΑ	ΚΩΔΙΚΟΣ ΣΥΜΜΕΤΕΧΟΝΤΑ

ΟΔΗΓΙΕΣ: Κάθε ημέρας λίγο πριν τον ύπνο καταγράψτε, **ΚΑΤΑ ΜΕΣΟ ΟΡΟ**, τα εξής: Α) ένταση πονοκεφάλων Β) το επίπεδο της ανικανότητας που σας προκλήθηκε από τους πονοκεφάλους Γ) το επίπεδο του στρες Δ) την ποσότητα και ποιότητα του ύπνου, χρησιμοποιώντας την παρακάτω κλίμακα μέτρησης.

ΕΝΤΑΣΗ ΠΟΝΟΚΕΦΑΛΟΥ		ΑΝΙΚΑΝΟΤΗΤΑ ΕΞ ΑΙΤΙΑΣ ΤΟΥ ΠΟΝΟΚΕΦΑΛΟΥ	ΣΤΡΕΣ	ΠΟΣΟΤΗΤΑ ΥΠΝΟΥ	ΠΟΙΟΤΗΤΑ ΥΠΝΟΥ
10. ΥΠΕΡΒΟΛΙΚΑ ΕΠΙΠΟΝΟΣ	Ο πονοκέφαλος μου είναι τόσο επίπονος που δεν μπορώ να κάνω τίποτα	**10.** ΕΝΤΕΛΩΣ ΑΝΙΚΑΝΟΣ/Η ΝΑ ΚΑΝΩ ΟΤΙΔΗΠΟΤΕ	**10.** ΥΠΕΡΒΟΛΙΚΟ ΣΤΡΕΣ	**10.** ΠΑΡΑ ΠΟΛΥ	**10.** ΕΞΑΙΡΕΤΙΚΗ
9.		**9.**	**9**	**9.**	**9.**
8. ΠΟΛΥ ΕΠΙΠΟΝΟΣ	Ο πονοκέφαλος κάνει την συγκέντρωση μου δύσκολη, αλλά μπορώ να κάνω διάφορες απαιτητικές δραστηριότητες (π.χ. καθάρισμα σπιτιού, δουλειές γραφείου κλπ).	**8.** ΣΟΒΑΡΑ ΑΝΙΚΑΝΟΣ/Η ΝΑ ΚΑΝΩ ΟΤΙΔΗΠΟΤΕ	**8.** ΠΟΛΥ ΣΤΡΕΣ	**8.**	**8.** ΠΟΛΥ ΚΑΛΗ
7.		**7.**	**7**	**7.**	**7.**
6. ΕΠΙΠΟΝΟΣ	Ο πονοκέφαλος μου είναι επίπονος, αλλά, την ώρα που τον έχω, μπορώ να συνεχίσω οτιδήποτε κάνω	**6.** ΜΕΤΡΙΑ ΑΝΙΚΑΝΟΣ/Η	**6.** ΜΕΤΡΙΟ ΣΤΡΕΣ	**6.**	**6.** ΚΑΛΗ
5.		**5.**	**5**	**5.** ΤΕΛΕΙΑ	**5.**
4. ΜΕΤΡΙΑ ΕΠΙΠΟΝΟΣ	Μπορώ να αγνοήσω τον πονοκέφαλο μου, τις περισσότερες φορές	**4.** ΕΛΑΦΡΑ ΑΝΙΚΑΝΟΣ/Η	**4.** ΕΛΑΦΡΟ ΣΤΡΕΣ	**4.**	**4.** ΙΚΑΝΟΠΟΙΗΤΙΚΗ
3.		**3**	**3.**	**3.**	**3.**
2. ΕΛΑΦΡΩΣ ΕΠΙΠΟΝΟΣ	Παρατηρώ ότι έχω πονοκέφαλο, μόνο εάν επικεντρώσω την προσοχή μου σε αυτόν	**2.** ΕΛΑΧΙΣΤΑ ΑΝΙΚΑΝΟΣ/Η	**2.** ΛΙΓΟ ΣΤΡΕΣ	**2.** ΕΛΑΧΙΣΤΟΣ ΥΠΝΟΣ	**2.** ΦΤΩΧΗ
1.		**1.**	**1.**	**1.**	**1**
0. ΚΑΘΟΛΟΥ ΠΟΝΟΚΕΦΑΛΟ		**0.** ΚΑΘΟΛΟΥ ΑΝΙΚΑΝΟΣ/Η	**0.** ΚΑΘΟΛΟΥ ΣΤΡΕΣ	**0.** ΚΑΘΟΛΟΥ ΥΠΝΟΣ	**0.** ΠΟΛΥ ΦΤΩΧΗ

	ΗΜΕΡΑ:	ΔΕΥΤΕΡΑ	ΤΡΙΤΗ	ΤΕΤΑΡΤΗ	ΠΕΜΠΤΗ	ΠΑΡΑΣΚΕΥΗ	ΣΑΒΒΑΤΟ	ΚΥΡΙΑΚΗ
	ΕΝΤΑΣΗ							
	ΑΝΙΚΑΝΟΤΗΤΑ							
	ΣΤΡΕΣ							
	ΠΟΣΟΤΗΤΑ ΥΠΝΟΥ							
	ΠΟΙΟΤΗΤΑ ΥΠΝΟΥ							

Σημειώστε εαν πήρατε κάποιο επιπλέον φάρμακο, από τα σταθερά, για τον πονοκέφαλο (π.χ. παναντολ)	Επισκεφτήκατε γιατρό την τελευταία εβδομάδα εξαιτίας του πονοκάλου σας; Εάν ναι παρακαλώ γράψτε τι γιατρό.