#### Supplemental materials for:

Effectiveness of Collaborative, Trauma-Informed Care on Depression Outcomes in Primary Care: A Cluster Randomized Control Trial in Chile

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## XVII NATIONAL CONTEST FOR HEALTH RESEARCH AND DEVELOPMENT PROJECTS

TITLE OF THE PROJECT

DESIGN, IMPLEMENTATION AND EVALUATION OF THE EFFECTIVENESS OF A MULTIDIMENSIONAL COLLABORATIVE MODEL TO IMPROVE THE RESOLUTION OF DEPRESSION IN PRIMARY CARE TEAMS IN THE MAULE REGION

#### **ABSTRACT**

In Chile, depression is a common, long-lasting, and debilitating condition, officially recognized as a health concern since 2006 under the GES (Explicit Health Guarantees) program. The national clinical guidelines currently offer a step-based treatment approach based on the severity of symptoms. Primary care, or Primary Health Care (PHC), handles about 90% of depression cases. However, observational studies indicate that 40% to 50% of patients in Chile remain symptomatic or fail to recover their normal functioning within a year of treatment. This is attributed to a lack of professional skills and adherence to the guidelines.

In line with international research, consultations for depression in Chilean primary care settings, particularly in the Maule Region, have identified clinical and functional factors, as well as histories linked to poor depression outcomes, which are often overlooked in standard practice. Comorbid psychiatric conditions, mainly from the anxiety spectrum, and adverse life experiences like adverse childhood experiences, domestic violence, and recent life events, are common among depressed patients in the Maule Region (50-80%). These factors contribute to more severe depression at the time of consultation, earlier onset, recurrence, and poor response after a year of treatment. They also suggest different depressive subtypes that require specific strategies not covered by the current clinical guidelines.

Collaborative models for depression treatment have shown the most promising results, but their implementation nationwide is limited. Studies using technology-assisted methods and training following guideline recommendations have not proven effective in resolving depressive symptoms in primary care settings.

Given the healthcare goals for the 2011-2020 decade, this study aims to assess the efficacy of a collaborative model that includes skills to address clinical, functional, and historical variables from multiple perspectives, alongside the current practices in depression management in primary care. We expect that demonstrating the effectiveness of this multidimensional collaborative model will lead to the development of standardized educational tools to improve depression management in Chilean primary care. This model may introduce new recommendations to the current clinical guidelines, especially for patients with complex clinical presentations tied to personal adversity. Additionally, it will equip primary care professionals with the necessary skills to address the challenges faced by adult patients with both physical and mental health conditions and adverse life histories.

## **1. RELEVANCE OF THE TOPIC AND PROBLEM CHARACTERIZATION**

## **1.1. RELEVANCE OF THE TOPIC**

Depression is a mood and affective disorder characterized by a lack of enthusiasm, feelings of sadness or distress, abrupt mood swings, irritability, changes in usual sleep and appetite patterns, and difficulty concentrating or remembering beyond what might be considered normal fluctuations in a person's functioning (1,2). The International Classification of Diseases (ICD-10) and the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) establish criteria for the diagnosis of major depressive episodes or unipolar major depression (single or recurrent episodes) and bipolar disorder (1,2).

According to the World Health Organization, depression is the leading cause of disability worldwide, making a significant contribution to the overall global burden of morbidity and mortality (2). It is estimated to affect nearly 300 million people globally, with one of its most severe complications being suicide (2).

In Chile, according to the Burden of Disease and Attributable Burden study, unipolar depression is the second leading cause of disability-adjusted life years (DALYs) lost in the general Chilean population and the primary cause among women aged 20 to 44 (1). These figures align with what is observed globally (1).

According to the results of the latest National Health Survey (ENS) for 2016-2017, the prevalence of depressive symptoms in individuals over 15 years of age is 15.8%, and depression affects 6.2% of the population (3). These statistics have remained largely unchanged compared to the ENS for 2003 and 2009-2010. A recent report from the Center for the Study of Conflict and Social Cohesion raised the prevalence of depressive symptoms to 18.2%, placing it above the global average of 12% (4).

In line with the literature, national evidence shows that depression affects women twice as much as men, individuals with lower income, lower education levels, and those of working age (2). Longitudinal studies and clinical research concur in describing its chronic and recurrent course, significantly impairing work and academic capabilities and the challenges of modern life (2). In Chile, two-thirds of patients seeking help for depression in Primary Health Care (PHC) have experienced a previous episode, and 20-30% of medical leaves are due to mental disorders (1,2). Since 2006, depression has been covered by the Explicit Health Guarantees (GES) program, with ministerial clinical guidelines for its screening, diagnosis, and treatment at various levels of care (1,2).

Primary care (PHC) serves as the gateway for patients seeking treatment, with 90% of depression cases managed at this level. Patients are referred to specialized care when they exhibit suicidal attempts or high current suicidality, psychosis, treatment refractoriness, or signs of bipolarity (1,2). Depression can be treated with both pharmacological and psychotherapeutic approaches (cognitive-behavioral and interpersonal therapies) with proven effectiveness (2). However, in PHC, 40-50% of treated patients remain symptomatic or have not regained their pre-morbid functioning after one year of treatment (5,6).

Considering the Mental Health goals outlined in the Health Objectives for the 2011-2020 decade (reducing the prevalence of disability in people with mental illness, improving healthcare resources, and decreasing user dissatisfaction), it is essential to investigate how to enhance the outcomes of depression treatment in PHC.

#### **PROBLEM STATEMENT**

The current clinical guideline recommends a stepped treatment approach for depression, addressing it according to its severity and classifying it according to ICD-10 criteria (1). In Primary Health Care (PHC), psychoeducational activities, exercise, and structured group psychosocial workshops are provided for mild depression. For moderate cases, pharmacotherapy is added, and validated psychotherapeutic interventions are incorporated for more severe cases (1). Since the inception of the national program for depression in PHC, there have been few studies on follow-up and assessment of outcomes in naturalistic settings (5,6,7).

In a study conducted by the research team behind this proposal during the FONIS project SA13/20135 (8) in the Maule Region in 2013, while monitoring a cohort of 297 depressive patients across 8 PHC clinics, remission rates were determined to be 38.7% at three months, 47.9% at six months, and 53.9% at twelve months (5). These results indicate that nearly half of the patients remain symptomatic one year into treatment, aligning with the literature regarding the course of depression in naturalistic settings (5). Deficits in professional competencies for appropriately addressing this condition in PHC and a lack of adherence to clinical guideline recommendations have been identified (7). Additionally, national depressive samples have shown poor treatment adherence and the presence of clinical, functional, and historical variables associated with poorer outcomes that require specific approaches not considered in the current clinical guideline

Specifically, in the mentioned FONIS project, during the intake evaluation, it was observed that 75% of the sample had a recurrent condition; 89.1% had some psychiatric comorbidity (PC), and 55% had medical comorbidity; 35% reported a history of suicide attempts without high current risk; 82% reported adverse childhood experiences (ACE); 58.1% reported a history of domestic violence (DV), and 91.2% reported recent life events (RLE) (9,10). Moreover, ACE, DV, RLE, and PC, along with the history of suicide, were associated with an earlier age of depression onset and greater severity upon intake (9,10). Of these factors, PC, ACE, and previous suicide attempts were associated with lower remission at 12 months (5). Another analysis of the same sample found that ACE was associated with a subtype of patients with dysfunction in the interpersonal and social domain (11). These findings are consistent with those in other national studies: Martinez (12) determined a 78% rate of medical or psychiatric comorbidity alongside a high prevalence of suicidality in the Metropolitan Region. Alvarado (7), in an initial evaluation of the national program for depression, found that 50% of women admitted to treatment had experienced DV. This corroborates the accumulated findings in the

literature over the past 30 years, indicating that both PC and ACE, especially ACE, are associated with a more chronic and/or complex clinical presentation (13,14).

Collaborative models have proven to be the most effective for improving depression treatment outcomes in PHC (15). However, there is limited evidence regarding the implementation of this model using technology-assisted methods based on the recommendations of the current clinical guideline, which has not demonstrated its effectiveness in resolving depressive symptoms compared to standard treatment (16). There is no evidence regarding the efficacy of a collaborative model that, in addition to depression management in PHC, incorporates the acquisition of tools by primary care teams for the proper recognition and addressing of clinical, functional, and historical variables associated with poorer therapeutic outcomes, necessitating a multidimensional approach.

## **1.3. ANALYSIS OF THE STATE OF THE ART**

The findings in individuals seeking help for depression in Chilean Primary Health Care (PHC) are consistent with the accumulating evidence over the past 30 years, suggesting that both psychiatric comorbidity (PC) and Adverse Childhood Experiences (ACE), especially Adverse Life Experiences (ACES), are linked to a more intricate clinical presentation (13,14). These findings also indicate the presence of depressive subtypes that necessitate distinctive approaches (11,17).

**Depressive Subtypes**: While the standardized nosological classification ICD-10 considers unipolar depression as a single entity (1), compelling clinical and neurobiological evidence supports the notion that depression is a heterogeneous condition with varying prognosis and the need for distinct treatment approaches (17). Latent Class Analysis (LCA) is a statistical technique used to identify heterogeneity within seemingly homogeneous samples. In the context of depression, LCAs have traditionally relied on symptomatic indicators. However, a recent meta-analysis suggests that these symptomatic indicators alone have not consistently revealed depressive subtypes, emphasizing the importance of including other variables in LCAs (17).

Using the dataset from project FONIS SA13/20135, the principal investigators of this project conducted an LCA with a sample of 297 individuals. They included clinical variables associated with a poorer response (psychiatric comorbidity and a history of suicide attempts) and functional variables related to interpersonal and social dysfunction as indicators (11). The results obtained in this sample from Chilean Primary Health Care (PHC) were robust and unveiled the presence of three clinically relevant subtypes: 'suicidal' (58% of the sample), 'single episode' (8%), and 'recurrent depression' (34%). Notably, the non-recurrent subtype (single episode) was characterized by low psychiatric comorbidity (PC). The 'suicidal depression' subtype stood out from the other two due to indicators such as interpersonal and social difficulties and a history of suicide attempts (11). Logistic regression analysis further confirmed that this particular subtype differed from the others in its association with Early Life Adversities (ELA), domestic violence (DV), and recent life events (RLE) (11).

These findings corroborate the evidence, as observed in a Chilean PHC sample, that both psychiatric comorbidity (PC) and a history of Early Life Adversities (ELA) are indicative of depressive subtypes.

**Anxiety Comorbidity and Depression**: Anxiety comorbidity, is one of the most important factors associated with greater symptom severity (18). Epidemiological studies conducted in the general population show that this comorbidity occurs in approximately 50% of cases, reaching up to 80% in PHC patients. However, this comorbidity is not typically recognized at this level of care, leading to a poorer prognosis, greater chronicity, a higher risk of suicide, and increased healthcare costs (19). The significance of comorbid depression-anxiety is acknowledged in the new nosologies. The DSM-V introduced a specifier for depression with anxiety (13), and in the new proposal of the ICD-11, it is included in the depressive disorders, unlike ICD-10, which includes it in the anxiety disorders. According to current knowledge, patients with depression-anxiety require higher and prolonged pharmacological treatment and a psychological approach that considers techniques for anxiety control (19)

.In Chile, anxiety disorders are the most prevalent mental health disorders. The recent report from the Center for the Study of Conflict and Social Cohesion revealed that in Chile, one million people suffer from anxiety, a figure greater than the 800,000 affected by depression (4). This difference is likely even greater today, considering the stress generated by the social upheaval and the COVID-19 epidemic currently facing our country. In our FONIS study (8), 28.3% of patients presented with at least three PC, with the most prevalent being generalized anxiety disorder (25.5%), panic disorder (29.3%), and agoraphobia (28.3%) (10,20). Subsequently, a relationship was determined between different PC and various types of ACES (20). In this context, we propose the need to incorporate clinical guideline recommendations for managing anxiety comorbidity in patients treated for depression in Chilean PHC.

Complex Depressive Subtype Associated with ACES: The Adverse Childhood Experiences (ACE) study provided evidence of how ACES (physical abuse, sexual abuse, physical and mental neglect, among others) constitute a vulnerability factor for the development of high-prevalence chronic medical and mental disorders in adulthood (21). ACEs can also be traced in other adverse interpersonal situations, such as DV (9). ACES not only serves as a nonspecific risk factor for the development of depression but is associated with greater severity, suicidality, chronicity, and a poorer response to standardized depression treatments (14). This complexity is understood through biological findings associated with exposure to toxic stress, resulting in epigenetic changes, neuroendocrine alterations, changes in brain neurotransmission, changes in the pro-inflammatory system modulated by cytokines, and specific damage to brain areas involved in emotional regulation (14). A recent study, using a sophisticated data analysis approach in individuals with depression, identified a neurophysiological subtype related to specific neural circuits and ACES (22). In summary, the evidence is increasingly compelling regarding the existence of a depressive subtype with greater clinical complexity associated with ACES(11, 14).

However, Van der Kolk (23) states that the devastating consequences of ACES and other adverse early-life experiences on adult health have not yet been incorporated into current diagnostic systems or current clinical-therapeutic guidelines. An exception to this fact is the recent introduction of Complex Post-Traumatic Stress Disorder (C-PTSD) in the ICD-11 (24), which includes, in addition to the classic diagnostic criteria of PTSD, the presence of interpersonal difficulties, affective dysregulation, and alterations in self-image. These new

domains are known as "disorders of the self-organization" (DSO) and account for the social and psychological consequences of exposure to extreme interpersonal environmental situations. DSO is the primary focus in the treatment of C-PTSD (24).

Following the logic of C-PTSD, we suggest that the suicidal class observed in the PHC sample, in the Maule Region, could be conceptualized as 'complex depression,' for which the management of depression requires an integrated approach that considers the emotional, social, and interpersonal consequences of psychological stress or trauma. In this line of work, the principal investigator of this project demonstrated the effectiveness of a protocolized treatment for women with severe depression and a history of ACES in a secondary healthcare service, focusing on their present interpersonal difficulties and understanding them as repetitions of an adverse past (25).

According to UNICEF statistics, 75% of Chilean children report having experienced some form of child abuse, and it is known that 38% of Chilean women report being victims of DV. These figures become even more important when considering the violence observed in the recent sociopolitical crisis as an epiphenomenon of affective-behavioral dysregulation and the current COVID-19 pandemic as a massive and unavoidable with consequences on mental health that have not yet been fully realized. The knowledge accumulated over the past 30 years regarding the consequences of ALE needs to be incorporated into the design of clinical practices to improve the management of individuals seeking help for depression and, more broadly, mental health problems.

#### References

1- Ministerio de salud, Guía clínica para el tratamiento de la depresión 2013,2017b. Gobierno de Chile

2- Salvo L. Magnitud, impacto, recomendaciones de manejo para la depresión en referencia a Chile. Rev Med Chile 2014; 142: 1157-1164.

3- Ministerio de Salud. Encuesta Nacional de Salud 2016-2017. Segunda entrega de resultados Gobierno de Chile

4- Centro de estudios de Conflicto y Cohesión Social–COES.Resultados Primera Ola. Estudio Longitudinal Social de Chile (ELSOC). Santiago, Chile: COES. Recuperado de http://www.elsoc.cl/publicaciones

5- Vitriol V, Cancino A, Serrano C, et al. Remission in depression and associated factors at different assessment times in Primary Care in Chile. Clin Pract Epidemiol Ment Health 2018; 14: 78-88

6- Navarrete G, Saldivia S, Vicente B et al. Evaluación de las acciones de resultado de la detección, diagnóstico y tratamiento del episodio depresivo realizada en consultantes en el primer nivel de atención de la provincia Concepción Chile. Rev Chil Neuro-psiquiatría 2017-55(3) 160-169

7-Alvarado R, Rojas G. El Programa Nacional para el diagnóstico y tratamiento de la depresión en Atención Primaria: una evaluación necesaria. Rev Med Chile. 2011;139(5):592–

8- FONIS SA13/20135. Informe final. "Factores asociados a las distintas evoluciones que presentan los pacientes ingresados a GES depresión en la atención primaria en la séptima región: seguimiento de una cohorte"

9-Vitriol, V., Cancino, A., Leiva-Bianch, M et al. Depresión adulta y experiencias infantiles adversas: Evidencia de un subtipo depresivo complejo en consultantes de la atención primaria en Chile. Rev Med Chile, 2017: *145*(9), 1145–1153. https://doi.org/10.4067/s0034

10-Cancino, A., Leiva-Bianchi, M., Serrano, C. et al.Factors Associated with Psychiatric Comorbidity in Depression Patients in Primary Health Care in Chile. Depression Research and Treatment, *2018*, 1–9. https://doi.org/10.1155/2018/1701978

11- Vitriol V, Caceres C, Cancino A et al.Subtypes of depression using latent class analysis, including clinical and functional variables: evidence of a complex depressive subtypes Journal Affective disorders in review

12-Martínez, P., Rojas, G., Fritsch, R et al. Comorbilidad en personas con depresión que consultan en centros de la atención primaria de salud en Santiago, Chile. Rev Med Chile2017; 145(1): 25-32.

13- Gaspersz R, Lamers F, Kent J, et al Longitudinal predictivevalidity of the DSM-5 anxious distress specifier for clinical outcomes in a large cohort of patients with major depressive disorder. J Clin Psychiatry 2016; Mar 29.

14-Nemeroff, C. B. (2016). Paradise Lost: The Neurobiological and Clinical Consequences of Child Abuse and Neglect. Neuron, 89(5), 892–909. https://doi.org/10.1016/j.neuron.2016.01.019

15-Archer J, Bower P, Gilbody S et al. Collaborative care for depression and anxiety problems .Cochrane Database Syst. Rev. 2012, Oct 17; CD006525. doi: 10.1002/14651858.CD006525.pub2. Review

16-Rojas G, Guajardo V, Martínez P, et al. A Remote Collaborative Care Program for Patients with Depression Living in Rural Areas: Open-Label Trial. J Med Internet Res. 2018;20(4):e158. Published 2018 Apr 30. doi:10.2196/jmir.8803

17- Ulbricht, C. M., Chrysanthopoulou, S. A., Levin, L., & Lapane, K. L. (2018). The use of latent class analysis for identifying subtypes of depression: A systematic review. Psychiatry Research, *266*, 228–246. https://doi.org/10.1016/j.psychres.2018.03.003

18-Vitriol V, Cancino A, Ballesteros S, Potthoff S, Serrano S. Factors associated with greater severity of depression in Chilean primary care patients.

Companion CNS Disord 2017 may 4; 19(3). doi: 10.4088/PCC.16m02051.

19-Coplan, J. D. (2015). Treating comorbid anxiety and depression: Psychosocial and pharmacological approaches. World Journal of Psychiatry, 5(4), 366. https://doi.org/10.5498/wjp.v5.i4.366

20-Vitriol, V., Cancino, A., Leiva-Bianchi, M.. Childhood trauma and psychiatric comorbidities in patients with depressive disorder in primary care in Chile. Journal of Trauma and Dissociation, 2017; 18(2), 18–205.https://doi.org/10.1080/15299732.2016.1212449

21-Hughes K, Bellis MA, Hardcastle KA, Sethi D, Butchart A, Mikton C, et al. The effect of multiple adverse childhood experiences on health: a systematic review and meta-analysis. The Lancet Public Health. 2017;2(8):e356-e66.

22- Tokuda, T., Yoshimoto, J., Shimizu, Y., Okada, G., Takamura, M., Okamoto, Y., ...Doya, K. (2018). Identification of depression subtypes and relevant brain regions using a data-driven approach. *Scientific reports*, *8*(1), 14082. doi:10.1038/s41598-018-32521-z

23-Van Der Kolk, B. (2016). Commentary: The devastating effects of ignoring child maltreatment in psychiatry - A commentary on Teicher and Samson 2016. *Journal of Child Psychology and Psychiatry and Allied Disciplines*, *57*(3), 267–270. https://doi.org/10.1111/jcpp.12540 24-Karatzias, T., Cloitre, M., Maercker, A et al. (2018). PTSD and Complex PTSD: ICD-11 updates on concept and measurement in the UK, USA, Germany and Lithuania. European journal of psychotraumatology, 8(sup7), 1418103. doi:10.1080/20008198.2017.1418103 25- Vitriol, V., Ballesteros, S., Florenzano, R., Weil, K., & Benadof, D. (2009). Evaluation of an Outpatient Intervention for Women With Severe Depression and a History of Childhood Trauma. *Psychiatric Services*, *60*(7), 936–942. https://doi.org/10.1176/ps.2009.60.7.936

## 2-SOLUTION AND RESEARCH

## 2.1. PROPOSED SOLUTION AND APPLICABILITY SCENARIOS

Collaborative models constitute the paradigm that has demonstrated its greatest effectiveness in the treatment of depression in Primary Health Care (PHC). Among these models, the most effective ones incorporate clinical education, personalized case management by a non-medical professional, greater integration between primary and secondary care, and the inclusion of quality measures to improve outcomes.

Given the reported lack of competencies among PHC professionals for effectively managing depression, combined with the presence of variables in depressed patients that necessitate proper recognition and management within the context of PHC, this study proposes a solution to "structure, implement, and validate a collaborative model in PHC to address depression using a multidimensional approach." This comprehensive approach encompasses clinical training, the promotion of interprofessional collaboration, coordination between primary and secondary levels of care, and rigorous management control.

in addition to the existing interventions for depression in PHC, this model integrates the recognition and management of other critical variables, particularly Adverse Childhood Experiences (ACEs) and Adverse Life Events (ALEs), along with their associated clinical aspects, within a multidimensional framework. Furthermore, it incorporates clinical practices derived from Trauma-Informed Care (TIC).

## Trauma-Informed Care (TIC)

TIC (Trauma-Informed Care) is an evolving paradigm focused on providing holistic care for individuals with adverse or traumatic histories. Its core objective is to educate individuals by fostering an understanding of their responses to the traumatic impact of ACEs and adverse Life Events. TIC places a strong emphasis on ensuring physical, psychological, and emotional safety for both care providers and individuals affected by trauma. It also aims to create opportunities for those who have experienced adversity to regain a sense of control and empowerment over their lives. TIC seeks to offer a compassionate and responsive approach to survivors of psychological trauma, a population that has historically been underserved, marginalized, and even retraumatized within care settings. Central to TIC is the perspective that current symptoms are better understood as behavioral remnants of past responses to adversity, which at the time, may have been adaptive. This shift in approach moves from immediate questioning such as "What's wrong with you?" or "What symptoms do you have?" to a more empathetic inquiry, asking "What has happened to you?" TIC promotes a transformation from a care model that may inadvertently retrigger past adverse experiences to one that actively avoids retraumatization.

The Substance Abuse and Mental Health Services Administration (SAMHSA) is at the forefront of incorporating this model into its organizational policy. For an overview of TIC principles, please refer to Figure 1 in the annexes, based on a recent review. Guidelines for implementing TIC in the context of general medicine can be found in annex 2, and recently, the National Council for Behavioral Health in the U.S. issued a guide for Primary Health Care (PHC) in annex 3.

TIC places a strong emphasis on patient autonomy and recognizes resilience as a fundamental factor in explaining human capabilities to overcome and even develop psychological growth following exposure to traumatic or adverse situations. While TIC is an emerging paradigm, its widespread practice and the evidence of its impact are still limited. Globally, the incorporation of clinical practices based on TIC in the management of depression is yet to be established.

#### References

26-Reeves E. A Synthesis of the Literature on Trauma-Informed Care. Issues Ment Health Nurs 2015;36(9):698-709.

27-Hopper EK, Bassuk EL, Olivet J. Shelter from the storm: Trauma-informed care in homelessness services settings. The Open Health Services and Policy Journal. 2010;3(2):80-100.

28-Administration SAaMHS. SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2014.

37- Reeves E. A Synthesis of the Literature on Trauma-Informed Care. Issues Ment Health Nurs 2015;36(9):698-709.

29- Raja S, Hasnain M, Hoersch M, Gove-Yin S, Rajagopalan C. Trauma informed care in medicine: current knowledge and future research directions. Fam Community Health. 2015;38(3):216-26.

30-"Fomentode la resilencia y recuperación" (<u>https://www.thenationalcouncil.org/fostering-resilience-and-recovery-a-change-package/</u>)

31- Vitriol V, Cancino A, Sciolla A et al. Cuidado informado en trauma: un modelo emergente para el aboradje del subtipo depresivo con historia de adversidad infantil. Rev Neuropsiquiatria en revision (se adjunta en anexos).

32-Sciolla AF. An Overview of Trauma-Informed Care. Trauma, Resilience, and Health Promotion in LGBT Patients: Springer; 2017. p. 165-81.

33-Weinreb L, Fletcher K, Candib L, Bacigalupe G. Physicians' perceptions of adult patients' history of child abuse in family medicine settings. The Journal of the American Board of Family Medicine. 2007;20(4):417-9

34- Weinreb L, Savageau JA, Candib LM, Reed GW, Fletcher KE, Hargraves JL. Screening for Childhood Trauma in Adult Primary Care Patients: A Cross-Sectional Survey. Prim Care Companion to The J of Clinical Psychiatry. 2010;12(6):PCC.10m00950.

## 2.2. 2.2. RESEARCH QUESTION

Is the design and implementation of a multidimensional collaborative model more effective in improving depression outcomes than usual treatment in primary care centers in the Maule Region?

## 2.3. HYPOTHESIS OR RESEARCH ASSUMPTIONS

- 1- Adult patients undergoing treatment for depression in APS centers in the Maule Region, after being randomized and treated under the multidimensional collaborative model, will achieve a 20% higher remission rate than the control group at 3 and 6 months of treatment, assessed through a score equal to or lower than 7 on the PHQ-9 Health Questionnaire.
- 2- Adult patients undergoing treatment for depression in PHC centers in the Maule Region, after being randomized and treated under the multidimensional collaborative model, will achieve a significant improvement in anxiety symptoms compared to the control group at 3 and 6 months.
- 3- Adult patients undergoing treatment for depression in PHC centers in the Maule Region, after being randomized and treated under the multidimensional collaborative model, will achieve a significant improvement in interpersonal dysfunction, social dysfunction, and emotional dysregulation compared to the control group at 3 and 6 months.
- **4-** Adult patients undergoing treatment for depression in PHC centers in the Maule Region, after being randomized and treated under the multidimensional collaborative model, will achieve significantly better adherence than the control group at 3 and 6 months.

## 2.4. OBJECTIVES

## 2.4.1. GENERAL OBJECTIVE

To evaluate the effectiveness of a multidimensional collaborative model compared to standard care in improving depression outcomes in healthcare centers in the Maule Region through a randomized controlled cluster trial.

## 2.4.2. SPECIFIC OBJECTIVES

Design and implement a collaborative, interprofessional model in primary care centers in the Maule Region that integrates customary practices for managing depression with competencies for screening, diagnosing, and addressing clinical, functional, and historical variables associated with poorer depression outcomes from a multidimensional perspective including a TIC aproach

Compare the level of depressive symptoms in adults treated for depression through a multidimensional collaborative model versus standard treatment in primary care in the Maule Region at baseline, three months, and six months.

Compare the level of anxiety symptoms in adult depressive patients treated for depression through a multidimensional collaborative model versus standard treatment in primary care in the Maule Region at baseline, three months, and six months.

Compare the level of functional variables' symptoms in adult depressive patients treated for depression through a multidimensional collaborative model versus standard treatment in primary care in the Maule Region at baseline, three months, and six months.

Compare the level of therapeutic adherence achieved in adult depressive patients treated for depression through a multidimensional collaborative model versus standard treatment in primary care in the Maule Region.

#### 3. METHODOLOGY, ETHICS, AND PLANNING

#### 3.1. METHODOLOGY AND PROCEDURES

**DESIGN** To address the research question, a cluster randomized clinical trial will be employed.

**GENERAL DESCRIPTION**: At least 8 teams of primary care professionals, each consisting of a physician, psychologist, and social worker from different PHC centers in the Maule Region, will be randomly allocated into two arms (intervention and control). The teams in the intervention arm will be trained in the Multidimensional Collaborative Model for Depression (MCMD), while the teams in the control arm will continue with standard treatment. After the

training period in MCMD, an external team, blinded to the interventions, will assess a sample of 394 patients from both study arms who meet the inclusion criteria at baseline, three months, and six months, following informed consent.

The primary outcome of this study is a significant improvement in depressive symptoms, and the secondary outcomes include improvements in anxiety symptoms, interpersonal dysfunction, social role, emotional regulation, and treatment adherence.

After the patient follow-up process is completed, teams that were not exposed to MCMD will be offered training in depression management in APS, regardless of the study's funding status.

#### **INTERVENTION CHARACTERISTICS**

#### **Intervention Group**

The Multidimensional Collaborative Model (MCMD) will be designed to include:

I- Clinical Training: The training program will be a structured course formally supported by a syllabus. It will comprise a 12-hour online module delivered over six weeks, covering the following topics: general concepts of depression, psychiatric comorbidity adverse life experiences (including their definition, epidemiology, and the concept of toxic stress), complex depression, Trauma-Informed Care (TIC), and general treatment considerations. Upon successful completion of the online module, including the corresponding assessment, professionals will participate in a 16-hour clinical skills workshop conducted over two days, focusing on interview techniques and intervention strategies. The workshop will be assessed using a rubric developed by the research team, and feedback on the teaching activities will be solicited from the participants. Upon completing this stage, the teams will receive a specialization certificate in depression management in PHC issued by the University of Talca.

**Implementation:** The research team will initiate contact with clinic directors to introduce the model and seek their cooperation for implementation at their respective centers. Each team will designate a case manager for the more complex patients and establish a framework for interprofessional collaboration. We will also propose the inclusion of a higher-level nursing technician (TENS) who can receive limited training in TIC and depression management. Teams will be encouraged to implement a patient intake and follow-up form to consolidate pertinent information in a secure and encrypted format. This form has already been integrated into the daily practices of PHC. Additionally, the use of basic screening tools and telephone follow-ups with patients will be recommended.

Clinical Supervision by Specialists: Supervision sessions will be scheduled at least every 15 days, involving specialists from the research team and various primary mental health teams through virtual meetings. Consultations via telephone and email will also be available if needed by the teams.II- I

#### **Control group**

The control group teams will be instructed to read or review the current clinical guideline for addressing Depression in PHC and will continue to provide this treatment on a regular basis.

#### CALCULATION OF SAMPLE SIZE

To calculate the sample size, we will assume a maximum error of 5%, a confidence level of 95%, a power of 80%, and a maximum variance of 50%. This requires a total of 341 individuals diagnosed with depression. This calculation is based on previous studies conducted in the country. The first study is a research protocol that evaluates the effectiveness of a comprehensive training and technology-assisted supervision program to improve depression management in APS. It compares the efficacy of the proposed program with standard care (Rojas et al., 2015). The second study is a randomized clinical trial that compares pharmacotherapy monitored by phone with standard treatment, showing greater effectiveness in antidepressant responses and certain dimensions of quality of life at 3 and 6 months of treatment (Fritsch et al., 2007). The third study determines clinical and psychosocial variables associated with a higher number of adverse childhood experiences (ACEs) in a sample from the Maule Region (Vitriol et al., 2017).

Additionally, we anticipate that the intervention will yield positive results, preventing the possibility of statistically significant negative effects. Finally, considering at least 8 APS centers in the Maule Region (2 in Curicó, 2 in Talca, 2 in Linares, 1 in Teno, and 1 in Molina), and an 85% retention rate, we expect the participation of 394 individuals from the Maule Region diagnosed with depression, approximately 50 individuals per center.

- Fritsch, R., Araya, R., Solís, J., Montt, E., Pilowsky, D., & Rojas, G. (2007). Un ensayo clínico aleatorizado de. 587–595.
- Rojas, G., Martínez, P., Vöhringer, P. A., Martínez, V., Castro-lara, A., & Fritsch, R. (2015). Comprehensive technology-assisted training and supervision program to enhance depression management in primary care in Santiago, Chile: study protocol for a cluster randomized controlled trial. *Trials*, 1–6. https://doi.org/10.1186/s13063-015-0845-4
- Vitriol, V., Cancino, A., Leiva-Bianch, M., Serrano, C., Ballesteros, S., Potthoff, S., ... Asenjo, A. (2017). Depresión adulta y experiencias infantiles adversas: Evidencia de un subtipo depresivo complejo en consultantes de la atención primaria en Chile. *Revista Medica de Chile*, *145*(9), 1145–1153. https://doi.org/10.4067/s0034-98872017000901145

#### RECRUITMENT

The target population for this study will encompass adults between the ages of 18 and 70 who seek treatment for depression through the GES (Explicit Health Guarantees) program at APS centers in the Maule Region.

Inclusion Criteria: Age 18-65, confirmed diagnosis of depression according to the MINI (Mini-International Neuro-Psychiatric Interview).

Exclusion :Criteria:Sensory disability.Inability to provide informed consent, lack of access to a telephone, currently undergoing treatment for depression.Presenting a high risk of suicide and/or bipolar disorder and/or psychosis at the initial evaluation.

#### Patient Contact:

Patients will be contacted by an external evaluator who is blinded to their treatments. This evaluator will maintain close communication with a member of the healthcare center and invite the patient for the evaluation.

#### Population Recruitment Process:

An employee from the corresponding from the PHC center will be responsible for informing eligible patients about the project. If the patient expresses an interest in learning more about the project, they will be scheduled for an in-person interview with a member of the research team. During this interview, the patient will receive detailed information about the project, the importance of their participation, and it will be explicitly mentioned that their decision to participate or decline will not impact their treatment. If the patient agrees to participate, they will be presented with the informed consent document to review and sign, and the initial assessment for entry into the follow-up will be conducted.

## DATA COLLECTION

As previously mentioned, participants who meet the inclusion criteria and have signed their informed consent will be assessed at the beginning, at three months, and at six months using a battery of instruments by an evaluation team that is blinded to the interventions. This team will undergo an 4-hour training for data standardization. The data will be entered into a virtual spreadsheet where various instruments will be digitized, and the results will be sent via a network to the researcher's computer at the University of Talca using a dedicated server. Each evaluator will have access to a tablet and will be able to enter data using a password, with the survey data not stored on these devices.

#### **INSTRUMENTS:**

Initially, patients will be evaluated by the team, which has received prior training in administering the MINI to confirm the diagnosis of depression according to the ICD-10 or DSM, and inquire about potential ACEs (Adverse Childhood Experiences).

At baseline a semiestructured interview, the MINI, and ACE screening will be applied.

**The primary outcome** of this study, which pertains to depressive symptoms, will be assessed using the Patient Health Questionnaire (PHQ-9). This instrument will be administered at the study's onset, as well as at the three-month and six-month follow-up points (additional details provided in the annex).

**For secondary outcomes**, the GAD-/ Anxiety Inventory, the OQ45-2 for interpersonal and social functioning, and the DER-S for evaluating emotional regulation will be used. These instruments will be administered at the beginning, three months, and six months.

The adherence scale will be applied at the end of the study (details in the annex).

Lastly, a self-efficacy questionnaire for healthcare professionals will be designed and validated. It will be administered to all team members, both before and after the training for the intervention team and at the end of the observation period for both teams.

## DATA ANALYISIS

Data analysis will involve the utilization of SPSS software to examine the data. To commence, we will conduct an initial examination of the sociodemographic and clinical attributes within our sample. Additionally, we will compute the assessments of the scales employed in our study. The presentation of our findings will adhere to the CONSORT guideline for randomized clinical trials, including its extensions for cluster and non-pharmacological interventions.

An intention-to-treat analysis will be conducted for the primary outcome. In the preliminary descriptive analysis, we will assess the congruity of characteristics across the various samples. For the primary outcome analysis, we will employ a multivariable linear regression to discern differences at both 3 and 6 months, while adjusting for initial data imbalances if necessary. Furthermore, we will conduct a sensitivity analysis to explore the potential effects of missing data based on various assumptions. This comprehensive analysis will also extend to our secondary outcomes.

## **3.2. ETHICAL IMPLICATIONS ANALYSIS**

## 3.2.1. RISK-BENEFIT ANALYSIS:

The current proposal's primary goal is to enhance therapeutic outcomes for depression. However, working in mental health with patients suffering from depression entails inherent risks associated with the illness itself, such as the risk of self-harm or the emergence of psychotic symptoms.

To address these concerns, a well-defined protocol will be implemented to facilitate prompt communication with the treating team when any situation requiring urgent evaluation and treatment arises. The protocol for addressing adverse events will follow these steps:

1-Patients who present a suicide attempt, serious risk of suicide, and/or psychosis will not be included in the study follow-up (exclusion criteria). These individuals will continue their treatment with their existing care team.

2-In both models, even though the teams already have experience in managing depression and its associated risks, they will receive specialized training on addressing the specific risks associated with depression. This training will include a protocol stipulating that if the primary care team becomes aware of a patient at risk during their treatment, they must promptly assess the situation and determine the necessary course of action.

3-The informed consent process with the patient will emphasize their responsibility to inform their primary care team in case of a risk of losing the will to live or a significant worsening of their depression. It will be explicitly stated in the informed consent that if this information emerges during the evaluation with the research team, the research team will contact the treating team to notify them of the situation.

4-Upon learning of a patient's risk situation during the follow-up process, the external research team will promptly reach out to the respective CESFAM's mental health coordinator, ensuring that the primary care team becomes aware of the case within 24 hours. This enables them to perform the necessary evaluation and decide on the appropriate course of action.

The model's aim, focused on demonstrating its effectiveness, enhances comprehensive clinical evaluation and mitigates risks by having well-defined protocols and effective communication strategies in place to address any adverse events promptly.

**CONFIDENTIALITY SAFEGUARDS:** To ensure confidentiality in this research, all personal data of patients and professionals will be encoded with an abbreviation that has no possible association with their identities. A list will be created with the general data of the patient and the professional (name and ID), along with their corresponding code. Information will only be collected using tablets by the follow-up teams, and the data will be entered into a cloud-based system (Google Docs spreadsheet). No information will be stored on the researchers' tablets. The data generated during the administration of the instruments, identified only by an alphanumeric code, will be restricted to the principal investigator and the data analyst during the observation period. After this period, only the principal investigator will have access through a password. Paper consent forms will also be kept in locked folders in Dr. Vitriol's office.

All researchers will sign a confidentiality agreement for handling this data. The information will be retained for 5 years, after which the documents will be shredded, and the collected data will be deleted from the computer.

**3.2.3. INFORMED CONSENT/ASSENT:** Patients and professionals will sign an informed consent form previously approved by the Scientific Ethics Committee of the University of Talca, which outlines the objectives, procedures, confidentiality, and communication of the results.

#### 3.2.4. REQUIRED INSTITUTIONAL APPROVALS:

University of Talca: The sponsoring institution of the project, providing its personnel and facilities for conducting online and in-person courses, technical support for meetings and training sessions, and issuing the necessary certification.

Maule Health Service: An affiliated institution supporting the project by facilitating communication between the research team and various municipalities and healthcare centers (see both attached letters).

Contact was also made with directors of PHC who expressed interest in participating, but due to the current COVID-19 situation, these authorizations could not be formalized.

## 3.3. PLAN DE TRABAJO

Specific	Activities						One	e yea	ar										Two	yeaa	r						-	Three	e yeai		
Objectives	Adamaco	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
1- Design and implement a collaborative, multidimensio nal	Presentation and ethics committee approval Conduct a limited qualitative study Sample selection Information analysis	x	x	x	x	x	x																								
interprofessio	Broporo training	x	x	x	x	x	x																							┢──┤	
(MCMD) in primary care centers in the Maule Region.	Establish contact with PHC centers, Select centers, statify and randomize them Train and implement collaborative model			x	x	x	x	x	x	x	x	x	x																		
2-Compare the level of	Select and train external evaluation team										х	x	x																		
depressive	Recruitment patients													Х	Х	Х	Х	Х	Х												
adults treated for depression through the MCMD versus standard treatment in primary care in the Maule Region.	To evaluate with the PHQ 9 at the beginning, three and six months a sample of patients admitted to treatment for depression in care centers in the Maule region.													x	x	x	x	x	x	x	x	x	х	x	x						
3- Compare the level of anxiety symptomsn adult depressed	IT o evaluate with the GAD 7 at the beginning, three and six months a													х	х	х	x	x	x	х	х	х	х	х	x						

patients treated	sample of patients																				
for depression	admitted to																				
through the	treatment for																				
MCMD vs. usual	depression in care																				
treatment.	centers in the Maule																				
Evaluate a sample	region.																				
of patients	· ·																				
admitted to																					
treatment for																					
depression with																					
the OQ45 and the																					
DERS scale at the																					
beginning, three																					
and six months. in																					
care centers in the																					
Maule regio																					
4Compare the																					
level of																					
symptoms of																					
functional																					
variables in																					
adult depressed	To evaluate with the																				
patients treated	OQ45.2 and DERS																				
for depression	at the beginning,																				
through the	three and six																				
MCMD vs. usual	months a sample of						v	v	v	v	v	v	v	V	v	v	v	v			
treatment. In a	patients admitted to						^	^	^	^	^	^	^	^	^	^	^	x			
sample of	treatment for																				
patients	depression in care																				
admitted to	centers in the Maule																				
treatment for	region.																				
depression at																					
three and six																					
months. in care																					
centers in the																					
Maule																					

5. Compare the level of adherence to treatment in patients treated with MCMD vs. usual treatment.	To evaluate at 3 and 6 nonth with the adherence scale								x	x	x	x	х	x	x	x	x						
Analisys	Analyisis											х	Х	х	х	х	х	Х					
Finalized	Disseminate results and elaboarte final report																	х	х	х	х	х	x

## 4. RESULTS, IMPLEMENTATION, AND DISSEMINATION

## 4.1. IMPLEMENTATION OF THE EXPECTED PRODUCT(S)

## 4.1.1. RESULTS AND/OR EXPECTED PRODUCTS

TRAINING COURSE IN THE COLLABORATIVE MULTIDIMENSIONAL MODEL FOR DEPRESSION FOR PRIMARY HEALTHCARE TEAMS	Specialized competency, TIC aproach course designed to enhance the skills of primary healthcare professionals in the treatment of depression.
RECOMMENDATIONS FOR COMPREHENSIVE MANAGEMENT OF PATIENTS WITH COMPLEX DEPRESSION IN THE CURRENT CLINICAL GUIDELINE	Protocol for a comprehensive, integrated, personalized interview could incorporated into the Depression Clinical Guideline, including specifications for the assessment of clinical, functional, and factors not covered by the current clinical guideline. Approach strategies for patients with depression and comorbid anxiety.
RECOMMENDATIONS FOR MANAGING THE DEPRESSION PROGRAM IN A PHC ACCORDING TO A COLLABORATIVE MODEL- TIC APROACH	Management protocol for interprofessional care of patients with depression in PHC. Definition of the role of the complex depression case manager in PHC Supervision protocol via telemedicine
REPORTS IN SCIENTIFIC JOURNALS	The clinical trial methodology must be published prior to its implementation, in accordance with the requirements for publishing randomized clinical trial results.

#### 4.1.2. IMPLEMENTATION OF THE EXPECTED PRODUCT(S)

The beneficiaries of this project will be as follows:

Individuals seeking treatment for depression within the public primary healthcare system in the Maule Region. These individuals will receive comprehensive care provided by an interprofessional treatment team. This team will address the clinical aspects associated with the condition from an inclusive perspective, expanding the biopsychosocial model to a bio-psycho-biographical approach. Additionally, in patients with depression, the importance of difficulties in functional areas such as interpersonal relationships and emotional dysregulation in the diagnosis and treatment of depression will be actively recognized. Patients who require it may have access to a case manager to optimize their treatment.

**Primary healthcare teams in the Maule Region**. The primary care teams, including primary care physicians, will receive training in a competency-based model for the management of depression, along with clinical and functional variables (anxious comorbidity, interpersonal difficulties, emotional dysregulation, etc.), which are prevalent in patients seeking treatment for depression (and emotional disorders in general). The current clinical guideline and undergraduate training are found lacking in addressing these issues within the clinical service context. Several of the competencies acquired will have a cross-cutting focus, particularly in recognizing the significance of biographical adversity, especially in childhood, as a risk factor and a clinically relevant element in addressing the most prevalent physical and mental health issues in adults.

**Current clinical guidelines for depression**. Based on the results of this research, specific recommendations for screening, diagnosis, and management of complex depression and the clinical aspects associated with it will be provided.

**Scientific community**: The results will be communicated through presentations at conferences and scientific journals.

#### 4.2. DISSEMINATION ACTIVITIES

1-International Seminar with Dr. Andrés Sciolla from the University of Davis as a guest speaker, specializing in Trauma-Informed Care for primary healthcare teams (Dr. Sciolla's biography is included in the annexes).

2-Outreach event to present the final project results to primary healthcare teams in the Maule Region.

3-Presentation of the results through the University of Talca's media channels.

4-Community dissemination of the results through local news outlets.

5-Presentation of the results at the annual Congress of the Society of Neurology, Psychiatry, and Neurosurgery.

6-Presentation of the results at international conferences to be determined.

7-Clinical training for the primary healthcare teams in the Maule Region that participated in the research and were not included in the intervention branch, along with corresponding certification.

8-Online training course for primary healthcare teams in the Maule Region or other regions that could not participate in the research but, following the study, and in coordination with the Maule Health Service or other services, wish to receive training.

## 5. MANAGEMENT AND ASSOCIATION CAPACITY

## .1. MANAGEMENT CAPACITY.

NAME	INSTITUTIO N	PROFESSION	PROYECT CHARGE	Critical Functions and Capabilities	% Monthly dedication (calculate d based on 180 hours)a 180hrs.)	\$/HH
		EQUIP	O DE INVESTIGACIÓ	N		
Verónica Vitriol	U de Talca	Psychiiatrist	Director	Psychiatrist with vast experience in clinic and teaching with. Research in depression in the area she has been director of the FONIS Project	11	26.000
Alfredo Cancino	U De Talca	Medical specialist in Family Medicine, Mental Health area. Psychotherapis t	Director alterno	Clinical- administrative functions in the Mental Health Program of the Curicó-Centro Family Health Center, where he has organized a clinic for patients with Depression and biographical adversity. He has worked with the main researcher of this work on depression and EIA research, with publications in national and foreign journals.	7	22.000
María de la Luz Aylwin	U De Talca	PHD Neurobiology	Randomization Coordination	PHD in Neurophysiolog y and cognitive processing is coordinator of the committee of the Specialization	5	22.000

				Scholarship in		
				Psychiatry and		
				will be in charge		
				of coordinating		
				the external		
				evaluation team		
				Head of		
				Psychiatry		
				Service at		
				Curico Hospital		
			<b>T</b> · · · <b>O</b> P · · ·	Professor at the		
Jorge	U De Talca	Psychiatrist		University of	5	23000
Calvo		5	Guide	laica		
lahanna			Protessional who	Psychologist in		
Jonanna	U de Talca	Psychologist	contacts patient to	charge of	4	15000
Kreitner			external evaluation	analizys		
			team	Oliniaal		
				Professor		
				Professor of		
			Drafaggianal who			
Soledad			Professional who	Psychology U.		
Ballestero	U de Talca	Psychologist	contacts patient to	de l'aica	7	10000
s			external evaluation	She has been		
			team	part of this		
				research team		
				in successive		
				works and		
				publications		
		PERSON	IAL TECNICO DE APO	ΟΥΟ		
				Psychologist,		
				advisor to the		
Marcola	Servicio de		Professional who	Mental Health		
Ormazbal	Salud del	Psychologist	contacts patient to	Program of the	7	15000
Omazbai	Maule		external evaluation	Maule Health		
				Service.		
				Clinical		
			Responsible for			
			technical support			
			for online training			
			and clinical			
			simulation in the	Responsible for		
			skills workshop	technical		
Sergio			Computer Engineer	support for		22000
Guíñez	U de Talca	Ingeniero	and Doctor of	online training	4	22000 A
Guíñez			Medicine and	and clinical		U
			Translational	simulation in the		
			Research,	skills workshop.		
			specialist in			
			telecommunication			
			s and distributed			
			systems.			

|--|--|

	Porcentaje de Dedicación mensual en otros Proyectos											
CARGO EN EL PROYECTO	NOMBRE	2020	2021	2022								
Director	Verónica Vitriol G	0	0	0								
Director Alterno	Alfredo Cancino A	0	0	0								
Investigadores	María de la Luz Aylwin	8	8	8								
	Jorge Calvo C	0	0	0								
	Sergio Guíñez	0	0	0								
	Joahanna Kreither	0	0	0								

#### 5.2. CURRICULAR BACKGROUND OF THE RESEARCH TEAM

**Director**: Verónica Vitriol G, Psychiatrist, Master in Psychology with a focus on psychoanalysis, Professor at the School of Medicine at the University of Talca, responsible for undergraduate courses, and since 2019, Head of the Psychiatry Scholarship at the University of Talca. She has conducted research and published in national and international journals in the areas of depression and childhood trauma. To date, she has been the principal investigator in two FONISSA05 20037 SA13 20135 projects.

**Alternate Director**: Alfredo Cancino A, Specialist in Family Medicine-Mental Health; Post-Rationalist Cognitive Psychotherapist; Professor in the field of Mental Health and Psychiatry, and Head of the Psychopathology module at the School of Medicine of the University of Talca. He is a researcher in the fields of depression and childhood trauma, with national and international publications. He served as the alternate director of a FONIS SA 20135 project.

#### **Researcher:**

**Andres Sciolla:** Medical Doctor University of Chile, Psychiatrist University of San Diego, Professor Emeritus of the University of Davis Medicine Clinic. Co-founder and director of the RESTAT Program (Resilence, Education and Supportive Tools for Adults Recovering from Trauma). He has conducted research and published in international journals in the areas of clinicaland education in care of vulnerable populations, depression, telemedicine, doctorpatient relationship among others **María de la Luz Aylwin**: Neurophysiology in Human Behavior, specifically studying behavioral and electrophysiological changes during sensory learning processes in humans. She is part of a research project funded by the University of Talca titled "Translational Associative Research Program on Cognitive, Neural, and Relational Processes of Adaptive and Psychopathological Behavior." She coordinates the Psychiatry and Mental Health Scholarship at the University of Talca.

**Johanna Kreither** Psycologist, PhD University Davis and post PHD Psychology University of Columbia, Professor Psycholoy Universidad de Talca,. She is part of a research project funded by the University of Talca titled "Translational Associative Research Program on Cognitive, Neural, and Relational Processes of Adaptive and Psychopathological Behavior.

**Soledad Ballesteros**: Clinical Psychologist, Pontifical Catholic University of Chile (2001). Specialization in Clinical Psychology and Postgraduate in Focal Psychoanalytic Psychotherapy, University of Chile, Chilean Psychoanalytic Association (APCH), and Hospital del Salvador (2003). She is Professor at the University of Talca, teaching modules on Medical Psychology, Psychopathology, and Psychotherapy for Medical students.

**Marcela Ormazábal**: Clinical Psychologist, university lecturer, currently Mental Health Advisor at the Maule Health Service, responsible for the Emergency and Disaster Program. She participated in the FONIS SA 13 20135 project and in publications derived from the results of this project.

**Jorge Calvo C**: Head of the Psychiatry and Mental Health Unit of the San Juan de Dios Hospital in Curicó. Lecturer at the School of Medicine of the University of Talca. Co-author in research works sponsored by the Faculty of Psychology and the School of Medicine of the University of Talca.

**Sergio Guiñez**: Computer Engineer and Doctor in Translational Medicine, specializing in telecommunications and systems. He directs the Clinical Informatics and Precision Medicine Laboratory at the Faculty of Medicine of the University of Talca, where he also serves as an academic. His research focuses on clinical simulation and software development.

#### **5.3. PARTICIPATION OF RESEARCHERS IN TRAINING**

Roberto González, second-year Psychiatry fellow at the University of Talca, is a Psychiatry resident at the University of Talca. His training includes research activities. As part of his training program, he is required to carry out a research project, and depending on his interests, he may join the current project, with the possibility of it leading to a thesis.

Our goal is to include the three Psychiatry and Mental Health fellows who joined this project in 2020. We will invite thesis students from the Faculty of Psychology of the University of Talca to write their theses within this project.

## 5.4. ASSOCIATION

The researchers involved in this project have gained extensive experience in both clinical care (at primary and secondary healthcare levels, where they actively practice) and teaching medical students, including psychiatry fellows at the University of Talca since 2019. Throughout their work, they have progressively incorporated the study and recognition of clinical variables, functional aspects, and previously unexplored backgrounds in patients with mental health issues. This gradual accumulation of knowledge has enabled them to develop an intervention plan that encompasses multidimensional variables, which have been under-addressed thus far, with the aim of enhancing the treatment of depression in public health settings.

Their previous work has already been cited in the current Ministerial Clinical Guide. Additionally, Dr. Andrés Sciolla, a Professor at the University of Davis with extensive experience in clinical care and teaching within the context of health inequality, will be invited to participate as an expert.,

The University of Talca, as a Higher Education Institution, has established itself as a prominent advocate for Skills-Based Education within the Maule region. The educational activities provided, both at the undergraduate and postgraduate levels in the field of Medicine, have been distinguished by their psychosocial orientation. University of Talca students have actively engaged with the social challenges facing the Maulina community and the country, fostering a growing interest in psychiatric specialization among medical graduates.

Furthermore, the Maule Health Service, tasked with implementing public mental health policies in the region, has consistently extended its support to promote the involvement of primary and secondary healthcare facilities within the public network in the proposed thematic area and the research projects presented.

## TECHNICAL SPECIFICATION FORM FOR PROJECTS THAT WILL CREATE, USE OR ADAPT MEASUREMENT INSTRUMENTS

#### 1. TYPE OF INSTRUMENTS TO USETIPO DE INSTRUMENTOS A UTILIZAR

The p	project contemplates the use of:		
Х	Instrument(s) previously used and validated ir population.	n Chile, commonly used a	nd in the general
	Instrument(s) previously used and validated ir population.	n Chile, commonly used a	nd in the general
	New instrument to create for the project:		
In the	e case of using existing instruments:		
Consid	der Use Rights (CopyRights)	SI	NO
in Chi	lean pesos)	\$	

## 1-INSTRUMENTS TO USE, QUANTITATIVE METHODOLOGY

TABLE OF GENERAL TECHN	CAL INFORMATION ON QUANTITATIVE
IN	STRUMENTS
INSTRUMEN	TS PREVIOUSLY USED
PATIENT HE	ALTH QUESTIONAIRE
Reliability (reported values and	Sensitvity 0,8
calculation statistics)	Especificidity 0,7
	Cronbach alpha 0,89
Validity (Content, criterion and construct. According to available information and case statisticians: % of the explained variance and factors or components, inter-judge correlation, re- test, concurrence, % of the domain, structure, etc.)	Average score 4.85+-5.75. High internal consistency McDonald's coefficient 0.9
References from previous uses of the instrument	Saldivia et al Propiedades psicométricas del PHQ-9 (Cuestionario de salud general del paciente) en centros de atención primaria Chile. Rev. Med Chile 2019;147:53_60
Measurement Scale (type) and scores it provides (range)	Cut off point 7 Subdepresivo 6-9 Leve 11-15 Moderada 16-20 Severa 21 o mas
Normas y población normativa	Primary care patients
ENorms and normative population Standardization (Conditions of use – self-applied, by interviewer, other – and qualified personnel)standarización (	Self applied
Traslation	Validated in Chile
Linguistic adaptation	
Semantic Adaptation (to the cultural uses of the target population)	
Authors' agreement to the generated versión	
Standardization (formulation/translation of manuals and conditions of use)	
GENERAL ANXIETY DISORDER	GAD 7
Reliability (reported values and	Sensitvity 0,9
calculation statistics)	Especificidity 0,8
	Cronbach alpha 0,86
Validity (Content, criterion and construct. According to available	AUC = 0.957-0.985); p < 0.001

information and case statisticians: % of the explained variance and factors or components, inter-judge correlation, re-	
test, concurrence, % of the domain,	
References from previous uses of the instrument	García-Campayo J, Zamorano E, Ruiz MA, Pardo A, Pérez-Páramo M, López-Gómez V, Freire O, Rejas J: Cultural adaptation into Spanish of the generalized anxiety disorder-7 (GAD-7) scale as a screening tool. <i>Health Qual</i> <i>Life Outcomes</i> 2010, <b>8</b> :8.
Measurement Scale (type) and scores it provides (range)	Cut off point 10
Normas y población normativa	Primary care patients
ENorms and normative population Standardization (Conditions of use – self-applied, by interviewer, other – and qualified personnel)standarización (	Self applied
Traslation	
Semantic Adaptation (to the cultural uses of the target population)	
Reverse Translation (Backtranslation)	
versión	
Standardization (formulation/translation of manuals and conditions of use)	
DERS-E Emotional Regulation E	Difficulties Scale
Reliability (reported values and	
calculation statistics)	Cronbach alpha 0.92
Validity (Content, criterion and construct. According to available information and case statisticians: % of the explained variance and factors or components, inter-judge correlation, re- test, concurrence, % of the domain, structure, etc.)	Test-retest 0.74p<0.01
References from previous uses of the	Guzman Gozalez et al. Validez y confiabilidad de la
instrument	version adaptada al español de la escala de dificultades en la regulación emocional DERS_E en poblacion Chilena .Terapia Psicologica 20141 19-29
Measurement Scale (type) and scores	Emotional descontrol 1,51-2,59
it provides (range)	Emotional regret 1,79-2,79
	Emotional intention 195-267
	Emotional confusioion 1,70-2,61
Normas y población normativa	Clinical and general population
ENorms and normative population	Self applied

Standardization (Conditions of use –	
self-applied, by interviewer, other – and	
qualified personnel)standarizacion (	Malidada an Ohila
Semantic Adaptation (to the cultural	
uses of the target population)	
Reverse Translation (Backtranslation)	
Authors' agreement to the generated versión	
Standardization (formulation/translation of manuals and conditions of use)	
THE OQ-45-2 interpersonal and	social role questionnaire,
Reliability (reported values and	Sensitivity:0.9
calculation statistics)	Especifity 0.9
Validity (Content, criterion and construct. According to available information and case statisticians: % of the explained variance and factors or components, inter-judge correlation, re- test, concurrence, % of the domain, structure, etc.)	Test-retest 0.74p<0.01
References from previous uses of the instrument	von Bergen A, de la Parra G: OQ-45.2, Cuestionario para evaluación de resultados y evolución en psicoterapia: Adaptación, validación e indicaciones para su aplicación e interpretación. [OQ- 45.2, An Outcome Questionnaire for Monitoring Change In Psychotherapy: Adaptation, Validation and Indications for its Application and Interpretation.]. <i>Terapia Psicológica</i> 2002, 20:161-176.
Measurement Scale (type) and scores it provides (range)	Interpersonal relationships subscale containing 12 questions and the social role subscale including 9 questions with cut-off points of 16 or more for interpersonal dysfunction and of 14 or more for social role dysfunction
Normas y población normativa	Clinical and general population
ENorms and normative population Standardization (Conditions of use – self-applied, by interviewer, other – and qualified personnel)standarización (	Self applied
Traslation	Validated in Chile
Linguistic adaptation	
<b>°</b>	

Semantic Adaptation (to the cultural	
uses of the target population)	
Reverse Translation (Backtranslation)	
Authors agreement to the generated	
Standardization (formulation/translation	
of manuals and conditions of use)	
GENERAL HEALTH ADHERENCE TRE	ATMENT SCALE
Reliability (reported values and	Crophophi 0 01
calculation statistics)	Ciondach.u.91
Validity (Content, criterion and construct. According to available information and case statisticians: % of the explained variance and factors or components, inter-judge correlation, re- test, concurrence, % of the domain, structure, etc.)	Estructure of 4 factors for the scale ( <i>CMIN/DF</i> =2.879; <i>RMSEA</i> =.108; <i>NFI</i> =.780; <i>CFI</i> =.843; TLI=.819; <i>PNFI</i> =.680; <i>SMC</i> =.590)
References from previous uses of the instrument	Cristian Cáceres y Rodrigo Cordero Tesis de Psicología Universidad de Talca (Proyecto FONIS SA 20135).
Measurement Scale (type) and scores	For the general treatment adherence scale, the
it provides (range)	following scores are obtained: $\leq 86$ (low score), $> 86$ and $< 109$ (medium score) and $\geq 110$ (high scor)
Normas y población normativa	Clinical and general population
ENorms and normative population Standardization (Conditions of use – self-applied, by interviewer, other – and qualified personnel)standarización (	Self applied
Traslation	Validated in Chile
Linguistic adaptation	
Linguistic adaptation	
Linguistic adaptation Semantic Adaptation (to the cultural	
Linguistic adaptation Semantic Adaptation (to the cultural uses of the target population)	
Linguistic adaptation Semantic Adaptation (to the cultural uses of the target population) Reverse Translation (Backtranslation) Authors' agreement to the generated	
Linguistic adaptation Semantic Adaptation (to the cultural uses of the target population) Reverse Translation (Backtranslation) Authors' agreement to the generated versión	
Linguistic adaptation Semantic Adaptation (to the cultural uses of the target population) Reverse Translation (Backtranslation) Authors' agreement to the generated versión Standardization (formulation/translation of manuals and conditions of use)	
Linguistic adaptation Semantic Adaptation (to the cultural uses of the target population) Reverse Translation (Backtranslation) Authors' agreement to the generated versión Standardization (formulation/translation of manuals and conditions of use) ADVERSE CHILDHOOD EXPERINCE II	NVENTORY TRANSLATED INTO SPANISH FROM
Linguistic adaptation Semantic Adaptation (to the cultural uses of the target population) Reverse Translation (Backtranslation) Authors' agreement to the generated versión Standardization (formulation/translation of manuals and conditions of use) ADVERSE CHILDHOOD EXPERINCE II THE ADVERSE CHILHOOD STUDY	NVENTORY TRANSLATED INTO SPANISH FROM
Linguistic adaptation Semantic Adaptation (to the cultural uses of the target population) Reverse Translation (Backtranslation) Authors' agreement to the generated versión Standardization (formulation/translation of manuals and conditions of use) ADVERSE CHILDHOOD EXPERINCE II THE ADVERSE CHILHOOD STUDY Reliability (reported values and	NVENTORY TRANSLATED INTO SPANISH FROM
Linguistic adaptation Semantic Adaptation (to the cultural uses of the target population) Reverse Translation (Backtranslation) Authors' agreement to the generated versión Standardization (formulation/translation of manuals and conditions of use) ADVERSE CHILDHOOD EXPERINCE II THE ADVERSE CHILHOOD STUDY Reliability (reported values and calculation statistics)	NVENTORY TRANSLATED INTO SPANISH FROM Cronbach's alpha = .88

test, concurrence, % of the domain,	60.526 (19); RMSEA = 0.036; CFI/TLI =
structure, etc.)	0.990/0.986]. Metric invariance was supported in all
	sexes. Internal consistency was good (0.83) for the
	sexual abuse scale and poor (0.57) for the
	physical/emotional abuse scale.
References from previous uses of the	Felitti, Anda, Nordenberg, Williamson, Spitz,
Instrument	Edwards, Marks. (1998). Relationship of
	Childhood Abuse and Household Dysfunction to
	Many of the Leading Causes of Death in Adults: The
	Adverse Childhood Experiences (ACE) Study.
	American Journal Of Preventive Medicine 14(4),
	245-258.
	Cuestionario para adultos de experiencias adversas
	en la infancia. Aces aware
	https://www.acesaware.org/wp-
	content/uploads/2019/11/ACEs-Screener-Identified-
	Spanish.pdf
	- <u>-</u>
Measurement Scale (type) and scores	It is a screening scale on 10 adverse childhood
it provides (range)	experiences in dichotomous form, each one
	represents an EIA, it has no cut-off point.
	There are versions of 8,10,14 questions. The 10 is
	translated into Spanish
Normas y población normativa	
ENorms and normative population	
Standardization (Conditions of use –	Self-report
self-applied, by interviewer, other – and	
qualified personnel)standarizacion (	
	No requiere
Linguistic adaptation	No requiere
Somentia Adaptation (to the quiltural	
Semantic Adaptation (to the cultural	Si
Reverse Translation (Backtranslation)	
Authors' agreement to the generated	
versión	
Standardization (formulation/translation	
of manuals and conditions of use)	

1. INSTRUMENTOS A UTILIZAR, METODOLOGÍA CUALITATIVA





## SUPLEMENT 2

1.	Program Training CMTIC-D	page 2-8
2.	Program Training Usual Care	page 9-12
3.	Implementation Components CMTIC-D	page 13-14
4.	Randomization	page 15
5.	Sample Size Calculation	page 16
6.	Emergencies Protocol	page 17





## TRAINING PROGRAMS

## CMTIC-D

Course Name	COLLABORATIVE MULTIDIMENSIONAL TRAUMA INFORMED CARE (CMTIC- D) DEPRESSION APROACH		
Prerrequisits	Title Health Professional		
Credits (No hours)	1 SCT 14 (Online work hours) 13 (Hours of Self-Employed Work)		
Duration	8 (weeks)		
Class Schedule	4 Expository classes 4 Workshops via teler	natics	
Name of Responsible Professor	Dra. Verónica Vitriol		
Participating Teachers	Dra. Verónica Vitriol Dr. Alfredo Cancino Dr. Andrés Sciolla		

	The primary focus of the Multidimensional Collaborative Model - Trauma informed care aproach for Depression (MDTIC-D) is to equip primary healthcare teams with the necessary skills to enhance their ability to effectively address depression. This innovative model redefines depression as a complex and multifaceted condition, viewed through a biopsychosocial lens with a strong emphasis on the psychological and biographical aspects.
Course Objectives	In addition to the existing knowledge outlined in the GES Guide for depression, this model incorporates insights from, Difficult to treat Depression (DTD), Trauma-Informed Care (TIC), including the understanding of toxic stress, disorganized attachment, mentalization, and resilience. Furthermore, it places a strong emphasis on fostering competencies in effective and patient-centered communication.
	The key aspect of this model is its promotion of interprofessional collaboration in managing depression and the ability to intervene effectively during crises. It recognizes that addressing depression requires a comprehensive and multidisciplinary approach, bringing together a range of healthcare professionals





	to work together towards a common goal.
	Discuss the current model for the management of depression in Primary Care
	• Critically analyze current evidence regarding the management of depression in primary care
	• Integrate the recognition of complex and/or difficult-to-treat depression into clinical practice
	Compare approaches to difficult-to-treat depression and refractory depression
	• Compare and critically analyze the proposal of the MCTIC-D compared to the proposal of the current Clinical Guide.
	<ul> <li>Incorporate practices from the TIC paradigm</li> </ul>
Objectives	Describe attachment theory
Objectives	<ul> <li>Integrate the concept of mentalization and its role in understanding the depressed patient</li> </ul>
	<ul> <li>Integrate the concept of resilience and its role in understanding the depressed patient</li> </ul>
	<ul> <li>Integrate the neurobiological bases of attachment and mentalization</li> </ul>
	• Compare attachment modalities in adulthood and their relationship with the behavior of patients with depression
	<ul> <li>Explain the impact of different attachment styles on the manifestations of depression according to their clinical complexity</li> <li>Define differential therapeutic approach strategies for different types of attachment in patients with depression</li> </ul>





<ul> <li>Know the principles of the collaborative model for the treatment of chronic diseases</li> </ul>
• Analyze the evidence regarding the effectiveness of collaborative models in the treatment of depression
• Critically analyze the elements that can be implemented in PHC of a collaborative model in depression from a multidimensional approach
• Carry out a comprehensive and multiprofessional evaluation of clinical cases of a primary care consultant with suspected depressive symptoms in PHC with different elements of clinical complexity.
• Design a comprehensive and multiprofessional management plan for clinical cases of consultants for depression in primary care according to their clinical complexity
• Design a comprehensive and multiprofessional monitoring plan for clinical cases of consultants for depression in primary care according to their clinical complexity
I- General framework MCTIC-D Current clinical guideline for depression, comprehensive evaluation according to current clinical guideline, evidence of depression results in APS, Complex Depression, Refractory Depression, Difficult to Treat Depression, Multidimensional Depression Model
<b>II- Trauma informed care TIC</b> History, Principles of trauma-informed care, epidemiological and neurobiological bases, clinical implications, principles of trauma-informed care in health.
<b>III- Bonding and mentalization</b> Attachment theory, attachment in adulthood, mentalization as a form of intersubjectivity, neurobiology of attachment, social brain, depressive manifestation according to attachment styles, interpersonal dynamics in the help encounter with patients with depression, mentalization as a strategy in helping relationship.





Contents	<ul> <li>IV- Resilience         Theoretical and neurobiological bases, clinical implications         V- Multiprofessional comprehensive diagnostic workshop         Clinical case workshop through MCTIC_D         Diagnostic algorithm, EVA approach, EIA, understandinconsultation.         VI- Multiprofessional comprehensive treatment workshop         Clinical case workshop through collaborative learning model         Pharmacological indication, how to build a crisis intervention focus.         VII- Multiprofessional comprehensive monitoring workshop         Clinical case workshop through collaborative learning model         Pharmacological indication, how to build a crisis intervention focus.         VII- Multiprofessional comprehensive monitoring workshop         Clinical case workshop through collaborative learning model         Case manager (functions), monitoring plan, psychoeducation, monitoring instruments         VIII- Collaborative Model Workshop         Definition of collaborative model, evidence of collaborative model in PHC, central         Clanical case workshop through collaborative model in PHC, central         Clinical case model         VIII- Collaborative model, evidence of collaborative model in PHC, central         Clinical case workshop         Definition of collaborative model, evidence of collaborative model in PHC, central         Clinical case workshop         Definition of collaborative model, evidence of collaborative model in PHC, central         Clinical case workshop         Definition of collaborative model, evidence of collaborative model in PHC, central         Clinical case workshop         Definition of collaborative model         Clinical case workshop         Definition of collaborative model         Clinical case workshop         Clinical case workshop         Clini</li></ul>		
Evaluation mode (Types of evaluations and calculation of the final grade)	<ul> <li><b>1.</b> Knowledge multiple choice individual test (30%)</li> <li><b>2.</b> Rubric in workshops (70%)</li> </ul>		
Approval requirements	<ul> <li>100% asistencia a talleres</li> <li>Nota mínima: 5</li> </ul>		
Bibliography	<ol> <li>Ministerio de salud; Guía Clínica depresión 15 años y más, 2013</li> <li>Ministerio de Salud; Guía Clínica trastorno Bipolar 15 años y más, 2013</li> <li>Ministerio de salud, Programa Nacional Prevención del Suicidio, Norma Técnica, 2013</li> <li>Ministerio de Salud, Resumen ejecutivo Guía Practica Clínica Trastorno Ansioso, 2020</li> <li>Valdés, G., Contreras, X., Romero, W., Medina, M., Norero, B., Dussaillant, C., Pérez, M., &amp; Franzani, A. (2006). Subdiagnóstico de depresión en atención primaria, en pacientes del área sur-oriente de Santiago, 2006. <i>Revista Chilena de Salud Pública, 10</i>(3), p. 158-163.</li> </ol>		





Consultado

de <u>https://revistasaludpublica.uchile.cl/index.php/RCSP/article/view/2450/2</u> 461

- 6. Vitriol et al. Latent Class Analysis in Depression, Including Clinical and Functional Variables: Evidence of a Complex Depressive Subtype in Primary Care in Chile. Depress Res Treat. 2021 Feb 11;2021:6629403. doi: 10.1155/2021/6629403. PMID: 33628499; PMCID: PMC7895584.
- 7. Vitriol et al : Cuidado informado en trauma un modelo emergente para el abordaje del subtipo depresivo con historia de adversidad infantil 348 www.sonepsyn.cl REV. CHIL NEURO-PSIQUIAT 2020; 58 (4); 348-362
- 8. Vitriol V, Cancino A, Serrano C, et al. Remission in depression and associated factors at different assessment times in Primary Care in Chile. Clin Pract Epidemiol Ment Health 2018; 14: 78-88
- Salvo, "Magnitud, impacto y estrategias de enfrentamiento de la depresión, con referencia a Chile," Revista médica de Chile, vol. 142, no. 9, pp. 1157–1164, 2014.
- 10.COES (Center for Conflict and Social Cohesion Studies), First wave results, 2019, <u>http://www.elsoc.cl/publicaciones</u>.
- 11.MINSAL, Ministerio de Salud de Chile, National Health Survey, ENS, 2009-2010, 2011.
- 12. Navarrete G, Saldivia S, Vicente B et al. Evaluación de las acciones de resultado de la detección, diagnóstico y tratamiento del episodio depresivo realizada en consultantes en el primer nivel de atención de la provincia Concepción Chile. Rev Chil Neuro-psiquiatría 2017-55(3) 160-169
- 13. Alvarado R, Rojas G. El Programa Nacional para el diagnóstico y tratamiento de la depresión en Atención Primaria: una evaluación necesaria. Rev Med Chile. 2011;139(5):592–
- 14.Wagner et al (2001) Quality improvement in chronic illness care: a collaborative approach. Journal on quality improvement. Vol 27(2): 63-80
- 15. American Psychiatric Association; Dissemination of integrated care model within adults primary care settings, 2016
- 16.Baron-Cohen S, Leslie Ay Frith U (1985). Does the autistic child have a theory of mind? Cognition 21(1): 37-46
- 17.Blakemore SJ (2008). The social brain in adolescence. Nat. Rev. Neurosci. Vol 9 Issue 4: 267-277
- 18.Dunbar R (1998). The social brain hypotesis. Evol. Anthropol. Vol 6, Issue5: 178-190
- 19.Lacoboni M, Dapretto M (2006). The mirror neuron system and the consequences of its dysfunction. Nat. Rev. Neurosci. vol 7(12): 942-951
- 20. Ainsworth M, Wittig B (1969). Attachment and the exploratory behavior of one-year-olds in a strange situation. En B.M. Foss (ed), Determinants of infant behavior (vol.4, pp.113-136). London: Methuen.
- 21.Main, M, Solomon J. (1986). Discovery of an insecuredisorganized/disoriented attachment pattern. In T. B. Brazelton & M. W.





Yogman (Eds.), Affective development in infancy (p. 95–124). Ablex Publishing.

- 22.Qiuyue Xu et al (2020) Early Life Stress Induced DNA Methylation of Monoamine Oxidases Leads to Depressive-Like Behavior. Front. Cell Dev. Biol. <u>https://doi.org/10.3389/fcell.2020.582247</u>
- 23.Bowlby J (1998). El apego. (Tomo 1 de la trilogía "El apego y la pérdida"). Barcelona: Paidós.
- 24. Ainsworth M, Blehar M, Waters E, Wall S (1978). Patterns of Attachment: A Psychological Study of the Strange Situation. Hillsdale, NJ: Erlbaum
- 25.Allen J (2012). Restoring mentalizing in attachment relationships. American Psychiatric Association Publishing.
- 26. Wallin D (2007). Attachment in psychotherapy. NY: The Guilford Press.

\*1 SCT = representa 27 horas cronológicas de trabajo académico de un estudiante, que incluye clases en aula, trabajos prácticos, seminarios, estudio individual y pruebas u otras actividades de evaluación.





## MANAGEMENT OF DEPRESSION IN PRIMARY HEALTH CARE IN ACCORDANCE WITH THE RECOMMENDATIONS OF THE AUGE-GES-MINSAL CLINICAL GUIDEL

1 STC (27 hours)

## ADVANCED

Be a participant in the research Project

JORGE CALVO

ANTONIO ARELLANO

Depression is a mood and mood disorder that manifests itself through a series of symptoms that include sudden changes in mood, irritability, lack of enthusiasm and a feeling of distress or anguish, transcending what is considered normal. . Depression is the leading cause of disability in the world, in terms of total number of DALYs. The adequate management of this public health problem is a priority objective for the State of Chile.

At the end of the module, the student will have acquired the skills to substantiate the main aspects of Depression based on the critical analysis of the psychopathological, neurobiological and psychosocial bases that make up the disorder, in the different stages of the life cycle, which will allow him to propose diagnoses. , study plans and comprehensive therapeutic plans, with special emphasis on the correct prescription of psychotropic drugs and valuing adjuvant therapies, recognizing the importance of teamwork, at the different levels of health care, framed in the current ethical and legal framework, and considering the protocols established by the Ministry of Health. (AUGE-GES Clinical Guide)

## **COMPETENCE N°1: PREVENT**

Prevent Depression at the primary level of health care, throughout the life cycle, placing emphasis on the promotion of healthy lifestyles, with the aim of interposing barriers in the natural history of the health-disease process of individuals, families and /or communities.

#### **COMPETENCE N°2: DIAGNOSIS**

Diagnose, in an effective, efficient and timely manner, Depression, at any stage of the life cycle, identifying risk factors for morbidity, discriminating priority and complexity, integrating biological, psychological and social aspects, using health networks to do so, with the purpose of contributing to correct, improve and/or resolve this health problem and its possible comorbidities and concomitant





pathologies.

Achievement level: Advanced

## **COMPETENCE N°3: TREAT**

Treat, in an effective, efficient and timely manner, Depression, at any stage of the life cycle, discriminating priority and complexity, integrating biological, psychological and social aspects, using health networks, applying medical and/or surgical procedures, with the purpose of contributing to correct, improve and/or resolve this health problem and its possible comorbidities and concomitant pathologies.

Achievement level: Advanced

## **COMPETENCE N°4: DERIVE**

Refer, in an effective, efficient and timely manner, Depression, at any stage of the life cycle, discriminating priority and complexity, using existing health networks, with the purpose of contributing to correct, improve and/or solve this health problem. and its possible comorbidities and concomitant pathologies.

Achievement level: Advanced

## **COMPETENCE N°5: REHABILITATE**

Rehabilitate the health status of people affected by Depression, applying health actions aimed at addressing sequelae and/or dysfunctions resulting from this pathology and its possible comorbidities, with the aim of contributing to restoring physical, psychological and work capabilities and functions, to a satisfactory social reintegration.

Achievement level: Intermediate





T

Fecha		Activities	Responsable
05/08/21	Class	Epidemiology class, prevention, screening, diagnostic suspicion	Dr. Calvo
12/08/21	Class	Diagnostic criteria, types of depression, differential diagnosis, complementary study, comorbidity	Dr. Calvo
19/08/21	Class	Suicide and Depression	Dr. Arellano
26/08/21	Class	General aspects of treatment, Pharmacological treatment	Dr .Arellano
02/09/21	Class	Non-pharmacological treatments, treatment of depression in special populations	Dr. Calvo
09/09/21	Workshop	Role-playing workshop on clinical cases	Equipo
16/09/21	Workshop	Role-playing workshop on clinical cases	Equipo
23/09/21	Workshop	Role-playing workshop on clinical cases	Equipo
LESSON PLAN			

- Synchronous and asynchronous theoretical classes
- Simulations
- Workshops

	Puntaje Máx.	Puntaje Obtenido
a pre-establishe At least it mu nsultation, clos addictions, fam	ed ust se iily 2,0 ce	
addictions, fataining a bal ions.	am Ian	amily 2,0 lance





Mental status	Perform and then describe a complete mental examination, exploring each of the psychic functions	1,0	
Diagnostic Hypothesis and Diferential Diagnosis	It proposes one or more syndromic diagnoses, supported by the data collected in the interview and mental examination. Provide clinical judgment arguments that guide a particular diagnosis according to ICD 10 or DSM 5, and other possible diagnoses that would need to be confirmed or ruled out.	1,5	
Complementary exams (Laboratory, Images, Test)	Requests, interprets and uses laboratory tests, images, intelligence tests, personality tests, neuropsychological tests, etc., to support or rule out the diagnostic hypothesis(es) raised	1,0	
Management and treatment plan	It proposes a comprehensive management plan that includes general measures of sleep hygiene, diet, physical activity, and rest. It proposes a medical treatment that includes psychotropic drugs and other relevant medications. Refers to other professionals on the mental health team for psychosocial interventions if appropriate. Provides psychoeducation elements.	1,5	
		7,0	

Ministerio de Salud. Guía Clínica Depresión en personas de 15 años y más. Santiago, MINSAL, 2013

https://drive.google.com/file/d/1wayRyZRCwIUEj6B8NxQPIbiNkoBqDwAa/view?usp=sharing





## IMPLEMENTATION CMTIC-D

The approach consists of an integrated interprofessional model of patient care, including a case manager, an individualized treatment plan, and follow-up using validated self-reporting tools. It also involves continuous supervision by a specialist through consultations for a period of at least six months.

## Integrated Model of Interprofessional Patient Care:

Teams should designate a case manager for patients and promote interprofessional collaboration, including psychiatry, to ensure comprehensive care.

## The Multidimensional Interprofessional Interview:

Assesses categorical diagnosis, clinical severity, screens for bipolar disorder, diagnoses medical and psychiatric comorbidities, and delves into psychobiographical history to gain a deeper understanding of the reason for the current consultation. At the conclusion of the interview, the team collaboratively establishes a treatment goal that addresses the patient's current concerns within a crisis intervention model.

#### Patient follow-up:

Follow-up is done through a self-report instrument card (PHQ-9, GAD-7) to monitor the patient's progress and well-being.

## **Collaborative consultations:**

Monthly evaluations are carried out by a specialist in collaboration with the team and the patient through teleconsultation sessions.





## CONTROL CARD WITH MINITORING INSTRUMENTS







### RANDOMIZATION

### **CENTERS PAIRS**

	1	
1	Las Américas (Talca)	
2	Dionisio Astaburuaga (Talca)	
3	Betty Muñoz Arce (Ccó)	
4	Los Niches (Ccó)	
5	Colón (Ccó)	
6	Constitución	
7	Romeral	
8	Rural (Linares)	

2	
Faustino González (Talca)	
La Florida (Talca)	
Miguel Angel Arenas (Ccó)	
Sarmiento (Ccó)	
Julio Contardo (Talca)	
Sgda Familia	
Pelarco	
Villa Prat (Sgda. Familia)	







#### Sample size calculation

For the sample size, a maximum error of 5% will be estimated, with a confidence level of 95%, a power of 80% and a maximum variance of 50%, a total of 341 people diagnosed with depression are required. This calculation will be made based on previous studies carried out in the country. The first, a study protocol that evaluates the effectiveness of a comprehensive technology-assisted training and supervision program to improve depression management in primary care, by comparing the effectiveness of the proposed program versus usual care (Rojas et al. , 2015). The second, a clinical trial that randomly compares a treatment with pharmacotherapy monitored by telephone versus a usual treatment, which obtained greater effectiveness in antidepressant responses and in some dimensions of their quality of life at 3 and 6 months after treatment (Fritsch et al., 2007). And third study, which determines the clinical and psychosocia

I variables associated with a greater number of adverse childhood experiences in a sample from the Maule region (Vitriol et al., 2017). Furthermore, it is expected that the intervention will have favorable results, ruling out the possibility of statistically significant results for a negative effect.

Finally, taking into consideration at least 8 primary health care clinics in the Maule region (2 Curicó, 2 Talca, 2 Linares, 1 Teno and 1 Molina) and a retention of 85%, 394 depressed people in the region will participate, approximately 50 people per primary care clinic.

Fritsch, R., Araya, R., Solís, J., Montt, E., Pilowsky, D., & Rojas, G. (2007). A randomized clinical trial of. 587–595.

Rojas, G., Martínez, P., Vöhringer, P. A., Martínez, V., Castro-Iara, A., & Fritsch, R. (2015). Comprehensive technology-assisted training and supervision program to enhance depression management in primary care in Santiago, Chile: study protocol for a cluster randomized controlled trial. Trials, 1–6. https://doi.org/10.1186/s13063-015-0845-4.

Vitriol, V., Cancino, A., Leiva-Bianch, M., Serrano, C., Ballesteros, S., Potthoff, S., ... Asenjo, A. (2017). Adult depression and adverse childhood experiences: Evidence of a complex depressive subtype in primary care consultants in Chile. Revista Medica de Chile, 145(9), 1145–1153. https://doi.org/10.4067/s0034-98872017000901145.





# Protocol to communicate any potential situation that requires urgent evaluation and treatment to the treating team.

The protocol to be followed in response to this adverse event will be as follows:

Patients with a suicide attempt or serious risk of suicide and/or psychosis, by definition, will not be included in the study follow-up (exclusion criteria). These patients will continue their treatment with their treating team.

In both models, despite the teams already having experience in managing depression and its risks, training on the management of depression risks will be provided. Additionally, this training will include a protocol that, if the primary care team becomes aware of a patient's risk situation under their care, it should be promptly evaluated to determine the appropriate course of action.

In the patient's informed consent, emphasis will be placed on the need for the patient to inform their primary care team in the event of a risk of loss of the will to live or significant worsening of their depression as part of their treatment. Furthermore, the informed consent will explicitly state that if this information arises during the assessment with the research team, they will contact the treating team to report the case.

Upon becoming aware of a patient's at-risk situation during the follow-up process, an emergency response protocol has been established. This protocol allows the residents to contact the Principal Investigators (PIs), who will then inform the primary care teams about the situation. Additionally, the research team will reach out to the respective CESFAM mental health coordinator to ensure that the primary care team is informed of the case within 24 hours, enabling them to conduct the necessary evaluation and decide on the appropriate course of action.