



INNOVATIONS IN WOMEN'S MENTAL & REPRODUCTIVE HEALTH

Women of All Ages and their HCPs,
Desire Treatment Options Designed
to Address their Unique Mental and
Reproductive Health Needs
Effectively and Safely

References can be found at the end of this presentation



Clinically Proven Effectiveness for:

- ❖ Depression and Anxiety
- ❖ Including in and Around Pregnancy
- ❖ PMS/PMDD & Menopause
- ❖ High or Low Risk Prenatal Vitamin

EnBrace HR Small Gel Cap

INGREDIENTS

“EnBrace HR contains the exact clinically recommended vitamin coenzymes, mineral cofactors and omegas needed to normalize uterine and CNS intracellular methylation for normal mental and reproductive clinical outcomes.”

Towny Robinson, CEO JayMac Pharmaceuticals
Inventor of EnBrace HR

Most Diverse Natural Folates: FDA 15mg DFE

L-Methylfolate Magnesium	7mg
Folinic Acid	2.5mg
Folic Acid	1mg

B Vitamins in their Bioactive Coenzyme Form

B12 (Adenosylcobalamin)	50mcg
B6 (Pyridoxal-5-Phosphate)	25mcg
B1 (Thiamine Pyrophosphate)	25mcg
B2 (Flavin Adenine Dinucleotide)	25mcg
B3 (Nicotinamide Adenine Dinucleotide)	25mcg
Piperine (B Vitamin Bioenhancer)	500mcg

Minerals in their Bioactive Cofactor Form

Magnesium Ascorbate	24mg
Magnesium L-Threonate	1mg
Zinc Ascorbate	1mg
Iron (Ferrous Glycine Cysteinate)	1.5mg

Phospholipid Form – Brain Ready

PS-Omega-3 (Phosphatidylserine, EPA, DHA)	20mg
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Absorption Enhancer

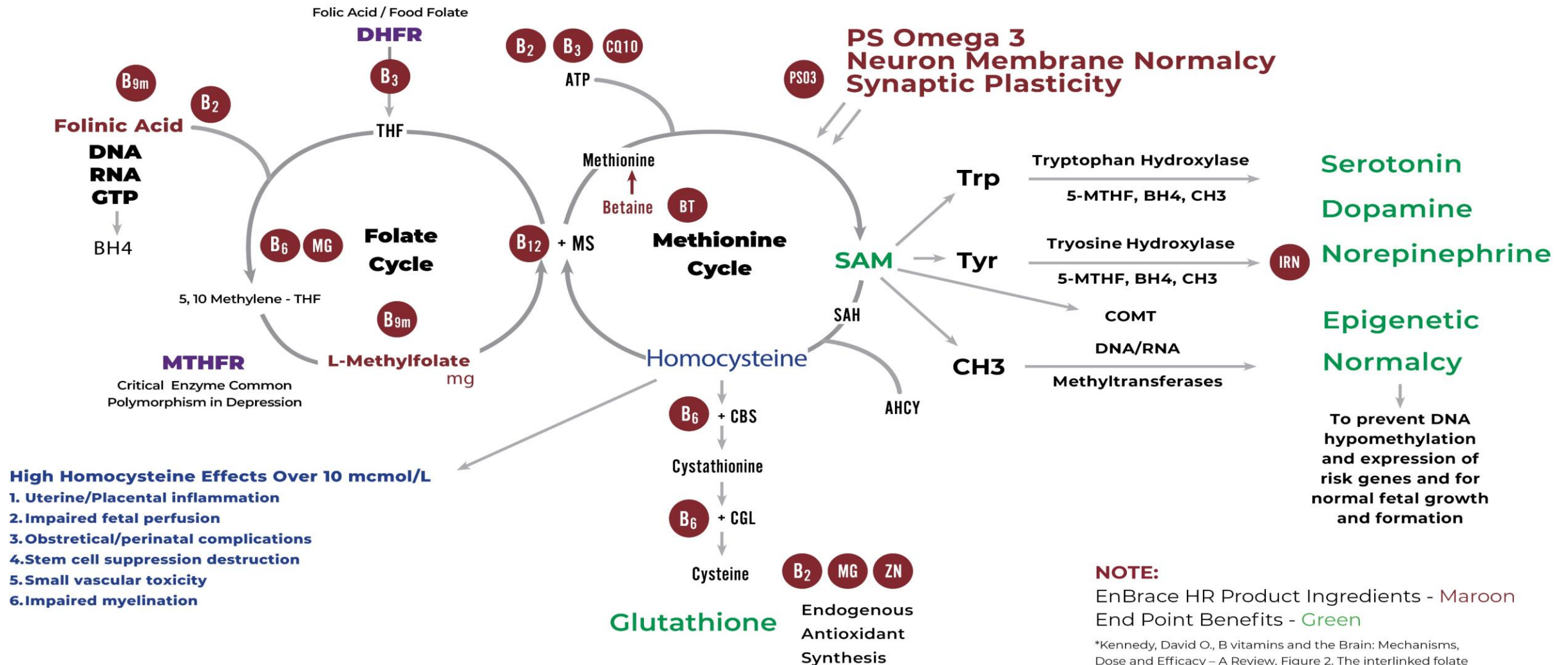
Sodium Citrate	10mg
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Energizer

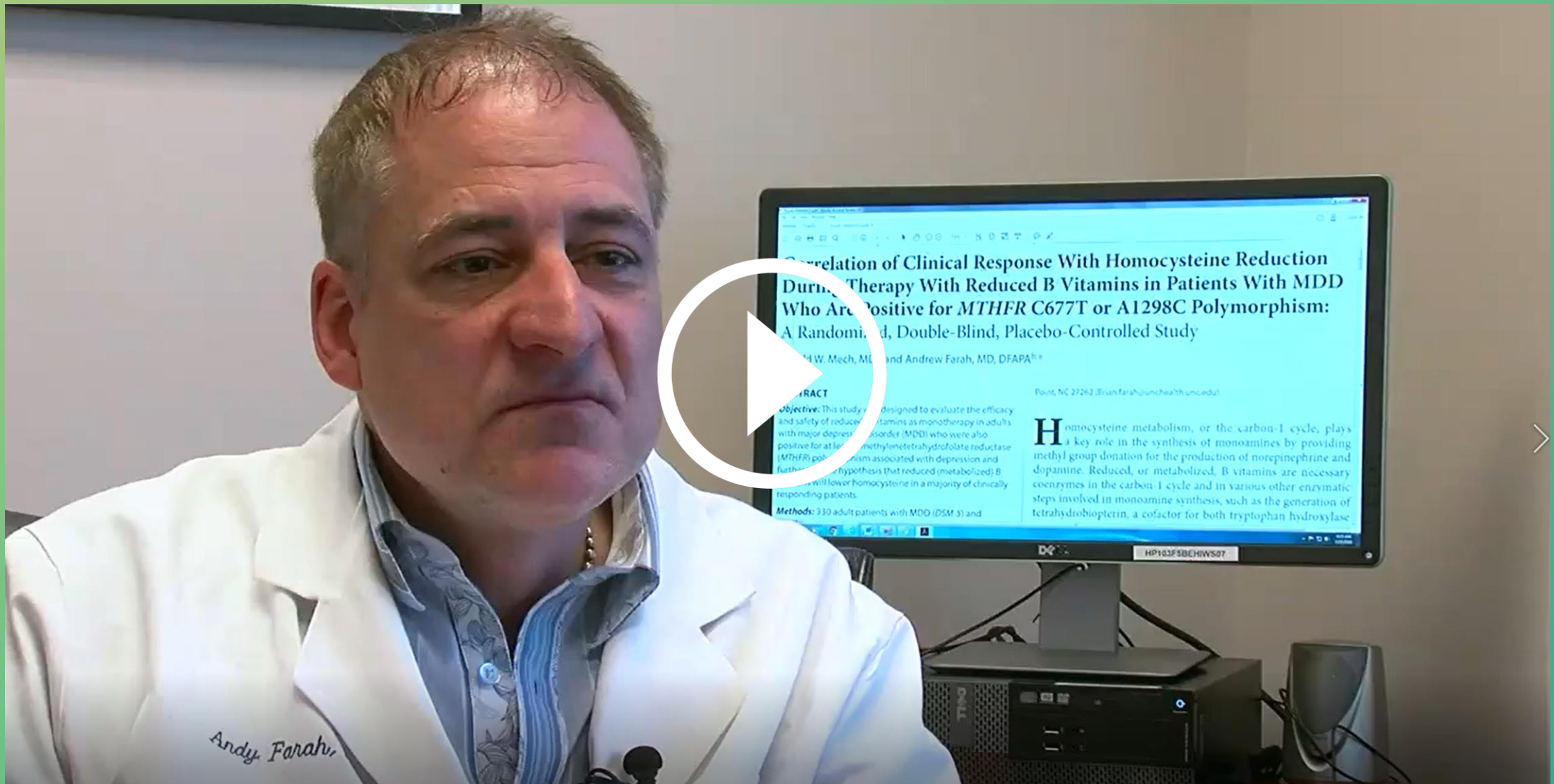
CoQ10	500mcg
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Intracellular Biochemical Root Cause Methylation Chart

EnBrace HR Normalizes All Co-Enzyme/Cofactor Deficiencies and Methylation Disruption, No Matter the Cause and Converts to Normal Mental and Reproductive Health Outcomes Based on Well-Controlled Clinical Trials.



CLINICAL STUDY OVERVIEW



THE JOURNAL OF CLINICAL PSYCHIATRY

330 ADULT PATIENT RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED STUDY

OBJECTIVE:

This 8-week study was designed to evaluate the efficacy and safety of EnLyte/EnBrace HR as monotherapy in adults with major depressive disorder (MDD) who were also positive for at least 1 methylenetetrahydrofolate reductase (MTHFR) polymorphism associated with depression and further test the hypothesis that EnLyte/EnBrace HR will lower homocysteine in a majority of clinical responding patients.

MAY 2016

Correlation of Clinical Response With Homocysteine Reduction During Therapy With EnLyte/EnBrace HR in Patients With MDD Who Are Positive for MTHFR C677T or A1298C Polymorphism - Andrew Farah, MD

1) Mean MADRS Symptom Score of EnBrace HR Versus Placebo



2) 30% Reduction in Homocysteine Levels (Compared to Placebo)

**NO SIDE EFFECT WAS REPORTED AT GREATER RATE
THAN PLACEBO**

ONSET OF ACTION: 2 WEEKS

ENBRACE HR STUDY

regnant <28 weeks. Group 1 participants were well (not in depressive episodes) and planned to have a baby. Group 2 participants were depressed at baseline. Primary outcomes included MDD relapse and depressive symptoms, verified by the Mini International Neuropsychiatric Interview and the Montgomery-Åsberg Depression Rating Scale (MADRS), respectively. Folic acid metabolism and inflammation were collected.

Group 1 participants (N=11; well at baseline) experienced no significant decreases in MADRS scores of depressive relapse (27.3%; $p=0.005$) than expected when compared to historical controls. Group 2 participants (N=11; depressed at baseline) experienced significant improvements in MADRS scores ($p=0.001$), with improving >50% and one improving 33.3%. One adverse event occurred, a hospitalization for

Results suggest EnBrace HR is a well-tolerated intervention with potential efficacy for the treatment of perinatal depression. Larger controlled trials are necessary.

Introduction

Major Depressive Disorder (MDD) and Major Depressive Episodes (MDEs) in Women: MDD is approximately twice as often in women compared to men.^{1,2} High risk for MDEs during pregnancy and the postpartum period.³ Women often discontinue standard antidepressant medications prior to or during pregnancy for safety concerns.^{4,5}

Few evidence-based alternatives to antidepressant medications for the treatment and prevention of perinatal depression, leaving pregnant women and clinicians with the clinical dilemma of weighing potential exposure to medication against impact of untreated maternal depression.

Folate and Folate-Related Therapies:

Folate suggests various folate forms including folic acid, folinic acid, and methylfolate may have significant effects.⁶⁻¹² These interconvertible folate forms constitute the one-carbon cycle and are essential for DNA synthesis and neurotransmitter synthesis.¹³ Folate must be converted to its active form, methylfolate, for use in the body; polymorphisms in the MTHFR gene may limit the efficacy of folic acid as an intervention targeting MDD.^{14,15} Folate methylation may be more readily absorbed in the brain than folic acid, and methylfolate has potential as a treatment for MDD.¹⁶⁻¹⁸

Folate treatment in early trials has been found to induce significant improvements in depressive symptoms both when used as an adjunct to antidepressant therapy and when used as a monotherapy.^{19,20} Folate-related compounds reduce rates of neural tube defects and improve child neurodevelopmental outcomes, conferring benefits and minimizing potential risks of antidepressants during pregnancy.²¹⁻²³

EnBrace HR is a prescription prenatal/postnatal dietary management product that contains 5.53 mg L-methylfolate and other folate derivatives (1 mg folic acid, and 2.2 mg folinic acid), optimal for a population with high rates of polymorphisms that affect folic acid metabolism.

Methods

Group 1: Well at Baseline; Relapse Prevention Group

Inclusion Criteria:

- Age ≥18
- MDD as primary diagnosis
- Have prescribing clinician
- Planning to conceive or <28 weeks pregnant at enrollment
- No dose increase of current antidepressant or start of new antidepressant medication
- Currently depressed, as verified by MINI
- "Depressed", baseline MADRS score ≥15

Primary Outcome: To obtain preliminary data on the efficacy of EnBrace HR for treatment of acute MDEs and to avoid starting on a new antidepressant during pregnancy.

Demographics (N=11)	
Age (mean ± SD)	32.8 ± 5.0
Race	
White/Caucasian	10 (90.9%)
Black/African American	1 (9.1%)
Native Hawaiian or other Pacific Islander	0
Asian	0
American Indian or Alaska Native	0
Ethnicity	
Non-Hispanic or non-Latina	10 (90.9%)
Hispanic or Latina	1 (9.1%)
Marital status	
Married	10 (90.9%)
Separated/divorced/widowed	1 (9.1%)
Never married/Single	0
Education	
Some high school	0
High school or GED	0
Some college or Associate Degree	1 (9.1%)
Graduated college (BA, BS)	4 (36.4%)
Master's Degree	11 (100%)
Doctoral Degree (PhD, MD, etc.)	0
Employment status	
Full or part-time work	11 (100%)
Homemaker	0
Student	0

Table 1. Demographics are listed for all 11 women who initiated study drug. Two women in Group 1 who were trying to conceive, decided to discontinue EnBrace HR upon becoming pregnant, but did not conceive during the trial. These women thus did not receive or discontinue EnBrace HR during treatment phase, and were not included in analyses.

Figure 1. Mood and Quality of Life Outcomes



Figure 1. The aim for Group 1 was to prevent depression relapse, and the aim for Group 2 was to improve depressive symptoms. MADRS (Montgomery-Åsberg Depression Rating Scale) is a 10-item self-report questionnaire that measures the severity of depressive symptoms. The Y-axis represents the MADRS score, with higher scores indicating more severe depression. The X-axis represents time in weeks. Group 1 (Relapse Prevention Group) shows a slight increase in MADRS score over time, while Group 2 (Acute Treatment Group) shows a significant decrease in MADRS score over time.

Adverse Events	
Adverse Event	# of patients reported
Headache	1 (9.1%)
Nausea	1 (9.1%)
Constipation	1 (9.1%)
Diarrhea	1 (9.1%)
Stomach pain	1 (9.1%)
Back pain	1 (9.1%)
Joint pain	1 (9.1%)
Weight gain	1 (9.1%)
Weight loss	1 (9.1%)
Changes in appetite	1 (9.1%)
Changes in sleep	1 (9.1%)
Changes in energy	1 (9.1%)
Changes in mood	1 (9.1%)
Changes in behavior	1 (9.1%)
Changes in thinking	1 (9.1%)
Changes in feeling	1 (9.1%)
Changes in perception	1 (9.1%)
Changes in sensation	1 (9.1%)
Changes in taste	1 (9.1%)
Changes in smell	1 (9.1%)
Changes in vision	1 (9.1%)
Changes in hearing	1 (9.1%)
Changes in touch	1 (9.1%)
Changes in pain	1 (9.1%)
Changes in temperature	1 (9.1%)
Changes in blood pressure	1 (9.1%)
Changes in heart rate	1 (9.1%)
Changes in blood sugar	1 (9.1%)
Changes in blood count	1 (9.1%)
Changes in liver function	1 (9.1%)
Changes in kidney function	1 (9.1%)
Changes in thyroid function	1 (9.1%)
Changes in hormone levels	1 (9.1%)
Changes in enzyme levels	1 (9.1%)
Changes in antibody levels	1 (9.1%)
Changes in cell count	1 (9.1%)
Changes in cell size	1 (9.1%)
Changes in cell shape	1 (9.1%)
Changes in cell function	1 (9.1%)
Changes in cell death	1 (9.1%)
Changes in cell growth	1 (9.1%)
Changes in cell division	1 (9.1%)
Changes in cell differentiation	1 (9.1%)
Changes in cell maturation	1 (9.1%)
Changes in cell aging	1 (9.1%)
Changes in cell death	1 (9.1%)
Changes in cell growth	1 (9.1%)
Changes in cell division	1 (9.1%)
Changes in cell differentiation	1 (9.1%)
Changes in cell maturation	1 (9.1%)
Changes in cell aging	1 (9.1%)

Discussion and Conclusions

Results Summary

- We assessed EnBrace HR in two samples of women planning pregnancy in early pregnancy to obtain data regarding:
- (1) Prevention of depressive relapse in women with history of MDD
- (2) Acute treatment of depressive symptoms in women with history of MDD

Group 1 (Relapse Prevention Group) who were well at baseline and who were planning pregnancy, and Group 2 (Acute Treatment Group) who were depressed at baseline and who were planning pregnancy. Both groups showed significant improvements in MADRS scores over time, with Group 2 showing a more pronounced improvement than Group 1.

Strengths

- We assessed a novel product, a critical gap in the literature.
- Other strengths include the use of a validated measure of depressive symptoms (MADRS) and the use of a validated measure of quality of life (SF-36).

Limitations

- The most important limitation is the lack of a placebo arm. We drew from historical data for the placebo arm, which may not be representative of the current population.
- Another limitation is the small number of subjects enrolled in the study, which may limit the generalizability of the results.

Conclusions and Future Directions

- Study results suggest EnBrace HR is a novel and well-tolerated intervention with potential efficacy for the prevention and treatment of depression among women planning pregnancy and who are pregnant.
- Larger controlled trials are necessary to definitively determine efficacy and to test in the general population.

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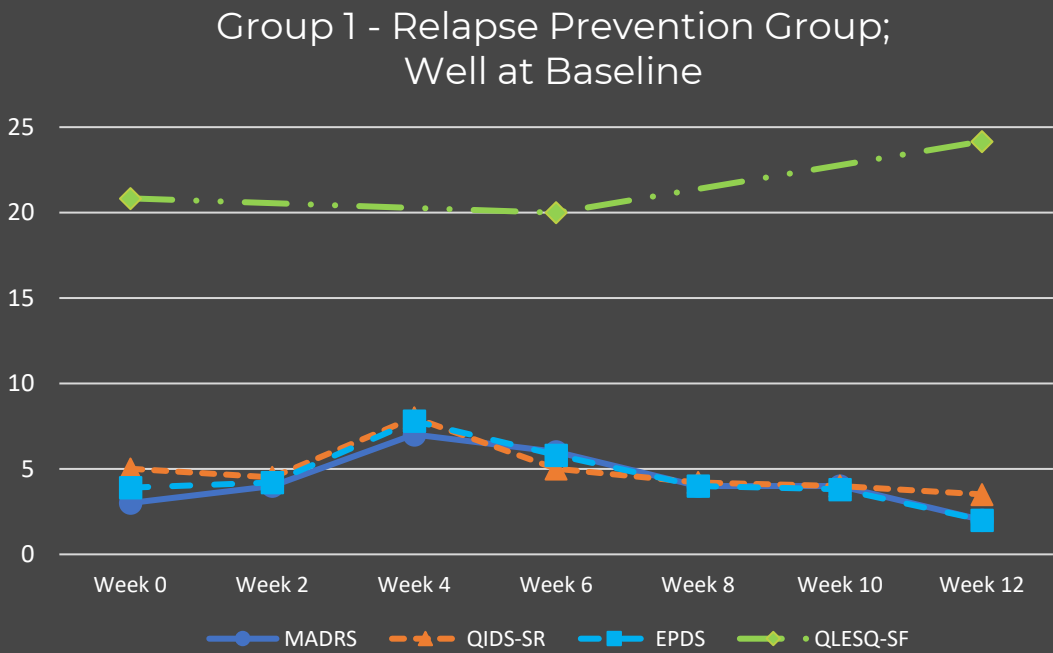
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EnBrace HR For The Treatment and Prevention of Depression in Women

Trying to Conceive and During Pregnancy

Marlene P. Freeman, MD et al, Annals of Clinical Psychiatry February 2019



CONCLUSION

Study results suggest EnBrace HR is a novel and well tolerated intervention with efficacy for the prevention and treatment of depression among women planning pregnancy and who are pregnant.

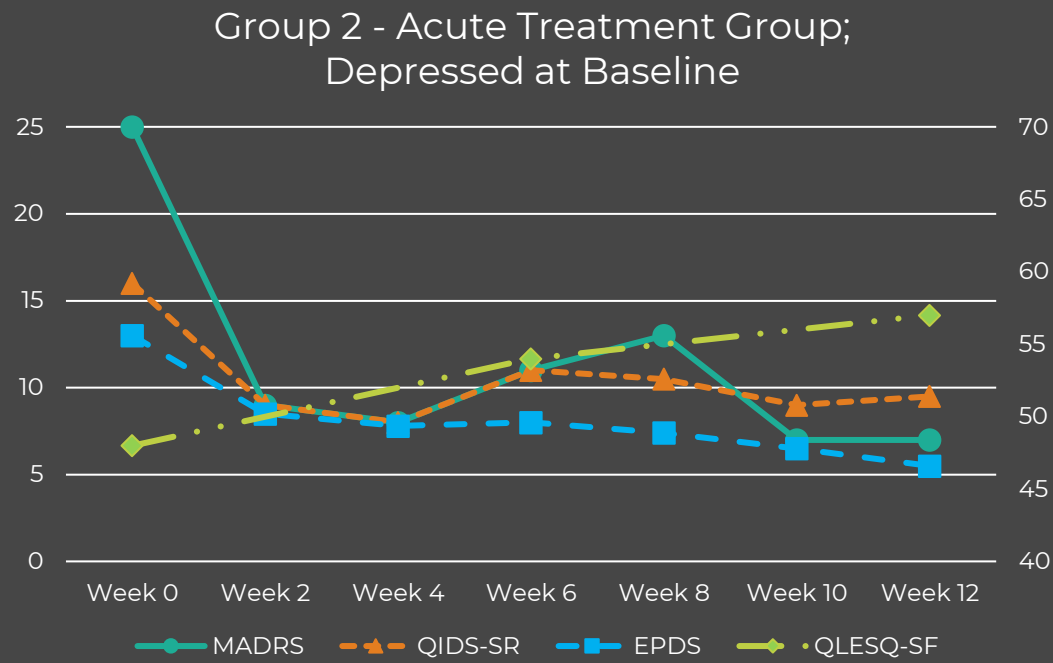


Figure 1. The aim for Group 1 was to prevent depression relapse, and the aim for Group 2 was to improve depression symptoms, measured through several mood and quality of life questionnaires. Trends shown by group for the primary mood outcome measure, the MADRS (Montgomery-Asberg Depression Rating Scale) in dark blue; for secondary mood measures, the QIDS-SR (Quick Inventory of Depressive Symptomatology-Self Report) in orange and the EPDS (Edinburgh Postnatal Depression Scale) in light blue; and for a quality of life outcome, the QLESQ-SF (Quality of Life Enjoyment and Satisfaction Questionnaire -Short Form) in green. Group 1 experienced no significant changes in any of the four measures, and Group 2 experienced significant improvements in the mood questionnaires but not the quality of life questionnaire. All ANOVAs indicating significance are reported in Table 3.

PMS

(Premenstrual Syndrome)

Mild/Moderate

Menopause

Cyclic hormonal changes of the menstrual cycle causes fluctuations of serotonin levels leading to adverse symptomology
– Mayo Clinic –

PMDD

(Premenstrual Dysphoric Disorder)

Severe (DSM-5)



**Tension/Anxiety, Depressed Mood – Irritability/Anger – Appetite Changes – Cravings – Insomnia
– Social Conflict Withdrawal– Feeling overwhelmed – Hopelessness – Hot Flashes**

Biochemical Wellness

EnBrace HR normalizes serotonin levels and is an effective, all-natural, safe, root cause monotherapy option or adjunct to SSRIs, oral contraceptives, NSAIDs, diuretics, and/or HRT in the prevention or treatment of PMS/PMDD/MENOPAUSE.

Dietary B Vitamin Intake and Incident of Premenstrual Syndrome. Manson et al. Am J Clin Nutr. 2011

Clinical Result Example

A 17-year-old on Paxil for PMDD experienced side effects and withdrawal symptoms after discontinuing Paxil. She was hesitant to resume antidepressant medications after presenting again with PMDD depression, and a MADRS of 20. The patient elaborated she was “putting on a happy face”. She was prescribed EnBrace HR and within 4 weeks her MADRS dropped from 20 to 6.

Coenzyme Treatment of Childhood and Adolescent Depression: A Case Series. Farah et al. Clinical Psychiatry Vol 7 #5S3:93 April 2021

“For the emotional dysregulation of PMS, PMDD, and Menopause we turned first-line to the natural, broad spectrum B vitamin coenzymes and mineral cofactor agent, EnBrace HR. This product has provided safe and effective relief for countless patients with female hormonal fluctuations or deficiency”

Andrew Farah, MD

Attending Psychiatrist, Novant Health System, Winston-Salem, NC
Medical Director of Strategic Mental Health Interventions



Provides the most diverse combination of folates and methylation vitamin coenzymes and mineral cofactors for maximum prevention of NTDs and other birth defects in low or high-risk pregnancies.

An optimal serum folate level for birth defect prevention should be reached 4 weeks prior to conception, 50% of pregnancies are unplanned.

Mechanism of Cellular Action

Normalize impaired cellular "homocysteine/methionine" metabolism disorders that can lead to placental inflammation, impaired fetal perfusion, impaired nucleotide and DNA synthesis and faulty epigenetic expression.

To Prevent or Reduce Risk For:

- ❖ All Neural Tube Defects
- ❖ Congenital Heart & Kidney Disorders
- ❖ Down Syndrome
- ❖ ADHD
- ❖ Autism Spectrum Disorders
- ❖ Orofacial Clefts
- ❖ Drug Related Birth Defects
- ❖ Pregnancy Complications
- ❖ Congenital Structural Malformation

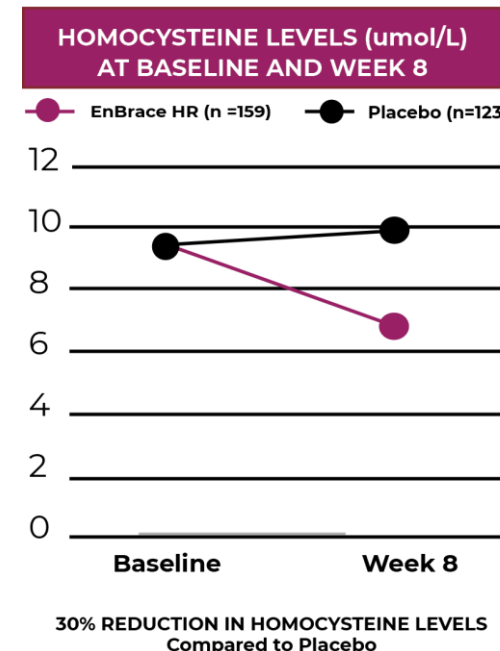
EnBrace HR Helps Eliminate the Risk for Adverse Pregnancy Outcomes, NTDs, and Other Birth Defects Associated with the effects of MTHFR Gene Variant

MTHFR gene variants prevent the production of the enzyme that converts folate to methylfolate leading to high homocysteine and low neurotransmitter production causing negative reproductive and CNS outcomes.

- 60%** of women have the heterozygous form of MTHFR gene variant
- 25%** of women have the homozygous form of MTHFR gene variant
- 50%** of folate related NTDs and other birth defects are linked to MTHFR
- 85%** of depressed and addicted women have an MTHFR gene variant

MTHFR Polymorphisms are Documented Risk Factors for these Adverse Pregnancy Outcomes:

- Miscarriage
- Perinatal/ Post-Partum Depression
- Pre-Term Delivery
- Low Birth Weight
- Pre-Eclampsia
- Placental Inflammation
- Impaired Fetal Perfusion
- Chromosomal Abnormalities



EnBrace HR is proven in a 330 patient, randomized, controlled trial in patients with an MTHFR variant to lower homocysteine 30% compared to placebo group.

Andrew Farah, MD et al.
Journal of Clinical Psychiatry, May 2016

HOW TO PRESCRIBE

STEP 1

USE OUR ONLINE PRESCRIBER FORM

Fill in prescriber and patient information and then hit “submit”

CLICK HERE

STEP 2

WE WILL OFFER YOUR PATIENT THEIR FIRST 60 DAYS FOR \$60

We will also provide them with the insurance steps and help determine the most cost-effective option moving forward

STEP 3

IF IT'S COVERED ON INSURANCE, WE WILL CONTACT YOUR OFFICE WITH PRESCRIBING INFO

If your patient does not have coverage or has a high co-pay, we will offer our discounted cash-pay option for EnBrace HR. No further action is needed for your office.

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