

## ORIGINAL PAPER

*A randomized controlled trial of primary care physician motivational interviewing versus brief advice to engage adolescents with an Internet-based depression prevention intervention: 6-month outcomes and predictors of improvement*

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### ABSTRACT

We believe that primary care physicians could play a key role in engaging youth with a depression prevention intervention. We developed CATCH-IT (Competent Adulthood Transition with Cognitive Behavioral and Interpersonal Training), an adolescent Internet-based behavior change model. We conducted a randomized comparison of two approaches in engaging adolescents with the Internet intervention: primary care physician (PCP) motivational interview + CATCH-IT Internet program (MI) versus PCP brief advice + CATCH-IT Internet program (BA). Participants (N=84) were recruited by screening for risk of depression in 13 primary care practices. We compared depressive disorder outcomes between groups and within groups over 6 months and examined potential predictors and moderators of outcomes across both study arms. Depressive symptom scores declined from baseline to 6 weeks with these statistically significant reductions sustained at the 6 months follow-up in both groups. No significant interactions with treatment condition were found. However, by 6 months, the MI group demonstrated significantly fewer depressive episodes and reported less hopelessness as compared to the BA group. Hierarchical linear modeling regressions showed higher ratings of ease of use of the Internet program predicting lower depressive symptom levels over 6 months. In conclusion, a primary care/Internet-based intervention model among adolescents demonstrated reductions in depressed mood over 6 months and may result in fewer depressive episodes.

## INTRODUCTION

Depressive disorders are highly prevalent in adolescence and are often accompanied by co-morbid psychopathology and overall decreased functioning.<sup>1</sup> While substantial progress has been made in developing face-to-face interventions to prevent depressive disorders in adolescents, the challenges group psychotherapy models face (stigma, loss of autonomy, complexity of organization, fear of disclosure) may limit implementation in many settings.<sup>2-5</sup> As Internet-based interventions maximize autonomy, reduce stigma, and provide convenient and low cost access, they could be an effective and appropriate mode for delivery of self-guided interventions focusing on improving affect regulation and resiliency against mental disorders.<sup>6-8</sup> There have been few rigorous studies of child/adolescent Internet-based mental health interventions<sup>8</sup>. Results from school-based interventions have produced inconsistent results, suggesting the form of engagement and context may play important roles in outcomes.<sup>8</sup>

We developed CATCH-IT (Competent Adulthood Transition with Cognitive Behavioral and Interpersonal Training) on the premise that coupling a primary care physician interview with a structured Internet-based behavior change program could increase both adherence and the efficacy of treatment.<sup>9</sup> We conducted a randomized comparison of two approaches to engage youth in an Internet program: brief advice (BA), where the physician directs the adolescent to the Internet program based on his or her authority (external motivation), and motivational interviewing (MI), where the physician seeks to help the adolescent to identify his/her own motivation for engaging the Internet program (internal motivation). At the twelve week assessment point, both groups experienced declines in depressed mood, and the MI group demonstrated higher levels of adherence, lower cumulative prevalence of clinician diagnosed depressive episodes and lower prevalence of hopelessness relative to BA group participants.<sup>10, 11</sup> However, we do not know if the evidence of benefit of the intervention will be sustained or which factors engender more favorable outcomes in Internet-based interventions in adolescents. Knowledge of predictors of intervention response (in general and also specific approaches) could greatly improve intervention design.<sup>12, 13</sup>

This was a phase 2 clinical trial intended to lay the foundation for randomized clinical trial comparing the optimized CATCH-IT intervention with control arm (treatment as usual + with attention control Internet intervention). Consequently, the aims of this study were twofold: (1) to determine if the a motivational interview was superior to brief advice in terms of clinical outcomes and (2) to determine if pre/post changes observed within groups supported the potential efficacy of the CATCH-IT intervention. We hypothesized that (1) the MI group would demonstrate superiority over the MI group in clinical outcomes and (2) that both MI and BA interventions show sustained reductions in depressed mood. Additionally, we seek to identify possible predictors of depressed mood over 6 months<sup>9, 11, 14</sup> including participant characteristics (demographics, vulnerability and protective factors, and motivation<sup>15</sup>) and aspects of adolescent experience based on the Principles of Effective Prevention framework (positive relationships (e.g., physician), dose, training and socio-cultural relevance<sup>12, 13, 16, 17</sup>), and their potentially different predictive ability in the two intervention groups. No a priori hypotheses about predictors of treatment response were made.

## METHODS

### *Study design*

*Overview:* Previous publications by our research group provide a detailed description of the study design and procedures.<sup>10, 11</sup> Two versions (PCP brief advice + Internet program versus PCP motivational interview + Internet program) of a primary care/Internet-based intervention were evaluated in a diverse group of adolescents in 13 primary care sites in the United States. Because PCPs performed the interviews, they could not be blinded as to condition. Recruitment was accomplished by screening all adolescents visiting the primary care physician (PCP) for risk of depressive disorder (having any core symptom, i.e., depressed mood, anhedonia, and/or irritability for “at least a few days in last two weeks”).<sup>18</sup> Adolescents with major depression, frequent self-harm thoughts/intent, substance abuse disorder, schizophrenia, bipolar disorder, or probable conduct disorder were excluded. Participants were randomized, and their group assignment was provided to them after

enrollment. Both groups received equal and private (secure sign-in) access to the Internet site. Details of recruiting, inclusion/exclusion criteria, enrollment consent, sample size calculations, and stopping rules have been reported in prior publications.<sup>10, 11</sup> All protocols were approved by the University of Chicago Institutional Review Board and local sites' Institutional Review Boards.

#### *Intervention overview:*

Both groups received a PCP interview before and after the Internet intervention use as well as three safety assessment calls during the intervention. The MI group also received 3 motivational phone calls and completed a motivational interview questionnaire before meeting with the physician. The intervention consisted of 14 modules based on Behavioral Activation (BAC), Cognitive Behavioral Therapy (CBT),<sup>19, 20</sup> Interpersonal Psychotherapy (IPT),<sup>21, 22</sup> and a community resiliency concept model (Figure 1), with the overarching goal of providing a sense of mastery over emotions in a range of domains (e.g., peer, family, school). The CATCH-IT intervention, including training of physicians, fidelity of physician interviews and adolescent adherence, has been extensively described in prior publications.<sup>10, 11, 14</sup> The Internet site is freely available to the public at <http://catchit-public.bsd.uchicago.edu>.

#### *Outcome Variables and Predictor Variables*

Table 1 provides a description of all the outcome and predictor variables.

#### *Data analysis*

*Assessment of outcomes and attrition:* Analyses for the present study were based on the 83 adolescents included in the intervention. Outcomes were ascertained through blinded phone assessment interviews at baseline, 6 weeks, 12 weeks, and 6 months post randomization. Blinding and assessment of blinding has been reported in prior publications.<sup>10, 11, 14</sup> As appropriate, the t-test, the Pearson chi-square test, or the Fisher's exact test was used to evaluate the impact of missing data by comparing those missing from

6 month follow-up to those present. Stopping rules and sample size calculations have been previously reported.<sup>10, 11, 14</sup>

*Within and between group comparisons:* Pre-test data were available for all participants. Hierarchical linear modeling (HLM) was performed to establish within and between group differences with regard to improvement over time (baseline, 6 weeks, 12 weeks, and 6 months). A two-level model was used with time points nested within participants. Time was a fixed factor. As part of this analysis we included a random intercept to model individual variability in starting point. (We also checked for individual variability of slope over time, and since this did not improve our model we only report the results from random intercept model). Effect sizes were calculated according to Cohen's *d* for both within group pre/post (baseline to 6 months) and between group comparisons as have been described in prior publication.<sup>11</sup> HLM models account for missing data and can fit individual trajectories over time even if time points are missing. The method assumes that data are missing at random and these missing data do not impact or bias the intervention effects. Stata SE Version 10.0 was used for within and between group analyses.<sup>25</sup>

*Prediction analysis:* We selected variables based on a prediction model that included socio-demographic characteristics, baseline vulnerability and protective factors related to depressive disorder, participant attitudes toward intervention, motivation, and Internet experience. Predictors were assessed at baseline (participant factors) and during/post intervention (intervention experience). To identify those variables with evidence of a univariate association with the outcome, a separate HLM model was conducted for each potential predictor variable for the outcome of depressive mood (6 weeks, 12 weeks, and 6 months) as measured by the CESD-10 total score. All models were adjusted for depressed mood at baseline, as measured by the CESD-10 total score. Time was a fixed factor. In order to mitigate the possibility of Type 1 error, *P* values were adjusted for the number of comparisons with Bonferroni's method ( $0.05/14=0.004$ ). Variables with  $P>0.004$  from the exploratory analyses were dropped from further consideration. The final predictors were selected for inclusion in the multivariate regression model to see which of the variables

showed an independent contribution to treatment outcome. SPSS version 16.0<sup>26</sup> was used for prediction analyses.

## RESULTS

*Sample characteristics:* We evaluated 116 individuals for participation of which 103 were eligible, 84 were enrolled, and 83 were included in the analyses (Figure 2). One participant was immediately disenrolled because of meeting exclusion criteria. The sample was ethnically diverse (40% non-white) and approximately divided equally by gender (female 56.6%, male 43.4%) with a mean age of 17.47 (SD = 2.04) years. There were no significant differences between the two treatment groups at baseline in gender, ethnicity, age, education, family, or teen variables, past treatment history, family history, or baseline depressed mood and disorder.

*Attrition analysis:* A total of N=19 had no data at 6-months for analysis (withdrew n=3, disenrolled n=3, lost to follow-up n=13 and died n=1 (see adverse events below), Figure 2). There were no significant differences for baseline and 6 weeks for depressed mood, gender, ethnicity and age between those not available for follow-up at 6 months (N=19, 23%) and those who were available.

### *Within-group comparisons*

*CESD-10:* CESD-10 scores declined significantly from baseline to 6 months follow-up for both treatment groups (6 weeks, MI:  $B=-3.58$ ,  $SE=0.96$ ,  $P<0.001$ ; BA:  $B=-5.27$ ,  $SE=1.11$ ,  $P<0.001$ ; 6 months, MI:  $B=-5.83$ ,  $SE=0.96$ ,  $P<0.001$ ; BA:  $B=-6.35$ ,  $SE=1.31$ ,  $P<0.001$ ). A similar pattern followed those who reported depressive symptoms (CESD-10 score > 9), which also declined from baseline to 6 months follow-up for both groups (6 weeks, MI:  $B=-2.46$ ,  $SE=0.83$ ,  $P<0.001$ ; BA:  $B=-2.10$ ,  $SE=0.71$ ,  $P<0.001$ ; 6 months, MI:  $B=-3.34$ ,  $SE=0.91$ ,  $P<0.001$ ; BA:  $B=-2.96$ ,  $SE=0.81$ ,  $P<0.001$ ) (Table 1). Baseline to 6-month effect sizes were in the moderate to large range: .98 for the MI group, and 1.15 for the BA group. The percentage of those reporting depressive symptoms by virtue of having a CESD-10 score > 9 also significantly declined from baseline to 6 months for both groups (MI:

67.44% to 27.91%, McNemar's test= 17.00,  $P < .001$ ; BA: 65.00% to 17.50%, McNemar's test= 15.70,  $P < .001$ ).

*PHQ-A depressive disorder:* Depressive symptoms (PHQ-A total score) decreased over 6 months (6 weeks, MI:  $B = -2.87$ ,  $SE = 0.59$ ,  $P < 0.001$ ; BA:  $B = -2.10$ ,  $SE = 0.78$ ,  $P = 0.01$ ; 6 months, MI:  $B = -4.29$ ,  $SE = 0.63$ ,  $P < 0.001$ ; BA:  $B = -2.86$ ,  $SE = 0.86$ ,  $P < 0.001$ ) and the likelihood for reporting a core symptom of depression only at 6 months and only for the BA group ( $B = -2.12$ ,  $SE = 0.85$ ,  $P = 0.01$ ). In the MI group, the likelihood of reporting a core symptom of depression at 6 weeks and 6 months did not differ from baseline (6 weeks,  $B = 0.59$ ,  $SE = 0.78$ ,  $P = 0.45$ ; 6 months,  $B = -0.59$ ,  $SE = 0.64$ ,  $P = 0.36$ ). The prevalence of any likely depressive disorder at 6 weeks and 6 months remained low and not significantly different from baseline for both treatment groups. Effect sizes were 1.12 for the MI group, and 0.63 for the BA group.

*PHQ-A self-harm and hopelessness:* Self-harm thoughts significantly declined only for the BA participants from baseline to 6 months ( $B = -2.48$ ,  $SE = 1.32$ ,  $P = 0.06$ ). The feeling of hopelessness declined significantly only for the MI participants from baseline to 6 months ( $B = -1.71$ ,  $SE = .84$ ,  $P = 0.04$ ).

*Between-group comparisons for all outcomes:*

Mood outcomes at 6 months were similar between the MI and BA groups for the outcomes of depression with two exceptions. First, for hopelessness, the MI group reported significantly less hopelessness than the BA group at 6 months ( $X^2 (1) = 4.04$ ,  $P = 0.044$ ). Second, the cumulative prevalence of self-reported depression treatment episode as assessed by physicians (described in Table 1) was significantly lower in the MI group at 4.5% ( $N = 2$ ,  $N = 2$  with PHQ-A diagnosis) versus 27.4 % ( $N = 11$ ,  $N = 2$  with PHQ-A diagnosis and  $N = 9$  with primary care or mental health specialist diagnosis and treatment) for the BA group ( $X^2 (1) = 4.08$ ,  $P = 0.04$ ) with an  $NNT = 4.36$ . The multilevel analyses yielded no significant findings of treatment group for any of the main outcomes of depression, PHQ-A depressive disorders or self-harm ideation and hopelessness. Furthermore, no significant



interaction between treatment condition and time of assessment was obtained for any of the reported measures.

#### *Adverse events*

One participant attempted suicide one week after enrollment. There was one completed suicide 5 months after enrollment. Neither of these events was believed to be study related. Both individuals had prior histories of self-harm behaviors and psychiatric hospitalizations.

#### *Predictors of treatment outcome*

Table 3 shows results from multilevel univariate analyses (all results adjusted for baseline depressed mood). Regression analyses for CESD-10 depression outcomes over 6 months (adjusted for baseline CESD-10 depression score) revealed one trend toward significance for automatic negative thoughts ( $P=0.02$ ) predicting higher CES-D 10 scores. In terms of principles of effective prevention, greater levels of ease of use significantly predicted lower CESD-10 depression scores over 6 months ( $P=0.004$ ). No other variables were significant at the 0.004 Bonferroni-corrected alpha levels. Consequently, we did not perform a multivariate analysis. Also, there were no significant interactions between predictor variables and intervention group (analyses not shown).

### DISCUSSION

This study aimed to investigate intervention effects and predictors of intervention success over 6 months, for 2 versions (Motivational Interviewing (MI) and Brief Advice (BA)) of a primary care/Internet-based intervention intended to prevent depressive disorders in a diverse group of adolescents in 13 US primary care practices. There was some support for hypothesis (1) that the MI yielded superior outcomes (hopelessness and depressive episodes). As hypothesized (2), both intervention groups demonstrated substantial declines in depression symptoms that were sustained at 6 months after treatment. Moreover, the cumulative prevalence of clinically significant depressive episodes and prevalence of

hopelessness were significantly lower in the MI group than the BA group. There was some evidence that higher ratings of Internet site ease of use was significantly associated with lower levels of depressed mood over 6 months.

To our knowledge, this is the first report of a long-term follow-up from a primary care and Internet-based depression prevention study for adolescents. Gillham and colleagues have demonstrated that primary care based model for depression prevention using a face-to-face version of the Penn Resiliency Program reduced risk of depressive and anxiety disorders for adolescents with high symptom levels at baseline.<sup>37</sup> Within-group (pre/post) effect sizes were in the moderate to high range (Cohen's  $d = 0.63 - 1.15$ ). The size of treatment effects in the present study is either comparable to or somewhat higher than long-term within-group effect sizes of successful targeted preventive interventions for adolescents using face-to-face group psychotherapy (Cohen's  $d = 0.51 - 1.08$ ),<sup>3, 27</sup> and to preventive Internet interventions in adults (Cohen's  $d = .60 - .99$ ).<sup>28-30</sup> However, variations in study design such as baseline levels of depressed mood, setting and circumstances of recruitment, and variations in length of follow-up warrant a tentative approach to such comparisons. Our findings support the use of well-designed cost-efficient Internet interventions for adolescents. The intervention included many characteristics reported to predict larger intervention effects including: enrolling high-risk individuals, older adolescents, shorter intervention duration that included homework assignments, delivered by professional interventionists, and combining three or more intervention methods.<sup>31, 32</sup>

Between-group differences for depressed mood were insignificant; however the MI group demonstrated a lower cumulative prevalence of clinically significant depressive episodes and hopelessness. Given the limitations of the clinically significant depressive episode outcome as measure (largely based on adolescent report of treatment in limited partial cohort follow-up), primacy in interpretation of these apparent disparate outcomes should be given to the more standardized self-report data from the CES-D and PHQ-A. One interpretation would be that "clinically significant depressive episodes" variable is primarily a

“health services utilization” variable and not so much a “clinical” outcome. In this scenario, similar CES-D 10 scores but greater levels of clinically significant depressive episodes could be found if: 1) a much greater proportion of the BA participants were diagnosed with depressive episodes and received antidepressant medication and/or face-to-face psychotherapy after the study began, resulting in a lower CES-D score; 2) the BA group participants may have experienced greater distress and/or lower levels of self-efficacy with regard to life situations at similar levels of depressed mood that resulted in more treatment seeking behaviors or 3) there’s physician and/or participant bias. These possibilities are supported by the findings that individuals with similar levels of depressed mood may adopt different treatment seeking behaviors based on perceived impairment, need or attitudes.<sup>38, 52</sup> Similarly, primary care physicians rarely utilize formal criteria and depression treatment and are often influenced by subjective factors. Additionally, participants or physicians may have been biased by a sense of investment in the success of the MI.

An alternative perspective is that the participants, despite similar levels of depressed mood, did experience greater levels of perceived impairment related to depressed mood. In this framework, several explanations could be considered: 1) greater levels of motivation leading to greater fidelity (adherence/dose in Internet study) influenced better coping strategy and reduced the inter assessment interval episodes for MI participants, or 2) the MI participants simply perceived themselves as being less impaired and more capable, without necessarily being so. The finding of greater adherence, lower prevalence of hopelessness, and increased positive affect and motivation for depression prevention in the MI group 12 weeks that we have previously reported could support one or both of these interpretations.<sup>9-10</sup> Similarly, the hopefulness is an important protective factor and Gilliam demonstrated that greater fidelity was associated with better primary care depression prevention outcome.<sup>37, 39-</sup>

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Although there were a number of predictors analyzed for CESD-10 scores, we only found higher ease of use to be significant after applying the stringent Bonferroni criteria. Previous research on providing health care information to patients emphasized the

importance of ensuring that the readability level is appropriate for the targeted patient group<sup>33</sup>. However, the ease of use items perhaps more closely approximates a global appraisal of satisfaction (“module was easy to use”) with the user experience rather than only with one element. No treatment outcome moderators were found, suggesting that possible subgroups of adolescents who are more likely to benefit from one of the two approaches in engaging youth in the Internet program cannot be identified. Although no treatment outcome moderators were found, future studies should evaluate whether the proposed moderators change during the intervention. Such find was not possible to assess in our study due to limited data values on the moderators only for baseline.

The results presented here should be interpreted with respect to the following limitations. Without a treatment as usual control group, it is possible that findings were due to depressive symptoms resolving over time,<sup>34</sup> regression to the mean, or a tendency for those with fewer symptoms to respond to the follow-up call at 6 months.<sup>35</sup> However, there were no differences in baseline and 6-week outcomes between responders and non-responders which may reduce the bias. Another limitation of this study was its lack of power due to its small sample size, making our analyses exploratory with regard to the prediction of intervention effect. Moreover, it is unclear whether the MI participants had higher levels of engagement with the intervention because of the physician-conducted MI interview, because of the pen and paper questionnaire with MI questions completed as preparation for the interview or because the participants received three phone calls, regardless of whether the content was consistent with MI techniques. However, many adolescents did not receive the phone calls, making this possibility less likely. We acknowledge that the findings of non-significance for many possibly relevant variables in the regression models have to be interpreted with caution because of our design limitations, such as the relatively small sample size.

We are not aware of another study of a public health approach (screening, primary care engagement and low cost Internet intervention) to prevent adolescent depression, particularly one implemented in community practice settings. This study provides support for

the potential impact of a primary care/Internet-based intervention for the sustained reduction of depressive symptoms among adolescents. The next step would be to conduct a randomized controlled trial to test the efficacy of our interventions in comparison to a control condition. Considering the difficulty in disseminating and implementing public health approaches for preventing mental disorders like depression,<sup>36</sup> this study indicates that using modern technology in what we call “behavioral vaccines”, could be a useful strategy to tackle this public health dilemma. Short-term psychological interventions provided via the Internet through a primary care setting may be more cost-effective and more accessible to adolescents than a relatively longer treatment using traditional mental health practitioners. Our results clearly call for more studies on this form of treatment, involving a true control condition, larger samples, and perhaps consideration of a factorial design that could elucidate the contribution of components of the current intervention such as the parent workbook. Two phase-3 randomized controlled trials of CATCH-IT or adaptations of CATCH-IT have been funded by United States National Institute of Mental Health and the Robert Wood Johnson Foundation and are scheduled to begin in October 2011. Also, future comparative treatment studies should clarify and identify additional predictors of treatment impact.

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All other contributing authors have read the journal's policy on conflicts of interest and have none to declare.

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