BRIEF REPORT

Primary Care Physicians Treat Somatization

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BACKGROUND: We hypothesized that somatizing patients managed by primary care physicians (PCP) would improve with a relationship-based intervention.

METHODS: We randomized 30 adults with medically unexplained symptoms to treatment or usual care. Four PCPs were trained to intervene with cognitive-behavioral, pharmacological, and patient-centered management and deployed the intervention with seven scheduled visits over 12 months. Outcomes obtained at baseline and 12 months were: Mental component summary (MCS), the primary endpoint, and measures of physical and psychological symptoms and of satisfaction with the PCP.

RESULTS: Patients averaged 52.5 years; 83.3% were female; 79.6% were black. Using a difference of differences approach, we found that the intervention produced a large effect size (ES) (0.82; CI: 0.08 to 1.57) for the MCS in the predicted direction, similar to the ES for physical (−0.80; CI: −1.55 to −0.04) and psychological (−1.06; CI: −1.83 to −0.28) improvement and for increased satisfaction with the PCP (0.94; CI: 0.15 to 1.74). Using ANCOVA in a sensitivity analysis, we found that the ES fell slightly (0.59), while other measures were unchanged.

CONCLUSIONS: Moderate-large effect sizes support the hypothesis that PCPs can effectively treat somatization. This points to the importance of performing a full RCT.

KEY WORDS: somatization; medically unexplained symptoms; primary care mental health; patient-centered; provider–patient relationship.
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INTRODUCTION

Patients with somatization are common and have physical symptoms with little documented basis in disease[1]. The prevalence of primary care patients with one or more somatizing symptoms ranges from 33% upwards in outpatient settings, and their care has occasioned safety and cost problems[1]. We recently demonstrated that nurse practitioners (NP) achieved clinically significant improvement following a 12-month intervention for distressed, high-utilizing patients with medically unexplained symptoms (MUS)[1,2]. However, treatment of MUS by primary care providers has been infrequent and the results are mixed[3–6]. Not using the cognitive-behavioral treatment (CBT) and antidepressants we used, two studies had no impact on outcomes[3,5], while the other showed a decrease in symptoms[6], according to a recent review of RCTs for treatment of somatoform disorders[4].

This brief report describes a pilot study of MUS treated by primary care physicians (PCP) assisted by a case manager (CM) with an intervention similar to our previous one using NPs.

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METHODS

1) *Study Design.* High-utilizing MUS patients at Henry Ford Health System (HFHS) were randomly allocated to treatment conducted by trained PCPs and a case manager (CM) or to usual care. The Mental Component Summary (MCS) of the Short Form-36 (SF-36) was evaluated 12 months post-baseline as the primary endpoint[7,8]. Supplementary outcomes also were measured.
2) *Subjects and Settings. Nonclinical criteria* included being members of Health Alliance Plan (HAP), an HFHS-owned and operated HMO, for at least 2 years, literate, able to communicate in English, planning to be in the HMO practice for at least 12 months, accessible by telephone, not currently under care of a mental health professional more than once/month, and willingness to see a new PCP for treatment. *Exclusion criteria* included: medically unstable or unable to ambulate, pregnancy, substance use disorders, actively suicidal, organic mental syndromes, psychosis, or non-severe MUS, defined as the Mental Health (MH) subscale of the SF-36 being >77[7].
3) *Research PCPs and CM.* We trained one experienced CM and four experienced PCPs for 24 hours over 6 weeks to deliver the intervention, which focused on antidepressant management, cognitive-behavioral treatment (CBT), and the provider–patient relationship (PPR). The CM received an additional 4 hours didactic and role play training for her telephone work and 4 hours of additional CBT training. Because the position was lost, the CM participated in the care of only the first six Treatment patients. The HFHS IRB approved the study, and patients signed a consent form.
4) *Subject identification.* From the administrative database (ADB) at two HFHS sites, we randomly selected subjects 18 years or older with at least eight visits yearly for the two years preceding study. From the ADB, we identified ICD-9 diagnosis codes suggesting MUS[9]. The PI then rated the

Table 1. Baseline, Follow-up and Difference Measures in Control and Intervention Groups*

	Control Group (n=15)			Treatment Group (n=15)			Difference-in-differences (DID) (95% CI)	Effect Size for DID (95% CI)
	Baseline	Follow-up	Difference (95% CI)	Baseline	Follow-up	Difference (95% CI)		
MCS - Mental Health Function	46.6	46.1	−0.50 (−9.7, 8.7)	35.7	47.9	12.2 (1.4, 22.9)	12.7 (−1.5, 26.8)	0.82 (0.08, 1.57)
PCS - Physical Health Function	32.6	33.6	0.97 (−4.3, 6.3)	38.2	38.0	−0.19 (−6.4, 6.0)	−1.2 (−9.3, 7.0)	−0.13 (−0.85, 0.58)
BP - Body Pain	43.8	39.9	−3.9 (−18.7, 11.0)	45.8	51.8	6.0 (−11.1, 23.1)	9.9 (−12.8, 32.6)	0.39 (−0.33, 1.11)
CESD - Depression	18.3	22.9	4.6 (−4.0, 13.2)	26.3	15.7	−10.6 (−20.8, −0.41)	−15.3 (−28.6, −1.9)	−1.06 (−1.83, −0.28)
SSAS - Anxiety	47.6	47.8	0.12 (−3.5, 3.7)	47.3	46.8	−0.45 (−4.6, 3.7)	−0.57 (−6.1, 4.9)	−0.09 (−0.82, 0.64)
PHQ-15-Physical Symptoms	27.5	26.8	−0.69 (−2.5, 1.1)	27.9	24.8	−3.1 (−5.2, −0.96)	−2.4 (−5.2, 0.40)	−0.80 (−1.55, −0.04)
SQ-1 - PPR Satisfaction	100.0	101.4	1.4 (−3.0, 5.8)	99.8	108.0	8.2 (3.1, 13.3)	6.8 (0.06, 13.6)	0.94 (0.15, 1.74)

Within group, the difference is follow-up minus baseline. For DID, treatment minus control
MCS = Mental Component Summary; PCS = Physical Component Summary; BP = Bodily Pain; CESD = Depressive Symptoms; SSAS = Spielberger State Anxiety; PHQ-15 = Patient Health Questionnaire; PPR = provider–patient Relationship. Higher scores on the SF-36 items (MCS, PCS, BP) and SQ-1 are associated with better function, while higher scores on the remaining items connote worse function. The (+) and (−) signs are all in the predicted direction except for the PCS

electronic charts of these patients to identify primary MUS, guided by a reliable rating procedure[10].

All 19 providers at the two sites agreed that their patients participate. HFHS research team members then called each patient, and subjects who agreed were then further screened with the MH to exclude less severe subjects.

5) *Randomization/Blinding*. We randomized 1/2 of subjects to treatment (trained PCP/CM teams) and 1/2 to usual care (UC) using a random number generator.
6) *Intervention*. The intervention was similar to our earlier study except for using PCPs instead of NPs[1,2], and we only summarize it here. PCPs used CBT focused, for example, on regular visits and specific healthy behaviors. They delivered the CBT in the context of a behaviorally-defined, evidence-based patient-centered method to maximize communication and the provider–patient relationship[11]. Finally, subjects who met Patient Health Questionnaire-9 (PHQ-9)[12] criteria for major depression received antidepressants (AD) according to a specific protocol based in STAR*D[13]. Subjects taking controlled substances entered a gradual tapering program that aimed at complete cessation[1].
7) *Intervention Delivery*. The intervention was delivered over 12 months in seven visits with the PCP (and three with the CM who also made eight scheduled phone calls). Following a careful history and physical examination and PHQ-9 administration, PCPs evaluated patients clinically for depression, anxiety, alcohol and related psychiatric disorders as well as for comorbid physical disorders. The CM monitored and delivered CBT at telephone visits and addressed medication adherence.
8) *Study Outcomes and other Measures*. At *baseline and 12 months*, research interviewers obtained: a) SF-36 - the MCS, the Physical Component Summary (PCS)[8], and the eight SF-36 subscales, which includes Body Pain (BP)[7]; b) Center for Epidemiological Studies Depression (CES-D)[14]; c) Patient Health Questionnaire-15 (PHQ-15), a physical symptom evaluation[15]; d) the Spielberger State Anxiety Scale (SSAS)[16]; e) and a satisfaction with the PPR Questionnaire (SQ-1)[17].
9) *Statistics*. For each outcome measure the baseline and last follow-up assessments were analyzed jointly using a linear model with treatment group, time and group by time interaction effects, and an unstructured covariance for the residual error. Time was measured in days from baseline. We estimated the expected change in outcome from baseline to 12 months in each group by least-squares means, and then the difference-in-differences (DID) for the treatment relative to usual care[18]. Sensitivity analyses included ANCOVA testing to determine between-group differences in 12 month outcomes with adjustment for the baseline to reduce confounding by regression to the mean. Unbiased estimates of effect size and 95% confidence intervals were obtained by the method of Wu et al.[19].

RESULTS

1) *Subjects*

Of 82 eligible subjects, 44 were interested (54%); 79.6% were African Americans. Of these, 30 were recruited (68%) and

Table 2. Process of Conducting the Intervention

1) Mean number of encounters over one year (average number of minutes per encounter):
office visits-7 (38.3)
scheduled phone-3 (20.5)
after-hours phone-3 (14.7)
coordination of care-1 (20)
2) Percentage of visits at which selected CBT activities occurred:
goal setting/homework (46.0%)
physical therapy scheduled (6.7%)
relaxation exercise outlined (17.6%)
physical exercise detailed (34.1%)
spirituality discussed (7.1%)
symptom diary addressed (14.0%)
3) Percentage of visits when medications were prescribed for:
pain-63.1%
sedation-41.3%
anxiety-48.0%
depression-61.2%.

followed at one or more post-baseline interviews (15 Treatment and 15 UC). There were 73% females in Treatment and 93% in UC, with an average age of 52.5 years in each group.

2) *Randomization Success*

At baseline, shown in Table 1, treatment patients had significantly greater deficits on the MCS (p=0.02), perhaps due to somewhat higher depressive symptoms (CES-D). Treatment and UC control patients were comparable on other measures.

3) *Intervention Impact on Outcome*

Shown also in Table 1, an effect size (ES) in the large range (0.82; CI: 0.08 to 1.57) occurred in the predicted direction for the MCS. The intervention also had large effect sizes in the predicted direction for supplementary measures including PHQ-15 (−0.80; CI: −1.55 to −0.04), CES-D (−1.06; CI: −1.83 to −0.28), and SQ-1 (0.94; CI: 0.15 to 1.74). The DID for CES-D was statistically significant (p=0.03), and approached significance for MCS (p=0.08), PHQ-15 (p=0.09), and SQ-1 (p=0.05). To evaluate regression to the mean, a standard ANCOVA yielded a smaller but still impressive ES of 0.59 for MCS; there were no substantive ES changes for other measures on ANCOVA.

Following Chuang-Stein & Tong[20], we evaluated the magnitude of regression to the mean (RTM). The adjustment for RTM may be particularly relevant for MCS and CES-D because one of the exclusion criteria in our trial is non-severe MUS, defined as the MH subscale of the SF-36 being greater than 77. The standard ANCOVA adjustment for RTM partials out the baseline differences in outcomes. Such adjustment yielded a treatment effect of 4.6 for MCS and −8.5 for CES-D, with DID estimates of 12.7 and −15.3, respectively. For all other outcomes, the RTM effects were not very large. Thus there was still a substantive treatment effect after eliminating the RTM effects.

To evaluate the impact of the CM, we compared the nine non-CM intervention cases to the control group. The difference in difference score for MCS was reduced to 3.8 points, suggesting that the CM made a contribution to the strength of the intervention. For CES-D, the difference in difference score remained approximately the same (−15.8 points).

Table 2 summarizes key data about the PCPs' process of care.

DISCUSSION

In a small trial using PCPs to manage somatizing patients, we found moderate to large effect sizes for better mental functioning accompanied by improved somatization and pain in the context of high levels of satisfaction with the provider–patient relationship.

We cannot yet view these results as clinically significant, however, because full clinical trials will be needed to say this. Because trained nurse practitioners achieved a clinically significant 4.0 point MCS improvement in this population[2], we suspect that a full clinical trial using PCPs will produce a much smaller ES. The data also suggest that trained PCPs can obtain even greater MCS improvement with CM participation, a finding supported by the depression literature[21].

We cannot exclude the possibility that the selected PCPs would have achieved better outcomes with this patient population without any additional training. Pre-post training patients seen by intervention PCP group would be needed to resolve this. We evaluated possible regression to the mean, but our sensitivity analysis using ANCOVA indicated that was not a major issue.

CONCLUSIONS

We have demonstrated moderate to large effect sizes in the direction predicted by previous research. While these encouraging results hold promise that PCPs may be effective with distressed MUS patients, these pilot data with a small number of subjects only allow us to conclude that a full clinical trial is indicated.

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Conflict of Interest: *None disclosed.*

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