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Efficacy of psychosocial intervention in improving quality of life and psychological well-being of Chinese patients with colorectal cancer: a randomised controlled trial

Key Messages

1. The Eastern Body-Mind-Spirit (BMS) model of group intervention is a psychosocial intervention which integrates eastern philosophies and health practices with western psychotherapeutic techniques.
2. The BMS intervention demonstrated efficacy in facilitating post-traumatic growth and positive attitudes towards the cancer experience. Its impact on post-traumatic growth was maintained up to 4 months after the intervention.
3. The BMS intervention should be considered in the overall oncological care for patients with colorectal cancer. However, given its limited maintenance effect, a booster session at 4 months and beyond might be needed.

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Introduction

Colorectal cancer is the second most common cancer and the second leading cause of cancer-related death in Hong Kong.[1] Surgery and adjuvant treatment are invasive and may impact negatively on psychological health and functional status of patients. Together with the threat of recurrence and mortality, this causes colorectal cancer patients to experience substantial psychological distress and compromised quality of life.[2]

There is some evidence to suggest beneficial effects from psychosocial interventions on quality of life and psychological well-being in cancer patients. Findings from meta-analytic studies are encouraging, and showed that models with a multidimensional and multimodal approach and incorporating a cognitive-behavioural component are the most promising.[3,4] In this regard, the role of cultural values in facilitating improvements in well-being should be emphasised. Culturally relevant models of psychosocial interventions for Chinese cancer patients are lacking. Established models for colorectal cancer patients are unavailable.

The Body-Mind-Spirit (BMS) model[5] is a multidimensional group intervention approach that takes into account patients' physical, psychological, social, and spiritual needs on the one hand, and incorporates Chinese cultural values and philosophical concepts on the other. It integrates western psychotherapeutic techniques with eastern philosophies and Chinese traditional health practices. It takes into account the often neglected but important spiritual aspects of therapy. The BMS approach is grounded on the principle that physical states (body), emotion and social relationships (mind), and life values and philosophies (spirit) are interconnected. Hence, one's health and well-being depends on a balance between these three elements.

Aims and objectives

The present study aimed at systematically assessing the immediate and long-term efficacy of the BMS model of group intervention to improve psychological well-being and quality of life among colorectal cancer patients in Hong Kong, using a randomised controlled trial design.

Methods

Participants

The study was conducted from September 2004 to October 2007. Participants were colorectal cancer patients recruited from three regional hospitals in Hong Kong. Inclusion criteria were a diagnosis of colorectal cancer, age above 18 years, and the ability to read and speak Cantonese. Patients with serious concomitant disease, history of psychiatric illness, life expectancy of less than 3 months (as assessed by the treating oncologist), or presence of other cancers were

excluded. Informed written consent was sought. The study was approved by the Institutional Review Boards of the University of Hong Kong and relevant Hospital Authority clusters.

Study design

A randomised controlled trial design was adopted. Participants were randomly assigned to either the BMS intervention group or the control group. Randomisation was stratified by potential confounding factors, namely, disease stage, need for adjuvant therapy, and presence of a stoma. Randomisation lists were generated by computer using the block randomisation method. Codes representing intervention and control were put into sealed envelopes and distributed to the patients in the order in which they were recruited.

Participants assigned to the intervention group received the BMS group intervention totalling 15 hours. Each group consisted of 10 to 12 members and met weekly for 5 weeks; each meeting lasted 3 hours. The BMS model integrates western group psychotherapeutic techniques with Chinese philosophical concepts and health practices. It focuses on the four main themes of normalisation of traumatic experiences; letting go of the need for absolute attachments and acceptance of the unpredictability of life; forgiveness and self love; and reinforcement and stabilisation of changes through social support and helping others. The principle intervention components included in-depth sharing, emotional expression, meditation, and physical exercise. Groups were led by trained facilitators. Participants in both groups received health education materials on colorectal cancer and its treatment. They were assessed at five time-points: at baseline (T0), immediately after intervention (T1), 4 months post-intervention (T2), 8 months post-intervention (T3), and 12 months post-intervention (T4).

Instruments

The main outcome measures were quality of life and psychological well-being. Quality of life was measured by the validated Chinese version of the Short Form-36 Health Survey (SF-36). Psychological well-being was examined in terms of post-traumatic growth, cancer-related coping, emotional control, and anxiety and depression. The four aspects were measured respectively by the validated Chinese versions of the Post-Traumatic Growth Inventory (PTGI), the Mini-Mental Adjustment to Cancer Scale (Mini-MAC), and the Courtauld Emotional Control Scale (CECS).

Analysis

Statistical analysis was performed on an intention-to-treat basis. Repeated measures analysis of variance (ANOVA) was conducted for each outcome measure to assess the efficacy of BMS intervention. Repeated measures analysis of covariance (ANCOVA) was also conducted to adjust for any baseline imbalance between the two groups. When baseline differences were found between the two groups, they were treated as potential confounding factors and entered as covariates in the analyses. Time and group (intervention versus control) interactions were tested for statistical significance. For each outcome measure, charts were plotted to visually represent the trends of the two groups from baseline (T0) to 12 months post-intervention (T4). Post hoc analyses for within-subject effects (repeated measure: time) were also conducted for outcomes with significant time and group interactions so as to identify the two successive time points on which a significant difference was found.

Results

Participant flow

A total of 172 eligible participants were recruited. Of these, 86 were randomised to the BMS intervention group and 86 to the control group. Due to deteriorating health, two participants from the intervention group and four from the controls did not complete baseline assessment (T0) and did not receive the allocated intervention. In total, 121 participants completed all assessments, (66 in the intervention group and 55 in the controls). As analyses were performed on an intention-to-treat basis, the total number of participants included in the analyses was 166 (84 in the intervention group and 82 in the controls), which was the number of all participants with baseline assessment (T0) data.

With respect to core demographic variables and outcome measures at baseline, attrition analysis showed no significant difference between those who completed the study and those who did not, except for the physical component summary (PCS) of the SF-36 (P=0.049) and the positive attitude subscale of the Mini-MAC (P=0.041). Those who dropped out had marginally lower scores for PCS (mean, 256.6 vs 273.6; standard deviation [SD], 50.9 vs 47.1) and higher scores for positive attitude (mean, 19.8 vs 18.2; SD, 3.5 vs 4.5), compared with those who completed the study.

Sample characteristics

The mean age of the sample was 60 years (SD, 10.8; range, 28-85 years). About 33.7% of the sample was female. Most participants were married (86.6%). The mean number of children was 2.4 (SD, 1.4). Most participants (79.5%) achieved secondary level of education. About 51.5% were retired, whereas 21.2% were working full time.

Baseline characteristics of intervention and control group participants

There were no significant differences between the intervention and control group participants with respect to demographics (Table 1), time since diagnosis, tumour staging, stoma status or use of adjuvant therapy. At baseline, the two groups were also similar with respect to all outcome measures except for the anxiety subscale of the CECS. Participants in the intervention group had marginally greater suppression of anxiety than the controls (mean, 18.95 vs

17.62; SD, 4.26 vs 3.94; $t_{(164)}$=4.20; P=0.042).

Immediate intervention effect

Table 2 shows the results of repeated measures ANOVA and ANCOVA of PTGI, Mini-Mac, CECS, and SF-36 subscale scores from baseline (T0) to immediately after intervention (T1). The comparisons for unadjusted and adjusted results are also shown in Table 2. Significant time and group interaction effect was found for all four subscales of the PTGI, namely life orientation ($F_{(1,165)}$=12.93, P=0.000 / $F_{(1,165)}$=12.74, P=0.000 for unadjusted and adjusted analyses, respectively), spiritual ($F_{(1,165)}$=35.78, P=0.000 / $F_{(1,165)}$=35.18, P=0.000), interpersonal ($F_{(1,165)}$=45.68, P=0.000 / $F_{(1,165)}$=45.49, P=0.000), and self ($F_{(1,165)}$=57.43, P=0.000 / $F_{(1,165)}$=62.00, P=0.000). The interaction effect for the positive attitude subscale of the Mini-MAC was also significant ($F_{1,165)}$=4.59, P=0.034 / $F_{1,165)}$=4.65, P=0.033). The intervention effect remained evident even after controlling for baseline differences between the two groups in terms of the emotional control of anxiety. This showed that compared with participants in the control group, those having the intervention achieved greater improvements in all four dimensions of posttraumatic growth as well as greater increases in positive attitudes to cancer. No significant interaction effect was found for SF-36 and CECS subscale scores.

Maintenance effect

The maintenance effect in the BMS intervention group was tested with repeated measures ANOVA and ANCOVA for all outcome measures over the entire study period (T0 to T4). Significant findings are graphically represented in the Figure. Long-term maintenance effect was only found for life orientation (P=0.025 / P=0.023 for unadjusted and adjusted analyses respectively), spiritual (P=0.000 for both unadjusted and adjusted analyses), interpersonal (P=0.000 for both unadjusted and adjusted analyses), and self (P=0.000 for both unadjusted and adjusted analyses) subscales of the PTGI, which was inferred from significant two-way interaction effects. Post-hoc analyses in the repeated measures ANCOVA showed that for the life orientation subscale, significant interaction effects were found between baseline (T0) and immediately after the intervention (T1) [$F_{(1,165)}$=13.96, P=0.000], and between immediately after the intervention (T1) and 4 months post-intervention (T2) [$F_{(1,165)}$=5.63, P=0.019]. The same was observed for the spiritual ($F_{(1,165)}$=37.92, P=0.000 between T0 and T1; $F_{(1,165)}$=18.44, P=0.000 between T1 and T2; $F_{(1,165)}$=3.99, P=0.048 between T3 and T4), interpersonal ($F_{(1,165)}$=41.47, P=0.000 between T0 and T1; $F_{(1, 165)}$=22.10, P=0.000 between T1 and T2), and self ($F_{(1,165)}$=55.11, P=0.000 between T0 and T1; $F_{(1,165)}$=33.22, P=0.000 between T1 and T2) subscales. Thus, the effect was maintained until 4 months after the intervention. Thereafter, there were no significant differences between the intervention and the control groups for improvement on the PTGI subscales. No maintenance effect was observed for other outcome measures. The Figure shows that the measures reached maximum levels immediately after the intervention (T1) for intervention group in all four subscales of the PTGI. For all the subscales of PTGI, there were significant decreases from T1 to T2, bringing the levels back to those in the control group.

Table 1. Baseline demographic and clinical characteristics of participants in the intervention and control groups*

Parameter	Intervention group (n=84)	Control group (n=82)	P value
Age (years)	58.9 (10.5)	60.5 (10.8)	0.340
Gender			0.520
Male	63.6	69.0	
Female	36.4	31.0	
Marital status			0.963
Single	3.5	3.5	
Married/cohabiting	90.7	88.4	
Divorced/separated	1.2	2.3	
Widowed	4.7	4.7	
No. of children	2.3 (1.3)	2.5 (1.4)	0.440
Education level			0.671
None	4.7	5.9	
Primary	24.4	27.1	
Form 1 to 3	22.1	23.5	
Form 4 to 5	31.4	21.2	
Form 6 to 7	3.5	3.5	
Tertiary or above	14.0	16.5	
Other	-	2.4	
Work status			0.429
Full-time	12.8	21.7	
Part-time	4.7	8.4	
Retired	54.7	45.8	
Housewife	23.3	19.3	
Other	4.7	4.8	
Time since diagnosis (months)	25.39 (15.90)	22.29 (16.61)	0.226
Late stage	59.5	58.5	0.897
Stoma	29.8	28.0	0.808
Adjuvant therapy	70.2	69.5	0.919
Post-traumatic Growth Inventory			
Life orientation	4.31 (2.21)	3.79 (2.31)	0.143
Spiritual	5.61 (3.76)	4.86 (3.58)	0.193
Interpersonal	5.31 (3.63)	4.88 (3.27)	0.529
Self	12.33 (8.57)	10.61 (7.80)	0.181
Mini-Mental Adjustment to Cancer Scale			
Positive attitude	18.94 (4.39)	18.4 (4.32)	0.430
Negative emotion	16.06 (8.04)	16.71 (9.32)	0.637
Cognitive avoidance	7.06 (2.66)	7.14 (2.12)	0.836
Courtauld Emotional Control Scale			
Anxiety	18.95 (4.26)	17.62 (3.94)	0.042
Depression	17.64 (4.78)	16.85 (4.54)	0.282
Anger	18.68 (4.11)	17.78 (4.27)	0.173
Short Form-36 Health Survey			
Physical	35.6 (9.6)	37.9 (10.1)	0.149
Mental	55.9 (10.2)	55.0 (10.4)	0.555

* Data are presented as mean (SD) or %

Discussion

Our randomised controlled trial showed that the BMS intervention is able to bring about significant positive changes among colorectal cancer patients, particularly in terms of facilitating growth after the traumatic cancer experience as well as positive attitudes to the experience. The intervention effect was still evident even after controlling for baseline imbalance between the intervention and control groups in terms of emotional control of anxiety. The post-traumatic growth was still observed 4 months after the intervention but was not maintained thereafter.

Table 2. Repeated-measures ANOVA and ANCOVA (controlling for baseline CECS-anxiety) comparing changes in quality of life and psychological well-being outcome measures from baseline (T0) to immediately after intervention (T1) in the intervention and control groups*

Outcome measures	Intervention group (n=84)		Control group (n=82)		Repeated-measures ANOVA			Repeated-measures ANCOVA		
	T0	T1	T0	T1	Time main effect	Group main effect	Time & group interaction effect	Time main effect	Group main effect	Time & group interaction effect
Post-traumatic Growth Inventory										
Life orientation	4.31 (2.21)	5.04 (2.26)	3.79 (2.31)	3.60 (2.02)	0.015	0.003	0.000	0.959	0.007	0.000
Spiritual	5.57 (3.77)	8.91 (3.55)	4.86 (3.58)	4.94 (2.88)	0.000	0.000	0.000	0.519	0.000	0.000
Interpersonal	5.27 (3.63)	7.98 (3.23)	4.98 (3.67)	4.9 (2.96)	0.000	0.000	0.000	0.433	0.000	0.000
Self	12.21 (8.55)	20.13 (7.93)	10.62 (7.8)	10.73 (7.18)	0.000	0.000	0.000	0.972	0.000	0.000
Mini-Mental Adjustment to Cancer Scale										
Positive attitude	18.93 (4.41)	19.21 (3.54)	18.39 (4.35)	17.62 (3.78)	0.319	0.070	0.034	0.072	0.177	0.033
Negative emotion	16.04 (7.98)	15.43 (7.91)	16.71 (9.31)	17.66 (7.83)	0.704	0.244	0.085	0.576	0.351	0.114
Cognitive avoidance	7.05 (2.67)	7.18 (2.26)	7.14 (2.12)	6.82 (1.82)	0.457	0.671	0.078	0.222	0.848	0.139
Courtauld Emotional Control Scale										
Anxiety	18.95 (4.26)	19.11 (4.34)	17.62 (3.94)	17.38 (3.67)	0.876	0.012	0.385	0.000	0.096	0.096
Depression	17.60 (4.79)	17.73 (4.76)	16.85 (4.54)	16.75 (4.22)	0.948	0.200	0.653	0.009	0.767	0.359
Anger	18.69 (4.11)	19.13 (4.02)	17.78 (4.27)	17.74 (3.74)	0.331	0.059	0.248	0.102	0.455	0.189
Short Form-36 Health Survey										
Physical	36.00 (9.45)	36.67 (10.71)	38.00 (9.75)	36.79 (7.79)	0.565	0.469	0.052	0.283	0.374	0.065
Mental	55.95 (10.36)	57.97 (9.87)	54.84 (10.43)	54.97 (9.87)	0.294	0.310	0.401	0.328	0.247	0.578

* Data are presented as mean (SD) or P value

The benefit of the BMS intervention was most evident in facilitating growth after the traumatic cancer experience. Different dimensions of growth were facilitated, including positive changes in life priorities (life orientation), stronger faith and better understanding of spiritual matters (spiritual), enhanced closeness and compassion to others (interpersonal), and improved self-confidence (self). This testifies to the importance of incorporating a culturally relevant and spiritually orientated dimension into psychosocial therapy for cancer patients. The BMS model places great emphasis on traditional Chinese philosophies of 'endurance of suffering'. In circumstances where health problems are beyond the individual's control, acceptance and willingness to endure pain are paramount in bringing about a more positive outlook on the illness and life. Patients who could accept the illness are able to get on with life productively and even grow through the experience. The traditional concept of letting go and forgiveness is another important component of the BMS model. By helping patients let go of their bitterness and resentment towards their illnesses, individuals are better able to achieve emotional tranquility and appreciate themselves, others, and life. These culturally relevant spiritual elements may well have brought about the various dimensions of growth.

Among patients in the intervention group, a significant increase on the positive attitude subscale of the Mini-MAC was also observed, which reflected that BMS intervention was efficacious in increasing positive attitudes towards the cancer experience and in dealing with the challenges associated with the experience. This could possibly be due to the BMS model's focus on the promotion of acceptance, self-love, and forgiveness which enhances positive appraisal of the illness and self.

Effects were maintained for all growth dimensions up to 4 months after the intervention. Thus, although the BMS intervention was effective in fostering immediate and short-term growth among colorectal cancer patients, the growth became stabilised after a short period of time. Due to the exceedingly complicated nature of the cancer experience, patients may require more support and skill reinforcement after the intervention to fortify their positive transformations. In this regard, 'booster sessions' might be necessary to reinforce and maintain the positive changes.

Although the preliminary results from this study are encouraging, there are several caveats. First, we excluded patients with a life expectancy of less than 3 months. This was based on logistic considerations but render our findings not generalisable to such patients. However, this was a highly distressed group needing psychological help, for whom further studies should aim at developing and testing treatment modalities. Another limitation was that our outcome measures depended solely on self-reporting. Subtle changes in psychological well-being and quality of life may not be captured by these instruments and thus not reflected in our findings. More qualitative assessment could have provided a more sophisticated picture of the efficacy of the BMS intervention in areas that are of relevance to colorectal cancer patients.

Nonetheless, our findings attest to the efficacy of the BMS intervention in facilitating short-term post-traumatic growth and positive attitudes among colorectal cancer patients in Hong Kong. It was likely that the BMS model's

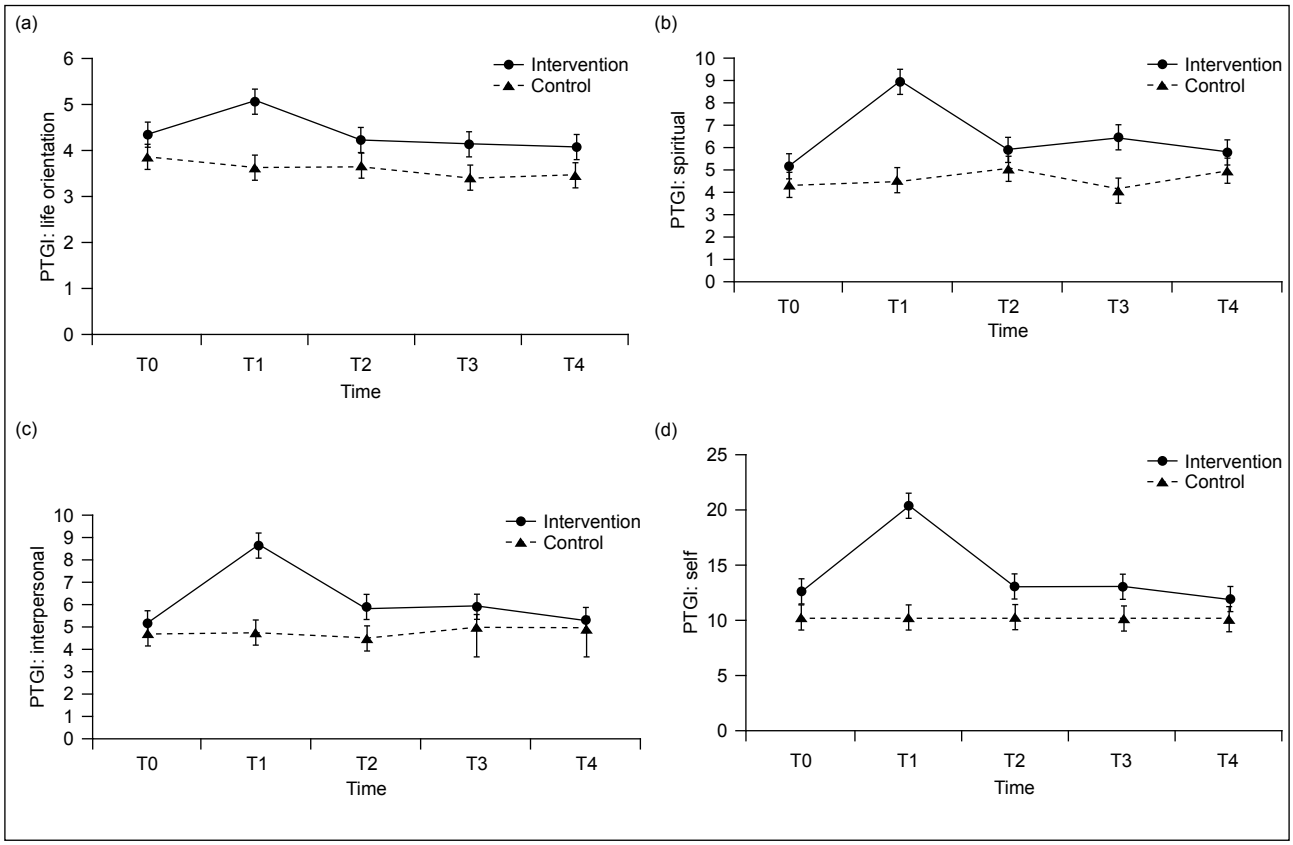

Fig. Mean Post-traumatic Growth Inventory (PTGI) scores from baseline (T0) for (a) life orientation, (b) spiritual, (c) interpersonal, and (d) self to 12 months post-intervention (T4) for intervention and control groups

emphasis on the spiritual aspect of well-being and its culturally relevant philosophical and physical exercise components contributed to these positive changes. However, our results did not support long-term maintenance of positive effect. Further studies should build on the current findings to examine ways to reinforce the changes so that long-term benefits can be secured. Future studies should also aim at identifying specific therapeutic components and mechanisms that contributed to the success of BMS in the domains identified in the present study.

Based on the findings of the current study, the BMS psychosocial intervention is a promising model that should be seriously considered as an integral component of any comprehensive management programme for colorectal cancer patients in Hong Kong. Further investigation of the maintenance effect and mechanisms is warranted, but it is likely that additional booster sessions will be required four months after the core intervention is delivered, in order to facilitate the long-term maintenance of therapeutic gains.

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