Title
Effectiveness of cognitive behavioral therapy based on the pain sustainment/exacerbation model in patients with tension-type headache: a pilot study

Author(s)
Motoya, Ryo; Oda, Keiko; Ito, Eiji; Ichikawa, Masahiro; Sato, Taku; Watanabe, Tadashi; Sakuma, Jun; Saito, Kiyoshi; Niwa, Shin-Ichi; Yabe, Hirooki

Citation
Fukushima Journal of Medical Science. 60(2): 133-140

Issue Date
2014

URL
http://ir.fmu.ac.jp/dspace/handle/123456789/427

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DOI
10.5387/fms.2014-15

Text Version
publisher
EFFECTIVENESS OF COGNITIVE BEHAVIORAL THERAPY BASED ON THE PAIN SUSTAINMENT/EXACERBATION MODEL IN PATIENTS WITH TENSION-TYPE HEADACHE: A PILOT STUDY

RYO MOTOYA1),2), KEIKO ODA3), EJI ITO3), MASAHIRO ICHIKAWA3), TAKU SATO3), TADASHI WATANABE3), JUN SAKUMA3), KIYOSHI SAITO3), SHIN-ICHI NIWA1)4) and HIROOKI YABE1)

1)Department of Neuropsychiatry, Fukushima Medical University School of Medicine, 2)Center for Medical Education and Career Development, Fukushima Medical University, 3)Department of Neurosurgery, Fukushima Medical University School of Medicine, 4)Fukushima Prefecture, Hospital Business Administrator

(Received June 9, 2014, accepted August 1, 2014)

Abstract: The purpose of this study was to carry out a program of Cognitive Behavioral Therapy (CBT) based on the pain sustainment/exacerbation model for tension-type headache (TTH) patients and to examine the effectiveness as a pilot study. The participants were 4 TTH patients who consulted the outpatient clinic of a university hospital. It consisted of 4 individualized sessions as CBT program (including psychological education, self-monitoring, relaxation technique, cognitive restricting and exposure), and a follow-up examination was carried out 1 month after its completion. The sessions, each of which was 60 minutes long, were executed at weekly intervals. As a result, the score of the Pain Catastrophizing Scale (PCS) decreased after program compared with before program in all patients. The score of escape/avoidance was also reduced at the post-program and follow-up (1 month later) compared with the score of pre-program in patients except Case 2, in whom the score was 0 throughout the study. The degree of the Headache Impact Test (HIT-6) improved by program and changed to “mild” or “none” in all participants. These findings show that in patients with TTH this short CBT program has effect on pain catastrophizing, escape/avoidance and daily disability.

Key words: tension-type headache (TTH), cognitive behavioral therapy (CBT), pain catastrophizing, escape/avoidance, daily disability

INTRODUCTION
Tension-type headache (TTH) has some characteristics such as bilateral location, pressing or tightening quality, and mild or moderate intensity1). Also, TTH is a typical psychosomatic disease2) and a high percentage (about 22%) of the general population fulfills the diagnostic criteria of TTH3,4). It is necessary for TTH patients to receive the psychosomatic treatment, including the non-pharmacologic therapy, to improve pain-related daily disabilities5). Motoya et al.6,7) formulated a pain sustainment/exacerbation model concerning patients with TTH (Fig. 1), carried out a program of Cognitive Behavioral Therapy (CBT), and showed that the program may be effective for mitigating impairment of daily activities. This model, which is called “fear-avoidance model” and advocated in chronic pain patients such as low back pain, is the model of the pain chronicity on the cognitive behavioral theory. In this model, pain catastrophizing and escape/avoidance behavior have a negative impact on daily disabilities and cause persisting pain8,9). Pain catastrophizing means a negative cognitive response for pain such as
as helplessness and rumination\(^8,9\). It is a major factor in the pain sustainment/exacerbation model and the strongest predictive power in making of the pain chronicity\(^10\). Escape/avoidance behavior is to avoid the behavior thought that the soreness is caused or the soreness becomes awful\(^9\). Although escape/avoidance is an adaptive behavior in the acute pain\(^11\), it is a maladaptive coping in the chronic pain and leads making of the soreness chronic\(^12-14\).

Intervention to reduce pain-associated catastrophic thoughts and escape/avoidance behaviors in patients with chronic back and lumbar pain has been reported to be effective for alleviating clinical symptoms of pain and impairment of daily activities\(^15-18\). Also, in consideration of the pain sustainment/exacerbation model derived from patients with TTH, a combination of interventions in pain-associated catastrophic thoughts and escape/avoidance behaviors is expected to have a therapeutic effect on impairment of daily activities\(^6\). However, no study on the effect of a combination of interventions in catastrophic thoughts and escape/avoidance behaviors actually administered to patients on impairment of daily activities has been reported.

In this study, therefore, a program of CBT based on a pain sustainment/exacerbation model of TTH is actually carried out to validate its effects on pain sustaining/exacerbating factors. In addition to evaluating short-term effects immediately after the end of the program, the duration of the effect of intervention is also evaluated by measuring the effect 1 month after the end of the program. The therapeutic effects are also evaluated specifically in patients who participated in the therapeutic program as a pilot study.

### METHODS

1. **Participants**

   The participants were 4 patients who consulted the outpatient clinic of Fukushima Medical University hospital primarily due to headache, and were diagnosed with TTH (based on the International Classification of Headache Disorders – II (ICHD-II)\(^19\)). Those who were suggested based on organic disorders, etc., to have secondary headache were excluded from the subjects. Case 1 (65-year-old) and Case 3 (30-year-old) are female, and Case 2 (68-year-old) and Case 4 (23-year-old) are male.

   Table 1 shows the characteristics of each patient according to the headache interview form. In the patients enrolled in this study, the duration of illness ranged from 1 to 20 years and was less than 5 years in 3 of the 4 patients. Concerning disorders related to the head, a history of cerebral infarction was present in 1 patient (Case 1), but the other 3 had no history. The score for fear of contracting (or recurrence of) head disorders was moderate (6) in 1 (Case 3) but was low in the remaining 3.

2. **Contents of the program**

   It consisted of 4 individualized sessions, and a follow-up examination was carried out 1 month after its completion. The sessions, each of which was 60 minutes long, were executed at weekly intervals. A textbook containing the contents of the sessions, “How to wisely deal with headache”, was prepared and used. Homework (HW) was assigned after each session, and the participants were asked to submit it at the next session.

<table>
<thead>
<tr>
<th>Case</th>
<th>Age</th>
<th>Sex</th>
<th>Duration of illness (years)</th>
<th>Presence or absence of diseases related to the head</th>
<th>Fear of (the recurrence) of diseases related to the head (0-10)</th>
<th>Possible causes of headache</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>65</td>
<td>F</td>
<td>20</td>
<td>Cerebral infarction</td>
<td>3</td>
<td>stiff shoulder, fatigue/overwork</td>
</tr>
<tr>
<td>2</td>
<td>68</td>
<td>M</td>
<td>1</td>
<td>none</td>
<td>2</td>
<td>none</td>
</tr>
<tr>
<td>3</td>
<td>30</td>
<td>F</td>
<td>4</td>
<td>none</td>
<td>6</td>
<td>stress, stiff shoulder, menstruation, fatigue/overwork</td>
</tr>
<tr>
<td>4</td>
<td>23</td>
<td>M</td>
<td>3</td>
<td>none</td>
<td>1</td>
<td>stress, stiff shoulder, fatigue/overwork</td>
</tr>
</tbody>
</table>
(1) Session 1 (Week 1)

The objectives of Session 1 were to promote the understanding of clinical symptoms of headache and sustainment/exacerbation of pain, and to have the participants learn techniques to cope with their symptoms. Concerning the understanding of clinical symptoms of headache and sustainment/exacerbation of pain, the epidemiology and clinical characteristics of headache and typical cases of TTH were presented to help the participants understand their symptoms, and psychological education to promote understanding of the psychosomatic mechanism of sustainment/exacerbation was given. In addition, self-monitoring using a headache diary was performed to have the participants follow-up changes in their clinical symptoms and identify and evaluate factors related to symptomatic changes. At the end of the session, the progressive relaxation technique was taught as a measure to cope with TTH.

(2) Session 2 (Week 2)

The objective of Session 2 was to modify the participants’ catastrophic thoughts about pain. First, the entries of the headache diary and execution records of the relaxation technique assigned as HW were reviewed and fed back to check the changes in the clinical symptoms of headache that occurred during the past week and factors related to the symptoms and to evaluate perceived changes in the symptoms after practicing the relaxation technique and psychological and physical effects of the technique. Then, after reviewing the mechanism of sustainment/exacerbation of pain explained in Session 1, the relaxation technique was performed, followed by training to modify inappropriate perceptions about pain. Specifically, a situation that causes pain was presented, thoughts and feelings elicited by the situation were organized, and the relationships between clinical symptoms of headache and perceptions and emotions about pain were evaluated. The participants were also urged to write down various thoughts about pain in the diary.

(3) Session 3 (Week 3)

The objective of Session 3 was to modify catastrophic thoughts about pain similarly to Session 2. First, as in the previous session, the contents of HW were checked and fed back, the contents of Session 2 were reviewed, and the relaxation technique was performed. Then, in Session 3, the participants were taught methods to induce adaptive perceptions about pain and practiced them to understand that symptoms of headache and mood change with changes in perceptions about pain using the patients’ actual situations of headache.

(4) Session 4 (Week 4)

The objective of Session 4 was to modify escape/avoidance behaviors. After the contents of HW were checked and fed back, practice to modify escape/avoidance behaviors was performed. Specifically, how escape/avoidance behaviors are related to the sustainment/exacerbation of pain and how escape/avoidance behaviors can be corrected were explained using examples mentioned in the textbook, and exposure was carried out by presenting the actual escape/avoidance behaviors of the patients themselves. In exposure, the participants reported that fear of activities that cause pain decreases with time if they do not avoid them and confirmed that fear is mitigated, and the time until the mitigation of fear is shortened, by repeatedly performing the actions that they have avoided.

3. Measures

(1) Headache interview form

- Presence or absence of diseases related to the head: Answers about the past history and familial history of diseases related to the head were obtained.
- Fear of (the recurrence of) diseases related to the head: Answers concerning fear of contracting (or recurrence of) diseases related to the head were obtained using a 11-point scale (0: No fear, to 10: Very strong fear).
- Frequency of headache: Answers were obtained as the number of days with headache during the past month.
- Duration of illness: The subjects were asked when they first experienced headache of the present type. (a: This is the first time. b: ( ) days ago. c: ( ) months ago. d: ( ) years ago)
- Intensity of headache: Answers were obtained using an 11-point scale (0: No pain, to 10: Severe pain).
- Possible causes of headache: The subjects were asked to choose all items they considered possible from those mentioned in an inquiry sheet.
- Controllability: The controllability of headache by the subjects’ customary measures to control it was asked using an 11-point scale (0: Completely uncontrollable, to 10: Very controllable).
- Presence or absence of Analgesic (If present: frequency)

(2) Pain Catastrophizing Scale (PCS)

This is a scale to measure catastrophic thoughts about pain consisting of 5-point scales with 13 items (score range: 0-52).
(3) Pain Anxiety Symptoms Scale-20 (PASS-20)\textsuperscript{22}

This is a scale to measure fear of pain consisting of 6-point scales with 20 items. In this study only “escape/avoidance behaviors”, a subscale of the PASS-20, was used for the analysis (score range: 0-25).

(4) Headache Impact Test-6 (HIT-6)\textsuperscript{23}

This is a scale to measure the severity of impairment of daily activities due to chronic headache consisting of 5-point scales with 6 items (score range 36-78). The severity of headache related daily disabilities according to the HIT-6 score based on the report by Sakai et al.\textsuperscript{23} was “none” (≤49), “mild” (50-54), “moderate” (55-59) and “severe” (≥60).

(5) Hospital Anxiety and Depression Scale (HADS)\textsuperscript{24}

This is a scale to measure anxiety and depression in patients with physical symptoms consisting of 7 items each concerning anxiety and depression. In this study, only 7 items related to depression were used (score range: 0-21).

4. Ethical consideration

In executing this study, the attending physician and clinical psychologist orally explained the study according to the contents of the study enrollment form. The consent form specifically described the withdrawal of the consent, medical use of the information, protection of personal information, etc., in addition to the investigation items.

This interventional study was carried out after evaluation and approval by the ethical review board.

RESULTS

1. Changes in catastrophic thoughts about pain and escape/avoidance behaviors

Fig. 2 and 3 show the changes in the scores of the PCS and escape/avoidance behaviors of the PASS-20 in the participants. The score of the PCS decreased after Session 4 compared with before Session 1 in all patients. At the follow-up 1 month after the end of the program, the score was slightly increased compared with that immediately after the program in 1 but decreased further or remained the same in the other 3. The score of escape/avoidance behaviors of the PASS-20 was reduced at the follow-up compared with the score before Session 1 in 3 patients except 1 (Case 2), in whom the score was 0 throughout the study.

2. Degree of impairment of daily activities

Fig. 4 shows changes in the total HIT-6 score. It decreased after compared with before the program in all patients. The degree of impairment of daily activities changed from “mild” to “none” in 2 (Cases 1 and 2) and from “severe” to “none” in 1 (Case 4), resulting in alleviation to “none” in all but Case 3, in whom the impairment remained “severe” despite a decrease in the score.

Concerning changes in the HIT-6 score from after the program until the follow-up, it decreased in 2 and remained the same in 2, and the level of impairment of daily activities at the follow-up was “none” in 3 and “mild” in 1.

3. Clinical symptoms of headache, controllability, medications, and depression

Table 2 shows changes in clinical symptoms of headache (frequency and intensity), controllability of headache, medications and the HADS score.

The frequency of headache decreased after compared with before the program in 3 and remained reduced at the follow-up in 2 of them. In 1 of the 3 patients who showed a decrease at the end of the program, the frequency was increased at the follow-
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up but was lower than the level before the program. The frequency showed no change from before the program to the follow-up in 1. The intensity of headache was reduced after the program or at the follow-up compared with before the program in all patients, and no temporary increase was noted at the end of the program in any patient.

The controllability of pain improved in all patients after compared with before the program. At the follow-up, the score decreased slightly compared with immediately after the program in 1 but was 6 or higher in all patients, indicating that pain was moderately or highly controllable.

The state of no medication was maintained both at the end of the program and follow-up in 2 (Cases 2 and 4), who were not medicated before the program. In the 2 patients who were medicated before the program, the frequency of medication was reduced in both. The medication rate became 0% after the program and remained 0% until the follow-up in 1 (Case 1), and the medication rate at the end of the program remained unchanged until the follow-up in the other.

The depression score of the HADS decreased after the program and at the follow-up compared with before the program or remained unchanged, and a state of “no depression” was maintained in all 4 patients.

DISCUSSION

This study was carried out to evaluate the effectiveness of a program of CBT based on the pain sustainment/exacerbation model of TTH. The results showed that catastrophic thoughts and escape/avoidance behaviors associated with pain were reduced in patients with TTH by this program, which focused on mitigation of these symptoms. The degree of impairment of daily activities on the HIT–6 score improved to “none” in 3 of the 4 patients and to “mild” in 1. At the follow-up, impairment of daily activities remained alleviated, and catastrophic thoughts and escape/avoidance behaviors showed no marked exacerbation, remaining lower than the level before the program. These results were the same as the previous study intended for the chronic pain with the waist and the back. Also, a medical practice meaning of this short program is large in the point to have suggested effectiveness in severe patients with TTH such as Case 3 or Case 4.

Moreover, the controllability of pain improved to a moderate or higher level in all 4 patients through this program. Helplessness leads the decrease at the activity level and an increase in the psychological distress, and self-efficacy for pain management related to clinical symptoms of pain. So we can guess that an increase of the pain controllability relates to the improvement of pain-related cognitions, behaviors and daily disabilities. Concerning analgesic medication, the 2 patients did not use analgesics after as well as before the program, and those who used analgesics before the program showed decreases in the medication rate.

Table 2. Clinical symptoms of headache, controllability, analgesic, and depression

<table>
<thead>
<tr>
<th>Case</th>
<th>Frequency (0–31)</th>
<th>Intensity (0–10)</th>
<th>Controllability (0–10)</th>
<th>Analgesic Frequency (0–100%)</th>
<th>Subjective effect (0–100%)</th>
<th>HADS (0–21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>2.5</td>
<td>2.5</td>
<td>3</td>
<td>1</td>
<td>1</td>
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<tr>
<td>2</td>
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<td>0</td>
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<tr>
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<tr>
<td>4</td>
<td>20</td>
<td>3.5</td>
<td>10</td>
<td>5</td>
<td>5</td>
<td>4</td>
</tr>
</tbody>
</table>

Note
1. HADS: Hospital Anxiety and depression Scale
2. FU: Follow up
this program, participants might be flexible their
cognitions for pain. Therefore, they could learn the
adaptive coping for pain instead of analgesic when
the soreness was caused or the soreness became
awful.

Concerning individual patients, Case 1 showed
marked decreases in the scores of the PCS, escape/
avoidance behaviors and the HIT-6. So, this pro-
gram is considered to have been effective for reduc-
ing catastrophic thoughts, escape/avoidance and dai-
ly disability associated with headache in Case 1.
Case 1 had a 20-year history of TTH, but the results
of this study suggest that catastrophic thoughts and
escape/avoidance behaviors may be reduced, and the
degree of impairment of daily activities mitigated,
by this program even in patients with a long history of
TTH.

In Case 2, the PCS score decreased through the
program, but the score of escape/avoidance behav-
iors of PASS-20 was originally 0, indicating no es-
cape/avoidance behaviors, and did not increase after
the program. Concerning the degree of impairment
daily activities, the HIT-6 score decreased
through the program as in Case 1, and the scores at
the end of the program and at the follow-up both
corresponded to “none”. Therefore, in Case 2,
only catastrophic thoughts were reduced by the pro-
gram, leading to alleviation of impairment of daily
activities, and escape/avoidance behaviors did not
appear to have affected daily activities. Also, at the
follow-up, the scores of PCS and escape/avoidance
behaviors of the PASS-20 were 0, and the HIT-6
score was 36, which is the minimum score, with
complete disappearance of headache after the pro-
gram (2 before the program → 0 at the end of the
program and at the follow-up), indicating resolution
of both psychological and physical distresses associ-
ated with headache. Studies of chronic low back
pain and fibromyalgia syndrome reported that exces-
sive activities that markedly burden the site of injury
as well as escape/avoidance behaviors are important
as variables related to impairment of daily activities
due to low back pain. Some patients with
chronic pain allow pain to linger due to an uneven
activity pace, e.g., temporary overwork mixed with
strong escape/avoidance behaviors. Therefore, in
TTH, also, it is considered necessary to evaluate the
sustainment/exacerbation of pain due to disturbance
of the activity pace including temporary overwork
rather than the level of escape/avoidance behaviors
alone.

In Case 3, while the scores of the PCS, escape/
avoidance and the HIT-6 improved at the end of
compared with before the program, the improve-
ments were unsatisfactory, but they were improved
markedly at the follow-up. Also, impairment of
daily activities, which was severe both at the begin-
ning and end of the program, was alleviated to “mild”
at the follow-up. Case 3 characteristically showed
severe clinical symptoms of headache, “severe” im-
pairment of daily activities before the program, and
marked fear of contracting or the recurrence of head
Disorders. However, Case 4, who also had severe
clinical symptoms of headache and “severe” impair-
ment of daily activities before the program, showed
decreases in the scores of the PCS, escape/avoid-
ance behaviors of the PASS-20 and HIT-6 after the
program, with alteration of inappropriate perceptions
and behavior associated with pain, and impairment of
daily activities was alleviated to the “mild” level,
at the end of the program. Therefore, one of the
causes of the unsatisfactory improvement at the end
of the program in Case 3 is considered to have been
a strong fear of head disorders. Thus, if a patient is
preoccupied with fear of head disorders, it may in-
terfere with modification of catastrophic thoughts or
escape/avoidance behaviors, and the degree of im-
pairment of daily activities remains high, in a short-
term (4-week) program. Case 3 had a history of
hospitalization due to viral meningitis and experi-
enced repeated headache as an accessory symptom.
In the present illness, the patient worried about the
recurrence of viral meningitis, and the higher level
of fear of head diseases of this patient compared with
the other 3 may be related to this history of viral
meningitis. Since this suggests the presence of
factors interfering with the control of sustainment/
exacerbation of pain, it may be necessary, in patients
who show no effect after the program or at the fol-
low-up, to re-check their background and add ses-
sions with contents more appropriate for their condi-
tion to the program performed in this study.

There are two limitations in the present study.
The first point is to say four cases as a pilot study.
It is necessary to increase participants, to set the
control group and to make comparative study of the
effect. The second is to be able to pursue only one
month. TTH is easy to relapse and make chronic.
So, it is necessary to examine the effect after six
months and 1 year. Moreover, it is important to
clarify the feature between the patient not main-
tained with the one to whom the effect of the pro-
gram was maintained.
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ACKNOWLEDGEMENT

This work was supported by JSPS KAKENHI Grant Number 22830057.

CONFLICT OF INTEREST DISCLOSURE

The authors declare that they have no competing interests.

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