Based on the patient's rest/activity data recorded by actigraphy for 7 days, an estimation of their sleep was made using the algorithm devised by Cole *et al.*,[18] which has a capability of more than 90% agreement with nocturnal PSG.[19] From this result, the authors obtained the 7-day averaged data for objective SONT, SOFT, SOL, and the number of awakening episodes lasting more than 5 min (NOA), awakening time after sleep onset (WASO), TST, sleep efficiency (SE), and moving time during sleep (MT). SE was also calculated as the percentage of objective TST for each patient's actigraphy chart per TIB, recorded objectively on the sleep log by family members, as indicated above.

Pittsburgh Sleep Quality Index

The authors assessed for sleep quality and quantity using the Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J).[20] PSQI-J consists of seven components, (i) overall sleep quality (SLPQUAL), (ii) sleep latency (LATEN), (iii) duration of actual sleep time (DURAT), (iv) sleep efficacy (HSE), (v) sleep disturbance (DISTB), (vi) medications necessary to sleep (MEDS), and (vii) day dysfunction due to sleepiness (DAYDYS). Each component was rated from 3 to 0, with global PSQI-J scores rating from 21 to 0.

Dysfunctional Beliefs and Attitudes about Sleep Scale

Sleep-related cognition plays an important role in perpetuating insomnia, and it is reported that reduction of DBAS is correlated with improvement of sleep parameters. Therefore in the present study, the authors used the Japanese version of the DBAS (DBAS-J)[21] to grasp the patients' faulty cognition about sleep. The DBAS is a self-recorded questionnaire developed by Morin *et al.*[17] It consists of a 28-item scale that extracts various beliefs and attitudes about sleep, focusing on the following five themes: (i) consequences of insomnia, (ii) control and predictability of sleep, (iii) sleep requirement expectations, (iv) causal attributes of insomnia, and (v) sleep-promoting practices. A higher score indicates a more dysfunctional belief. The average scores for the five themes were compared between the pre- and post-treatment situations.

Statistical analysis

Data were analyzed using Stat View-J5.0 for Windows (SAS Institute, Tokyo, Japan). Each parameter for demographic data was compared between the two groups, I-CBT-I and G-CBT-I, using the unpaired *t*-test or χ^2 test. Analysis of variance (ANOVA) with repeated measures was used to determine variances over time (pre-treatment and post-treatment), between the two groups (I-CBT-I and G-CBT-I), along with the interaction of the group over time. *P*-values of group difference were calculated using pre-treatment data. Statistical significance was determined at $P < 0.05$.

Approval of the study

The study protocol and therapy regimen were approved by the Jikei University School of Medicine Ethics Committee. Written informed consent to participate in the study was obtained from all the participants after they were given an explanation of the study and its potential risks. All of the procedures were carried out in accordance with Good Clinical Practice, the Helsinki Declaration, and related laws.

RESULTS

Table 2 shows comparisons of demographic and clinical variables; no significant differences were seen between

Table 2 Comparison of demographic variables for the patients between I-CBT-I and G-CBT-I

	I-CBT-I ($n = 20$)	G-CBT-I ($n = 25$)
Age (years, [range])	56.9 ± 12.6 [27–76]	61.7 ± 11.3 [35–81]
Sex (M:F, [%male])	6:14 [30.0]	14:11 [56.0]
Duration of insomnia (years, [range])	8.9 ± 6.2 [1–22]	8.0 ± 6.4 [0.5–21]
Dairy dosage of hypnotics (flunitrazepam1 mg = 1, [range])	1.6 ± 1.2 [0–4.0]	1.9 ± 1.1 [0.33-4.0]
Pre-treatment global PSQI-J scores [range]	12.7 ± 3.0 [6–18]	12.2 ± 2.4 [9–17]
No. drop-out patients (%)	4/24 (16.7)	4/29 (13.8)

Mean ± SD or N unpaired *t*-test, χ^2 test: N.S. Duration of insomnia: the subjectively reported period from initial appearance of insomnia to the time of receiving CBT-I. PSQI-J: the Japanese version of the Pittsburgh Sleep Quality Index.

the patients of I-CBT-I and G-CBT-I regarding age, sex, duration of insomnia, daily dosage of hypnotics, pre-treatment global PSQI-J scores, and the numbers of dropout patients.

Table 3 through to Table 6 shows the results from sleep logs (Table 3), actigraphy (Table 4), PSQI-J (Table 5), and DBAS-J (Table 6). The results of ANOVA with repeated measures were as follows. There was a significant group effect for NOA ($P = 0.010$) as measured by actigraphy and for DISTB ($P = 0.032$) as measured by PSQI-J. There was a significant time effect for bed time ($P = 0.003$), rising time ($P = 0.001$), SOL ($P = 0.001$), and TST ($P = 0.009$), as measured by sleep logs, for SOL ($P = 0.001$), WASO ($P = 0.001$), TIB ($P = 0.001$), SE ($P = 0.001$), and MT ($P = 0.006$), as measured by actigraphy, for SLPQUAL ($P = 0.001$), LATEN ($P = 0.001$), DURAT ($P = 0.001$), HSE ($P = 0.034$), global PSQI-J ($P = 0.001$) as measured by PSQI-J and for consequences of insomnia ($P = 0.001$), control and predictability of sleep ($P = 0.001$), sleep requirement expectations ($P = 0.001$), and sleep-promoting practices ($P = 0.001$) as measured by DBAS-J. Further, there was a significant group × time interaction for SOL ($P = 0.004$) as measured by sleep logs, for SOL ($P = 0.001$), SE ($P = 0.017$), and MT ($P = 0.046$) as measured by actigraphy, for SLPQUAL ($P = 0.046$) and DURAT ($P = 0.023$) as measured by PSQI-J, and for consequences of insomnia ($P = 0.001$), control and predictability of sleep ($P = 0.001$), sleep requirement expectations ($P = 0.040$), and sleep-promoting practices ($P = 0.004$) as measured by DBAS-J. Figure 1 shows a comparison of changes in the themes of DBAS-J between I-CBT-I and G-CBT-I.

Table 3 Comparison of changes in sleep logs between I-CBT-I and G-CBT-I

	Pre-treatment		Post-treatment		*P*-value		
	I-CBT-I	G-CBT-I	I-CBT-I	G-CBT-I	G	T	G × T
Bedtime (h)	23.1 ± 0.3	23.3 ± 0.3	23.7 ± 0.2	23.6 ± 0.2	0.917	0.003*	0.209
Rising time (h)	7.2 ± 0.2	7.1 ± 0.2	6.8 ± 0.2	6.8 ± 0.2	0.836	0.001*	0.738
SONT (h)	24.3 ± 0.3	24.1 ± 0.3	23.8 ± 0.3	24.1 ± 0.2	0.819	0.236	0.261
SOFT (h)	5.9 ± 0.3	5.7 ± 0.2	6.1 ± 0.3	6.0 ± 0.2	0.695	0.069	0.897
SOL (min)	69.3 ± 8.5	46.9 ± 6.0	26.3 ± 3.4	31.5 ± 2.7	0.181	0.001*	0.004*
TST (min)	328.6 ± 17.4	324.8 ± 12.7	351.9 ± 10.3	348.2 ± 7.7	0.807	0.009*	0.999

Mean ± SE, I-CBT-I: individual CBT-I ($n = 20$), G-CBT-I, group CBT-I ($n = 25$). Analysis of variance (ANOVA) with repeated measures, G, groups (individual vs group), T, time (Pre-treatment vs Post-treatment), G × T, interaction, *P*-values of Group difference were calculated using pre-treatment data. *$P < 0.05$. SOFT, sleep offset time; SOL, sleep onset latency; SONT, sleep onset time; TST, total sleep time.

Table 4 Comparison of changes in actigraphy between I-CBT-I and G-CBT-I

	Pre-treatment		Post-treatment		*P* value		
	I-CBT-I	G-CBT-I	I-CBT-I	G-CBT-I	G	T	G × T
SONT (h)	23.6 ± 0.3	23.7 ± 0.3	23.8 ± 0.2	24.0 ± 0.2	0.766	0.105	0.916
SOFT (h)	6.8 ± 0.3	6.6 ± 0.2	6.7 ± 0.2	6.5 ± 0.2	0.497	0.290	0.945
SOL (min)	30.4 ± 6.2	20.0 ± 2.2	7.2 ± 1.0	20.1 ± 2.8	0.743	0.001*	0.001*
NOA (times)	3.1 ± 0.7	1.5 ± 0.2	2.9 ± 0.7	1.4 ± 0.1	0.010*	0.487	0.991
WASO (min)	24.9 ± 4.1	15.9 ± 2.8	15.8 ± 2.5	12.5 ± 2.1	0.109	0.001*	0.098
TIB (min)	475.5 ± 18.6	458.4 ± 12.6	425.6 ± 10.3	428.3 ± 8.5	0.636	0.001*	0.309
TST (min)	397.0 ± 10.8	388.1 ± 11.5	391.4 ± 9.3	376.0 ± 9.6	0.377	0.146	0.589
SE (%)	84.4 ± 1.9	85.5 ± 1.7	92.1 ± 0.8	88.5 ± 1.4	0.522	0.001*	0.017*
MT (counts/min)	10.4 ± 1.0	8.2 ± 0.9	8.4 ± 0.8	7.9 ± 0.8	0.254	0.006*	0.046*

Mean ± SE, I-CBT-I: individual CBT-I ($n = 20$), G-CBT-I: group CBT-I ($n = 25$). Analysis of variance (ANOVA) with repeated measures, G: groups, T: time, G × T, interaction, *P*-values of Group difference were calculated using pre-treatment data. *$P < 0.05$. MT, moving time during sleeping; NOA, numbers of awakening episodes lasting more than 5 min; SE, sleep efficiency; TIB, total time in bed; WASO, awakening time after sleep onset.

Table 5 Comparison of changes in PSQI-J between I-CBT-I and G-CBT-I

	Pre-treatment		Post-treatment		*P*-value		
	I-CBT-I	G-CBT-I	I-CBT-I	G-CBT-I	G	T	G × T
SLPQUAL (C1)	2.3 ± 0.1	2.1 ± 0.1	1.2 ± 0.1	1.5 ± 0.1	0.443	0.001*	0.046*
LATEN (C2)	2.4 ± 0.2	2.0 ± 0.2	1.6 ± 0.2	1.4 ± 0.2	0.242	0.001*	0.310
DURAT (C3)	2.3 ± 0.2	1.8 ± 0.2	1.4 ± 0.2	1.6 ± 0.1	0.430	0.001*	0.023*
HSE (C4)	1.6 ± 0.3	1.4 ± 0.2	0.9 ± 0.2	1.0 ± 0.2	0.920	0.034*	0.461
DISTB (C5)	1.0 ± 0.1	1.2 ± 0.1	1.0 ± 0.1	1.2 ± 0.1	0.032*	0.999	0.999
MEDS (C6)	2.5 ± 0.2	2.8 ± 0.1	2.4 ± 0.3	2.8 ± 0.1	0.144	0.352	0.589
DAYDYS (C7)	0.8 ± 0.2	0.8 ± 0.1	0.5 ± 0.1	0.8 ± 0.1	0.213	0.150	0.295
Global PSQI-J	12.7 ± 0.7	12.2 ± 0.5	8.9 ± 0.6	10.1 ± 0.7	0.615	0.001*	0.066

PSQI-J: the Japanese version of Pittsburgh Sleep Quality Index, I-CBT-I: individual CBT-I ($n = 20$), G-CBT-I: group CBT-I ($n = 25$), mean ± SE, Analysis of variance (ANOVA) with repeated measures, G: groups, T: time, G × T: interaction, *P*-values of Group difference were calculated using pre-treatment data. *$P < 0.05$. dayDYS, day dysfunction due to sleepiness; DISTB, sleep disturbance; DURAT, duration of actual sleep time; HSE, sleep efficiency; LATEN, sleep latency; MEDS, need medications to sleep; SLPQUAL, overall sleep quality.

Table 6 Comparison of changes in DBAS-J between I-CBT-I and G-CBT-I

	Pre-treatment		Post-treatment		*P*-value		
	I-CBT-I	G-CBT-I	I-CBT-I	G-CBT-I	G	T	G × T
Consequences of insomnia	5.5 ± 0.5	5.7 ± 0.4	3.0 ± 0.6	5.1 ± 0.4	0.053	0.001*	0.001*
Control and predictability of sleep	4.9 ± 0.4	4.8 ± 0.3	2.7 ± 0.5	4.2 ± 0.4	0.163	0.001*	0.001*
Sleep requirement expectation	4.2 ± 0.6	3.8 ± 0.3	2.3 ± 0.4	3.2 ± 0.3	0.567	0.001*	0.040*
Causal attributions of insomnia	3.4 ± 0.5	3.7 ± 0.5	2.2 ± 0.5	3.5 ± 0.4	0.153	0.074	0.179
Sleep-promoting practices	3.5 ± 0.4	3.4 ± 0.3	1.7 ± 0.2	3.1 ± 0.3	0.091	0.001*	0.004*

DBAS-J, Dysfunctional Beliefs and Attitudes about Sleep scale Japanese version. I-CBT-I, individual CBT-I ($n = 20$), G-CBT-I: group CBT-I ($n = 25$), mean ± SE. Analysis of variance (ANOVA) with repeated measures. G, groups; T, time; G × T, interaction; *P*-values of Group difference were calculated using pre-treatment data. *$P < 0.05$.

DISCUSSION

Controlled trials have established the efficacy of CBT-I for primary insomnia.[5,6] However, the relative efficacy of individual versus group treatment formats in real-world settings is not well established. The present study compared the short-term efficacy in a clinical setting between I-CBT-I and G-CBT-I for primary insomnia outpatients undergoing the same treatment components and providers. This trial represents the first attempt to compare different formats of CBT-I using actigraphy as the objective sleep measurement. As there is reportedly an underestimation of objective sleep evaluation and dissociations between subjective and objective evaluation of sleep in primary insomnia,[22] it is important to evaluate the therapeutic changes in objective measurements.

The findings in the present study complemented previous studies[3,4,7] showing that CBT-I was effective treatment for primary insomnia. The comparison of pre-treatment to post-treatment, as the short-term outcome, showed that CBT-I produced significant changes in many parameters. In the post-treatment measurements, subjective bedtime was delayed, subjective rising time was advanced, subjective TST increased, subjective and objective SOL shortened, objective TIB, WASO, and MT decreased, and objective SE increased. All of these suggested the improvement of nocturnal sleep after the treatment. At the same time, subjective evaluations of sleep quality and quantity improved, and the patients' faulty cognition about sleep was corrected after the treatment.

In the present study, different outcomes between I-CBT-I and G-CBT-I were shown. In regard to objective and subjective sleep onset latency time, objective sleep efficacy and moving time during sleeping, overall sleep quality and duration of actual sleep time in PSQI, the consequences of insomnia, control, and predictability

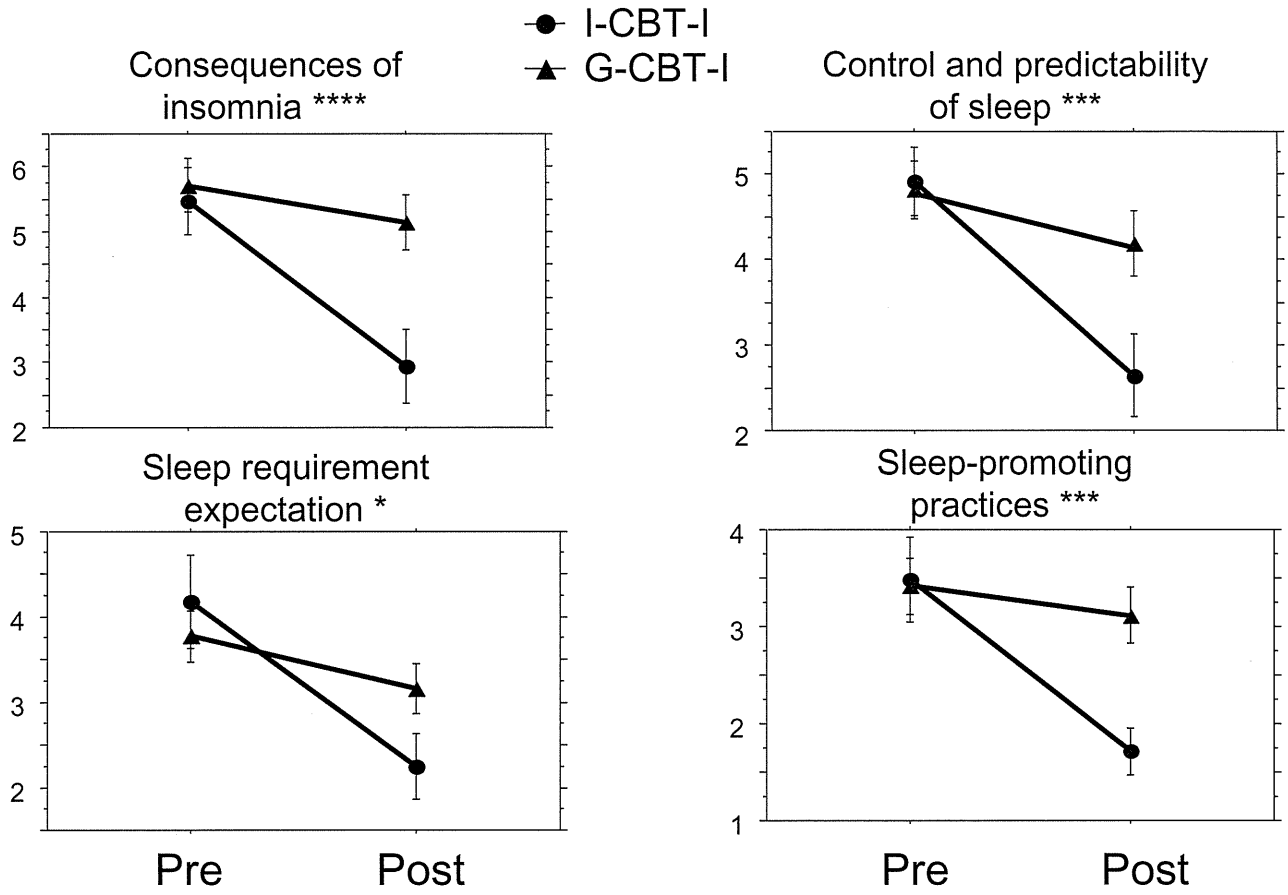

Figure 1 Comparison of changes in sleep-related cognition (DBAS-J) between I-CBT-I and G-CBT-I. DBAS-J: Dysfunctional Beliefs and Attitudes about Sleep Scale, Japanese version. Mean ± SE, Analysis of variance (ANOVA) with repeated measures, G × T: interaction, $^{*}P < 0.05$, $^{***}P < 0.005$, $^{****}P < 0.001$.

of sleep, sleep requirement expectation, and sleep-promoting practices in DBAS, I-CBT-I resulted in larger improvements compared with G-CBT-I. Although these results were contrasted with the previous studies[8,9,23] the present study suggested a slight superiority of I-CBT-I over G-CBT-I in the improvements of not only subjective but also objective sleep measurements. Furthermore, the superiority was remarkable in the correction of dysfunctional beliefs and attitudes about sleep. One reported advantage of I-CBT-I is its fit within traditional medical and mental health outpatient settings. I-CBT-I also allows maximum flexibility in tailoring treatment to best address each individual patient's problematic sleep-related cognition and behavior.[6] On the other hand, G-CBT-I may afford patients less individualized attention.[6] A possible explanation will be able to propose that patients who are more severely insomniac or socially anxious may generally find it harder to engage in group treatment, and therapists in a group setting may have less opportunity to address specific patient needs. Most previously described G-CBT-I protocols were typically provided in four to eight treatment sessions to a group of patients.[6] Another explanation will be able to propose that numbers and hours spent in the sessions in this study may be insufficient. It will be important for future research to determine if individual and group CBT-I have a similar or different relationship to the maintenance of efficacy in routine clinical settings.

Concerning CBT for depression, a clinical study that investigated outcome, costs, and patient engagement for group and individual CBT for depression mentioned that no significant differences were found in depressive symptoms between group and individual CBT at post-treatment and follow-up, and concluded that there were no differences between group differences in attrition or satisfaction.[24] Another recent study that evaluated the

effectiveness of group CBT compared to individual CBT for depressed outpatients mentioned that individual CBT was associated with larger effect sizes and significantly higher rates of recovery compared with group CBT.[25] Regardless, systematic cost-effectiveness and cost-benefit comparisons between individual and group CBT for primary insomnia or depression have not yet been conducted. From a cost-effectiveness perspective, however, there are certainly advantages to implementing treatment in a group format.[5,6] Future research should seek to replicate these findings under similar and controlled conditions, and to establish the comparative cost-effectiveness of each format of treatment.

The present study has several limitations. The first limitations of the present study lie in the fact that there was no randomization for I-CBT-I and G-CBT-I. The periods of implements were also different for a few years. Not all of the present results can be considered to indicate the efficacy of CBT-I. All of the participants wished to receive CBT-I and therefore might have been very motivated. The second limitation lies in the fact that there was no control group. In the absence of a control group, it is impossible to rule out improvements over time. The third limitation lies in the fact that the authors could observe and compare only the short-term outcome. It is important to keep in mind and follow up on the fact that primary insomnia patients who benefit from short-term evaluation might remain vulnerable to recurrent insomnia episodes in the long term. In the present study, however, at 6 months after the treatment, sleep improvements and drug tapering achieved with G-CBT-I patients were well sustained.[12] Although these limitations should be further discussed, in conclusion, the findings of the present study support the view that in a more clinically representative setting, I-CBT-I is a superior treatment format for primary insomnia compared to G-CBT-I.

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DISCLOSURE STATEMENT

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