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Title Page
A randomised controlled trial on evaluation of the clinical efficacy of massage therapy in a multisensory environment for residents with severe and profound intellectual disabilities: A pilot study

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E-mail: wai.tong.chien@polyu.edu.hk; Fax: 852-2364 9663' Tel: 852-2766 5648A randomised controlled trial on evaluation of the clinical efficacy of massage therapy in a multisensory environment for residents with severe and profound intellectual disabilities: A pilot study

Abstract

Background. Recent literature has suggested that relaxation activities can reduce the challenging behaviours of people with intellectual disabilities, particularly those with severe and profound grade, due to the counteractive effect of muscle relaxation on emotional distress. Despite indicating inconclusive results, multisensory environment (MSE) and massage therapy (MT) are common methods used separately of relaxation among these people, but they are seldom practiced and tested in combined use for reducing challenging behaviour of these people.

Methods. A pilot randomised controlled trial was conducted to evaluate the effects of MT, MSE and their combined use for residents with intellectual disabilities on reducing their challenging behaviours in a long-term care facility. Eligible residents were recruited and randomly assigned into one of the four study groups, i.e. MT in MSE, MSE alone, MT alone, and usual care, for 10 weeks intervention after one month washout period. Outcome measures, including Behaviour Problem Inventory, pulse and respiration rates, Behaviour Checklist, and Alertness Observation Checklist, were assessed at recruitment and immediately after completion of the interventions.

Results. In total, 42 participants (17 males and 25 females) completed the study. Results of nonparametric test indicated that there were no significant differences in frequency and severity of challenging behaviours and physiological responses of the participants between the four study groups. The adaptive and maladaptive behaviour also showed no statistical differences between the three treatment groups. Only alertness level was significantly different between the three treatment groups and one control group. The severity nature of intellectual disability affected the interaction between residents and their environment, considering capacity of perceptual and information processing in response to external stimuli. The sensory stimulations may make persons with severe and profound ID exhausted and much reduced attention span. Such exhaustion was very brief and would not relate to social withdrawal. But it was a state of "passive alertness" where attention span on environment was maintained and in context socially.

Conclusions. This pilot randomised controlled trial showed that participants of massage therapy in multisensory environment (MT-MSE) acquired more inactive state than other groups. A clear delineation of "passive alertness", which belongs to active state, should be highlighted, especially studies related to persons with severe and profound ID.

Keywords: severe and profound intellectual disability, massage therapy, multisensory environment, challenging behaviours, relaxation, alertness

Introduction

Intellectual disability (ID) is a long-term condition and required substantial community resources to facilitate ID persons in daily living (Maulik et al. 2011). The diagnostic criteria of intellectual disability include three components: (a) mental age or intellectual functioning is significantly sub-average than normal people; (b) at least two adaptive functions, in areas of communication, social and interpersonal skills, use of community resources and self-directed activities, are severely disturbed; and (c) the onset of ID must occur before 18 years-old (American Psychiatric Association 2013). The global prevalence of ID is between 1% and 3% in the general population (Emerson & Einfeld 2011).

In Hong Kong, the prevalence of intellectual disability (ID) is about 1-1.4% of the general population accounting for about 71 000 to 101 000 persons [Census and Statistics Department, Hong Kong (HKSAR) 2014; Labour and Welfare Bureau, HKSAR 2016]. The estimated number of severe and profound ID in accordance to the four-tier classification of Diagnostic and Statistical Manual of Mental Disorders (DSM) is about 5% of the ID population (Rehabilitation Division, Health and Welfare Bureau, Government Secretariat 1999), which is comparable to overseas data (American Psychiatric Association 2013).

Challenging behaviour is common among individual with ID because challenging behaviour is often interpreted as a desire for attention or an expression of distress resulting from their limited communication and language understanding abilities (González et al. 2009), especially for those severe and profound ID (Vlaskamp *et al.* 2003; Vlaskamp & Nakken 1999).

The new definition of challenging behaviour has addressed the importance of social constructs. It refers to "culturally abnormal behaviour of such an intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour that is likely to seriously limit use of, or result in the person being denied access to, ordinary community facilities" (Emerson & Einfeld 2011, p.7). In England, the prevalence rate of "more demanding" challenging behaviour in ID persons is 4.5 per 10000, accounting to 10-15% in ID persons with displaying self-injurious behaviour, aggressive behaviour toward others, and destructive behaviour to immediate environment (Emerson & Einfeld 2011). Whereas the prevalence rate of challenging behaviour of these people in Norway is 11.1% (Holden & Gitlesen 2006). According to a Hong Kong survey conducted in the research setting (Lee & Tso 2011), the prevalence rate of their challenging behaviours was 68.87%. The major patterns of challenging behaviour included various forms of self-stimulating behaviours, in which the persons with ID frequently ignored the immediate environmental stimulations if not intervened. Some exhibited self-injurious behaviours, and a few presented aggressive behaviours (Lee & Tso

2011).

Most literature has suggested appropriate use of relaxation could reduce challenging behaviours (Chan et al. 2010; Deakin 1995; Lindsay & Baty 1986; Schilling & Poppen 1983). Relaxation generally means "unspecified states of psychophysical easing of tension or resting" or just "absence of tension" (Kokoszka 1992, p.4). The assumption is that muscle relaxation could not coexist in emotionally excited persons and could eventually alleviate physiological arousal (Chan et al. 2010).

Both multisensory environment (MSE) (Ashby et al. 1995; Chan et al. 2007; Slevin & McClelland 1999) and massage therapy (MT) (Croghan 2009; Solomons 2005) are not cognitively demanding and frequently adopted to promote relaxation for persons with severe and profound ID. Massage was believed promoting relaxation and body awareness, and the relationship between residents and staff could be substantially improved due to physical proximity and tenderness during the massage process (Ayer, 1998). For persons with challenging behaviours, the specific purpose of using massage therapy was to divert their attention to experience pleasure, and induce relaxation (McEvoy et al., 1987). Despite the limited relaxation effects noted, MSE alone could bring about reduction in challenging behaviours of people with ID (Lindsay et al. 1997; 2001).

Indeed, studies showed that MT alone or MSE only could produce positive outcomes (Croghan 2009; Hegarty & Gale 1996; Lindsay et al. 1997; 2001). These studies used crossover design to evaluate the individual effects of MSE and MT with neither combined use of MSE and MT nor involving a control group. There were a few studies using MT in MSE (Ayer 1998; Hutchinson & Hagger 1994), but largely focused on MSE effect relating to relaxation, and leisure enjoyment. There was also no evaluation of the effect of the combined MSE and massage therapy versus individual therapies and versus usual care. Whether massage therapy in MSE can produce significant relaxation effect and subsequently reduce challenging behaviours and increase adaptive behaviours are still uncertain. The combined use of these therapies, if found effective, may breakthrough the barrier of visual and hearing loss to maximise their sensory pleasure and adaptation to the institutional environment. Therefore, the aim of this study was to evaluate the effectiveness of multisensory environment (MSE) and massage therapy (MT), either single or combined (MT-MSE), in reducing challenging behaviours of people with ID in residential care. This study also examined the potential confounding variables of drug regime, family visits, and social activities on challenging behaviours (Ali et al. 2014).

Hypotheses

Three hypotheses were tested in this study:

- There was a reduction of frequency and severity of challenging behaviours in MT-MSE, MSE, and MT than the control group immediately after completion of 10-week interventions.
- There were a lower pulse and respiration rates, decrease maladaptive, but increase adaptive behaviours and alertness level in the three treatment groups than the control group after completion of the interventions.
- The combined effect of MT-MSE had lowest frequency and severity of challenging behaviours than individual interventions.

Methods

Study design

The pilot study adopted a pre- and post-test design to explore the process of subject selection, data collection and methods of data analysis for the preparation of a larger scale of future study. The pilot study was conducted between February and May 2013.

Setting

The research setting was an infirmary care centre of a regional mental hospital exclusively for adults with severe and profound ID. The institution comprised 10 units with 500 beds. All residents were required the assistance of direct care staff in daily living activities.

Participants

Most of the potential subjects were not mentally fit for giving consent and thus proxy consents were obtained from their parents, next-of-kin or guardians. Anonymity and confidentiality of personal data were strictly assured. Ethical approvals to conduct this study was granted by the Human Subjects Research Ethics Committee of The Hong Kong Polytechnic University, and the hospital under study.

As this study aimed at reducing challenging behaviours of the residents, only those displaying challenging behaviours in recent two months were included. Other inclusion criteria of participants were the residents who:

- admitted into the long-term care residence for at least 3 months with clear observation and records of their daily behaviour;
- aged 18 to 64 years (i.e., skin texture and mechanoreceptors' reactions to pressure were not much reduced, as suggested by literature (Gescheider et al. 1994; Humes et al. 2009).

The exclusion criteria included:

- being seriously ill or physically unwell that prevented their attendance of intervention sessions;

- having infectious diseases, e.g., Methicillin-resistant staphylococcus aureus (MRSA);
- being restless and resistive to stay in MSE or to receive massage therapy; and
- having severe deformity in limbs that make massage therapy hard to apply.
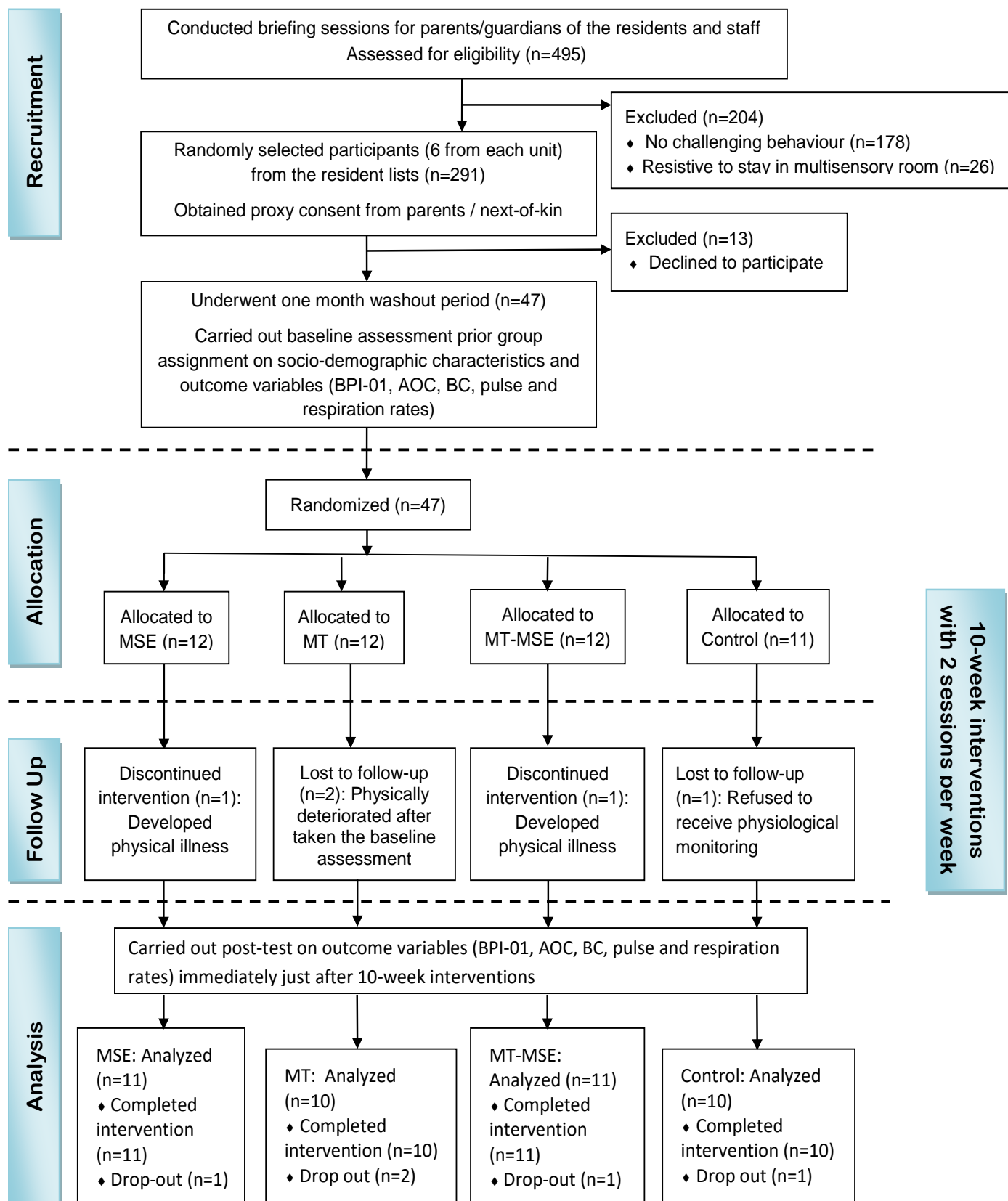
Sample size calculation

Estimation of sample size was based on the findings of Shapiro's (1997) study, using challenging behaviours as the primary outcome (Shapiro et al. 1997). Their Cohen's d effect sizes in post-tests were between 1.4-2.4, indicating large effects; and thus the required sample size would be 10-11 each group (i.e., 38-44 for four study groups) at the level of significance at 0.05 and study power of 0.80 (Portney & Watkins 2009), expecting an attrition rate at 20% (Shapiro et al. 1997). Since it was uncertain about the response rate, we randomly selected 60 participants (n=15 in each group) in order to ensure that there would be sufficient to meet the minimum sample size (11 per group) if 16 of them (27%) refused to participate.

Randomisation

Initially, 291 of 495 residents were found eligible and in each ward, they were listed and numbered in alphabetical order according to their surnames. To minimise the differences between ward nature and environment, the same number of residents (n=6) were randomly selected from each of the 10 lists/units using the computer generated random numbers made by an independent statistician. Of 60 residents who were invited to participate, 47 proxy consents were obtained and the response rate was about 78%.

Before the start of interventions, all participants went through an one-month washout period from the current available MSE and MT sessions to eliminate any residual effect from these interventions. At the end of the washout period, all baseline measurements were taken and the participants were then randomly assigned into one of the four study groups, including multisensory environment alone (MSE), massage therapy alone (MT), massage therapy in multisensory environment (MT-MSE), and control (usual care) group. All recruited participants were assigned with an identity code by a research assistant to keep them anonymous and let clinical staff and outcome assessors blind to their group assignment. A flowchart of the sampling and study procedures is shown in Figure 1.

Figure 1. A flow diagram of the study and sampling procedure

Recruitment	
Conducted briefing sessions for parents/guardians of the residents and staff Assessed for eligibility (n=495)	

Excluded (n=204)
- No challenging behaviour (n=178)
- Resistive to stay in multisensory room (n=26)

Randomly selected participants (6 from each unit) from the resident lists (n=291)

Obtained proxy consent from parents / next-of-kin

Excluded (n=13)
- Declined to participate

Underwent one month washout period (n=47)

Carried out baseline assessment prior group assignment on socio-demographic characteristics and outcome variables (BPI-01, AOC, BC, pulse and respiration rates)

Allocation

Randomized (n=47)

10-week interventions with 2 sessions per week

Allocated to MSE (n=12)	Allocated to MT (n=12)	Allocated to MT-MSE (n=12)	Allocated to Control (n=11)

Follow Up

Discontinued intervention (n=1): Developed physical illness	Lost to follow-up (n=2): Physically deteriorated after taken the baseline assessment	Discontinued intervention (n=1): Developed physical illness	Lost to follow-up (n=1): Refused to receive physiological monitoring

Carried out post-test on outcome variables (BPI-01, AOC, BC, pulse and respiration rates) immediately just after 10-week interventions

Analysis

MSE: Analyzed (n=11) • Completed intervention (n=11) • Drop-out (n=1)	MT: Analyzed (n=10) • Completed intervention (n=10) • Drop out (n=2)	MT-MSE: Analyzed (n=11) • Completed intervention (n=11) • Drop-out (n=1)	Control: Analyzed (n=10) • Completed intervention (n=10) • Drop out (n=1)

BPI-01: Behaviour Problem Inventory; AOC: Alertness Observation Checklist; BC: Behaviour Checklist; MSE: Multisensory environment; MT: Massage therapy; MT-MSE: Massage therapy in multisensory environment

Interventions

Participants were randomly allocated into one of the three treatment (MSE, MT and MT-MSE) groups and one control group (with usual care only). All interventions were given twice per week for 10 consecutive weeks; each session lasted 20-30 minutes. An 'enabling approach' to the residents' behavioural manifestations by one nurse (enabler) was adopted during each intervention session in order to facilitate their free behavioural expressions.

Multisensory environment (MSE)

The MSE was an adapted environment providing a wide variety of sensory stimulations by light, sound, touch, and smell to engage participants (Vlaskamp et al. 2003). During each 30-minute MSE session, the participants could choose their preferable equipment to play/work with. For those who were unable to make choices, they were provided with designated equipment, which did not create any irritation or discomfort to the participants as observed. The participants' behaviours were observed in the second half of the session (i.e., the last 15 minutes).

Massage therapy (MT)

Manual MT was employed to promote physical touch and stimulation, as well as resident-staff interactions. Two experienced nurses in each study unit who were trained by a qualified massage therapist performed this therapy for the participants in a quiet room of their units. To assure treatment fidelity, regular observation and monitoring of the trained nurses' performance in the units was done by the massage therapist in random order.

The choice of body part(s) for 20 minutes MT based on the participant's preference. For those unable to indicate preference, hand massage was the first choice and foot massage was for those with severe contracture or deformity on both hands (Croghan 2009). Only vegetable oil was used as lubricant to reduce skin friction during massage.

Massage therapy in multisensory environment (MT-MSE)

The MT-MSE group received the 20 minutes MT during the 30-minute playing/staying at the MSE. The MT was conducted after the participants had settled down in the MSE. As the MSE alone group, an enabler assisted the participants throughout the sessions.

Usual care alone

Participants in the usual care alone group received routine care by the clinical staff. Usually one nurse took care of 5-6 residents at daytime duty shifts. To balance the enabling effect with the other study groups, 20-30 minutes' attention and social

contacts with toy-playing were provided for the participants whenever the treatment groups underwent their intervention sessions.

Measures

Given the deficits of the residents in cognition and communication, any self-report measures would not be appropriate. Instead, observational measures on behavioural manifestations and physiologic changes were appropriate and feasible to evaluate the relaxation effect in the participants (Vlaskamp et al. 2003). The primary outcome measure was challenging behaviours using Behaviour Problem Inventory (BPI-01); whereas the secondary outcomes consisted of pulse and respiration rates, level of alertness using Alertness Observation Checklist (AOC), and adaptive and maladaptive behaviours using Behaviour Checklist (BC).

Behaviour Problems Inventory (BPI-01)

The 49-item Behaviour Problems Inventory (BPI-01) measured the frequency and severity of the challenging behaviours occurred in the last two months (Rojahn et al. 2001). It was designed and has been widely used for persons with ID of all age ranges and functioning levels (González et al. 2009; Rojahn et al. 2001). It captures three dimensions of challenging behaviours: self-injurious behaviour (SIB), self-stimulating behaviour (SSB), and aggressive/destructive behaviour. The total score of frequency scale can range from 0 to 208, while that of severity scale may range from 0 to 156.

One frontline nurse who closely observed and thus was familiar with the residents' behaviour in the units rated the challenging behaviours exhibited by the participants over the previous two weeks. The assessors were blind to the participants' group allocation. The intra-rater reliability of BPI-01 was very satisfactory in this study (intra-class correlation=0.88), which was higher than ICC=0.76 in the original study (Rojahn et al., 2001).

Pulse and respiration rates

Physiological data were reliable to indicate relaxation level, including pulse and respiration rate (Croghan 2009; Hegarty & Gale 1996), which was activated parasympathetic nerves to suppress the sympathetic activities (Fraser & Ross Kerr 1993; Moraska et al. 2008). A physiologic monitor was used to standardise the measurement of the pulse and respiration rate for 3 minutes continuously after the intervention and then finalised by their average values.

Alertness observation checklist (AOC)

The Alertness Observation Checklist (AOC) developed by Vlaskamp et al. (2009) was to detect the alertness state of people with severe and profound ID, indicating the

resident's interaction and engagement to the immediate environment, or an external stimulus. Such interaction and engagement comprised attention, responsiveness and concentration. The AOC measured four levels of alertness: active, inactive and withdrawn, sleeping and drowsy, and agitated, restless and discontented to the environment being, represented by green, amber, red, and blue color, accordingly. The resident's responses to environmental stimulus were observed at 20-second intervals over 10-20 minutes (Vlaskamp et al. 2009). Percentages of the occurrence of the various alertness levels were compared among treatment and control groups. The inter-observer agreement was 76.5% in this study, which was slightly lower than 80% set by Vlaskamp et al. (2009).

Behaviour Checklist (BC)

The maladaptive and adaptive behaviours were assessed by the 22-item Behaviour Checklist (BC) developed by Shapiro et al. (1997). There were 16 items for maladaptive behaviours (MB) such as stereotypic and self-stimulating behaviours, and 6 items for adaptive behaviours (AB) such as initiation of communicative attempts, rapport building, and concentration. The BC was validated for MSE intervention (Chan et al. 2007; Shapiro et al. 1997), with observation schedule per minute. The inter-rater reliability of BC was satisfactory with inter-class correlation of 0.66 for maladaptive behaviour and of 0.80 for adaptive behaviour in this study, similar to the original study (Shapiro et al. 1997).

Demographic profile and clinical characteristics

Participants' demographic data and clinical characteristics, including gender, age, medication, mobility level from ambulant to bedridden, feeding modes from self-feeding to enteral feeding, and type of sensory deficits were collected. Co-morbidities of other neurological disorders such as epilepsy and cerebral palsy was also recorded.

Procedure

After the 1-month washout period, the baseline measurement of all participants on the BPI-01, pulse and respiration rate, AOC, and BC, as well as demographic and clinical data, were made by the research assistants and specialty nurses who were blind to the treatment assignment. Trained specialty nurses of the units who were familiar with the participants rated their BPI-01 in the units, and recorded their heart and respiration rates at 10 minutes after the interventions. Two trained observers conducted the on-site behavioural observations (BC and AOC) during the interventions. Inter-rater reliabilities of the outcome measures were tested and found satisfactory, including 77-80% agreement for the AOC, and interclass correlations of 0.70-0.80 for BC and of 0.74-0.88 for BPI-01.

The outcome measurements (AOC, BC, BPI-01, and physiological monitors) for all participants were also repeated immediately after the 10-week interventions.

Data analysis

All quantitative data collected were coded and analysed using the IBM's SPSS for Windows, version 21.   Descriptive statistics were used to summarise the demographic and clinical data and outcome scores.   Goodness-of-fit Chi-square test was used to examine any group differences on categorical demographic data such as gender, activities of daily living and types of neurological disorders; and Kruskal-Wallis H test was used to compare the mean age between four study groups at baseline.

Due to small sample size, nonparametric Kruskal Wallis test was performed to analyse the outcome variables (BPI-01, pulse and respiration rates, and BC).   For those outcomes with significant results, Mann-Whitney U test was used to compare the post-test scores of each significant outcome between four groups in pairs to identify their relative treatment effects.   Since the outcome measures only involved pre- and post-test, hence the related samples Wilcoxon signed-rank test was used to estimate the occurrence of four different alertness levels in AOC to identify the time effects between subjects.

In addition, the relationships between score change (from pre- and post-test) in BPI-01 and four confounding variables, including as number of family visits, attendance on social activities and types of and changes in medication, were examined using Spearmen's or point bi-serial correlation test. Level of significance of all statistical tests was set at 0.05 (two-tailed).

Results

Participants

Forty-two of 47 participants completed the intervention and outcome measurements. Three participants withdrew after group allocation due to refusal for physiologic monitoring (n=1) or being physically ill (n=2).   Another 2 participants dropped out during the intervention period because of ill health.   These accounted for an attrition rate of 10.6%.   The final 42 participants comprised 60% female (n=25), with a mean age of 43.40 years (SD=10.92; range 18-64 years).

Descriptive data

Almost half (48%) of the participants was required restrictions of movements such as supporting body alignment, safety belt and limb holder in daily care.   In view of comorbidities, 31% had cerebral palsy and around 62% suffered from epilepsy; whereas, 88% of them needed regular medications.   About 76% participants required staff assistance in continence care, feeding, and physically transfer; whereas, all

required assisted or trolley bathing.   Around 9.5% and 33% of them had hearing and visual impairments, respectively.   Majority of them (79%) had traceable relatives. The participants' demographic and clinical characteristics (see Table 1) showed no statistical differences between the four groups (p>0.17).

Table 1.   Demographic and clinical characteristics of participants in four groups (N=42)

Characteristics	Total (N=42)	MSE (n=11)	MT (n=10)	MT-MSE (n=11)	Control (n=10)	χ^2 test	p value
Age (mean, SD)	43.40 (10.92)	45.64 (6.93)	41.70 (14.43)	42.27 (11.79)	43.90 (10.79)	1.05 [#]	0.790
Gender						0.32	0.956
Male	17 (40.5%)	5 (45.5%)	4 (40%)	4 (36.4%)	4 (40%)		
Female	25 (59.5%)	6 (54.5%)	6 (60%)	7 (63.6%)	6 (60%)		
Adaptive support						3.23	0.364
Yes	20 (47.6%)	5 (45.5%)	7 (70%)	5 (45.5%)	3 (30%)		
No	22 (52.4%)	6 (54.5%)	3 (30%)	6 (54.5%)	7 (70%)		
Bathing mode						1.85	0.688
Assisted	6 (14.3%)	3 (27.3%)	1 (10%)	1 (9.1%)	1 (10%)		
Trolley	36 (85.7%)	8 (72.7%)	9 (90%)	10 (90.9%)	9 (90%)		
Cerebral palsy						1.50	0.758
Yes	13 (31%)	4 (36.4%)	4 (40%)	2 (18.2%)	3 (30%)		
No	29 (69%)	7 (63.6%)	6 (60%)	9 (81.8%)	7 (70%)		
Continence level						0.75	0.963
Yes	10 (23.8%)	3 (27.3%)	3 (30%)	2 (18.2%)	2 (20%)		
No	32 (76.2%)	8 (72.7%)	7 (70%)	9 (81.8%)	8 (80%)		
Epilepsy						2.29	0.559
Yes	26 (61.9%)	7 (63.6%)	8 (80%)	6 (54.5%)	5 (50%)		
No	16 (38.1%)	4 (36.4%)	2 (20%)	5 (45.5%)	5 (50%)		
Feeding mode						8.86	0.421
Independent	10 (23.8%)	3 (27.3%)	3 (30%)	3 (27.3%)	1 (10%)		
Assisted	11 (26.2%)	3 (27.3%)	1 (10%)	4 (36.4%)	3 (30%)		
Dependent	17 (40.5%)	5 (45.5%)	3 (30%)	3 (27.3%)	6 (60%)		
Enteral	4 (9.5%)	0	3 (30%)	1 (9.1%)	0		
Hearing loss						4.42	0.170
Yes	4 (9.5%)	3 (27.3%)	0	1 (9.1%)	0		
No	38 (90.5%)	8 (72.7%)	10 (100%)	10 (90.9%)	10 (100%)		
Medication						3.28	0.362
Yes	37 (88.1%)	10 (90.9%)	9 (90%)	8 (72.7%)	10 (100%)		
No	5 (11.9%)	1 (9.1%)	1 (10%)	3 (27.3%)	0		
Mobility level						5.14	0.526

Characteristics	Total (N=42)	MSE (n=11)	MT (n=10)	MT-MSE (n=11)	Control (n=10)	χ^2 test	p value
Ambulant	10 (23.8%)	4 (36.4%)	1 (10%)	2 (18.2%)	3 (30%)		
Chair-bound	29 (69%)	6 (54.5%)	8 (80%)	8 (72.7%)	7 (70%)		
Bedridden	3 (7.1%)	1 (9.1%)	1 (10%)	1 (9.1%)	0		
Traceable relative						0.55	1.000
Yes	33 (78.6%)	8 (72.7%)	8 (80%)	9 (81.8%)	8 (80%)		
No	9 (21.4%)	3 (27.3%)	2 (20%)	2 (18.2%)	2 (20%)		
Visual impairment						2.16	0.585
Yes	14 (33.3%)	2 (18.2%)	4 (40%)	5 (45.5%)	3 (30%)		
No	28 (66.7%)	9 (81.8%)	6 (60%)	6 (54.5%)	7 (70%)		

 # Kruskal Wallis test used for comparing the mean ages between groups

Results of outcome measures at baseline

Mean scores and standard deviations of most outcome measures (BPI-01, physiologic measures and BC) in the four study groups at baseline are summarised in Table 2. Four levels of alertness (green, amber, red, and blue) of the four groups are summarised in terms of frequency and percentage. Medians of the distribution were calculated. All comparisons of the outcome variables showed no statistical significances (p= 0.076-0.979), indicating the homogeneity of the four study groups at baseline. The results of baseline assessment are shown in Table 2.

Table 2. Baseline assessment of different outcome measures in terms of mean and standard deviation.

Variables	MSE (n=11)	MT (n=10)	MT-MSE (n=11)	Control (n=10)	Kruskal Wallis H test	p value
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
Primary Outcomes						
Behaviour Problem Inventory (BPI-01)						
Frequency of CB	11.55 (8.07)	9.10 (7.49)	14.18 (11.90)	14.00 (12.18)	1.612	0.657
Severity of CB	7.09 (6.30)	5.80 (3.74)	7.91 (6.28)	8.30 (8.45)	0.192	0.979
Secondary Outcomes						
Physiologic monitoring						
Pulse	81.73 (11.57)	80.20 (18.56)	77.00 (13.89)	81.80 (13.78)	0.631	0.889
Respiration	16.82 (2.56)	17.40 (4.09)	18.09 (4.09)	20.00 (3.40)	4.709	0.194
Behaviour Checklist (BC)						
Number of MB	3.46 (5.65)	6.60 (6.77)	11.46 (8.03)	6.20 (6.80)	6.866	0.076
Duration of MB	3.36 (5.45)	5.90 (5.55)	9.27 (5.18)	5.70 (5.95)	6.330	0.097
Number of AB	6.36 (8.02)	3.00 (4.35)	4.55 (6.62)	5.40(15.69)	3.200	0.362
Duration of AB	5.55 (6.46)	2.80(4.08)	3.91 (5.07)	1.90(4.68)	3.446	0.328
Alertness Observation Checklist (AOC) [@]						

Variables	MSE (n=11)	MT (n=10)	MT-MSE (n=11)	Control (n=10)	Kruskal Wallis H test	p value
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
Green: active	39.39% (5)	23.78% (5)	32.32% (5)	49.78% (6)	1.057	0.788
Amber: inactive	28.48% (5)	42.22% (7)	33.13% (4)	18.44% (4)	2.222	0.528
Red: sleepy	32.12% (5)	34.00% (5)	25.86% (4)	31.78% (5)	0.305	0.959
Blue: discontented	0.00% (0)	0.00% (0)	8.69% (1)	0.00% (0)	2.818	0.421

@ Percentage of occurrence of alertness level (Median)

MSE = Multisensory Environment, MT = Massage Therapy, MT-MSE = Massage Therapy in Multisensory Environment, SD = Standard Deviation, CB = Challenging Behaviour, MB = Maladaptive Behaviour, AB = Adaptive Behaviour

Main treatment effects

The results of Kruskal Wallis tests showed that the interaction (group x time) treatment effect was only significant in alertness levels of the participants in which the 'active state' [H=15.456, df=3, p=0.001, effect size=0.73] and 'inactive state' [H=11.240, df=3, p=0.01, effect size=0.81] were found statistically significant difference between groups at post-test. The main treatment effects on the study outcome measures in the four study groups are shown in Table 3.

The percentages of occurrence of the three alertness levels (green, amber and red color) in the four study groups at pre- and post-tests are shown in Figures 1-3 to clearly indicate their changes over time. Contrast comparisons of the above two significant outcomes on alertness level were performed using Mann-Whitney U test to identify which groups showing significant difference in these two outcomes at post-test. The MT-MSE, MSE and MT participants showed significantly lower amounts/occurrences of 'active state' than the control group at post-test, with large effect sizes (U=10.00, p=0.001, effect size=1.60; U=20.50, p=0.013, effect size=0.86; and U=20.00, p=0.023, effect size=0.76, accordingly).

Results of Mann-Whitney tests also revealed that the MT-MSE group had significant more frequent or higher amount of 'inactive state' than the control and MT group, with large effect sizes (U=11.00, p=0.001, effect size=1.39; U=26.00, p=0.043, effect size=1.19, respectively). The contrast comparisons of treatment effect on alertness observation checklist (AOC) among 4 study groups by using Mann-Whitney test are shown in Table 4.

Table 3. Treatment effect of different outcome measures among 4 study groups in terms of mean and standard deviation. (Final data)

Variables	MSE (n=11)	MT (n=10)	MT-MSE (n=11)	Control (n=10)	Kruskal Wallis H test	p value
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
Primary Outcomes						
Behaviour Problem Inventory (BPI-01)						
Frequency of CB	8.73 (9.275)	9.70(12.202)	12.82(13.075)	17.60 (22.540)	0.936	0.817

Variables	MSE (n=11)	MT (n=10)	MT-MSE (n=11)	Control (n=10)	Kruskal Wallis H test	p value
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
Severity of CB	5.09(5.991)	4.30(4.523)	7.82(8.316)	10.40 (15.714)	1.059	0.787
Secondary Outcomes						
Physiologic monitoring						
Pulse	73.45 (10.250)	71.70 (16.634)	74.27 (9.034)	76.30 (13.208)	0.325	0.955
Respiration	17.73 (3.524)	16.10 (3.814)	16.55 (2.979)	16.80 (2.394)	1.254	0.740
Behaviour Checklist (BC)						
Number of MB	3.273 (5.985)	3.00 (4.807)	3.818 (6.353)	1.80 (2.616)	0.242	0.971
Duration of MB	3.273 (5.985)	3.00 (4.807)	3.727 (6.214)	1.80 (2.616)	0.242	0.971
Number of AB	0.318 (0.717)	1.10 (1.663)	0.273 (0.905)	4.10(5.425)	6.704	0.082
Duration of AB	0.318 (0.717)	1.10(1.663)	0.273 (0.905)	4.10(5.425)	6.704	0.082
Alertness Observation Checklist (AOC) [@]						
Green: active [@]	16.06% (2)	18.67% (2)	2.83% (1)	48.67% (9)	15.456	0.001**
Amber: inactive [@]	73.33% (0)	52.67% (0)	94.34% (0)	51.33% (0)	11.240	0.01*
Red: sleepy [@]	10.61% (2)	28.67% (4)	2.83% (1)	0% (0)	6.754	0.08

@ Percentage of occurrence of alertness level (Median value)   ***p<0.05, **<0.01, ***<0.001**

MSE = Multisensory Environment, MT = Massage Therapy, MT-MSE = Massage Therapy in Multisensory Environment, SD = Standard Deviation, CB = Challenging Behaviour, MB = Maladaptive Behaviour, AB = Adaptive Behaviour

Figure 1.   The profile of active state (green) between pre- and post-interventions across four study groups.
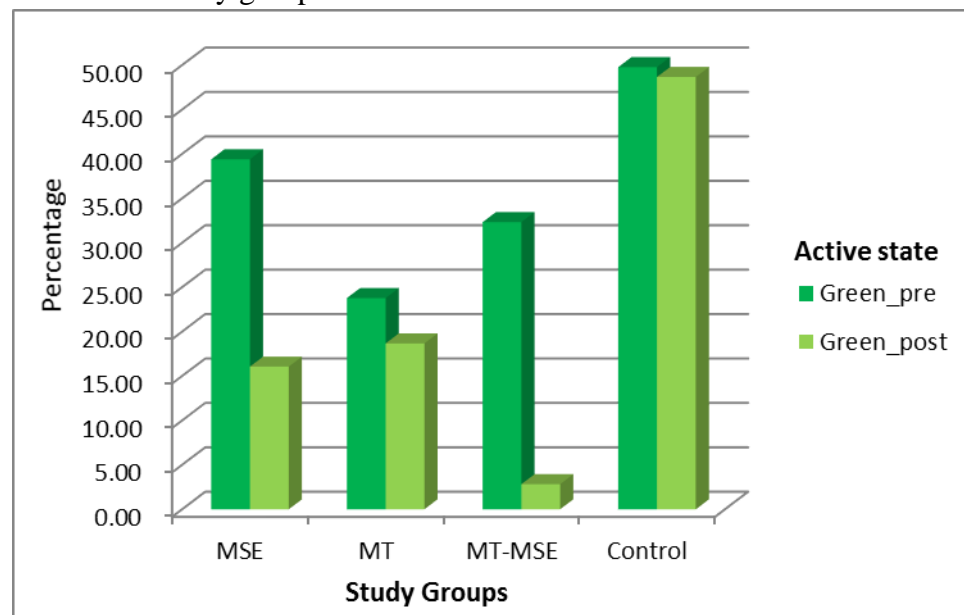

Figure 2.   The profile of inactive state (amber) between pre- and post-interventions across four study groups.
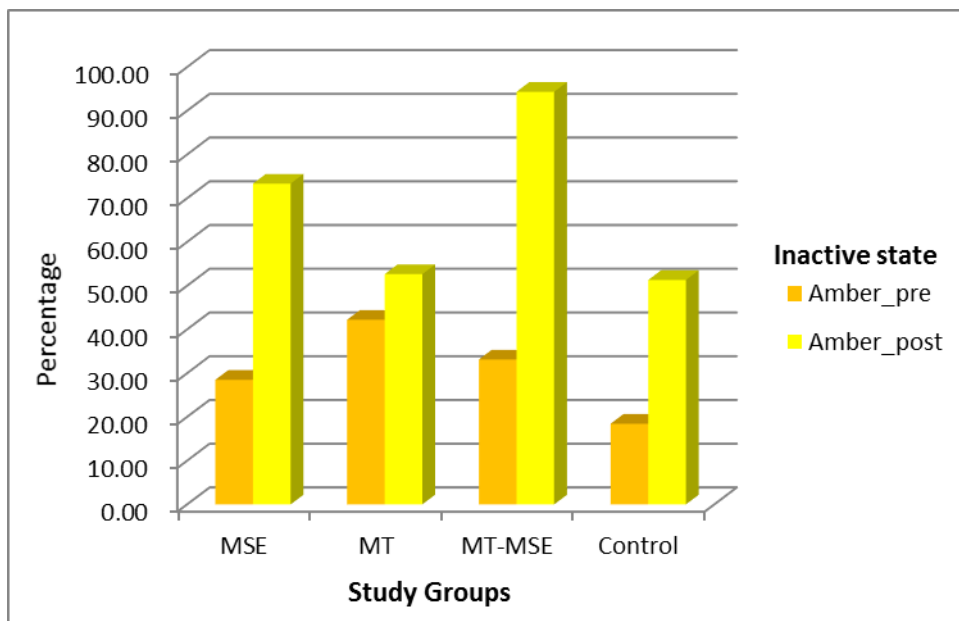
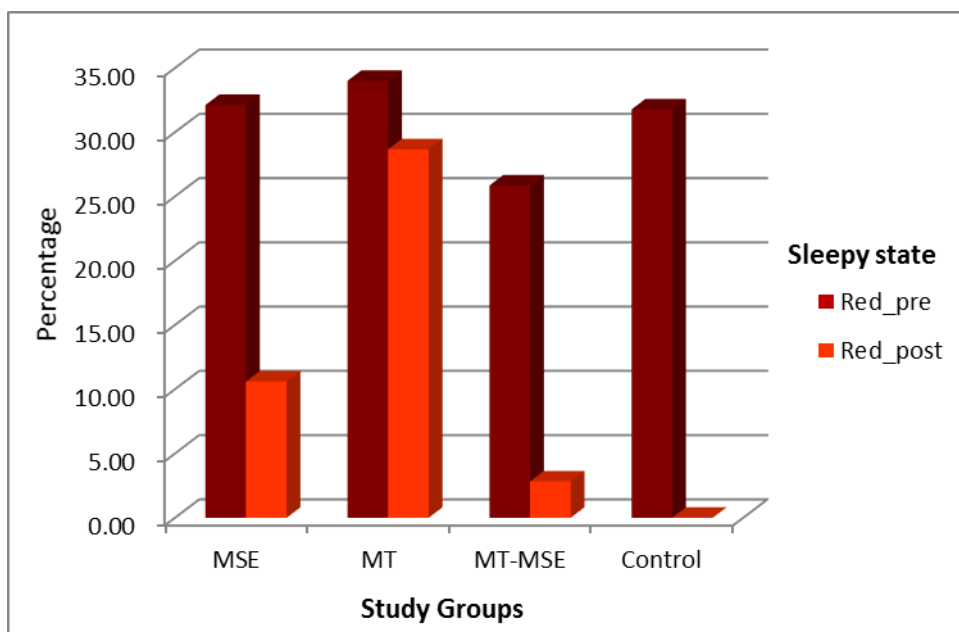Figure 3. The profile of sleepy level (red) between pre- and post-interventions across four study groups.

Table 4. Contrast comparisons of treatment effect on alertness observation checklist (AOC) among 4 study groups by using Mann-Whitney U test

AOC / Group comparisons		MSE vs CTL	MT vs CTL	MT-MSE vs CTL	MSE vs MT	MSE vs MT-MSE	MT vs MT-MSE
Green: Active	U (p)	20.50 (0.013*)	20.00 (0.023*)	10.00 (0.001**)	53.50 (0.918)	54.00 (0.699)	48.00 (0.654)
	Effect size	0.862	0.760	1.601	0.068	0.502	0.552
Amber: Inactive	U (p)	31.50 (0.099)	46.50 (0.796)	11.00 (0.001**)	41.00 (0.349)	43.00 (0.270)	26.00 (0.043*)
	Effect size	0.535	0.031	1.394	0.465	0.635	1.188

*p<0.05, **<0.01, ***<0.001

MSE = Multisensory Environment, MT = Massage Therapy, MT-MSE = Massage Therapy in Multisensory Environment, CTL = control

Descriptive data of the four selected potential confounders (i.e., types of drugs used, changes in drugs used, number of family visits, and attendance on social activities) during the intervention period are summarised in Table 5. Results of Spearman's correlation test indicated that the changes in (frequency of) challenging behaviours during the intervention period (from pre- to post-test) were negatively correlated with the types of drugs taken (Pearson's r= -0.310, p=0.046) among the five selected potential confounders. Whereas, there were not any significant correlations between the changes in severity of challenge behaviours and the five selected confounders.

Table 5.   Descriptive data of individual confounding variables.

Variable	Total (n=42)			MSE (n=11)			MT (n=10)			MT-MSE (n=11)			Control (n=10)			Kruskal Wallis H test	p value
	Median	Mode	Range	Median	Mode	Range	Median	Mode	Range	Median	Mode	Range	Median	Mode	Range		
Types of drugs taken	3	3	0-10	4	3	0-7	9	4, 5	0-10	4	0	0-8	3	3	0-8	4.858	0.183
Number of family visits	2	0	0-35	6	0	0-12	3	0	0-8	8	0, 3	0-35	3	0	0-30	1.956	0.582
Number of social activities	7.5	9	0-30	6	6, 9	0-23	5	1, 5	1-24	5	4, 7	3-17	5	5, 9	0-30	0.407	0.939
Drug change																2.120[#]	0.548
Yes	4 (9.5%)			0 (0%)			1 (10%)			2 (18.2%)			1 (10%)				
No	38 (90.5%)			11 (100%)			9 (90%)			9 (81.8%)			9 (90%)				

Chi square test χ^2

Discussion

The results of this study showed that there were not any statistical significant differences between three treatment groups (MT-MSE, MSE and MT) and usual care (control) group on reducing the challenging behaviours (frequency and severity) of people with severe/profound intellectual disabilities in the infirmary care centre immediately after 10-week intervention.   However, the participants in the three treatment groups showed significantly lower occurrences of 'active state' than the control group at post-test, with large effect sizes. In addition, the MT-MSE group had significant more frequent 'inactive state' than the control and MT group, with large effect sizes.   Active state was defined by Vlaskamp et al. (2009) as the moment that

participants focused on the environment and actively engaged in terms of concentration, responsiveness and social initiation, while the inactive state was exhibition of social withdrawal behaviour and showed no interest to the immediate environment. However, the participants with more frequent active state also presented more inactive alertness in which people would behave in a quiet and motionless manner but still paid attention to the immediate environment in a relaxed state. After consulting with the original authors, the active state could be subdivided into 'active alertness' and 'passive alertness' and their main difference was with or without body movement. Residents with active alertness involve more motions or body movements and initiatives in social contact, while those with passive alertness have limited physical movements and live as a passive recipient to external/social environment (Munde et al. 2012). People in passive alertness would be more likely in relaxation state than those in active alertness (Vlaskamp et al. 2009). The observational findings of this study suggest that the participants with inactive state were more likely in a state of passive alertness. Confirming about this finding, further study to explore or differentiate between active and passive alertness and their relationships with the inactive state is recommended.

Despite all study hypotheses were not supported, the combined use of MT and MSE were likely to induce more relaxation effect and better focused attention in the participants, indicating higher levels of inactive state and 'passive' alertness than the other groups. It is also important to note that the control group presented more frequent challenging behaviours than the three treatment groups, although this did not reach a statistical significant level. Likewise, there were overall but non-significant decreases in the pulse and respiration rates, maladaptive and adaptive behaviours, and sleepy and discontented state (in alertness) of the treatment groups.

Alertness state

The MT-MSE participants were generally passively engaged and showed little activity to the multisensory stimulation. According to previous studies (Munde et al. 2012; Vlaskamp et al. 2003), the multisensory environment promoted passivity of the participants because of their limited perceptual capacity and low information processing in responding to overwhelming stimuli. The sensory stimulations made persons with severe and profound ID easily exhausted and became motionless. The switching of active to inactive or vice versa found between 20-120 seconds (Munde et al. 2012). Switching of alertness state was common. The shifting between passive alert and active alert was very rapid and might not be picked up by instant on-site observer. Use of video-taking record was recommended and might enhance the inter-observer reliability (Munde et al. 2011; 2012). The delineation of active state into "active alert" and "passive alert" levels enhanced the precision of observation data of Alertness Observation Checklist (AOC) (Munde et al. 2012). In addition,

sleepy and discontented (or restlessness) states were obviously reduced in the four study groups following the 10-week interventions.   Such phenomenon indicated that the residents generally dozed off at daytime or attempted to express themselves, while they were not being engaged.

Frequency and severity of challenging behaviour

From the observation data, the frequency and severity of challenging behaviour was steadily increased in control group, showing that manipulation of environmental activity could influence the exhibition of challenging behaviour (Ali et al. 2014).

As the data profile BPI-01 was a behavioural summary of the past two weeks in usual care environment and the other outcome measures were obtained just after the intervention sessions, the therapeutic effect of the interventions might be shredded by robotic routine and few carer support.   In addition, the responses of direct care staff might aggravate the likelihood of challenging behaviour to occur, especially when the direct care staff stereotyped the occurrence of challenging behaviours in a way of individual habit or seeking attention without intention to intervene.   Such stereotypic view may promote the manifestation of challenging behaviours in usual care environment (Hastings, 2013).   Anti-epileptic drugs were commonly taken by the studied sample; the sedative effect would affect the frequency of challenging behaviour, as well as other outcome measures. The small sample size of this study might result a larger influence, hence, concluding remark on this confounding variable should be treated with caution.

Surprisingly, the number and duration of adaptive behaviours of the control group were higher than other treatment groups; similarly, number and duration of maladaptive behaviours of the control group were also lower than other intervention groups.   Though these observational data did not reach to statistically different between groups, the possible reasons were the active engagement through social interaction and structured toy play activity (Mansell et al. 2002).   More literature revealed that meaningful engagement, opportunities for choice making, increased social environment and use of positive behaviour support could decrease the manifestation of challenging behaviours (Koritsas et al. 2008; Beadle-Brown et al. 2012; Hastings et al. 2013),

Relaxation state

The intention of using MT and MSE was to induce relaxation, and subsequently, reduce frequency of the challenging behaviours.   The use of massage was supposed to enrich the relaxation of participant with visual and hearing loss through physical contact; the findings of this study could not affirm this assumption.   In general, visual and hearing impairments among people with severe ID accounted for 50% and 25% respectively (Evenhuis et al. 2001; Munde et al. 2011).   Comparatively, this

study had fewer subjects with visual (33%) and hearing (9.5%) impairment. Such difference might affect the appreciation of sensory stimulation. In addition, the atmosphere of the usual care environment may devastate the therapeutic milieu of massage therapy because other residents' behaviours could interrupt the pleasure of tactile sensation.

The physiologic data of pulse and respiration rates generally showed decreasing trend among study groups but did not meet significant level. Though there was no concrete evidence to support the expected relaxation state through the use of MT and MSE, as mentioned in previous paragraph, the inactive state which appeared corresponding to passive alertness level was comparable to relaxation status. Refinement of study process and data collection was necessary to achieve a significant level.

Limitations and Implications for future study

There are a few important limitations of the study. The research was conducted in one residential institute in which the homogeneity of daily living pattern may overshadow the diversity of individual characteristics, like daytime activity and sit out program. Therefore, the findings might not be representative of ID persons in other settings. Study samples with a wider range of living pattern, like home-based and residential care, are recommended for future study.

The use of toy play might sustain the alertness level of the subjects as literature showed that visual stimuli offered by staff increased the alertness state (Munde et al. 2009; Vlaskamp et al. 2003) which inevitably influenced the measure of adaptive behaviour, like attention to immediate environment and use of eye contact. In addition, individuals with severe and profound multiple disabilities need the presence of others to bring their attention to the immediate environment, otherwise they may ignore their surrounding (Vlaskamp et al. 2003). Hence, the use of toy play with active social interaction should be treated as another intervention in future study.

To improve the study outcomes of massage therapy, a quiet and less distracting environment should be provided for participants during massage therapy because disturbing usual care environment might devastate the appreciation of massage therapy and consequently compromised the clients' relaxation state.

Conclusions

To conclude, the interventions of MT and MSE did not induce sufficient relaxation effect to reduce the frequency and severity of challenging behaviour after the 10-week interventions. However, the combined effect of MT and MSE had better effect on inactivity and passivity of the participants, indicating the calmness atmosphere in a structured environment than other single interventions. A clear definition of 'active alertness' and 'passive alertness' levels of the active state in the AOC scale can

provide a clear and precise description or understanding about the alertness patterns of people with ID. Though all hypotheses were not supported in this pilot study, future study with refinement of measurement tools and larger-sized and diverse samples is suggested to improve the study design or validity, as well as its clinical outcomes.

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None.

Conflict of interest

The authors declare that they have no conflicting interest in the study.

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