

## ORIGINAL ARTICLE

# Knee Pain and Functional Disability of Knee Osteoarthritis Patients Seen at Malaysian Government Hospitals

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## ABSTRACT

**Introduction:** Osteoarthritis (OA) is the main cause of knee pain. It also affects individual's physical functioning. Anti-inflammatory drugs and knee replacement are the mainstay methods in the management of knee OA in Malaysia. However, patients with knee OA often suffer pain. The general objective of the study is to evaluate the effectiveness of a cognitive behavioural intervention module on knee pain, functional disability and psychological outcomes among knee OA patients attending Orthopedics Clinics in Hospital Putrajaya and Hospital Serdang, Malaysia. This study aims to determine the baseline level of knee pain and functional disability among knee OA patients. **Methods:** Baseline results on the knee pain and functional disability were obtained from a two arm parallel- group randomized controlled study. Three hundred patients aged 35 to 75 years diagnosed with knee OA were recruited. A set of pre tested and validated Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire was used in this study. **Results:** Mean baseline of KOOS pain was 56.09 ( $SD=21.75$ ) and 52.26 ( $SD=22.08$ ) for the intervention and control groups respectively. Participants in the intervention and control groups had a mean KOOS function in daily living of 61.11 ( $SD=21.20$ ) and 56.72 ( $SD=22.13$ ) respectively. Overall mean baseline of KOOS function in sport and recreation was 35.30 ( $SD=27.38$ ). **Conclusions:** Majority of participants had moderate level of knee pain and functional disability in daily living. However, participants had more extreme symptoms of functional disability in sport and recreation. Therefore, interventions to reduce knee pain and functional disability symptoms in knee OA are needed.

**Keywords:** Pain, Knee osteoarthritis, Musculoskeletal diseases, Malaysia

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## INTRODUCTION

Osteoarthritis (OA) knee pain is a major public health issue globally. It is a major cause of pain and locomotor disability worldwide<sup>1</sup>. According to the Global Burden of Disease 2010 Study, an estimated 251 million people are living with knee OA globally. Musculoskeletal disease such as OA was ranked as the second largest cause of disability by measuring years lived under disable conditions<sup>2</sup>. The incidence of OA is rising due to ageing population and ongoing resilience of obesity cases. Although it is more common with age and

affected persons aged 40 years and above, however, it also affects people of all ages, including children<sup>3,4</sup>. According to the report by Arthritis Alliance of Canada, the incidence rates of OA are estimated to increase 26% over the next 30 years, from 373428 new cases of OA observed in 2010 to 469467 new OA cases by the year 20405.

The prevalence of knee OA in Malaysia was estimated to be 10% to 20% of the elderly population<sup>6</sup>. The knee pain problems in Malaysia were more common in adults aged 40 years and above, and affected the Indian ethnicity the most. The Community Oriented Program for the Control of Rheumatic Diseases (COPCORD) study conducted in Malaysia reported that 64.8% of joint complaints were regarding knee, out of which more than half with knee pain showed clinical symptoms of OA. Besides this, there were 23% of patients over 55

years who complained of pain, and this figure increased to 39% in those over 65 years old<sup>7</sup>.

Knee OA also affects individual's physical functioning. A national Disability-Health Survey in France found that individuals with knee OA compared to the non- knee OA individuals had an almost doubled higher limitation in walking and carrying objects. Results also found that knee OA mainly affected walking (22%), carrying objects (18.6%), and dressing (12.8%)<sup>8</sup>. The COPCORD program which was conducted in Malaysia was to examine the nature and range of rheumatic complaints in a multiracial Malaysian population (Malay, Indian, Chinese) in a semirural area. Results found that the most significant disability faced was not being able to squat<sup>7</sup>.

Anti-inflammatory drugs are mainly used to treat the symptoms of mild to moderate OA despite being associated with various side- effects<sup>9</sup>. Patients who did not experience adequate response with these drugs would commonly require knee replacement to improve their condition<sup>10,11</sup>, a treatment which was increasingly more receptive by those below 55 years old<sup>10</sup>. However, a survey of patients' preferences and treatment received done among 415 chronic knee pain patients found that 81% of the patients would refrain from undergoing a surgery as they tended to perceive their pain to be tolerable which did not require a surgery<sup>12</sup>. A recent qualitative interview study on patients' and practitioners' opinions of the management of knee OA, the researchers found that pharmacological treatments effectively offered immediate pain relief but may evoke fear and avoidance in patients. Furthermore, patients expressed concerns about the lack of clarity concerning indications for surgery. Patients also had fear experience of the post-surgery period as the recovery time is long and painful. Those who experienced knee surgery felt disappointed and the knee pain remained after surgery<sup>13</sup>. A recent study by Dowsey and associates observed that 30% of their subjects recorded unfavourable pain scores while half of them recorded suboptimal functional scores after undergoing knee replacement surgery<sup>14</sup>.

There are currently no effective pharmaceutical treatments for patients suffering from pain and functional disability<sup>15</sup>. Furthermore, the surgical options are expensive. Thus, non- pharmacological interventions are still a driving force in managing symptoms of pain and the consequences of disability in knee OA. Many studies have assessed the level of pain and functional disability among individual with musculoskeletal pain<sup>7,8,16</sup>. However, there is limited number of research that has assessed the level of pain and functional disability among people living with knee OA in Malaysia.

This paper describes the baseline level of knee pain and functional disability of knee OA patients attending Orthopedics Clinics in Hospital Putrajaya and Hospital Serdang, Malaysia.

## MATERIALS AND METHODS

A two arm parallel- group randomized controlled study design was used in this study. This study involved diagnosed knee OA patients who were eligible to the study from November 2015 to August 2016 at Hospital Putrajaya and Hospital Serdang, Selangor, Malaysia. Patients were included in this study if they were aged 35 to 75 years, had been diagnosed with primary knee OA on the basis of medical evaluation (knee pain for most days of previous month and bony outgrowths (osteophytes) of the knee) and radiographic examination Kellgren- Lawrence (K-L) of grade II or more, had an average pain intensity of 40mm or more on a 100mm visual analogue scale (VAS) in the seven days before baseline assessment, and if written informed consent was obtained from each patients. Patients with knee pain caused by conditions other than knee OA were excluded from the study. Patients were also excluded if they had knee replacement surgery of the affected knee or undergone psychological treatment or any other clinical study during the past 12 months. Additional exclusion criteria were mental disorder, pregnancy or breastfeeding.

The sampling frame of this study was the list of all patients with knee OA seen at Orthopedics Clinics of each recruitment site. It was obtained from the medical records department of each hospital that had consulted for knee pain problem within the period of February 2015 to July 2015. The formula used for the sample size in this study was  $[n = 2\delta^2(Z_{1-\alpha/2} + Z_{1-\beta})^2 / (\mu_1 - \mu_2)^2]$ <sup>17</sup> using an assumed expected outcome of knee pain intensity decreases 20% within six months of therapy. The estimated standard deviation (assumed to be equal for each group) is 10.85 and mean baseline knee pain score is 20.68<sup>18</sup>. To factor in 20% attrition<sup>19</sup> randomised trial on health anxious patients attending cardiac, endocrine, gastroenterological, neurological, and respiratory medicine clinics in secondary care. We included those aged 16-75 years, who satisfied the criteria for excessive health anxiety, and were resident in the area covered by the hospital, were not under investigation for new pathology or too medically unwell to take part. We used a computer-generated random scheme to allocate eligible medical patients to an active treatment group of five-to-ten sessions of adapted cognitive behaviour therapy (CBT-HA group the total required sample size was 262. Potentially eligible patients were invited to attend a face- to- face appointment with a researcher to discuss participation in the trial and to confirm their eligibility. Ineligible patients and those who declined participation were referred back to their orthopedics doctors. Three hundred eligible patients who agreed to participate in this study were randomized after the written consent obtained. The randomization was done by applying independently operated computer-generated random sequence system with the block randomization of six (<http://random-allocation-software>).

software.informer.com/2.0/). Participants in intervention group received a three sessions of group cognitive behavioural intervention (two and a half hour for each session) in addition to standard routine care and participants in control group received standard routine care. The sessions were conducted in a group of eight to twelve participants and supervised by an experienced senior clinical psychologist and a physiotherapist.

Data on level of knee pain and functional disability was obtained using KOOS questionnaire. English and Malay version KOOS questionnaire<sup>20</sup> was pre tested and validated. The English version of KOOS was validated with Cronbach's alpha above 0.7<sup>21</sup>, and Malay version with Cronbach's alpha ranged from 0.94 to 0.96<sup>22</sup>. Permission of using the questionnaire was obtained from authors. KOOS questionnaire contained 42 items in five separately scored subscales: pain, other symptoms, function in activities of daily living (ADL), function in sport and recreation and knee-related quality of life. However, all the 31 items out of 42 items related to pain, ADL and function in sport and recreation were adapted in this study. The degree of knee pain and difficulty where participants have experienced in the past one week was taken into consideration when answering the questions. A normalized score (0 indicating extreme symptoms and 100 indicating no symptoms) was calculated for pain, ADL and function in sport and recreation. Each outcome was measured at baseline, immediate, one month and six months after intervention.

Data collected were analyzed using SPSS version 22. Exploratory data analysis was performed to detect any outliers, missing values, and assumptions checking on data normality, equality of variance, and multicollinearity. Descriptive statistics included mean and standard deviation were used to describe continuous data, and percentage was used to describe categorical data in this study. Besides, chi square test ( $\chi^2$ ) was used to compare whether the frequency distribution of participants in both intervention and control groups was equal or unequal. Fisher's exact test (FET) was referred when the expected frequency for a particular category was less than five. All significant levels were set at a p value of less than 0.05 ( $p < 0.05$ ).

The study was approved by the Medical Research Ethics Committee, Ministry of Health Malaysia (NMRR-15-74-24008) and University Putra Malaysia Ethics Committee for research involving human subjects, prior to the commencement of the study.

## RESULTS

Data on pain, ADL and function in sport and recreation were normal. Equality of variance and multicollinearity assumptions were met. Table 1 describes the demographic profile of the participants in the control

and intervention group. Majority (82.7%) of them were women, while the rest were men. The age distribution of participants showed that an overall majority were aged 56 to 65 years old (38.0%), followed by 46 to 55 years old (27.7%), 35 to 45 years old (21.0%) and 13.3% were 66 to 75 years old. Most of the participants (64.0%) were Malay ethnicity. Approximately 43.0% of the participants had attained secondary education background and a total of 33.3% had attained tertiary education. Only a small number (16.0%) had attained primary education. Majority of the participants (80.7%) were married, followed by single (9.0%), widow or widower (8.3%) and 2% were divorce. Most of the participants (90.0%) stayed with family (90.0%). Majority of them (44.7%) had retired, and a total of 41.3% being employed. Only a small proportion (0.3%) was permanently disabled. Approximately 40.8% of the participants earned a monthly income below RM1000.00. Only a small number (14.7%) earned a monthly income above RM4000.00. This income trend may be due to the fact that majority of the participants were retired.

Table 2 shows the clinical characteristics of the participants in the control and intervention group. Majority (80.3%) of the participants had known about their existing comorbidities. Among the 300 participants involved in the study, most of them (59.3%) were diagnosed with unilateral knee OA, and 40.7% were bilateral knee OA. Approximately 58.2% of the participants had knee OA symptoms within 1 to 5 years, followed by 6 to 10 years (15.4%), less than 1 year (14.0%), and 12.4% were more than 10 years. The overall mean age for the participants first diagnosed with knee OA was 50.10 years ( $SD=10.04$ ). Majority (68.9%) of the participants had knee pain score of four to six, and only minority (31.1%) had knee pain score of seven and above, according to 100mm VAS. Thus, the overall mean for the knee pain score was 5.59 ( $SD=1.623$ ). Two hundred and eighteen (72.7%) had body mass index (BMI) less than 30. Majority (43.3%) were diagnosed with K-L grade II of knee OA and 35.3% were K-L grade III knee OA. Only a small number (21.3%) were diagnosed with K-L grade IV knee OA.

Overall, demographic characteristics such as age ( $\chi^2(5.078)$ ,  $p=0.166$ ), gender ( $FET(1.489)$ ,  $p=0.286$ ), ethnicity ( $\chi^2(0.177)$ ,  $p=0.981$ ), education level ( $\chi^2(0.557)$ ,  $p=0.906$ ), marital status ( $\chi^2(2.928)$ ,  $p=0.403$ ), type of cohabitation ( $\chi^2(0.169)$ ,  $p=0.919$ ), occupation status ( $\chi^2(1.282)$ ,  $p=0.734$ ), and monthly income ( $\chi^2(3.485)$ ,  $p=0.480$ ) did not differ significantly between intervention and control groups. Besides, clinical characteristics such as pre-existing comorbidities ( $FET(3.566)$ ,  $p=0.081$ ), knee OA site ( $FET(0.884)$ ,  $p=0.411$ ), duration of knee pain symptoms ( $\chi^2(0.323)$ ,  $p=0.956$ ), knee pain score ( $FET(3.506)$ ,  $p=0.80$ ), BMI ( $FET(0.001)$ ,  $p=1$ ), and K-L grade of knee OA ( $\chi^2=2.093$ ,  $p=0.351$ ) also did not differ significantly between intervention and control groups.

Table 1: Demographic profile of the participants in the control and intervention group

| Characteristics            | Frequency, n (%)      |                            |            | Test     | p value |
|----------------------------|-----------------------|----------------------------|------------|----------|---------|
|                            | Control group (n=150) | Intervention group (n=150) | Total      |          |         |
| <b>1 Age</b>               |                       |                            |            | $\chi^2$ | 0.166   |
| 35 – 45                    | 26(17.3)              | 37(24.7)                   | 63(21.0)   |          |         |
| 46 – 55                    | 42(28.0)              | 41(27.3)                   | 83(27.7)   |          |         |
| 56 – 65                    | 65(43.3)              | 49(32.7)                   | 114(38.0)  |          |         |
| 66 – 75                    | 17(11.3)              | 23(15.3)                   | 40(13.3)   |          |         |
| Total                      | 150(100.0)            | 150(100.0)                 | 300(100.0) |          |         |
| <b>2 Gender</b>            |                       |                            |            | FET      | 0.286   |
| Male                       | 30(20.0)              | 22(14.7)                   | 52(17.3)   |          |         |
| Female                     | 120(80.0)             | 128(85.3)                  | 248(82.7)  |          |         |
| Total                      | 150(100.0)            | 150(100.0)                 | 300(100.0) |          |         |
| <b>3 Ethnicity</b>         |                       |                            |            | $\chi^2$ | 0.981   |
| Malay                      | 97(64.7)              | 95(63.3)                   | 192(64.0)  |          |         |
| Indian                     | 13(8.7)               | 13(8.7)                    | 26(8.7)    |          |         |
| Chinese                    | 37(24.7)              | 38(25.3)                   | 75(25.0)   |          |         |
| Others                     | 3(2.0)                | 4(2.7)                     | 7(2.3)     |          |         |
| Total                      | 150(100.0)            | 150(100.0)                 | 300(100.0) |          |         |
| <b>4 Education Level</b>   |                       |                            |            | $\chi^2$ | 0.906   |
| Primary                    | 25(16.7)              | 23(15.3)                   | 48(16.0)   |          |         |
| Secondary                  | 66(44.0)              | 63(42.0)                   | 129(43.0)  |          |         |
| Tertiary                   | 47(31.3)              | 53(35.3)                   | 100(33.3)  |          |         |
| Others                     | 12(8.0)               | 11(7.3)                    | 23(7.7)    |          |         |
| Total                      | 150(100.0)            | 150(100.0)                 | 300(100.0) |          |         |
| <b>5 Marital Status</b>    |                       |                            |            | $\chi^2$ | 0.403   |
| Single                     | 13(8.7)               | 14(9.3)                    | 27(9.0)    |          |         |
| Widow or Widower           | 16(10.7)              | 9(6.0)                     | 25(8.3)    |          |         |
| Married                    | 117(78.0)             | 125(83.3)                  | 242(80.7)  |          |         |
| Divorce                    | 4(2.7)                | 2(1.3)                     | 6(2.0)     |          |         |
| Total                      | 150(100.0)            | 150(100.0)                 | 300(100.0) |          |         |
| <b>6 Type Cohabitation</b> |                       |                            |            | $\chi^2$ | 0.919   |
| Family                     | 134(89.3)             | 136(90.7)                  | 270(90.0)  |          |         |
| With Carer                 | 2(1.3)                | 2(1.3)                     | 4(1.3)     |          |         |
| Alone                      | 14(9.3)               | 12(8.0)                    | 26(8.7)    |          |         |
| Total                      | 150(100.0)            | 150(100.0)                 | 300(100.0) |          |         |
| <b>7 Occupation</b>        |                       |                            |            | $\chi^2$ | 0.734   |
| Retired                    | 66(44.0)              | 68(45.3)                   | 134(44.7)  |          |         |
| Permanently Disabled       | 1(.7)                 | 0(.0)                      | 1(.3)      |          |         |
| Employed                   | 61(40.7)              | 63(42.0)                   | 124(41.3)  |          |         |
| Others                     | 22(14.7)              | 19(12.7)                   | 41(13.7)   |          |         |
| Total                      | 150(100.0)            | 150(100.0)                 | 300(100.0) |          |         |
| <b>8 Monthly Income</b>    |                       |                            |            | $\chi^2$ | 0.480   |
| Below RM1,000              | 62(41.3)              | 60(40.3)                   | 122(40.8)  |          |         |
| RM 1,001 - RM 2,000        | 26(17.3)              | 23(15.4)                   | 49(16.4)   |          |         |
| RM 2,001 - RM 3,000        | 23(15.3)              | 29(19.5)                   | 52(17.4)   |          |         |
| RM 3,001 - RM 4,000        | 13(8.7)               | 19(12.8)                   | 32(10.7)   |          |         |
| Above RM 4,000             | 26(17.3)              | 18(12.1)                   | 44(14.7)   |          |         |
| Total                      | 150(100.0)            | 149(100.0)                 | 299(100.0) |          |         |

Chi square test ( $\chi^2$ ); FET = Fisher's exact test

\*Significant at p<0.05

Table 2: Clinical characteristics profile of the participants in the control and intervention group

| Characteristics                             | Frequency, n (%)         |                               |            | Test     | p value |
|---|--------------------------|-------------------------------|------------|----------|---------|
|   | Control group<br>(n=150) | Intervention group<br>(n=150) | Total      |          |         |
| <b>1 Pre- existing comorbidities</b>        |                          |                               |            | FET      | 0.081   |
| No  | 36(24.0)                 | 23(15.3)                      | 59(19.7)   |          |         |
| Yes   | 114(76.0)                | 127(84.7)                     | 241(80.3)  |          |         |
| Total                                       | 150(100.0)               | 150(100.0)                    | 300(100.0) |          |         |
| <b>2 Knee OA</b>                            |                          |                               |            | FET      | 0.411   |
| Unilateral                                  | 85(56.7)                 | 93(62.0)                      | 178(59.3)  |          |         |
| Bilateral                                   | 65(43.3)                 | 57(38.0)                      | 122(40.7)  |          |         |
| Total                                       | 150(100.0)               | 150(100.0)                    | 300(100.0) |          |         |
| <b>3 Duration of Knee Pain Symptoms</b>     |                          |                               |            | $\chi^2$ | 0.956   |
| < 1 year                                    | 20(13.3)                 | 22(14.8)                      | 42(14.0)   |          |         |
| 1 - 5 years                                 | 87(58.0)                 | 87(58.4)                      | 174(58.2)  |          |         |
| 6 - 10 years                                | 24(16.0)                 | 22(14.8)                      | 46(15.4)   |          |         |
| >10 years                                   | 19(12.7)                 | 18(12.1)                      | 37(12.4)   |          |         |
| Total                                       | 150(100.0)               | 149(100.0)                    | 299(100.0) |          |         |
| <b>4 Pain intensity</b>                     |                          |                               |            | FET      | 0.08    |
| 4 - 6                                       | 111 (74.0)               | 96 (64.0)                     | 207 (69.0) |          |         |
| 7 – 10                                      | 39 (26.0)                | 54 (36.0)                     | 93 (31.0)  |          |         |
| Total                                       | 150(100.0)               | 150(100.0)                    | 300(100.0) |          |         |
| <b>5 Body mass index (kg/m<sup>2</sup>)</b> |                          |                               |            | FET      | 1       |
| Less than 30                                | 109(72.7)                | 109(72.7)                     | 218(72.7)  |          |         |
| 30 or more                                  | 41(27.3)                 | 41(27.3)                      | 82(27.3)   |          |         |
| Total                                       | 150(100.0)               | 150(100.0)                    | 300(100.0) |          |         |
| <b>6 K-L grade of knee OA</b>               |                          |                               |            | $\chi^2$ | 0.351   |
| II  | 69(46.0)                 | 61(40.7)                      | 130(43.3)  |          |         |
| III   | 54(36.0)                 | 52(34.7)                      | 106(35.3)  |          |         |
| IV  | 27(18.0)                 | 37(24.7)                      | 64(21.3)   |          |         |
| Total                                       | 150(100.0)               | 150(100.0)                    | 300(100.0) |          |         |
| <b>7 Hospital</b>                           |                          |                               |            | FET      | 0.546   |
| Putrajaya                                   | 75(50.0)                 | 75(50.0)                      | 150(50.0)  |          |         |
| Serdang                                     | 75(50.0)                 | 75(50.0)                      | 150(50.0)  |          |         |
| Total                                       | 150(100.0)               | 150(100.0)                    | 300(100.0) |          |         |

Chi square test ( $\chi^2$ ); FET = Fisher's exact test

\*Significant at p<0.05

Table 3: Mean scores and standard deviation of participants' KOOS knee pain, KOOS function in daily living, and KOOS function in sport and recreation

| No | Outcome measures                     | Mean score (standard deviation) |                 |                      | p value |
|----|--------------------------------------|---------------------------------|-----------------|----------------------|---------|
|    |                                      | All                             | Control (n=150) | Intervention (n=150) |         |
| 1  | KOOS pain                            | 54.176(21.96)                   | 52.259(22.08)   | 56.093(21.75)        | 0.131   |
| 2  | KOOS function (daily living)         | 58.916(21.75)                   | 56.724(22.13)   | 61.108(21.20)        | 0.081   |
| 3  | KOOS function (sport and recreation) | 35.300(27.38)                   | 31.933(25.51)   | 38.667(28.82)        | 0.033*  |

Total KOOS pain score = 100. Higher score indicates lower symptoms of pain; Total KOOS function (daily living) score = 100. Higher score indicates lower symptoms of functional disability (daily living); Total KOOS function (sport and recreation) score = 100. Higher score indicates lower symptoms of functional disability (sport and recreation)

\*Significant at  $p < 0.05$

Table 3 shows the mean scores and standard deviation of participants' KOOS pain, KOOS ADL, and KOOS function in sport and recreation. Overall, participants in intervention group tend to experience lower ( $M=56.09$ ,  $SD=21.75$ ) knee pain intensity, ( $M=61.11$ ,  $SD=21.20$ ) ADL, and ( $M=38.67$ ,  $SD=28.82$ ) function in sport and recreation than participants in control group. The baseline mean scores for KOOS pain ( $MD=3.83$ ,  $p=0.131$ ) and KOOS ADL ( $MD=4.38$ ,  $p=0.081$ ) did not differ significantly between intervention and control groups. However, there was a statistically significant difference in the baseline mean score of KOOS function in sport and recreation between participants in intervention group ( $M=38.6$ ,  $SD=28.82$ ) and control group ( $M=31.9$ ,  $SD=25.51$ ) with a large mean difference ( $MD=6.73$ ) and the p value at 0.033.

## DISCUSSION

The socio- demographic and clinical characteristics of participants in both intervention and control groups did not differ significantly at baseline. This indicates that random allocation to intervention and control group is effective to create groups that were comparable.

Majority (82.7%) of the participants in this study were women, which is similar to that seen in an exploratory study on health- related quality of life conducted among knee OA patients in Malaysia, in which most (78.8%) of the participants were women<sup>23</sup>. Other studies with a higher prevalence of female participants in Japan and United States (US), which reported 1465 (64.2%) and 79 (79%) respectively<sup>24,25</sup> Research on Osteoarthritis Against Disability (ROAD). The higher proportion of female participants could be attributed to the fact that female generally have better health seeking behaviors than men. The age distribution in this study was reported, where 154 (51.3%) of them were aged 56 to 75 years old. This finding is similar to past studies done amongst knee OA patients<sup>23,25</sup> cross sectional study using the Short Form-36 (SF-36. Majority (64.0%) of the

participants in this study were Malay, keeping consistent with a Malaysian studies on knee OA<sup>23</sup>. Proportions of participants being married (80.7%) and lived together with family members (90.0%) in this study were similar to the findings of Zakaria in Malaysia, in which among the knee OA participants, most of them 114 (75.5%) being married, and 146 (96.7%) of them were living with relatives<sup>23</sup>.

Majority 174 (58.2%) of the participants in this study had knee pain symptoms for at least 1 to 5 years. This finding was similar with the findings of Zakaria in Malaysia, who reported 87 (57.6%) of them had knee pain symptoms for 1 to 5 years<sup>23</sup>. Besides, proportions of participants 130 (43.3%) diagnosed with radiographic knee OA (K-L=II) with average pain rate of 5.59 in this study were found to be the highest proportion, as compared with radiographic knee OA (K-L=III) and (K-L=IV). This finding was similar with the past studies on knee OA which was conducted in Japan<sup>24</sup>, and in US<sup>25</sup> suggesting that treatment of insomnia may improve pain. The aims of this study were to evaluate the efficacy of cognitive-behavioral therapy for insomnia (CBT-I. Generally, most of the participants 218 (72.7%) in this study were non obese (BMI<30). This finding was consistent with the Malaysian knee OA study, in which 108 (71.5%) of the participants were found to be non obese<sup>23</sup>.

In the present study, participants had mean KOOS knee pain score of 54.18 ( $SD=21.96$ ) out of KOOS pain score of 100 at baseline. Higher KOOS score indicates lower symptoms of pain. Indeed, the mean Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain score in this study was 8.4 ( $SD=4.71$ ) out of WOMAC pain score of 20, where higher score on the WOMAC indicates worse pain (calculation according to KOOS scoring manual). The present study showed that majority of participants experienced moderate knee pain during walking, sitting or lying, and at night while in bed. Similar average knee pain intensity level was observed in a clinical trial study conducted by Karaman and colleagues in patients with knee OA in Turkey. His

study found that the mean baseline VAS pain score of the participants was 6.1 (95% CI 5.2-7.0) out of VAS pain score of 10, where higher score indicates worse pain<sup>26</sup> and that some of them have serious adverse effects that prompted the researchers to research different treatment methods. In this study, we investigated short- and mid-term effectiveness of intra-articular pulsed radiofrequency (PRF). In another overseas study conducted on knee OA patients in Canada, the result of knee pain intensity level reported at baseline was somehow replicated in the present study as the mean WOMAC pain score was shown to be average ( $M=8.2$ ,  $SD=4.2$ )<sup>27</sup> which may be associated with central sensitization (CS). However, the finding of this study was inconsistent with a local study. The finding of present study in which slightly higher symptoms of pain than that seen in a clinical trial study of the effectiveness of relaxation therapy among patients with knee OA in Malaysia, where its mean KOOS knee pain score was 74.35<sup>28</sup>. A factor contributing to this higher knee pain intensity level related to knee OA could be that participants in the comparison study only recruit knee OA patients that having moving difficulties regardless of knee pain.

The present study showed that the overall mean score of KOOS ADL was 58.92 ( $SD=21.75$ ), and in sport and recreation was 35.30 ( $SD=27.38$ ) out of KOOS function (daily living and sport and recreation) score of 100. Generally, participants showed moderate symptoms of functional disability in daily living such as walking on flat surface and getting in or out of bath, but more extreme symptoms of functional disability in sport and recreation such as squatting, running, jumping, twisting on injured knee, and kneeling. Indeed, the mean WOMAC function score in daily living for this study was 27.94 ( $SD=14.79$ ) out of WOMAC function score of 68, where higher score on the WOMAC indicates worse functional limitations (calculation according to KOOS scoring manual). Studies from Israel and Canada have findings supported the results of present study. The effect of group education program conducted in patients with knee OA in Israel found that participants had mean WOMAC function score in daily living of 34.0 ( $SD=15.2$ )<sup>29</sup> followed by a self-executed home-based exercise programme. The controls ( $n=25$ ). In Canada, knee OA participants had reported similar functional limitation, where its mean WOMAC function score in daily living was 27.0 ( $SD=13.3$ )<sup>27</sup> which may be associated with central sensitization (CS). The finding of this study also consistent with a local clinical trial study in patients with chronic pain which using Roland and Morris disability questionnaire, where total scores ranged from 0 (no disability) to 24 (severe disability). The mean disability score was reported at 14.48 ( $SD=5.3$ )<sup>30</sup>.

The major strength of this study was the fact that the baseline results were obtained from a two arm parallel-group randomized controlled trial. The random

allocation based on block randomization method by using random allocation software which ensured participants in both intervention and control groups were similar characteristics at the beginning of the study. However, the limitation of this study is that it is limited to two hospitals and hence may not be generalizable to all knee OA patients in Malaysia.

## CONCLUSIONS

Majority of the patients with knee OA still suffer from pain and physical disability. Although there are many pharmaceutical treatments for patients suffer from pain and functional disability have been implemented, it was still insufficient. Thus, non-pharmacological interventions are still a driving force in managing symptoms of pain and the consequences of disability.

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