

**RESEARCH ARTICLE**

# The minimum clinically important difference on the sleep disorders inventory for people with dementia

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**Objectives:** Sleep disturbances in dementia causes distress to people with dementia and their family carers and are associated with care home admission. The Sleep Disorders Inventory (SDI) is a validated questionnaire of sleep disturbances in dementia often used to measure treatment effectiveness, but the minimum clinically important difference (MCID) is unknown.

**Methods:** We triangulated three investigative methods to determine the MCID of the SDI. Using data on SDI from a randomised controlled trial (RCT) with 62 participants in an intervention for sleep disorders in dementia, we (1) calculated distribution-based values where  $MCID = 0.33$  of a SD (SD) (2) an anchor based approach using quality of life (measured using DEMQOL-Proxy) as an anchor. We also employed a Delphi consensus process asking 12 clinicians, sleep researchers and family carers to rate which changes on vignettes were equivalent to a MCID.

**Results:** We found that  $0.33$  SD in the SDI = 4.86. Reduction in SDI total score was not significantly correlated with improvement in DEMQOL-Proxy (Pearson's correlation =  $-0.01$ ;  $P = 0.96$ ) score. The Delphi consensus required two rounds to reach a consensus and concluded that changes equivalent to three points on the SDI equated to the MCID.

**Conclusions:** Taking into account both the distribution-based values and the Delphi process we used a whole number at the midpoint and judged the minimum clinically important difference MCID to be equal to four points. We note the clinicians and carers opinions from the Delphi process determined the MCID to be lower at three points.

**KEYWORDS**

anchor, Delphi, dementia, distribution, minimum clinically important difference, sleep disorders inventory, sleep disturbances

## 1 | INTRODUCTION

There are currently an estimated forty seven million people worldwide living with dementia, with projections that this number will triple by

2050 due to increasing life expectancy.<sup>1</sup> Sleep disturbances are common in people with dementia,<sup>2</sup> with meta-analyses finding the prevalence in people with Alzheimer's disease was 39%,<sup>3</sup> and in people with dementia living in care homes was 38%.<sup>4,5</sup> When an individual

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with dementia has disturbed night-time sleep, this can impact on other family members and often means their sleep is also interrupted.<sup>6</sup> This is associated with family carers developing depressive symptoms, and a higher likelihood that they become unable to continue caring at home and the person living with dementia is moved into a care home.<sup>7,8</sup>

Currently there are no known efficacious treatments for sleep disturbances for people with dementia.<sup>9–11</sup> Emerging evidence suggests multicomponent interventions including a combination of light therapy, cognitive behavioural therapy, and sleep hygiene<sup>2</sup> may prove to be effective, given that the causes of sleep disturbance in dementia are often multifactorial and relate to brain changes from the illness but also to discomfort, pain, anxiety and lack of daytime light and activity.<sup>12</sup>

Accurately measuring sleep disturbances in dementia is important for assessing the efficacy of treatments, however there is debate over whether questionnaires or actigraphy are the gold standard of measurement in people with dementia. Actigraphy, where an actigraph is worn on the wrist and measures movement, infers sleep from a lack of movement.<sup>13</sup> It is described as an objective measure, though it is not a direct measure of sleep disturbances and cannot accurately measure daytime sleepiness.<sup>4,13</sup> Furthermore, it is also common for people with dementia to remove their actigraph, accounting for the exclusion of a third of actigraphy data in studies with people with dementia.<sup>13</sup> Questionnaires, on the other hand, are cheaper than actigraphy, allow for more data to be collected, and report on a broader range of sleep disturbances.<sup>14</sup> However, they can be difficult as people with dementia often are unable to remember how they slept and therefore specific proxy rated questionnaires are commonly used.<sup>4</sup>

The only validated dementia specific questionnaire measuring sleep disturbance is the Sleep Disorders Inventory (SDI), which can be used as a proxy measure.<sup>15,16</sup> This scale comprises seven different sleep disturbances common in people with dementia, including getting up during the night, getting involved in inappropriate activities during the night, and excessive daytime sleepiness (see Table 1). Each item is rated by the frequency of how often it occurs (1–4) and how severe the disturbance is (1–3), with both scores multiplied together to give a potential item score of between 0–12, with a higher score meaning more frequent and severe sleep disturbance.<sup>15</sup> A score of  $\geq 4$  on any

## Key Points

- Sleep disorders in dementia are common and impact negatively on both people with dementia and society.
- Minimum Clinically Important Difference (MCID) is the minimum amount of change required for an intervention considered meaningful by the patient or family and there are to date no MCID in measures of sleep in dementia.
- Until now there has been no MCID defined for sleep disturbance in people with dementia. Our findings indicate that four point change on the Sleep Disorders Inventory constitute a MCID.

item indicates a clinically significant symptom, with the total SDI score (0–84) generated by adding the scores of individual items.

The minimal clinically important difference (MCID) is the smallest change after an intervention that is considered meaningful or valuable by patients and their families.<sup>17–19</sup> As the MCID will indicate clinical meaningfulness, it is an additional and possibly more useful measure of the effectiveness of an intervention than statistical difference.<sup>20</sup> To our knowledge no MCID has currently been reported for the SDI or any instrument to measure sleep disturbances in dementia. Therefore, we aimed to derive the MCID of the SDI using three different approaches.

## 2 | METHODS

### 2.1 | DREAMS START

This study used data collected from the DREAMS START project (Dementia RElAted Manual for Sleep; STRategies for RelaTives) to determine the MCID on the SDI. DREAMS START was a randomised control trial of the feasibility and acceptability of a multicomponent intervention for people with dementia and sleep disturbances.<sup>21,22</sup> The trial was approved by the London Queen Square Research Ethics Committee (reference number 16/LO/0670). It recruited 62 people

**TABLE 1** Correlation of Sleep disorders inventory (SDI) individual questions change and DEMQOL score changes

Sleep Disorders Inventory (SDI) Score Change	Number scoring as SDI cases at baseline	SDI mean baseline score	SDI mean change	Pearson's Correlation	P-Value
SDI question 1: (Difficulty falling asleep)	39	5.4	−2.0	−0.13	0.33
SDI question 2: (Getting up during the night)	49	6.4	−1.8	−0.12	0.39
SDI question 3: (Inappropriate activities at night)	29	3.6	−1.4	−0.07	0.61
SDI question 4: (Awakening you during the night)	44	5.9	−1.0	−0.08	0.55
SDI question 5: (Awakening during the night and planning to go out)	14	2.0	−1.0	−0.27	0.04
SDI question 6: (Awakening too early in the morning)	27	3.2	−0.9	−0.09	0.52
SDI question 7: (Sleeping excessively during the day)	38	4.2	−0.5	−0.02	0.90

from five memory services in London and Join Dementia Research, who had a clinical diagnosis of dementia and a significant sleep disturbance, defined by an SDI score of  $\geq 4$  in one item of the scale. In addition, the person with dementia or their family carer had to consider the sleep disturbance to be a problem. The person with dementia had to have a primary family carer who provided support at least weekly and they acted as the informant to score the SDI. The carer also acted as an informant for other measures, including the DEMQOL-Proxy,<sup>23</sup> a dementia specific measure of health-related quality of life. A researcher met with the carer and completed proxy measures before randomisation to the intervention or treatment as usual and then at the three month follow-up. The interviewer was blinded to randomisation status. 57/62 (92%) had follow-up data two withdrew consent, two were uncontactable, and one person with dementia died.

## 2.2 | Determining the MCID

Lassere et al<sup>24</sup> proposed three approaches for classifying the MCID: the distribution, anchor and Delphi approaches.

1. The distribution approach determine the level of change that is required to demonstrate that a change in an outcome measure after intervention is more than would be expected from chance.<sup>17</sup> A SD (SD) of 0.33, 0.4 or 0.5 can be classified as MCID,<sup>20</sup> though it has also been suggested that a value of 0.5 should be used as the default.<sup>25</sup>
2. The anchor-based method determines the MCID by comparing the change in the scale of interest and a different scale which measures improvement.<sup>17</sup> In this study we used the DEMQOL-Proxy measure of quality of life as the anchor.<sup>23</sup> It is a validated and frequently used quality of life measure, which is specific for dementia and is completed by a proxy informant.
3. The Delphi method involves the presentation of a questionnaire, in this case about meaningful change in sleep disturbance in a person with dementia, to a panel of individuals with expertise in a field in order to obtain a consensus.<sup>26</sup> There may be several rounds and the process ends when a consensus is reached.<sup>27</sup> Ten to fifteen participants are enough to reach a consensus decision.<sup>28</sup> In our Delphi consensus, we purposively chose a range of experts; health care professionals who worked with people with dementia (clinical psychologist, occupational therapist, nurse and psychiatrist); dementia researchers and those with personal experience of caring for someone with dementia and sleep problems. We sent each participant a questionnaire with three dementia vignettes derived from anonymised accounts from the DREAM START study (appendix A). Participants were then given a list of different changes that equated to changes in points on the SDI. Therefore, this meant that a vignette was described with specific changes. These were equivalent to changing from severe to moderate or frequencies in the sleep problem before and after an intervention. Thus, changes were from a disturbance every night to several times per week but

less than every day, or one to two times per week or less than once per week. Participants were asked which change they considered the MCID.

After all approaches have results they can be triangulated, considering the different perspectives of the approaches as long as researchers are open about the way in which they have determined and chosen their values for the MCID.<sup>29</sup>

## 2.3 | Analysis

All analyses were conducted on IBM SPSS version 25, with both baseline and follow-up data from the DREAMS START study used for the distribution and anchor methods. We calculated the SD of the SDI total score, and the values 0.33, 0.4 and 0.5 of the SD. We employed Pearson's correlation to test the relationship between change in SDI total score with change in quality of life (using the DEMQOL-Proxy total change score).

We analysed the results of the Delphi by using the SDI scores derived from the vignette descriptions to enable us to calculate the mean change across all participants in the Delphi consensus that were regarded as the MCID. We then calculated the post hoc the correlation of the individual items on the SDI and the DEMQOL-Proxy score change in quality of life.

## 3 | RESULTS

The original study recruited 62 people with dementia; 43 women and 19 men. They had a mean age of 80 years. Most had a diagnosis of Alzheimer's disease or of mixed dementia (41) and there was a mix of ethnicities (40 white; 9 Black, 6 Asian and 7 other). The majority of participants had mild (22) or moderate (27) dementia, with a minority having very mild (8) or severe (5) dementia. The carers had a mean age of 57 years, comprised 44 women and 19 men; and there was a mix of ethnicities (43 white; 8 Black, 6 Asian and 5 other).

### 3.1 | Distribution Results

Participants had a mean SDI baseline score of 30.66 (SD = 14.57), out of a possible score of 4-84; 0.5 SD = 7.29; 0.4 SD = 5.82; and 0.33 SD = 4.86.

### 3.2 | Anchoring Results

The SDI change and DEMQOL-Proxy change correlation =  $-0.01$ ;  $P = 0.958$ . Table 1 shows that the only significant correlation between change in individual items on the SDI and change in the DEMQOL-Proxy was an improvement in individuals who had previously got up at night and tried to go out.

### 3.3 | Delphi Results

Table 2 shows the demographic information for the 12 participants who took part in the Delphi questionnaire. The first round did not come to a consensus and participants made suggestions about clarifying the changes described in sleep disturbances so there were clearly different outcomes, which would help them to choose which option qualified as MCID. We then revised the questionnaire was then revised based on these comments.

### 3.4 | Second Round of Delphi

We sent a follow up questionnaire. The consensus was that a MCID symptom severity equivalent to a reduction in three points on the SDI was clinically significant; This meant that a severe sleep disturbance which reduced in frequency from occurring every night to occurring 3 to 4 times a week would be considered a MCID. This meant that having symptoms on fewer nights a week was clinically significant.

## 4 | DISCUSSION

This is to our knowledge the first study that has investigated what the MCID is in sleep disturbances for people living with dementia using the Sleep Disorders Inventory. We used a triangulation of three methods to define this MCID. The result from the distribution analysis using 0.33 SD of the SDI gave a value of 4.86. We compared this with the Delphi consensus where the MCID was 3 points. Previous literature suggests using a halfway value between the two methods of determining a MCID is one way to determine a final MCID value.<sup>20,29</sup> A midway point between 3 and 4.86 is 3.9, which when rounded to a whole number equates to 4 points being the MCID on the SDI. We did not find that SDI change correlated with overall quality of life, only improvement in awakening during the

night and planning to go out had a small to medium relationship to improved quality of life.

A recent study compared the validity of the SDI to actigraphy in care home residents with dementia, and suggested that a SDI total score of five or more should be used to define sleep disturbance in the care home population with dementia.<sup>30</sup> This is a low level of sleep disturbance, and this would mean that for a MCID of four to be achieved sleep disturbances would need to be no longer present after treatment, not just lower in severity or frequency. Though this is quite low, in the DREAMS START trial participants had an average score of 30.66 at baseline, however everyone had to have sleep disturbances to participate. Furthermore those who participate in a trial to treat sleep disturbances are probably more likely to have higher scores and more problematic sleep as they are willing to participate in a trial of a potential treatment.

For other health conditions, the MCID on specific sleep questionnaires have also been defined using similar methods. For example including rheumatoid arthritis using the anchor and Delphi process,<sup>31</sup> in Parkinson's disease using the anchor and distribution methods,<sup>32</sup> and for insomnia using an anchor question that was asked directly to participants about what was a MCID to them.<sup>33</sup> We were unable to do this to define the MCID as this data was not collected in the DREAMS START trial.

Overall in dementia studies, a systematic review found that in trials testing treatments to slow or stop the progress of dementia, only 46% used MCID's for the main outcomes used.<sup>34</sup> Of those 46% of studies, most tended to use an already established MCID for a cognitive scale or used the anchoring method, and none of them used a Delphi asking participants for their opinions of risks vs benefits of drug treatments in dementia.<sup>34</sup> It is important for trials to consider the opinions of people with dementia and their family carers, not just clinicians,<sup>34</sup> as the MCID should give the certainty that a treatment is benefitting the patient.<sup>19</sup> Later studies in dementia such as the Domino trial<sup>20</sup> have used similar methods to ours of a triangulation of methods in determining the MCID.

The results from the anchoring analysis concluded that quality of life improves with a reduction in awakening during the Night and planning to go out but not with sleep disturbance overall. However, only a small number of participants (14/62) were cases on this item at baseline. It was suggested by the Delphi participants from the post hoc analysis that this is because for a person with dementia, quality of life may be more likely to be measured whilst awake and therefore may not relate to someone's sleep disturbance if they do not impact them during the day. However, this is a difficult concept to determine as the quality of life of the person with dementia was measured on the DEMQOL-Proxy by the carer.<sup>35</sup> potentially this result may be influenced by that fact that it is not self-report. and proxy reports and self-report from people with dementia often differ as people with dementia tend to rate their quality of life more highly than their carer does.<sup>35</sup> However, there are positive aspects to using the DEMQOL-Proxy, which include the ability to measure quality of life across the range of severities in dementia and the availability of a tool which is widely accepted and well validated.<sup>36</sup>

**TABLE 2** Delphi participants' demographic Information

Delphi Participant Demographic Information		
Gender N(%)	Male	3 (25%)
	Female	9 (75%)
Profession N(%)	Psychiatrist	1 (8.3%)
	Clinical Psychologist	1 (8.3%)
	Nurse	1 (8.3%)
	Occupational Therapist	1 (8.3%)
	Researchers working in dementia	6 (50%)
	Dementia Carer	2 (16.7%)
Ethnicity N(%)	White	8 (66.6%)
	Asian	1 (8.3%)
	Black	1 (8.3%)
	Other:	2 (16.7%)

## 4.1 | Strengths and Limitations

The sample of people with dementia was mixed in terms of diagnosis, age, severity of dementia and ethnicity, and all lived in their own homes therefore results may be generalisable to populations in higher income countries. We used three different methods to explore the MCID results in different ways and we have been transparent in reporting our reports, so that other investigators in different studies can use the results which are most appropriate to their study as is recommended.<sup>29</sup> The distribution method is advantageous because it has the ability to account for change beyond a level of chance.<sup>17</sup> However, distribution-based methods rely solely on statistical analysis. There are however a limited number of agreed-upon benchmarks for establishing an MCID and three different SD options can be used.<sup>19,20</sup> Without an anchor to link the numerical values to an assessment of what is important to the person, distribution methods can fail in identifying meaningful changes for individuals.<sup>17</sup> Distribution-based methods are sample-specific, which means in a study where there is a large sample and wide distribution, there can be a statistical difference even if a MCID meaningful change is not present.<sup>19</sup>

On the other hand, anchor-based methods will produce different MCID values depending on the subjective choice of the anchor.<sup>19</sup> The Delphi consensus process required two rounds of questionnaires. The participants came from a range of different backgrounds and had a varied mix of demographic characteristics but there were only 12 participants, and a larger sample with more people with dementia and family carers would have been beneficial.

## 5 | CONCLUSIONS

It is important to deliver cost effective care which improves outcomes for people with dementia in clinical practice,<sup>37</sup> including for outcomes that can affect many aspects of a person with dementia's life, such as sleep disturbance. The results from the present study will help to understand whether interventions aimed at improving sleep disturbances people with dementia are clinically meaningful to the individual, regardless of if results are statistically significant. The results indicate that a decrease of 4 points on the SDI is considered the minimum value to be a meaningful and worthwhile change for the patient, derived from both distribution and Delphi consensus methods. We were unable to use the anchoring method as our anchor, quality of life, was not associated with overall sleep disturbances. As the SDI is currently the only validated dementia specific sleep disturbance questionnaire, and is being used in recently published studies measuring sleep in people with dementia including a randomised controlled trial,<sup>30,38-41</sup> these results will also be helpful for researchers to use in future studies.

### CONFLICT OF INTEREST

None Declared.

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### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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