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**Mild cognitive impairment and the uncertainties of diagnosis: reviewing the accuracy of the Montreal Cognitive Assessment and exploring the process of psychosocial adjustment**

***Amanda Stevenson***

*Submitted in part-fulfilment of the degree of Doctorate in Clinical Psychology at the University of Edinburgh*

***August 2014***

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## Front sheet

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*Submitted in part fulfilment of the degree of doctorate in Clinical Psychology at the University of Edinburgh*

*Date Submitted: 1<sup>st</sup> August 2014*

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## **Thesis abstract**

**Background:** Mild Cognitive Impairment (MCI) is a clinical construct reputed to represent an intermediate stage on a continuum between normal aging and cognitive decline. Conceptual and prognostic ambiguity can lead to significant diagnostic challenges and there is a need for accurate screening tests which can assist clinicians with decision-making. A diagnosis of MCI is also associated with considerable uncertainty for patients who may be adjusting to cognitive difficulties along with an increased risk of developing dementia. Beliefs about MCI may influence psychosocial adjustment, and individual differences in ‘psychological flexibility (PF)’, as conceptualised by the Acceptance and Commitment Therapy (ACT) model, may also be involved in this process.

**Objectives:** In order to evaluate the accuracy and clinical utility of a recently developed screening tool for MCI, the Montreal Cognitive Assessment (MoCA), a systematic review of validation and diagnostic test accuracy (DTA) studies for this measure was conducted. Psychosocial adjustment to a diagnosis of MCI was also a key focus. An empirical study was therefore carried out with the aim of evaluating the possible relationships between cognitive impairment, illness representations about MCI, psychological wellbeing and quality of life (QoL), and to assess the potential involvement of PF.

**Method:** Following a systematic search of relevant electronic databases and reference lists, validation and DTA studies of the MoCA were identified and evaluated for methodological quality. For the empirical study, patients recently diagnosed with MCI

were recruited from local NHS memory clinic services and completed the MoCA and a questionnaire pack assessing illness representations, PF, mood, anxiety and QoL.

**Results:** The systematic review identified 18 validation and DTA studies. Few of the studies achieved high ratings for methodological quality and problems with representativeness and generalisability were identified. Nevertheless, sensitivity levels appeared robust across studies, though specificity was variable. For the present empirical study, participants reported a spectrum of positive and negative beliefs about MCI. Distress attributed to MCI was associated with anxiety, along with perceptions of more serious illness consequences, while higher PF was associated with higher perceived QoL and mood. Lived experience of MCI appeared to have more relevance to psychosocial adjustment than objective cognitive impairment.

**Conclusions:** The results of the systematic review indicate that while the MoCA is a robust tool overall in the identification of cognitive impairment, estimates of accuracy may be exaggerated by inter-study variation and bias. More rigorous validation studies are therefore needed. Implications for clinical decision-making regarding MCI are discussed and recommendations for future accuracy studies are outlined.

The empirical study supported the findings of previous studies of the relevance of illness representations to psychosocial adjustment in MCI and added to the evidence base by providing preliminary support for the possible involvement of PF. The results suggest that both cognitive content and PF may represent possible vehicles for therapeutic change in patients with adjustment difficulties, and indicate that further investigation of these factors is warranted. Conclusions are limited, however, by small

sample size and low statistical power. Replication of these findings with a larger and more representative sample is therefore recommended.

## **Systematic Review**

**Title:** The accuracy and clinical utility of the Montreal Cognitive Assessment in the screening and diagnosis of mild cognitive impairment: A systematic review

**Running title:** Diagnostic test accuracy of the MoCA

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**Author contributions:** Amanda Stevenson designed and conducted the review under the academic supervision of Dr. David Gillanders and Dr. Nuno Ferreira, who assisted with the design and research question and provided comments on the final manuscript.

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This systematic review was prepared in accordance with the author specifications for the journal *Geriatrics & Gerontology International* (see Appendix A2).

## **Abstract**

### *Aims:*

The diagnosis of mild cognitive impairment (MCI) is associated with significant challenges. There is therefore recognition of the need for effective screening measures. The Montreal Cognitive Assessment (MoCA) is a recently developed tool which has grown in usage. The current review examines the available evidence for the diagnostic accuracy of the MoCA for people with MCI in clinical settings and evaluates its utility as a screening tool.

### *Methods:*

Relevant electronic databases were systematically searched from April 2005 to February 2014 to identify suitable papers meeting inclusion and exclusion criteria. Reference lists were also hand searched. The methodological quality of included studies was evaluated using an adapted assessment checklist.

### *Results:*

Inclusion and exclusion criteria were met by 18 studies. Most reported high levels of sensitivity for the MoCA, while specificity was more limited. There was substantial variability in quality ratings overall, with few studies achieving highly on the methodology domain. Population representativeness and generalizability was limited across studies. Reporting quality was generally poor, restricting assessment of the accuracy of diagnostic data, though some areas of bias were identified.

### *Conclusions:*

The MoCA appears to be a psychometrically robust tool in the identification and diagnosis of MCI despite cultural, language and methodological variation between studies. Areas of potential bias in study design may have exaggerated estimates of accuracy, however. More rigorous research evidence with representative population samples is therefore recommended.

**Key words:** dementia; diagnostic accuracy; mild cognitive impairment; Montreal Cognitive Assessment; screening tool

## **Introduction**

### Mild cognitive impairment

There has been considerable debate in recent years regarding the etiology, presentation and prognosis associated with mild cognitive impairment (MCI). A meta-analysis of longitudinal studies reported varying outcomes from dementia diagnosis to maintenance of cognition and functioning, and even improvement<sup>1</sup>. Many longitudinal studies vary in length of follow up, however, and by inclusion of different MCI subtypes, argued to represent different disease trajectories<sup>2</sup>. MCI is typically classified into amnesic and non-amnesic subtypes, which can be further differentiated into single and multidomain profiles of impairment. Thus, various factors may affect both the development and course of MCI, creating significant uncertainty for both clinicians and patients.

Despite disagreement whether MCI represents prodromal dementia, it is generally acknowledged that this diagnostic label confers an increased risk of developing Alzheimer's disease (AD) and other dementias<sup>2,3</sup>. The heterogeneity of MCI, combined with the lack of an official 'gold standard' for diagnosis and considerable variability in how the term is measured and applied<sup>4</sup>, has led to controversy regarding its conceptual utility, and it is accordingly associated with significant diagnostic challenges. Therefore, the development of accurate assessment and screening tools has been a key research imperative in recent years.

### Cognitive screening

While various cognitive screening measures for memory and cognitive complaints have been developed, the Mini-Mental State Examination (MMSE)<sup>5</sup> is perhaps the most widely used<sup>6</sup>. Despite a recent meta-analysis reporting high levels of sensitivity and specificity for dementia across a broad range of settings<sup>7</sup>, work by Wind et al.<sup>8</sup> suggested that the MMSE possessed limited value in identifying 'minimal' dementia. Indeed, Mitchell<sup>7</sup> also concluded that there was little evidence for the efficacy of the MMSE with MCI. Nasreddine and colleagues<sup>9</sup> further argued that the MMSE was susceptible to ceiling effects for milder cognitive difficulties. Thus, the MMSE potentially gives rise to significant numbers of false negative cases.

Nasreddine et al.<sup>9</sup> developed an alternative tool, the MoCA, for patients unlikely to be accurately identified by the MMSE. The MoCA was designed with reference to MCI neuropsychological profiles and covers eight cognitive domains, including memory,

visuospatial ability, language, attention and executive functioning. The MMSE in comparison has less emphasis on the latter two domains and contains items with lower difficulty. A cut-off of 26 or above across all domains on the MoCA is considered to be within the normal range, with an additional point added for people with 12 years of education or less.

Koski et al.<sup>10</sup> have reported that the MoCA provides an accurate quantitative measurement of cognitive functioning in MCI in outpatient settings, and a number of studies have reported the MoCA to be superior to the MMSE in identifying MCI<sup>11</sup>. High levels of sensitivity and specificity have been shown across both clinical<sup>12</sup> and community settings<sup>13</sup>, and with selected populations, such as Huntington's disease<sup>14</sup>. Studies of diagnostic and screening tools are vulnerable to bias and imprecision, however, which may give rise to unreliable estimates of a test's performance<sup>15</sup>. There is therefore a need to systematically evaluate the accuracy of such tools and their efficacy in clinical practice.

### Diagnostic accuracy

Diagnostic test accuracy (DTA) denotes the capacity of a measure, or index test, to differentiate between patients with and without a target condition, and typically compares the performance of the test against an agreed reference standard. The target condition is then usually judged present or absent.

The most frequently used statistical summary of DTA is a test's sensitivity and specificity at clinical cut-off<sup>16</sup>, or the ability to identify true positive and true negative cases respectively. Many studies use the Receiver Operating Characteristic Area under the Curve (ROC AUC) statistic which summarizes sensitivity and specificity levels across varying test thresholds, with values closer to 1.0 representing higher accuracy<sup>17</sup>. Additional predictive statistics can also be calculated, including positive (PPV) and negative predictive values (NPV) which are based on epidemiology, and positive (LR+) and negative (LR-) likelihood ratios which estimate a patient's likelihood of having or not having the condition based on their score. These statistics vary in their applicability to the interpretation of individual test results, however, and can be influenced by multiple artefactual and clinical factors<sup>18</sup>. Two common sources of bias in DTA studies include: target condition prevalence (spectrum bias), which can include use of selected populations, such as Parkinson's disease, and the procedures used to confirm disease presence or absence (verification bias). Experimental imprecision can also contribute to inaccuracy, such as via index test or reference standard execution<sup>19</sup>.

Screening tools such as the MoCA should not be used for diagnosis in isolation; however, DTA data can provide an assessment of the robustness of these measures and can assist diagnostic decision-making. It is therefore important to consider the quality of the available DTA evidence for the MoCA in MCI.

### *Systematic review objectives*

This review considers the available literature on the MoCA with the following objectives:

- To evaluate MoCA DTA in classifying patients with MCI.
- To examine MoCA utility in assisting with clinical decision-making.

## **Materials and Methods**

### Search Strategy

Systematic searches of the following electronic databases were conducted: EMBASE, Medline, PsychINFO, Web of Science, Scopus and ASSIA. Reference lists of included studies were also searched. The extant literature was initially scoped and search terms (Table 1) developed with reference to common key words. Since the original validation study for the MoCA was published in 2005, the search was restricted from April 2005 to February 2014. Following search completion, titles and abstracts were initially screened to remove studies not meeting inclusion criteria. The remaining studies were read in full and assessed for inclusion.

**Table 1** Electronic database search criteria: EMBASE, Medline, PsychINFO, Scopus and ASSIA

Search terms

---

- Montreal Cognitive Assessment
  - MoCA
  - Mild Cognitive Impairment
  - MCI
  - Dement\*
  - Cognitive impair\*
  - Screen\*
  - Diagnos\*
  - Valid\*
  - 1 or 2
  - 3 or 4 or 5 or 6
  - 7 or 8 or 9
  - 10 and 11 and 12
- 

Inclusion and exclusion criteria

Studies were screened against the following criteria:

*Inclusion criteria:*

- EITHER studies evaluating MoCA DTA for MCI OR Validation studies of the MoCA for MCI.
- Studies aiming to evaluate the MoCA as a tool for differentiating between MCI and no cognitive impairment (NCI) or dementia.
- Studies based in clinical settings, e.g., memory clinics, geriatric outpatient and inpatient departments, and primary care.

*Exclusion criteria:*

- Articles not in English
- Studies including the MoCA as part of a wider assessment protocol, or as

comparator to another index test.

- Editorials, conference posters, theses, review articles, guides and letters.
- Studies investigating selected clinical populations, e.g., Parkinson's disease.

### Assessment of methodological quality

No existing standardized tool was considered to sufficiently cover the key quality determinants for administration, interpretation and analysis of the MoCA for MCI. An assessment tool was therefore developed and adapted from the following standardized checklists: the QUADAS tool<sup>20</sup>, Scottish Intercollegiate Guidelines Network (SIGN) Methodology Checklist 5 for DTA studies<sup>21</sup>, and STARD guidelines for reporting of diagnostic studies<sup>22</sup>. The final assessment tool is presented in Figure 1 and has a total score of 20 derived from the following domains: abstract and introduction (2 points); methodology (10 points); results and discussion (8 points). Each item was coded according to operational criteria developed by the first author (AS) using the following ratings: Yes=1, No=0 Unclear=0. The full list of operational criteria for each item are presented in Appendix A1. All papers were evaluated by the first author. A subset of 6 studies was co-rated by an independent practitioner. Identification of papers for co-rating was based on overall score following initial rating by the first author and was selected so that a range of high, mid and low scoring studies were represented. Inter-rater reliability was fair at 68.3%. Where discrepancies were identified, these were resolved through discussion and rechecking of papers.

**Figure 1** Quality assessment tool

**CHECKLIST FOR DIAGNOSTIC ACCURACY**

**Study Authors:** \_\_\_\_\_ **Year:** \_\_\_\_\_

**Study title:** \_\_\_\_\_

**SCORING:**

Yes – 1

No/Unclear – 0

<b>Item</b>	<b>Score</b>
<i>Abstract and Introduction</i>	
1. Abstract identifies the article as a diagnostic accuracy study, and clearly reports study methodology, results and conclusions	
2. Introduction clearly outlines the research question(s) and/or study aim(s)	
<b>Total</b>	<b>/2</b>
<i>Methodology</i>	
3. The methods of recruitment of the study population are appropriate	
4. The study population is representative of the patients who would typically receive the test in practice	
5. The reference standard and its execution are appropriate (i.e. likely to correctly classify the target condition)	
6. The number and expertise of the persons executing and interpreting the reference standard would be considered appropriate	
7. The index test version and its execution would be considered appropriate	
8. The number and expertise of the persons executing and interpreting the index test would be considered appropriate	
9. All participants receive the same reference standard	
10. The index test results were interpreted without knowledge of the reference standard results	
11. The reference standard results were interpreted without knowledge of the index test results	
12. Index test results were interpreted according to a pre-determined cut-off	
<b>Total</b>	<b>/10</b>
<i>Results and discussion</i>	
13. Any withdrawals or exclusions from the study were explained	
14. Statistical methods used to calculate and/or compare measures of diagnostic accuracy were appropriate	
15. The results of statistical methods used to assess diagnostic accuracy were reported in full	
16. Clinical and demographic characteristics of the study population were clearly reported and any differences were accounted for in statistical analysis	
17. Index tests scores were appropriately adjusted for education level	
18. Estimates of diagnostic accuracy included measures of statistical uncertainty (e.g. 95% confidence intervals)	
19. Optimal cut-off values were calculated and reported	

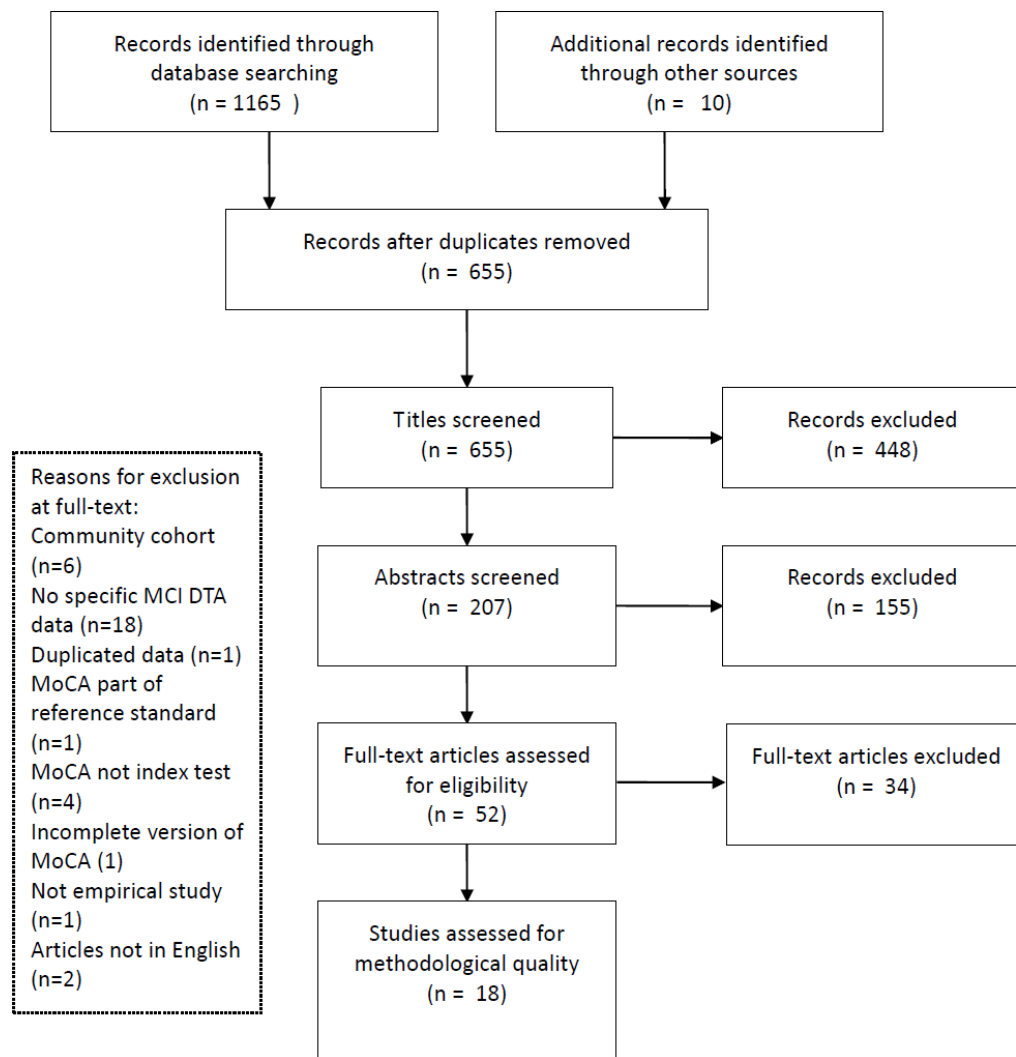
20. The clinical applicability of the study findings was discussed	
<b>Total</b>	<b>/8</b>
<b>Overall total</b>	<b>/20</b>

## Results

### Outcome of search process

This process is summarized in Figure 2. Electronic databases were searched on 19<sup>th</sup> February 2014, with 1165 studies retrieved. A further 10 studies were identified from study reference lists. Following de-duplication, 655 studies remained for screening of titles and abstracts. Review of titles excluded 448 studies, while 155 were excluded at abstract level. A total of 52 studies were read in full and assessed for eligibility using a data extraction form adapted from an existing tool developed by the Cochrane Collaboration<sup>23</sup>. After removing 34 studies, a final group of 18 studies was judged to meet inclusion and exclusion criteria.

**Figure 2** Flow chart of systematic search and study selection process



### Study characteristics

Study demographic information is presented in Table 2. Studies differed by country of origin, entailing significant variation in both translations of the MoCA and in numerous culturally-dependent items. In addition, studies varied in inclusion of MCI subtypes, with seven studies recruiting amnesic-MCI (aMCI) participants only. There

was also marked variation in sample sizes, with the number of MCI participants ranging from 23<sup>24</sup> to 150<sup>25</sup>. Razali et al.<sup>26</sup> was the only study without a comparison group. The remainder of studies recruited participants with dementia, typically AD, and NCI participants. Most studies incorporating an NCI group restricted inclusion criteria to those with no subjective or objective memory complaints; however, Smith and colleagues<sup>24</sup> comparison group comprised memory clinic attendees with other cognitive complaints. The majority of studies used Petersen et al.<sup>3</sup> MCI criteria supported by clinical diagnosis, while Lifshitz et al.<sup>27</sup> used alternative appropriate criteria outlined by Busse et al.<sup>28</sup> and Winblad et al.<sup>29</sup>, along with a computerized cognitive battery and clinical diagnosis. Overall, studies tended not to include participants over the age of 80, which may limit applicability of the MoCA with a significant proportion of older adults.

## Quality assessment of studies

### *Methodological review*

A summary of ratings for each study is presented in Table 3, with studies listed in order of overall score. The studies scoring highest on the rating tool were Luis et al.<sup>12</sup>, followed by Memoria et al.<sup>30</sup>, Smith et al.<sup>24</sup> and Lee et al.<sup>31</sup>. The lowest scoring studies were Duro et al.<sup>32</sup> and Lifshitz et al.<sup>27</sup>. Notably, however, there was high variability in methodology domain scores across studies, with only five meeting 50% or more of criteria. Therefore, overall scores cannot be considered an accurate representation of study quality, a limitation common to systematic reviews of DTA studies<sup>16,33</sup>

**Table 2:** Study demographic information

Study	MoCA version	Aim	MCI Reference Standard	Participants	Males	Age (SD)	Years of education (SD)	Mean MoCA score (SD)
<i>Luis et al.</i> <sup>12</sup>	English	Validation; DTA	Petersen et al. <sup>3</sup> ; CCD: physical; neurological; neuroimaging; neuropsych	24 aMCI 20 AD 74 NCI	15 aMCI 8 AD 36 NCI	78.9 (5.3) aMCI 79.9 (4.3) AD 78.9 (3.7) NCI	14.4 (4.1) aMCI 13.5 (2.6) AD 14.2 (2.5) NCI	20.5 (2.4) aMCI 15.8 (6.5) AD 25.9 (1.8) NCI
<i>Memoria et al.</i> <sup>30</sup>	Brazilian	Validation; DTA	Petersen et al. <sup>3</sup> ; CCD: clinical data; neuropsych	43 MCI 28 AD 41 NCI	14 MCI 13 AD 8 NCI	74.3 (5.6) MCI 76.53 (4.87) AD 71.68 (4.62) NCI	11.41 (4.23) MCI 11.1 (5.01) AD 13.41 (4.45) NCI	22.64 (2.83) MCI 16.42 (3.85) AD 26.3 (2.61) NCI
<i>Lee et al.</i> <sup>31</sup>	Korean	Validation; DTA	Petersen et al. <sup>3</sup> ; CCD: clinical history; neuropsych	37 MCI 44 AD 115 NCI	14 MCI 21 AD 34 NCI	71.3 (5.9) MCI 70.4 (8.6) AD 69.1 (6.1) NCI	8.3 (3.8) MCI 7.9 (3.7) AD 8.0 (3.5) NCI	18.5 (3.7) MCI 12.9 (5.0) AD 25.0 (2.6) NCI
<i>Smith et al.</i> <sup>24</sup>	English	Validation; DTA; predictive ability	Petersen et al. <sup>3</sup> ; neuropsych; CD	23 MCI 32 Dementia 12 MCC	10 MCI 20 Dementia 4 MCC	77.5 (7.8) MCI 74.4 (9.3) Dementia 64.0 (10.8) MCC	11.3 (2.5) MCI 12.7 (2.5) Dementia 12.0 (2.5) MCC	22.5 (3.5) MCI 21.0 (3.4) Dementia 25.0 (3.1) MCC
<i>Dong et al.</i> <sup>11</sup>	Chinese Malay	Validation; DTA	Petersen et al. <sup>3</sup> ; CCD: neuroimaging; clinical data; physical; neuropsych	25 sd-MCI 36 md-MCI 136 dementia 33 NCI	– – – –	68.5 (6.5) sd-MCI 71.1 (11.3) md-MCI 76.3 (8.5) dementia 62.8 (9.9) NCI	8.5 (4.2) sd-MCI 6.4 (4.8) md-MCI 4.7 (4.5) dementia 9.4 (3.9) NCI	22.4 (3.0) sd-MCI 15.2 (5.2) md-MCI 11.2 (4.8) dementia 24.9 (3.0) NCI
<i>Hu et al.</i> <sup>34</sup>	Chinese (Beijing)	Validation; DTA	Petersen et al. <sup>3</sup> ; CDR; CCD; Neuropsych	84 MCI 72 AD 146 NCI	36 MCI 32 AD 65 NCI	60.7 (5.0) MCI 68.4 (4.3) AD 67.2 (5.3) NCI	9.82 (3.0) MCI 8.9 (3.1) AD 9.3 (2.6) NCI	24.5 (1.9) MCI 17.2 (5.5) AD 27.7 (1.3) NCI

<i>Fujiwara et al.</i> <sup>35</sup>	Japanese	Validation; DTA	Petersen et al. <sup>3</sup> ; CDR; neuropsych	30 MCI 30 AD 36 NCI	7 MCI 11 AD 10 NCI	77.3 (6.3) MCI 77.5 (6.0) AD 76.4 (3.3) NCI	11.5 (3.1) MCI 12.1 (3.0) AD 12.3 (2.3) NCI	-- -- --
<i>Ng et al.</i> <sup>36</sup>	English (Singapore)	Validation; DTA	Petersen et al. <sup>3</sup> ; CDR; CD	49 aMCI 60 AD 103 NCI	27 aMCI 30 AD 41 NCI	62.43 (9.4) aMCI 72.58 (7.15) AD 56.35 (8.27) NCI	10.93 (4.28) aMCI 6.97 (4.47) AD 12.07 (3.2) NCI	27.0 (3.07) aMCI 20.8 (4.06) AD 28.56 (1.45) NCI
<i>Roalf et al.</i> <sup>37</sup>	English	Comparative DTA	Petersen et al. <sup>3</sup> ; CCD: clinical history; physical; biochem; neurological; neuroimaging; neuropsych	126 MCI 321 AD 140 NCI	64 MCI 122 AD 46 NCI	72.29 (8.12) MCI 75.69 (8.21) AD 71.19 (9.2) NCI	14.86 (4.2) MCI 13.33 (4.15) AD 15.91 (3.03) NCI	20.94 (4.5) MCI 13.04 (6.05) AD 26.83 (2.64) NCI
<i>Zhao et al.</i> <sup>25</sup>	Chinese	DTA	Petersen et al. <sup>3</sup> ; CCD: neurological; physical; neuroimaging; neuropsych	150 aMCI 150 NCI	79 aMCI 88 NCI	70.67 (4.27) aMCI 69.85 (5.21) NCI	-- --	20.5 (1.) aMCI 25.5 (2.3) NCI
<i>Chu et al.</i> <sup>38</sup>	Cantonese	Validation; DTA	Petersen et al. <sup>3</sup> ; Busse et al. <sup>28</sup>	87 aMCI 64 AD 115 NCI	32 aMCI 25 AD 28 NCI	77.2 (6.3) aMCI 78.5 (5.8) AD 72.2 (6.1) NCI	4.62 (5.19) aMCI 4.56 (5.0) AD 6.97 (4.69) NCI	18.7 (4.6) aMCI 11.3 (5.1) AD 24.4 (3.2) NCI
<i>Nasreddine et al.</i> <sup>9</sup>	English French	Validation; DTA	Petersen et al. <sup>3</sup> ; CD: Clinical history; neuropsych	94 MCI 93 AD 90 NCI	53 MCI 38 AD 36 NCI	75.19 (6.27) MCI 76.72 (8.83) AD 72.84 (7.03) NCI	12.28 (4.32) MCI 10.03 (3.84) AD 13.33 (3.4) NCI	-- -- --
<i>Freitas et al.</i> <sup>39</sup>	Portuguese	Validation; DTA; sensitivity to cognitive decline	Petersen et al. <sup>3</sup> ; CDR; CCD: biochem; physical; neuroimaging; neuropsych	90 aMCI 90 AD 90 C-aMCI 90 C-AD	35 aMCI 38 AD 35 C-aMCI 38 C-AD	70.52 (7.95) aMCI 74.22 (8.21) AD 69.59 (7.05) C-aMCI 73.10 (7.54) C-AD	6.5 (4.57) aMCI 6.23 (4.12) AD 6.53 (4.5) C-aMCI 6.24 (4.13) C-AD	18.31 (3.87) aMCI 10.06 (4.41) AD 23.64 (3.22) C-aMCI 22.33 (3.47) C-AD

<i>Razali et al.</i> <sup>26</sup>	Bahasa-Malaysian	Comparative DTA	Not specified	180 memory clinic attendees	With MCI: 49	Median age: With MCI 65.3 Without MCI 62.5	Median education: With MCI 6 Without MCI 10	-- --
<i>Costa et al.</i> <sup>40</sup>	German	Comparative accuracy of alternate form tests	Petersen et al. <sup>3</sup>	30 MCI 30 AD 100	15 MCI 15 AD 60 NCI	67.8 (8.13) MCI 71.07 (8.57) AD 65.4 (9.26) NCI	11.47 (2.85) MCI 10.60 (2.42) AD 11.94 (2.79) NCI	-- -- --
<i>Tsai et al.</i> <sup>41</sup>	Taiwanese	Validation; DTA	Petersen et al. <sup>3</sup> ; CCD; Clinical history; physical; biochem; neuroimaging; neuropsych	71 aMCI 98 AD 38 NCI	36 aMCI 62 AD 25 NCI	79.2 (6.8) aMCI 79.6 (6.4) AD 77.7 (6.0) NCI	8.9 (5.1) aMCI 8.4 (4.9) AD 10.1 (4.4) NCI	20.5 (4.0) aMCI 12.6 (5.2) AD 25.5 (2.3) NCI
<i>Duro et al.</i> <sup>32</sup>	Portuguese	Validation; DTA; CFA	Petersen et al. <sup>3</sup> ; CDR; CD: biochem; neurological; neuroimaging; neuropsych	82 aMCI 70 AD 25 VaD 35 other dementias				
<i>Lifshitz et al.</i> <sup>27</sup>	Hebrew	Validation; DTA	Gauthier et al. (2006); Mindstreams Cognitive Evaluation; CCD	74 MCI 80 NCI	38 MCI 43 NCI	76.3 (5.61) MCI 71.3 (4.65)	-- --	20.3 (3.31) MCI 26.73 (1.94) NCI

*AD: Alzheimer's disease; aMCI: amnesic mild cognitive impairment; Biochem: biochemical data; CD: clinical diagnosis; CCD: consensus clinical diagnosis; CDR: Clinical Dementia Rating Scale<sup>42</sup>; CFA: Confirmatory factor analysis; DTA: diagnostic test accuracy; md-MCI: multi-domain mild cognitive impairment; sd-MCI: single domain mild cognitive impairment; NCI: no cognitive impairment; Neuropsych: neuropsychological battery; VaD: vascular dementia*

**Table 3** Quality rating scores

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
<i>Luis et al.</i> <sup>12</sup>	+	+	-	-	+	+	+	?	?	+	+	+	+	+	-	+	+	+	+	+
<i>Memoria et al.</i> <sup>30</sup>	+	+	?	-	+	+	?	+	+	+	+	+	+	?	-	-	+	+	+	+
<i>Lee et al.</i> <sup>31</sup>	+	+	?	-	+	+	+	-	?	+	+	?	+	+	+	+	?	+	+	+
<i>Smith et al.</i> <sup>24</sup>	+	+	+	-	+	?	?	?	+	+	?	-	+	+	+	+	+	+	+	+
<i>Dong et al.</i> <sup>11</sup>	+	+	+	-	+	+	?	?	+	+	+	?	-	+	-	-	+	+	+	+
<i>Hu et al.</i> <sup>34</sup>	+	-	-	-	?	+	?	?	?	+	?	+	+	+	+	+	+	+	+	+
<i>Fujiwara et al.</i> <sup>35</sup>	+	+	-	-	+	?	+	?	?	?	?	?	+	+	+	+	?	+	+	+
<i>Ng et al.</i> <sup>36</sup>	+	+	-	-	+	?	?	?	?	?	+	+	+	+	-	+	+	-	+	+
<i>Roalf et al.</i> <sup>37</sup>	-	+	+	?	+	?	?	?	?	+	+	?	+	+	-	-	?	+	+	+
<i>Zhao et al.</i> <sup>25</sup>	-	-	-	-	+	+	-	?	?	+	+	?	+	+	+	+	?	+	+	-
<i>Chu et al.</i> <sup>38</sup>	+	+	-	-	+	?	+	?	+	?	?	?	+	+	-	?	+	-	+	+
<i>Nasreddine et al.</i> <sup>9</sup>	+	+	-	-	+	?	?	?	-	?	+	+	+	+	-	-	+	-	+	+
<i>Freitas et al.</i> <sup>39</sup>	+	+	-	-	+	?	-	-	-	?	+	?	-	+	-	+	+	+	+	+
<i>Razali et al.</i> <sup>26</sup>	-	+	+	-	-	?	+	?	?	?	?	+	+	-	-	+	+	+	-	+
<i>Costa et al.</i> <sup>40</sup>	-	+	-	-	+	?	-	-	?	?	+	?	+	+	-	+	?	+	+	+
<i>Tsai et al.</i> <sup>41</sup>	+	+	-	-	+	?	+	?	?	?	?	-	?	+	-	+	?	+	+	+
<i>Duro et al.</i> <sup>32</sup>	?	+	-	-	+	?	?	?	+	?	?	+	+	-	-	?	+	-	-	-
<i>Lifshitz et al.</i> <sup>27</sup>	+	?	-	-	+	?	?	?	-	?	?	+	+	+	-	-	?	-	-	+

Items 1-20 correspond with Figure 1. + = Yes; - = No; ? = Unclear

No study was judged to have evaluated a representative population. All studies using case-control methodology failed to meet this criterion since patients without subjective memory or cognitive complaints would be unlikely to receive the MoCA in practice. The two studies which did not use this design, Dong et al.<sup>11</sup> and Razali et al.<sup>26</sup> were considered to have employed restrictive inclusion and exclusion criteria which limit external validity. Similarly, most studies did not use appropriate recruitment methods, or did not sufficiently report methodology. Only Dong et al.<sup>11</sup>, Razali et al.<sup>26</sup>, Roalf et al.<sup>37</sup> and Smith et al.<sup>24</sup> reported recruiting all participants from a clinical setting, though the latter two studies subsequently employed a case-control design, limiting the representativeness of their sample.

Overall methodology reporting was poor. Various areas were consistently omitted, including the number and expertise of individuals executing and interpreting the MoCA, MoCA administration, reference standard application, independence of reference standard and MoCA outcomes and use of pre-determined MCI cut-offs. Where these factors were addressed, some studies did not meet quality criteria. Only Memoria et al.<sup>30</sup> clearly specified an appropriate number of people with sufficient expertise to administer and interpret the MoCA. Two studies did not outline appropriate execution, with the MoCA test being administered immediately following the MMSE. Performance on the MMSE may have influenced interpretation of the MoCA, and thus confirmation bias cannot be fully discounted. Three studies reported that not all participants received the same reference standard; thus, some participants were more highly investigated than others. One study did not use a pre-determined cut-

off, increasing the likelihood of confirmation bias. Considering the above factors, the potential for verification bias also cannot be excluded.

### *Statistical analysis and interpretation*

Three studies did not state clear objectives in their introduction. Judgment of the suitability of their statistical analysis is therefore limited. In addition, Memoria et al.<sup>30</sup> did not clearly report the statistics used in their DTA analysis. Duro et al.<sup>32</sup> and Razali et al.<sup>26</sup> did not meet criteria for appropriate statistical analysis. Both studies reported only one DTA measure. Thirteen studies did not fully report DTA results, many providing only optimal sensitivity and specificity figures without presenting the full range of thresholds. Few studies calculated PPV, PNV or probability data. Comparison of DTA across studies is therefore compromised. Five studies did not consistently report measures of statistical uncertainty. Thus, assessment of the reliability of their DTA data is restricted.

Reporting of demographic information was also variable. Some studies noted significant between-group differences in age and education level which were not subsequently accounted for in their analysis of MoCA scores. Increased age and lower educational levels have been associated with poorer MoCA performance<sup>40</sup>. This suggests that demographic discrepancies may explain some of the between-group variability in MoCA scores.

The appropriateness of adjustments to scores by educational level were unclear for seven studies, making it difficult to evaluate the possible impact of this on DTA results. Gagnon et al.<sup>43</sup> found that overall sensitivity, specificity and optimal cut-off scores on the MoCA were significantly altered when scores were corrected for education level.

### *Diagnostic accuracy*

Table 3 presents a summary of DTA statistics across all studies, including LRs based on available sensitivity and specificity data. It was not possible to calculate PPVs and NPVs due to the variation in available base-rate data for MCI in each country.

Sensitivity levels were high overall, ranging from 0.77<sup>25</sup> to 1.00<sup>40</sup> while specificity levels were more variable, ranging from 0.19<sup>36</sup> to 1.0<sup>35</sup>. This likely relates to the diverse methodological differences between studies, variation in reported optimal cut-offs and the ethnic, cultural and educational differences between included populations.

All studies apart from Smith et al.<sup>24</sup>, Ng et al.<sup>36</sup>, Nasreddine et al.<sup>9</sup> and Duro et al.<sup>32</sup> calculated the ROC AUC. Reported AUC values were high across all studies, ranging from 0.82<sup>26,30</sup> to 0.97<sup>12</sup>. ROC curves can be used to compare results from multiple studies; however, since not all studies reported sensitivity and specificity at varying thresholds it is not possible to provide a graphical representation in the current review.

Where possible, LR+ and LR- were calculated from reported sensitivity and specificity values. When LR+ is greater than 1, people with the target condition are more likely to score in the positive range, and when LR- is greater than 1, people with the target condition are more likely to score in the negative range<sup>44</sup>. LR+ values varied markedly, ranging from 1.16<sup>36</sup> to 44.5<sup>31</sup>, while LR- values ranged from 0<sup>40</sup> to 0.34<sup>24</sup>. This means that scores on the MoCA were generally likely to deliver an accurate diagnostic conclusion. Interestingly, data reported by Luis et al.<sup>12</sup> and Lee et al.<sup>31</sup>, both of which scored among the highest on the quality rating tool, resulted in notably large LR+ values. Both studies used small sample sizes with limited representativeness, however. Nevertheless, these figures suggest that the MoCA may produce more robust psychometrics with more rigorous study methodology.

**Table 4** Summary of diagnostic test accuracy statistics

<b>Study</b>	<b>MoCA version</b>	<b>Cut-off</b>	<b>Sensitivity</b>	<b>Specificity</b>	<b>AUC</b>	<b>LR+</b>	<b>LR-</b>
<i>Luis et al.</i> <sup>12</sup>	English	23 <sup>†</sup>	0.96	0.95	0.97	19.2	0.04
<i>Memoria et al.</i> <sup>30</sup>	Brazilian	26	0.91	0.56	0.82	2.07	0.16
<i>Lee et al.</i> <sup>31</sup>	Korean	22/23	0.89	0.98	0.94	44.5	0.11
<i>Smith et al.</i> <sup>24</sup>	English	26	0.83	0.50	–	1.66	0.34
<i>Dong et al.</i> <sup>11</sup>	Chinese Malay	19/20 <sup>‡</sup>	0.83	0.86	0.95	5.93	0.20
<i>Hu et al.</i> <sup>34</sup>	Chinese	26	0.92	0.85	0.93	6.13	0.09
<i>Fujiwara et al.</i> <sup>35</sup>	Japanese	25/26	0.93	1.00	0.95	N/A <sup>¶</sup>	0.07
<i>Ng et al.</i> <sup>36</sup>	English	<10 years education: 26 <sup>†</sup>	0.94	0.19	–	1.16	0.32
		≥10 years education: 27 <sup>†</sup>	0.96	0.30	–	1.37	0.13
<i>Roalf et al.</i> <sup>37</sup>	English	25	0.84	0.79	0.89	4.00	0.20
<i>Zhao et al.</i> <sup>25</sup>	Chinese	23/24 <sup>†</sup>	0.77	0.90	0.88	7.70	0.26
<i>Chu et al.</i> <sup>38</sup>	Cantonese	22/23 <sup>†</sup>	0.78	0.73	0.85	2.89	0.30
<i>Nasreddine et al.</i> <sup>9</sup>	English French	26	0.90	0.87	–	6.92	0.11
<i>Freitas et al.</i> <sup>39</sup>	Portuguese	22 <sup>†</sup>	0.81	0.77	0.86	3.52	0.25
<i>Razali et al.</i> <sup>26</sup>	Bahasa-	22/23	–	–	0.82	–	–

Malaysian							
<i>Costa et al.</i> <sup>40</sup>	German	MoCA 1: 26	0.93	0.62	0.85	2.45	0.11
		MoCA 2: 26	1.00	0.60	0.88	2.50	0
		MoCA 3:26	0.90	0.57	0.77	2.09	0.18
<i>Tsai et al.</i> <sup>41</sup>	Taiwanese	23/24 <sup>†</sup>	0.92	0.68	0.91	2.88	0.12
<i>Duro et al.</i> <sup>32</sup>	Portuguese	26 <sup>§</sup>	0.84	1.00	–	N/A <sup>¶</sup>	0.16
<i>Lifshitz et al.</i> <sup>27</sup>	Hebrew	26	0.95	0.76	0.96	3.96	0.07

<sup>a</sup>Comparison between *a*-MCI and NCI; <sup>b</sup>Comparison between *md*-MCI and NCI; <sup>c</sup>Comparison between MCI and dementia; <sup>d</sup>Ratio undefined due to denominator value of zero.

## **Discussion**

Findings from current review

### *Diagnostic accuracy*

Using a structured and comprehensive search strategy, 18 studies reporting psychometric properties and DTA statistics for the MoCA with MCI were identified. Sensitivity levels were consistently high and similar to that of the original validation study, supporting its efficacy in detecting ‘true’ MCI in line with the authors’ aims. Specificity was more modest, indicating that the MoCA may give rise to significant numbers of false positive cases. Comparisons of ROC AUC values showed that the MoCA performed similarly well across all included studies. Calculated LRs indicate that people with MCI are likely to score positively on the MoCA while people with NCI are likely to score negatively. These figures suggest that the MoCA is a robust screening tool for MCI.

### *Quality assessment*

Only five studies met 50% or more of quality criteria for the methodology domain, however, and there was significant variability in ratings across studies and domains. Thus, total scores are not considered to be a proxy of study quality. The majority of studies used case-control methodology, and all used populations not considered representative of memory clinic or geriatric outpatient attendees. Many studies did not fully report methodology or the results of statistical analysis, a significant number calculating only limited DTA statistics. Some areas of possible bias were identified, including spectrum and verification bias. Between-group demographic differences in

age and education were common, but the possible influence of these on MoCA performance was not always evaluated. The relationship between methodological quality domain scores and reported DTA also appears variable, with no consistent pattern identified. Studies with both high and low quality ratings published DTA data which was suggestive of high accuracy, suggesting that any conclusions drawn would be of limited reliability.

## Limitations of DTA studies

### *MCI prevalence*

Target condition prevalence within an included sample can significantly influence DTA findings<sup>19</sup>. Therefore an artificial patient spectrum can lead to inaccuracies in the assessment of a test's efficacy. Unrepresentative samples can arise through spectrum bias and experimental variability. Case-control methodology, in addition to restrictive inclusion and exclusion criteria, can inflate disease prevalence. This is particularly problematic where sample sizes are low, as was the case for numerous studies in the current review. Where participants known to have MCI are recruited separately to NCI participants, prevalence is skewed towards cases who would be easily identified by the index test, which could increase sensitivity estimates<sup>33</sup>. This risk is minimized, however, where all participants are sampled from the same setting, as with studies conducted by Smith et al.<sup>24</sup> and Roalf et al.<sup>37</sup>, though their inclusion criteria stipulated *a priori* diagnosis. It must also be noted that clinical settings will likely reflect a higher MCI prevalence compared to community studies.

Additionally, excluding other clinical presentations which might meet some MCI criteria, such as subjective memory complaints or psychiatric diagnoses, would not reflect the MoCA's clinical use as a screening measure. Memory clinic or geriatric outpatient attendees may present with cognitive difficulties of varying etiologies; thus, for a cognitive screen to be clinically useful it must also demonstrate efficacy with ambiguous presentations. Furthermore, since defined MCI cases in included studies are necessarily subject to greater investigation, it is arguable that some excluded ambiguous cases might have been classed as MCI if they had received the reference standard. MCI diagnostic criteria would not necessarily restrict patients with psychiatric complaints from being classified thus; for example, major depression presentation in older adults can be associated with cognitive impairment<sup>45</sup>. Therefore, there may be unknown numbers of false negative cases in these studies.

#### *Reference standard and verification*

The conceptual elasticity of MCI leads to inherent difficulties in delivering precise and valid diagnoses. Petersen et al.'s<sup>3</sup> criteria is generally accepted and is extensively applied; however, the lack of an established 'gold standard' may result in inaccuracies and imprecision in deploying reference standard criteria in DTA studies. The majority of studies in the current review employed Petersen and colleagues'<sup>3</sup> criteria, with supporting clinical, neuropsychological and neuroimaging data. Despite this general uniformity, studies varied in the number and expertise of diagnosing clinicians. This may have led to diagnostic variability and thus may have influenced reported MoCA sensitivity and specificity<sup>15</sup>.

Additionally, the extent to which patients undergo verification procedures can affect sensitivity and specificity. Partial-verification bias occurs where the reference standard is more likely to be applied to participants scoring above index test cut-off, a procedure that can inflate sensitivity<sup>15</sup>. Three studies in the current review reported that MCI and dementia patients received full diagnostic work-up while NCI participants were evaluated on less stringent criteria. Freitas et al.<sup>39</sup> separately recruited patients with an established diagnosis, Lifshitz et al.<sup>27</sup> used consensus diagnosis to confirm only cognitively impaired participants and Nasreddine et al.<sup>9</sup> applied the reference standard to only a subset of their NCI participants. Since performance on the MoCA itself did not determine eligibility for verification, the involvement of bias may be minimized; however, patients with established MCI are more likely to score significantly on the MoCA. Several other studies did not clearly state that all participants received the reference standard, therefore bias cannot be fully discounted.

### *Statistical analysis*

Few studies reported comprehensive DTA data. The majority summarized optimum sensitivity and specificity levels and reported ROC AUC figures. As noted above, these can depend on factors independent of index test efficacy and, given the methodological limitations of the studies in the current review, may not therefore be generalizable to clinical practice. Optimal cut-offs, while providing a trade-off between sensitivity and specificity, hinder comparison and consensus, particularly where there are also cultural and language differences between MoCA test versions.

The current review found that cut-offs also varied by adjustment for educational level, a necessary modification for populations with poor levels of literacy and education but which increases between-study inconsistency. Cross-cultural differences may be partly mitigated by reporting of PPVs and NPVs, since these rely on regional prevalence data<sup>46</sup>. Only seven studies reported these values, however.

### Quality of reporting

Reporting standard was generally poor across all studies. Numerous core quality determinants were frequently omitted, including MoCA administration and rater expertise, the independence of MoCA and reference standard results, blanket application of the reference standard and use of pre-determined cut-offs. Absence of this information restricted quality assessment and likely resulted in some studies attaining a lower overall rating. Under-reporting also limits conclusions from DTA data since possible bias and measurement error is hidden. The STARD initiative<sup>22</sup> was established to improve DTA study reporting and a corresponding assessment tool was developed. In the current review it was considered that studies with limited methodological quality might attain higher scores due to better reporting, and that this may skew quality assessment findings. Therefore, the emphasis of ratings was more heavily weighted to available methodological information rather than reporting quality.

## Clinical utility of the MoCA

The MoCA should not be used as a diagnostic test in isolation but in combination with physical, neurological, functional and neuropsychological data. Nevertheless, DTA analysis can be used to assess its efficacy in identifying patients requiring further investigation. DTA studies can facilitate clinical decision-making by providing parameters clinicians can apply to individual cases, evaluating test thresholds which are relevant to routine clinical practice, and reporting reliable and valid sensitivity and specificity values<sup>18</sup>.

All studies in the current review provide DTA statistics of MoCA performance in detecting MCI, but a number of factors hinder interpretation of these figures. The nature and direction of identified bias and artefactual imprecision are likely to have increased sensitivity and decreased specificity. This means that the accuracy of the MoCA in identifying and correctly classifying ‘true’ MCI may be inflated, and that it could misclassify a significant proportion of false positives. Moreover, since sensitivities and specificities are frequently, but not always, reported for optimal cut-offs, this leads to greater uncertainty regarding clinically significant thresholds. Differences in cut-offs may reflect MCI heterogeneity, but also likely relate to cross-cultural and language differences. At present it seems no threshold can be universally applied, and thus judgment of individual MoCA scores lies with the administering clinician. Frequently, ROC AUC figures are also reported, which facilitate between-test and between-study comparisons, but application in clinical practice is limited as the relevance of scores in individual cases cannot easily be extrapolated and they often

span cut-offs which are unrealistic<sup>18</sup>. In addition, the limited age ranges included in MoCA validation studies are likely to restrict the reliability of this cognitive screen with patients over the age of 80.

Where supplementary DTA statistics are reported, these can assist the clinician with individual decision-making. Clinicians can judge the prospect of a person with MCI scoring positively, and a cognitively healthy person scoring negatively on a test using LRs. They are argued to be more clinically useful than sensitivity or specificity data since they do not change by patient or prevalence<sup>47</sup>. The applicability of LRs depend on accurate sensitivity and specificity estimates, however. PPVs and NPVs can also be useful in estimating the probability of MCI presence or absence on the basis of test score, but are contingent on knowledge of the base rate of MCI within a given population.

### Limitations of review

This review included only articles written in English. The systematic search strategy identified 10 potential studies which did not meet this criteria and therefore could not be evaluated, representing a significant proportion of studies whose contribution to the literature was not assessed. A future review including these studies is therefore recommended.

Additionally, the inclusion of studies using translated versions of the MoCA, while ensuring that cross-cultural findings could be assessed, resulted in inherent restrictions in the comparison of results owing to modifications to the original measure, and population differences. Nevertheless, narrowing the focus of the review question would have led to a significant number of studies being omitted, as only five studies used an English version of the MoCA.

Inter-rater agreement for the quality assessment tool in the current review was only fair, limiting its reliability; however, the highest levels of disagreement reflected areas where reported information was variable and unclear. Reporting quality also significantly affected the scope of the conclusions drawn in this review, with many studies attaining only low scores on the methodology domain due to lack of clarity regarding procedure. Thus, a further limitation of the current review is that authors were not contacted for further information which may have gone unpublished. Use of this approach may have enriched the available data for evaluation.

## **Conclusions**

The accuracy of the MoCA in detecting ‘true’ MCI cases appears to be a robust finding across varying methodology, language, culture and ethnic background. Consistent reports of high sensitivity can give clinicians confidence in its use with this population ahead of other tests, such as the MMSE; however, this systematic review found evidence of potential inaccuracies in estimates of sensitivity across validation studies. Specificity rates are less favorable, but are also likely to be inaccurate. The impact of

this may be negligible in clinical practice as clinicians must frequently rely on subjective judgments of objective evidence when utilizing screening measures, especially where there may be a lack of conceptual clarity, as with MCI. Thus, diagnostic decisions should not be based wholly on evidence from such tests. Further investigation of identified cognitive difficulties should be enshrined within standard procedure.

In summary, the MoCA has evident clinical utility as a screening measure for MCI; however the current applicability of its psychometric properties requires more rigorous validation.

#### Implications for future research

- Future studies should employ STARD guidelines when presenting results of DTA research to ensure appropriately informative and detailed reporting.
- Validation studies should use appropriate sampling methods and should avoid use of case-control methodology.
- All participants should receive the reference standard and be subject to the same decision-making criteria.

- Authors should give consideration to reducing potential bias in MoCA administration by employing appropriately trained clinicians and by ensuring that results of other tests do not influence its interpretation, either via the order of test administration or via lack of appropriate blinding procedures.

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### **Disclosure statement**

No potential conflicts of interest were disclosed.

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## Amended Aims

The purpose of this brief section is to outline the recruitment difficulties encountered in the implementation of the study design and procedure, and the implications for the statistical analysis of the research questions.

### Original objectives

A key aim of the study was to conduct mediational analysis in order to evaluate the possible mediatory role of a major construct in Acceptance and Commitment Therapy (ACT), ‘psychological flexibility’ (PF) in the relationships between independent and dependent variables associated with psychosocial adjustment to MCI. Power calculations were based on recommendations by Cohen (1992) for a power of 0.8 at  $\alpha = 0.05$ , and by Fritz and Mackinnon (2007) for the appropriate sample size to detect the mediated effect. Using bias-corrected bootstrapping, a sample size of 53 was suggested on the basis of a medium magnitude pathway (0.39) between the independent variable and the mediator variable, and a large magnitude pathway (0.59) between the mediator variable and the dependent variable, on the expectation of a significant relationship between independent and dependent variables. These effect sizes were estimated from correlational data reported in previous studies with similar variables and populations (e.g. Ferenbach *et al.*, 2011; Hurt *et al.*, 2011). A sample of 53 was judged to be achievable on the basis of previous service-wide data on referral patterns, which suggested that approximately 20-25% of patients referred to memory services over an 18 month period met criteria for MCI (Lonie *et al.*, 2008). It was

anticipated that the project would have a recruitment window of approximately 6 months.

## Recruitment

Considerable recruitment difficulties were encountered following an unforeseen delay in the processing of the project ethics application, leading to a reduced recruitment period of 4 months. The number of people identified from case-file review across the health board region was also significantly lower than expected and there appeared to be widespread variation in how MCI was classified and recorded by clinicians. This may be related to the heterogeneity of MCI as a clinical population, and may reflect varying patterns of referrals from general practitioners (GPs), who may differ in their identification of patients requiring further assessment (Kaduszkiewicz *et al.*, 2010). A total of 83 patients were identified, of which 23 did not meet inclusion and exclusion criteria. The remainder were approached via post and invited to opt in to the study, which was a condition of ethical approval. It is possible that this form of approach may have contributed to reduced levels of participation as it placed a higher demand on the memory abilities of patients with cognitive difficulties. In addition, few patients with MCI were referred from clinic appointments, with clinicians reporting that they did not tend to see patients with MCI outside of memory service pathways.

Despite extending the length of the data gathering period, and widening study eligibility for people diagnosed with MCI within the past 9 months rather than within a 3 to 6 month window, numbers remained low.

## Implications and revised plan

It was considered that the number of participants recruited would not give sufficient power for mediation analysis and that the unreliability of conducting this type of analysis with a small sample size may violate its statistical assumptions, thereby increasing the risk of both type-I and type-II errors. On this basis, it was decided that bivariate correlational analysis would be a more appropriate method to describe and test the associations between independent and dependent variables. The emphasis of study objectives was therefore altered to reflect this and the journal article was written in accordance with these revised aims.

## **Empirical Paper**

**Running head:** Psychosocial adjustment to mild cognitive impairment

### **Psychosocial adjustment to mild cognitive impairment: assessing the involvement of illness perceptions, cognitive impairment and psychological flexibility**

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This empirical paper was prepared in accordance with the author specifications for the journal *Psychology and Aging* (see Appendix B17)

## **Abstract**

### **Background**

People with mild cognitive impairment (MCI) face various cognitive difficulties along with the considerable uncertainty posed by the increased risk of developing dementia in the future. Beliefs about MCI may play a role in psychosocial adjustment to this condition, but individual differences in ‘psychological flexibility’ (PF) may also be involved in this process.

### **Objectives**

To assess the possible relationships between illness representations, cognitive impairment, PF and psychosocial adjustment variables in people with MCI.

### **Method**

Nineteen older adults recently diagnosed with MCI were recruited from local NHS memory clinic services and completed measures assessing cognitive impairment, illness beliefs, PF, psychological wellbeing and quality of life (QoL) in this exploratory cross-sectional study. Associations between variables were tested using correlational analysis.

### **Results**

Participants reported both positive and negative appraisals about MCI. Negative emotional representations and perceptions of more serious consequences were associated with elevated anxiety, while higher PF was associated with more positive outcomes in mood and perceived QoL. The number of experienced MCI symptoms

appeared to be more associated with psychosocial adjustment than objective cognitive impairment.

## **Conclusions**

Both PF and the content of illness beliefs may be relevant to psychosocial adjustment processes in MCI, though further research is needed to replicate these findings with a larger and more representative sample.

**Key words:** adjustment; illness representations; mild cognitive impairment; psychological flexibility

## **Introduction**

Mild cognitive impairment (MCI) has emerged in both research and clinical practise as a classification which may represent an intermediate state of cognitive decline between normal aging and dementia. People with MCI are at increased risk of developing dementia, with estimated annual progression rates varying between 5% and 12% (Mitchell & Shiri-Feshki, 2009; Petersen et al., 1999). This can vary, however, by setting, methodology, diagnostic criteria, or whether impairment is classed as single or multidomain. A recent meta-analysis of 41 cohort studies spanning up to 10 years reported that a significant proportion of MCI patients either remain cognitively stable or improve (Mitchell & Shiri-Feshki, 2009), giving rise to considerable uncertainty for both clinicians and patients. Thus, the usefulness of MCI as a clinical entity continues to be disputed, across academic and clinical settings.

While there are no universally agreed guidelines for MCI classification, those suggested by Petersen and colleagues (1999) are commonly employed. These include subjective memory complaints underlined by objective evidence which does not meet criteria for dementia. Functional abilities are usually maintained. People with MCI therefore experience similar cognitive difficulties to people with dementia, but at attenuated levels. Currently, there are no available evidence-based treatments for patients with MCI in the UK (National Institute for Health and Care Excellence; NICE, 2012), and there is little prognostic certainty for this clinical group. In addition, mood and anxiety difficulties are also prevalent in MCI populations compared with age-matched control groups (Hwang, Masterman, Ortiz, Fairbanks & Cummings, 2008). Patients with MCI must therefore manage the practical and psychological consequences of cognitive problems without a clear explanation for their difficulties or a concrete disease trajectory. This may be viewed as a significant threat to health and wellbeing by people with MCI, both of which have implications for psychosocial adjustment processes.

### **The Common Sense Model (CSM) of Illness Representations**

One proposed theoretical model of how people conceptualise and manage illnesses and health threats is the CSM (Leventhal et al., 1984 cited in Leventhal, Diefenbach & Leventhal, 1992). The model posits that individuals develop internal illness schemata based on information integrated from various sources, including concrete data gathered from health professionals or the media, their own understanding of symptoms, and others' views and interpretations. These beliefs are said to influence

responsive coping behaviours and subsequently adjustment to the illness. Several core themes are considered to underlie these appraisals: illness chronicity, consequences, controllability, unpredictability and coherence, in addition to parallel emotional representations. The model hypothesises that negative appraisals trigger maladaptive ways of coping and are associated with lower perceived wellbeing. Numerous studies have investigated the CSM across different chronic physical health problems, finding broad support for the model (Hagger & Ornell, 2003; Petrie, Jago & Devcich, 2007).

Various qualitative and quantitative studies (for a review see Dean & Wilcock, 2012) have explored the impact of MCI from the individual's perspective. Frank et al. (2006) conducted focus groups with MCI and Alzheimer's disease (AD) patients and their carers, highlighting themes such as: uncertainty about diagnosis, skill loss and negative emotions. Joosten-Weyn Banningh and Vernooij-dassen (2008) conducted semi-structured interviews with MCI patients, noting similar concerns about the negative cognitive, physical and emotional consequences of MCI, and indicating a lack of coherence regarding explanations for MCI. Conversely, McIlvane, Popa, Robinson, Houseweart and Haley (2008) found a more mixed spectrum of emotional responses to MCI. Their cross-sectional study assessed a restricted range of illness beliefs about MCI, coping and quality of life (QoL). Their sample had generally low levels of distress and high QoL, reporting a range of positive emotional representations of MCI. Participants in their sample were already attending a support group, however, and tended to minimise the impact of their cognitive difficulties. Lingler et al. (2006) also noted mixed responses in their qualitative study, but identified meaning-making

themes from semi-structured interviews that were broadly consistent with the CSM, for example, appraisals regarding the consequences and understandability of MCI.

Two studies have explicitly explored illness representations of MCI based on the CSM. Lin, Gleason and Heidrich (2012) adapted the Illness Perception Questionnaire-Revised (IPQ-R) for use with MCI patients (IPQ-MCI) in an exploratory pilot study. Similar to McIlvane and colleagues (2008), levels of reported distress were low. In line with CSM predictions, participants endorsed more positive beliefs regarding chronicity, predictability, controllability and emotionality, though perceptions of consequences and coherence were more variable. Lin and Heidrich (2012) used the IPQ-MCI to evaluate the links between illness representations and coping style proposed by the CSM. They reported a similar pattern of beliefs, though MCI was viewed as more chronic in their sample, and identified associations between illness representations and the number of reported symptoms. People with few or moderate symptoms tended to have more positive beliefs while those with many symptoms tended to have more negative beliefs. These patterns were also associated with adaptive and maladaptive coping strategies, consistent with the CSM.

The CSM offers a compelling framework for conceptualising psychosocial adjustment processes in MCI; however, findings regarding the significance of coping behaviours have been inconsistent in some populations with cognitive difficulties, such as Parkinson's disease (PD; Kaptein et al., 2006) and subjective memory complaints (SMCs; Hurt, Burns & Barrowclough, 2011). Moreover, the model's emphasis on

coping does not necessarily allow for the possible involvement of other psychological factors.

### **Psychological Flexibility (PF)**

‘Psychological Flexibility’ is a central construct of Acceptance and Commitment Therapy (ACT), a psychological model forming part of the ‘Third Wave’ of cognitive behavioural therapies which is considered separately to the neuropsychological construct of cognitive flexibility, though there may be some conceptual overlap (Whiting, Deane, Ciarrochi, McLeod & Simpson, 2013). PF is argued to promote flexible internal and external behavioural change through the linkage of present moment acceptance of unwanted private experiences (thoughts, feelings, memories, sensations) which may otherwise be avoided or suppressed, to the more adaptive pursuit of valued living (Hayes, 2004). One of the main ways in which ACT differs from traditional cognitive behavioural therapy (CBT) is in its emphasis on how individuals relate to their negative thoughts rather than thought content. Indeed, one of the primary aims of ACT is not to reduce symptoms or negative affect per se, but to prevent them from acting as a barrier to valued living.

ACT has been delivered successfully across a range of physical and mental health problems, for example, positive outcomes have been reported for mood and anxiety difficulties (e.g. Forman, Herbert, Moitra, Yeomans & Geller, 2007), chronic pain (McCracken, Vowles & Eccleston, 2005) and multiple sclerosis (MS; Sheppard, Forsyth, Hickling & Bianchi, 2010). Positive relationships have also been noted

between PF, QoL and psychological wellbeing (Hayes, Luoma, Bond, Masuda & Lillis, 2006) in these clinical populations, and with a community sample of older adults (Butler & Ciarocchi, 2007). Furthermore, Wetherell et al. (2011) reported improvements in mood and anxiety in their use of ACT with a population of older people. While ACT has not specifically been employed with an MCI population, Joosten-Weyn Banningh and colleagues (2011) developed a group intervention for MCI patients with the aim of increasing 'acceptance' of cognitive impairment, conceptualised as the integration of difficulties into the self-concept. They compared the intervention group with a wait-list control group, finding that acceptance increased in the former but not the latter. While overall distress and QoL ratings remained unchanged, increased acceptance was significantly correlated with reported wellbeing.

Analysis of the links between change processes and outcomes in psychological therapy is common in ACT intervention studies. Despite some acknowledged variability in quality, numerous studies have consistently shown PF, along with specific ACT conceptualisations of 'acceptance' and 'values', to be significant mediators of change processes in both physical and mental health domains, at similar or superior levels to variables associated with other approaches, such as CBT (Hayes, Levin, Pulmb-Villardarga & Villatte, 2013). Few studies have investigated the possible influence of PF as a mediator of adaptive psychosocial adjustment to illness; however, work carried out by Ferenbach, Gillanders and Harper (2011) with an MS population reported that ACT constructs were stronger mediators of the relationships between MS symptoms, and psychological distress and life satisfaction outcomes than cognitive appraisals. A further study with MS patients also found evidence for the role of ACT constructs in

promoting positive adjustment outcomes (Pakenham & Fleming, 2011). Thus, there are some early indicators that PF may be a promising construct for further investigation of processes of change in psychosocial adjustment to MCI.

### **Study aims**

The main objective of this exploratory study was to establish some preliminary evidence for the possible utility of ACT for MCI by evaluating the interrelationships between illness perceptions, cognitive impairment, PF, psychological wellbeing and QoL. It was hypothesised that: (1) more negative illness perceptions would be associated with poorer reported psychological wellbeing and QoL (2) higher levels of cognitive impairment would be associated with poorer reported psychological wellbeing and QoL (3) illness appraisals would be more strongly associated with outcome variables than cognitive impairment and (4) lower levels of PF would be associated with more negative illness perceptions, greater severity of cognitive impairment and poorer adjustment.

## **Method**

### **Design**

This quantitative study used a cross-sectional, questionnaire-based design to analyse the relationships between cognitive impairment, illness representations, PF, psychological wellbeing and QoL. Ethical approval was granted by the NHS South East Scotland Research Ethics Committee 2 (See appendix B1).

## **Participants**

Nineteen patients were recruited from local NHS memory clinic services with a diagnosis of MCI according to ICD-10 criteria (WHO, 1992) supported by clinical history, physical examination, cognitive testing (Addenbrookes' Cognitive Examination-III, ACE-III; Hsieh, Schubert, Hoon, Mioshi & Hodges, 2013) and where deemed necessary, neuroimaging. During the period of March 2014 to August 2014, participants were either referred by memory service clinicians (Consultant Psychiatrists, Community Psychiatric Nurses, Clinical Psychologists) via assessment or follow-up appointments, or were identified following a case-file review of service attendees by the lead author (AS). Nine participants meeting criteria were referred by clinicians following clinic attendance, while 13 participants out of 60 who were invited by post following case-file review chose to opt in to the study, representing a response rate of 21.6%. Two of the participants referred by clinicians subsequently declined to take part and one was judged unable to provide informed consent.

Participants were required to be over the age of 60, fluent in English and diagnosed with MCI within the past 9 months in order to be eligible. This timeframe was limited in order to minimise the likelihood of further cognitive decline. Exclusion criteria comprised: pre-morbid cognitive difficulties; prior head trauma; history of substance misuse; current residential care placement; current psychiatric diagnosis; current significant physical illness. These criteria were chosen in order to eliminate potential confounding factors for subjective QoL ratings. Sample characteristics are summarised in Table 1.

During case-file review, a further 23 patients with MCI were identified who did not meet inclusion criteria for the following reasons: significant physical health comorbidity (n=8); diagnosis of MCI > 9 months (n=7); current or past history of substance misuse (n=3); current residential care placement (n=2); previous head trauma (n=2); significant sensory impairment (n=1).

### **Measures**

Participants completed self-report measures independently; all other measures (MoCA, IPQ-MCI) were administered by the lead author (AS). The following measures were completed:

**Montreal Cognitive Assessment (MoCA).** The MoCA (Nasreddine et al., 2005) is a brief cognitive screening tool which purports to measure various cognitive domains, including memory, visuospatial ability, language and executive functioning. The MoCA is scored out of 30, and a clinical cut-off of 26 and above is considered to be within the non-clinical range. An additional point is added for patients with 12 years of education or less. The MoCA was developed as an alternative to the Mini-Mental State Examination (MMSE; Folstein, Folstein & McHugh, 1975), reported to have limited efficacy for MCI (Mitchell, 2009). MoCA validation studies have consistently shown high levels of sensitivity for MCI, though specificity is more variable (for a discussion of these issues, see the current systematic review).

**Geriatric Anxiety Inventory – Short Form (GAI-SF).** The GAI-SF (Byrne & Pachana, 2011), adapted from the original Geriatric Anxiety Inventory (GAI; Pachana et al., 2007), comprises 5 items which participants either endorse or reject (agree/disagree). While the psychometrics of the longer GAI are more robust (Byrne & Pachana, 2011), it is still considered to be a psychometrically adequate scale and its brevity of administration made it a more suitable tool for the current study in order to minimise fatigue. Scoring 3 or more is considered clinically significant, with fair sensitivity and good specificity (Byrne & Pachana, 2011). While the GAI-SF has not been validated for use by people with MCI, it has been successfully administered to a population of memory clinic attendees (Byrne, Pachana, Arnold, Appadurai & Chalk, 2008). Cronbach's  $\alpha$  for the scale in the current population was .72.

**Geriatric Depression Scale-5 (GDS-5).** The GDS-5 (Hoyl et al., 1999) is a shortened version of the original 30-item scale developed by Yesavage and colleagues (1983) with high levels of sensitivity and specificity. Respondents either endorse or reject (yes/no) each item and the scale has a clinical cut-off of 2 or more. The GDS-5 has previously been administered successfully to patients with MCI (Lin et al., 2012). Cronbach's  $\alpha$  for the current population was .10.

**Acceptance and Action Questionnaire-II (AAQ-II).** The AAQ-II (Bond et al., 2011) is a 7-item measure of psychological inflexibility. Individual differences in PF are assessed via 7 statements, which participants rate using a 7-point Likert scale (never true to always true), with higher scores indicating lower levels of PF. The AAQ-II has

not previously been validated with an MCI population; however, it has been used successfully with an MS population (Ferenbach et al., 2011; Gillanders & Gillanders, in press). Cronbach's  $\alpha$  for the scale in the current population was .74.

### **Illness Perception Questionnaire – Mild Cognitive Impairment (IPQ-MCI)**

The IPQ-MCI was adapted from the IPQ-R (Moss-Morris et al., 2002), a broad measure of illness appraisals developed for applicability across a range of health problems. The IPQ-MCI has been piloted and validated for use with people with MCI (Lin et al., 2012) and comprises 9 subscales: identity (27 items); causes (25 items); consequences (12 items); chronic timeline (5 items); cyclic timeline (4 items); personal control (6 items); treatment control (5 items); coherence (5 items) and emotional representation (8 items). Items in the identity subscale are rated dichotomously (Yes/No) and are made up of a various cognitive and somatic symptoms which participants categorise as being related or unrelated to MCI. Participants also record the number of symptoms they currently experience. These are interpreted qualitatively in relation to whether participants tend to experience cognitive symptoms, such as forgetfulness, or somatic symptoms, such as headaches. Items in the remaining subscales are endorsed or rejected according to a 5-item Likert scale (strongly disagree to strongly agree). Higher scores indicate greater strength of negative illness beliefs. The cause subscale is interpreted qualitatively. Values of Cronbach's  $\alpha$  for IPQ-MCI subscales in the current study are as follows: chronicity (.85), consequences (.77), personal control (.86), treatment control (.83), coherence (.81), cyclic (.62), emotional representations (.79)..

**Quality of Life in Alzheimer's Disease (QOL-AD).** The QOL-AD (Logsdon, Gibbons, McCurry & Teri, 2002) is a self-report tool providing a subjective measure of QoL from the individual's perspective. It is commonly used in dementia research and the authors report good reliability and validity with this population. The scale comprises 13-items spanning various aspects of QoL which respondents rate on a 4-point Likert scale (poor to excellent). Higher scores indicate higher perceived QoL. Cronbach's  $\alpha$  for the QOL-AD in the current study was .83.

### **Procedure**

Participants met with an appropriately trained researcher experienced in working with this population (AS) to complete the 6 measures, along with a general questionnaire collecting demographic information, at a hospital clinic setting or in their own homes. Each participant provided written informed consent prior to commencing the assessment appointment. All measures were administered in the same order (MoCA, GAI-SF, GDS-5, AAQ-II, IPQ-MCI, QOL-AD) in a single session lasting approximately 60 minutes, apart from one participant who required 2 sessions after experiencing distress completing the IPQ-MCI.

### **Data analysis**

Analysis was conducted using SPSS 21. Descriptive statistics were computed for each study variable and are presented in Table 2. All participants who consented to take part

completed full data sets. No missing data was recorded. In order to address the research objectives, bivariate correlations were computed to test the associations between the following: illness representation variables (IPQ-MCI) and adjustment variables (GAI-SF, GDS-5, QOL-AD); cognitive impairment (MoCA) and adjustment variables (GAI-SF, GDS-5, QOL-AD); and PF (AAQ-II) and all other variables.

In order to meet the assumptions for correlational analysis, data for all interval variables was tested for normality using the Shapiro-Wilk test at  $p > 0.05$  based on recommendations by Field (2009) for small sample sizes. Four study variables and one demographic variable were found to violate parameters for normality: GAI-SF ( $p = 0.02$ ); GDS-5 ( $p < 0.001$ ); treatment control ( $p = 0.01$ ); emotional representation ( $p = 0.01$ ); retirement age ( $p < 0.001$ ). When z-score values of skewness and kurtosis were calculated for these values, the GAI-SF, GDS-5 and emotional representation variables were found to be within normal parameters of  $\pm 1.96$  (Field, 2009). The treatment control variable was negatively skewed, however, while the retirement age variable was also negatively skewed and had high kurtosis. Square root, 'log10' and 'reciprocal' transformations were computed for these two variables but did not result in a normal distribution. Spearman's  $\rho$  correlations were therefore computed for these variables. Pearson's  $r$  was used for the remainder of correlations.

## Results

### Sample characteristics

The mean age of the sample was 78 with the average retirement age being 61, though one participant remained in employment. The sample was skewed towards male participants and was well educated. The mean MoCA score was in line with normative data for MCI gathered from similar populations (e.g. Nasreddine et al., 2005). The majority of participants took part within 6 months of receiving an MCI diagnosis, though a considerable proportion of the group reported experiencing cognitive difficulties for more than 3 years prior to diagnosis.

Correlations between demographic characteristics and study variables were calculated in order to assess the potential for confounding factors. No significant correlations were found in relation to age, education, retirement status or number of months since diagnosis. Older age at retirement was, however, found to be associated with more negative beliefs regarding the consequences of MCI ( $\rho=.53$ ,  $p=.02$ ;  $p<0.05$ ) and regarding the cyclic nature of symptoms ( $\rho=.54$ ,  $p=.02$ ;  $p<0.05$ ).

**Table 1** Demographic characteristics of study sample

Characteristic (n=19)	Mean (SD)
Age, years	77.63 (4.89)
Education, years	14.16 (5.09)
MoCA score	22.21 (2.12)
Time since diagnosis, months	5.07 (2.59)
Age at retirement, years (n=18)	60.83 (5.48)
	Frequency (%)
Males	12 (63.16)
Retired	18 (94.74)
Marital status:	
<i>Married</i>	14 (73.68)
<i>Unmarried</i>	1 (5.26)
<i>Divorced</i>	1 (5.26)
<i>Widowed</i>	3 (15.79)
Onset of cognitive difficulties:	
<i>0-3 years</i>	12 (63.16)
<i>3-5 years</i>	4 (21.05)
<i>5-7 years</i>	3 (15.79)

### Descriptive statistics

Participants tended to score more highly on the GAI-SF than the GDS-5, indicating that anxiety was more prevalent within the study population than difficulties with

depressed mood. Scores on the AAQ-II are indicative of relatively high levels of PF, though the distribution of scores on this measure indicates some variability. The average number of symptoms reported by participants was 8, while the average

**Table 2** Descriptive statistics for study variables

Variable	Current Study (N=19)	Comparative Data	N
	Mean (SD)	Mean (SD)	
MoCA	22.21 (2.12)	22.20 (3.34) <sup>b</sup>	63
GAI-SF	1.79 (1.65)	1.1 (2.3) <sup>d</sup>	22
GDS-5	0.84 (0.83)	1.57 (1.41) <sup>c</sup>	30
AAQ-II	12.63 (5.42)	18.95 (11.30) <sup>f</sup>	133
Identity	13.37 (5.45)	7.00 (4.25) <sup>b</sup>	63
Chronicity <sup>a</sup>	3.59 (0.77)	3.82 (0.72) <sup>b</sup>	63
Consequences <sup>a</sup>	2.69 (0.64)	3.21 (0.69) <sup>b</sup>	63
Personal control <sup>a</sup>	2.59 (0.88)	2.57 (0.65) <sup>b</sup>	63
Treatment control <sup>a</sup>	2.6 (0.71)	2.74 (0.63) <sup>b</sup>	63
Coherence	2.95 (0.71)	2.80 (0.87) <sup>b</sup>	63
Cyclic <sup>a</sup>	2.57 (0.32)	2.75 (0.72) <sup>b</sup>	63
Emotional representation <sup>a</sup>	2.97 (0.65)	2.75 (0.66) <sup>b</sup>	63
QOL-AD	40.63 (6.18)	39.2 (4.7) <sup>e</sup>	47

Note: SD= standard deviation. <sup>a</sup>Mean item score; <sup>b</sup>From Lin et al. (2012) MCI sample; <sup>c</sup>From Lin et al. (2011)MCI sample; <sup>d</sup>From Byrne & Pachana (2011) older adult sample; <sup>e</sup>From Logsdon et al. (2002) dementia sample; <sup>f</sup>From Ferenbach et al. (2011) MS sample.

number of symptoms attributed to MCI was 13.47, suggesting that MCI may have been viewed as more severe than what was currently experienced. The most commonly reported symptoms were cognitive and related mainly to memory difficulties. Some somatic symptoms were noted, but these tended to be less associated with MCI than cognitive symptoms. The most frequently endorsed causes of MCI were: stress, heredity, age and abnormal changes in the brain.

Mean item scores were calculated for the remaining subscales of the IPQ-MCI, with higher scores corresponding with strength of negative beliefs. MCI was perceived to have a more chronic timeline and was associated with emotional distress and limited perceived understanding of MCI. Overall, however, participants tended to report feeling in control of their condition and believed that MCI could be managed by treatment. The mean QOL-AD score suggests that, in general, participants' perceived QoL was high, though the spread of scores was somewhat variable. Participants tended not to notice cyclic changes in their experience of symptoms and did not perceive the consequences of MCI to be significant.

### **Correlational analysis**

Correlation coefficients for study variables are summarised in Table 3.

**Illness representations.** The relationships between illness representation subscales of the IPQ-MCI were analysed. Perception of more severe chronicity was associated with a lower sense of personal control over MCI symptoms ( $p=.01$ ;  $p<0.01$ ), with higher levels of emotional distress ( $p=.05$ ;  $p<0.05$ ) and with less perceived treatment

effectiveness ( $p=.03$ ;  $p<0.05$ ). Decreased personal control was also associated with decreased belief in treatment ( $p<0.001$ ). When MCI consequences were perceived as more serious, this was associated with a perception of greater symptom unpredictability ( $p<0.001$ ) and greater emotional distress ( $p<0.001$ ).

**Illness representations, psychological wellbeing and QoL.** Higher anxiety as measured by the GAI-SF was significantly associated with more serious perceived consequences ( $p=.04$ ;  $p<0.05$ ) and with more negative emotional representations of MCI ( $p<0.001$ ), but there were no other significant correlations between the GAI-SF and IPQ-MCI subscales. Mood difficulties and QoL were not found to be associated with any category of illness representations; however, there was a relationship between increased mood difficulties and lower perceived QoL ( $p=.01$ ;  $p<0.05$ ).

**Cognitive impairment, psychological wellbeing and QoL.** No correlations were found between the MoCA, mood, anxiety or QoL. When the number of self-reported symptoms was considered, however, participants experiencing greater symptomatology perceived their QoL as lower ( $p=.01$ ;  $p<0.05$ ).

**The role of PF.** The relationships between PF, cognitive impairment, illness representations, psychological wellbeing and QoL were computed. Lower PF was associated with poorer QoL ( $p=.01$ ;  $p<0.05$ ). Low PF was also correlated with low levels of cognitive impairment on the MoCA ( $p=.02$ ;  $p<0.05$ ) and with lower mood ( $p=.01$ ;  $p<0.01$ ).

**Table 3** Correlations among study variables

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11. <sup>a</sup>	12.	13.	14.
1. MoCA	1	.12	.37	.52*	-.34	.44	-.36	.31	.06	.13	.08	.24	-.18	.13
2. GAI-SF		1	.22	.32	-.09	-.24	.00	.42	.48*	-.02	.14	.24	.00	.62**
3. GDS-5			1	.59**	-.57*	.10	-.01	.44	-.03	.27	.35	.15	-.02	.32
4. AAQ-II				1	-.55*	.40	-.28	.11	.07	-.07	.04	.39	.04	.32
5. QOLAD					1	-.51*	-.20	-.14	.02	-.29	-.25	-.17	-.03	-.07
6. Symptoms						1	.09	.12	-.05	.39	.25	.02	-.21	-.12
7. Identity							1	.13	.22	.23	.20	-.24	.20	.30
8. Chronicity								1	.37	.61**	.51*	.20	-.29	.46*
9. Consequences									1	.30	.35	.65**	-.04	.64**
10. Personal control										1	.73**	.22	-.29	.29
11. Treatment control <sup>a</sup>											1	.32	.00	.18
12. Cyclic												1	-.14	.33
13. Coherence													1	.19
14. Emotional representations														1

Note: <sup>a</sup>Denotes Spearman's  $\rho$  coefficient \* $p < 0.05$  \*\* $p < 0.01$

## Discussion

### **Illness representations and adjustment to MCI**

The results of the current study added to the evidence base for the CSM in psychosocial adjustment to MCI, finding partial support for hypothesised parallel processes. Belief in more negative consequences was significantly associated with increased anxiety. Previous quantitative studies of illness perceptions with MCI populations have not specifically assessed anxiety, however, a comparatively more anxious PD population also showed a significant relationship with negative consequences (Evans & Norman, 2009). In the current study, negative emotional representations were also associated with elevated anxiety, similar to relationships observed in other populations with cognitive difficulties, including PD (Evans & Norman, 2009) and SMCs (Hurt et al., 2011). Given the small sample size in the current study and use of correlational analysis, however, neither causality nor directionality of these relationships can be definitively concluded.

The uncertainty surrounding a diagnosis of MCI is likely to give rise to a spectrum of emotional representations and beliefs regarding consequences, especially since people with MCI may improve, remain stable or experience cognitive decline in the future. The nature of cognitive difficulties, in association with the increased risk of developing dementia could be involved in the development or exacerbation of anxiety in people with MCI (Frank et al., 2006; Joosten-Weyn Banningh & Vernooij-Dassen, 2008; Lingler et al., 2006), but this relationship is also likely to be reciprocal (Baudreau & O'Hara, 2008). Furthermore, positive emotional representations of MCI have been

reported where overall levels of distress are low (McIlvane et al., 2008). The way in which the potential outcomes of MCI are conveyed to patients may influence beliefs regarding consequences and the level of distress patients associate with this, and thus may subsequently affect adaptive psychosocial adjustment. Negative beliefs about the consequences of MCI, such as ‘MCI will progress to dementia’, and cognitions associated with negative emotional representations, such as ‘My MCI makes me feel uncertain about the future’ may therefore represent potentially useful therapeutic targets for patients who have adjustment difficulties.

No other domains of illness belief were found to be related to psychological wellbeing or QoL, in contrast to the results of previous studies using populations with cognitive problems (Evans & Norman, 2009; Ferenbach et al., 2011; Hurt et al., 2011; Jopson & Moss-Morris, 2003; Lin et al., 2012). One possible explanation is that the overall heterogeneity of MCI aetiology may have resulted in differences in individual experiences of MCI. Indeed, differences in coping, understanding and emotional responses to MCI are well documented (Dean & Wilcock, 2012; Joosten-Weyn Banningh & Vernooij-Dassen 2008; Joosten-Weyn Banningh et al., 2011; Lingler et al., 2006). Additionally, participants in the present study tended to score low on the GDS-5 and high on the QOL-AD, which was reflected in the significant correlation obtained between these two variables. This suggests that the current sample may represent a relatively well-adjusted group. Recruitment of patients with late-life depression into research studies has historically been associated with challenges (Thompson, Heller & Rody, 1994), and it is possible that patients with low mood were more likely to choose not to opt in to the current study. In addition, the internal

consistency of the GDS-5 with this population was low, which has implications for the overall validity of this scale as a measure of mood in the current study.

The hypothesised associations between illness representations and adjustment variables may also be more likely to emerge where severity of mood and anxiety difficulties is elevated. Indeed, Lin and Heidrich's (2012) sample scored more highly on the GDS-5 and reported an association between mood and perceived severity of illness identity. Furthermore, the current sample scored low overall on the GAI-SF, though significant associations with some illness representations were noted. It is possible, therefore, that replicating these findings with a more anxious population may yield further associations with domains of illness belief.

Findings of complex interrelationships between specific illness representations in the current study would intuitively suggest that these may be important for psychosocial adjustment, though only limited direct evidence was established. On a descriptive level, these interrelationships offer insight into additional potential drivers for therapeutic change for people with MCI. Appraisal of more serious consequences was associated with less perceived symptom controllability and more negative emotional representations, which was also related to the perception of greater chronicity. Heightened belief in incurability was also associated with decreased personal control and belief in treatment effectiveness. These relationships have been consistently reported in similar populations (Evans & Norman, 2009; Hurt, Burns, Brown & Barrowclough, 2010; Lin & Heidrich, 2012). There are currently no accepted or

prescribed interventions for MCI, and patients may have limited knowledge about what could be done to improve or alleviate the course of their illness. Perceptions of helplessness have been associated with emotional distress in previous studies with cognitively impaired individuals, including MS (Ferenbach et al., 2011), and may also interfere with psychosocial adjustment.

### **Cognitive impairment and adjustment to MCI**

Objective measurement of cognitive impairment using the MoCA was not associated with illness representations or outcome variables. While assimilation of concrete illness information is an integral component of the CSM, some studies have not found robust links between illness severity and psychosocial adjustment (e.g. Jopson & Moss-Morris, 2003), though this is not a consistent finding (Ferenbach et al., 2011; Schiaffino, Shawaryn & Blum, 1998). Given the inherent difficulties of quantifying cognitive impairment using screening measures, it is possible that use of the MoCA did not provide an accurate estimate of participants' functioning. While the MoCA has consistently been found to have high levels of sensitivity with this population, specificity is variable. In addition, the average educational level of the current sample was relatively high, which may have inflated cognitive scores. Nevertheless, each participant's classification status was supported by clinical investigation and the mean MoCA score in the current study was consistent with Lin & Heidrich's (2012) MCI sample.

An alternative explanation may relate to the aforementioned heterogeneity of MCI. The aetiology of this classification is commonly attributed to the onset of an early neurodegenerative process; however, cognitive impairment can result from both physical and mental health difficulties which are not necessarily neurodegenerative (Petersen, 2004), and which may result in different qualitative experiences for patients. Indeed, in the current study, though objective impairment was not associated with psychosocial adjustment, higher number of reported symptoms was significantly correlated with poorer QoL. This is similar to the pattern noted by Lin and Heidrich (2012). Symptoms may be both cognitive and somatic in nature. The latter may include underlying anxiety or physical health problems which impacted on perceived QoL; however, participants with significant physical illness were not contacted for participation in the current study and the overall level of anxiety was low. Thus, within the context of the CSM, lived experience of MCI may be more important in understanding the impact of MCI than measured cognitive impairment.

### **Illness representations or cognitive impairment?**

A further aim of the current study was to assess the comparative strengths of the relationships between negative illness representations, increased cognitive impairment and poorer adjustment outcomes. The only significant correlations in line with these posited relationships were between consequences and anxiety, emotional representations and anxiety, and between number of reported symptoms and QoL. All correlation coefficients were of similar magnitude; however, reported experiences of MCI symptomatology could be argued to have a greater emphasis on internal

representations of illness compared with objective cognitive measures. Clinical decisions regarding management, along with judgement of the likely effects of MCI, and how this is communicated to patients may be more reliant on cognitive evidence. The results of the current study therefore support findings from qualitative studies that consideration of individual experiences may be more crucial in understanding the implications of MCI for patients than considering the degree of cognitive impairment.

### **The role of PF**

A further aim of the current study was to assess the potential associations between psychological inflexibility, negative illness representations, greater severity of cognitive impairment and poorer adjustment outcomes. The results of the correlational analysis provide some preliminary, tentative evidence for the possible involvement of PF in psychosocial adjustment processes. Psychological inflexibility was associated with low mood and low perceived QoL, both of which may be indicative of maladaptive psychosocial adjustment; however, the low internal consistency of the GDS-5 in the current population is likely to have affected the validity of these findings. These relationships have been reported by a number of studies with various physical and mental health populations (for a meta-analysis see Hayes et al., 2006), and work by Butler and Ciarocchi (2007) found that high PF was predictive of higher perceived QoL in a community sample of older adults. As conceptualised in ACT, the mechanism by which increased PF is proposed to influence change is not through the reduction of psychological distress per se, but in the facilitation of valued living, which may in turn lead to the reduction of distress (Hayes, 2004). Thus, while interpretation

of the associations between PF, mood and QoL is constrained by statistical and sample size limitations, the current study offers a plausible rationale for further investigation of these potential interrelationships.

Interestingly, psychological inflexibility was also associated with less cognitive impairment, contrary to previous findings with an MS population (Pakenham & Fleming, 2011). There may be an overlap between PF and cognitive flexibility, an ability associated with executive functioning which includes the capacity to switch or 'shift' between different concepts. Whiting et al. (2013) investigated the relationship between PF and cognitive flexibility in a population of people with acquired brain injuries, finding associations between PF and some components of cognitive flexibility, such as verbal flexibility, but noting no overall association with cognitive 'shifting.' A decrease in cognitive flexibility would typically be expected as cognitive impairment increases. Thus, PF might also be expected to decrease. The finding of an association between lower PF and lower cognitive impairment in the current study is therefore unexpected. One possible explanation for this may relate to sample size, or to the high levels of PF in the study population.

Insight into cognitive difficulties may also be implicated. Depression has consistently been associated with greater insight into cognitive difficulties in people with dementia (Horning, Melrose & Sultzer, 2014), and the current study reported an association between low PF and low mood. The relatively low level of cognitive difficulty in MCI would suggest that poor insight is less likely, though this has been found to vary in

MCI populations (Roberts, Clare & Woods, 2009). The current study did not assess self-awareness of cognitive difficulty, but this may be an important consideration for future research in this area.

### **Limitations of the current study**

The current study was limited by small sample size and a high number of multiple comparisons with insufficient statistical power largely driven by significant recruitment difficulties. Low recruitment numbers may reflect the stringent inclusion and exclusion criteria applied in the current study; however, these criteria were designed to minimise potential confounding factors. The response rate for patients contacted by post was low (21.6%). Knechel (2013) argues that various factors can impede older adults' participation in research studies, including use of lengthy documents, and difficulty accessing research sites. The authors attempted to minimise the complexity of information sent to participants and offered home visits for those unable to attend NHS sites; however, it is possible that these factors reduced uptake of postal invitations.

Few UK MCI epidemiological studies have been conducted; however, a 2008 study by Fish and colleagues (cited in Ward, Arrighi, Michels & Cederbaum, 2012) reported a prevalence of 15.6% in a sample of male older adults, though these rates are likely to be affected by MCI heterogeneity and varying diagnostic practices. It is also possible that some MCI patients were not identified by their general practitioners

(GPs) as requiring further memory assessment. A recent study by Kaduszkiewicz et al. (2010) suggested that the sensitivity of GP judgement of MCI was only 11-12%.

The majority of participants in the current study were male and the overall education level of the sample was relatively high. Therefore, the pattern of results obtained may not be representative of the wider population of MCI patients. The high number of male participants who opted in to the study was unexpected. Men may be more likely to use problem-focussed coping strategies compared to women (Baker & Berenbaum, 2007), and they may have viewed research participation as a possible strategy; however, males may be less likely to use coping strategies overall in the management of health problems (e.g. Englbrecht et al., 2012). The current study did not assess coping style, which may have allowed further exploration of this issue and of the role of coping in adjustment to MCI. Evidence for the significance of coping style on psychosocial adjustment to cognitive difficulties is equivocal, however, with both supportive (Lin & Heidrich, 2012) and contradictory (Hurt et al., 2011) findings identified. It was also considered that including a measure of coping would increase the potential for fatigue in older adult participants with cognitive impairment.

The current study employed correlational analysis to explore the relationships between independent and dependent variables. The limitations for the use of correlations in cross-sectional studies to indicate causation are well known, thus, these results must be interpreted cautiously. In addition, correlation coefficients obtained from small samples tend to be more variable (Field, 2009), this means that the relationships

observed in the current study may have limited validity, and may also be susceptible to both type-I and type-II errors, particularly since high numbers of comparisons have been computed. These significant caveats restrict the conclusions which can be drawn from the current results. Replication of these findings with a larger sample, however, would have a number of important theoretical and clinical implications.

It is noteworthy that the IPQ-MCI subscales tended to correlate with each other more than with outcome variables. The exceptions to this are the relationships between consequences and anxiety, and emotional representations and anxiety, both of which are likely have a reciprocal component. Emotional representations and anxiety also have a considerable conceptual overlap, and though the size of the correlation coefficient was not indicative of collinearity in this small sample, a larger population may show this. Interestingly, in comparison to specific illness representations, the correlation coefficients in the relationships between PF and adjustment variables were larger. In line with this, the clinical and theoretical underpinnings of ACT would emphasise PF rather than appraisal content as being the main vehicle for therapeutic change. Thus, promoting PF may represent a promising direction for future research and may convey some therapeutic benefit; however, these results must be considered within the context of a high number of comparisons across a small population, with most comparisons resulting in non-significant relationships and small effect sizes. The limited number of significant relationships between specific illness beliefs and outcome variables may therefore reflect low statistical power. For example, the correlation coefficients denoting the relationships between chronicity and distress variables may well have achieved significance in a larger sample.

Clinically, considered within the context of the aforementioned statistical limitations these results would be consistent with previous findings that individuals' interpretations and experiences of MCI are likely to affect their adjustment to the condition. This could have implications for both how an MCI classification is delivered and explained, and how it is subsequently followed up. Increased awareness of these factors for clinicians and carers is therefore likely to be beneficial, and the current findings also suggest that offering psychosocial support to people with MCI following diagnosis in order to explore illness perceptions, particularly where there may be indications of adjustment difficulty, may be of therapeutic value. Thus, the possible viability of psychological interventions aimed at targeting thought content or PF with this population could represent a potentially fruitful avenue for future research.

### **Conclusions**

The current study provided some limited further support for the relevance of illness representations in psychosocial adjustment to MCI and added to the evidence base by also exploring the relationships between PF, distress and QoL in people with MCI. Both emotional representations of MCI and beliefs about the consequences of this condition were associated with anxiety in this population, and further exploration of this potential relationship with a larger sample may provide a more robust link. In addition, the current study found some limited evidence to suggest that individual experiences of MCI symptoms may be more relevant to the adjustment process than

objective cognitive impairment, though this was not a hypothesised finding. Finally, some early support was found for the potential involvement of PF in psychosocial adjustment. People who are able to take a more flexible stance in the presence of distress or other unwanted internal experiences, may be more likely to report positive wellbeing and QoL. Further research with a larger and more representative sample is needed to assess the robustness of these associations and to establish whether PF may be a mediator of change in this context, and hence whether ACT may convey some benefit to people who experience difficulty adjusting to MCI. Nevertheless, the current study has added to evidence that both cognitive content and acceptance factors may influence individual responses to MCI, and suggest that further research in this area is warranted.

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## **APPENDICES**

### **Appendix A – Systematic Review**

**Appendix A1** Systematic Review Assessment Checklist Operational Criteria  
for Scoring

**Appendix A2** Systematic Review Author Guidelines

## **Appendix A1** Systematic Review Assessment Checklist Operational Criteria for scoring

### **1. Abstract identifies the article as a diagnostic accuracy study, and clearly reports study methodology, results and conclusions**

Yes: Abstract uses term 'diagnostic accuracy', 'sensitivity and specificity', 'validation study' or equivalent. Methodology should cover setting (clinical versus population-based), groups and numbers of participants, and index tests used (with translated versions if applicable). The abstract clearly identifies the condition(s) being assessed. Results should contain the main outcomes of diagnostic statistical tests carried out (including AUC, sensitivity, specificity, PPV, NPV, optimal cut-off). Overall conclusions should be related to results reported and to overall accuracy/validity of MoCA.

No/Unclear: Study does not meet above criteria or reports results of diagnostic tests without clear use of terms 'diagnostic accuracy', 'sensitivity and specificity' or equivalent.

### **2. Introduction clearly outlines the research question(s) and/or study aim(s)**

Yes: There is a clear delineation of aims consistent with the content of the introduction and states these as either a set of questions or objectives which are clearly operationalised. Aims and objectives are stated in a way that allows the reader to judge the applicability of setting, inclusion/exclusion criteria, procedure and analysis.

No/Unclear: The aims of the study are either not stated, are inconsistent with introduction content OR are general/vague and do not allow the reader to judge the applicability of setting, inclusion/exclusion criteria, procedure and analysis.

### **3. The methods of recruitment of the study population are described and appropriate<sup>1</sup>**

Yes: Information is presented in sufficient detail to permit replication. Each stage of the recruitment process for each group (if more than one) should be present and it should be clear how participants were identified. <sup>1</sup>Participants should be identified based on presenting symptoms from consecutive referrals to the memory/dementia/geriatric clinic where MCI/dementia is suspected, or from a random sample of these.

No: Information is either absent OR bias may be present in how participants were recruited (i.e. study may be retrospective, based on data collected or performance on index test and reference standard, or different recruitment methods may have been used to recruit each group).

Unclear: Insufficient information is presented for the reader to be able to make a judgement.

### **4. The study population is representative of the patients who would typically receive the test in practice**

Yes: The sample population would be expected to receive the test as a result of attending a

memory clinic, geriatric inpatient or outpatient setting. Studies should score 'yes' if they do not use case-control methodology (i.e. comparison of participants confirmed to have the condition of interest with participants confirmed not to have the condition of interest), if they are judged to not have unnecessarily excluded groups of participants who might be expected to receive the test in practice (i.e. if the population is not restricted to, for example, specific MCI subtypes or particular physical health problems, such as cerebrovascular disease), and if the locations and settings are in line with stated aims (e.g. memory clinic, rural/urban setting).

No: Study clearly does not meet above criteria: case-control methodology is used, bias is present in inclusion/exclusion criteria or locations/settings do not correspond with stated aims.

Unclear: Insufficient information is reported to enable the reader to make a judgement.

### **5. The reference standard and its execution are appropriate (i.e. likely to correctly classify the target condition)**

Yes: The reference standard for MCI should be based on criteria outlined by Petersen and colleagues, which may be supplemented by other recognised valid clinical tools/standards for MCI (e.g. ICD-10), and is supported by clinical diagnosis on the basis of the following: clinical history, physical/neurological examination, neuroimaging, neuropsychological assessment.

Reference standard for dementia (if applicable) involves clinical diagnosis as above and is based on reliable and valid clinical criteria (i.e. DSM-IV, ICD-10, NINCDS-ADRDA, CDR).

Reference standard for NCI involves clinical diagnosis as above and is based on 'normal' criteria using the same diagnostic standards for MCI and dementia.

No: Study does not meet criteria outlined above. Bias is present in the choice of reference standard (i.e. an unvalidated test or one which has reduced validity in classifying the condition of interest).

Unclear: Insufficient information is available for the reader to be able to judge the appropriateness of the reference standard.

### **6. The number and expertise of the persons executing and interpreting the reference standard would be considered appropriate<sup>2</sup>**

Yes: The number of people is clearly stated, including position/level of training/experience.  
<sup>2</sup>Appropriate: consensus panel with a range of experience across categories of information gathered (i.e. psychiatrist, geriatrician, neuropsychologist, neurologist)

No: Information is absent OR bias is present in number/expertise (i.e. decisions made by persons who would be judged to have insufficient knowledge/experience, or by the judgement of a single person)

Unclear: Information is not presented with sufficient detail for the reader to be able to judge expertise/qualification to make diagnostic decisions

### **7. The index test version and its execution would be considered appropriate**

Yes: The appropriate language version of the test is used (i.e. the language of the test reflects the linguistic and cultural background of participants). If a translated version is used, translation should include back-translation, consensus decision-making, independent verification and pilot testing. Where other tests are employed (e.g. MMSE) these may influence interpretation of the MoCA and should therefore be carried out subsequently.

No: Bias may be present in the translation process (e.g. lack of independent translators or pilot testing), OR in the interval/timing of the index test (e.g. interval of longer than 6 months or index test is carried out after another diagnostic test such as the MMSE).

Unclear: Insufficient information is available for the reader to be able to judge

### **8. The number and expertise of the persons executing and interpreting the index test would be considered appropriate<sup>3</sup>**

Yes: The number of people is clearly stated, including position/level of training/experience.  
<sup>3</sup>Appropriate: The person(s) administering the MoCA should have training in neuropsychological assessment. If more than one person, level of agreement should be calculated. If additional neuropsychological tests are being co-administered by the same rater, the MoCA should be administered first.

No: Information is absent OR bias is present in number or level of training/expertise (i.e. conducted by a person who would be considered to have insufficient training; OR two or more raters with no consideration of interrater agreement; OR if one rater administers all tests and there is an indication that this may introduce bias due to order of test administration)

Unclear: Information is not presented with sufficient detail for the reader to be able to judge expertise/level of training, or number of test administrators.

### **9. All participants receive the same reference standard**

Yes: It is clearly stated that all participants, regardless of initial diagnosis (if this is applied), have their status confirmed using the same reference standard.

No: Only participants with clinical diagnoses receive the reference standard OR only a random sample receive the reference standard

Unclear: Insufficient information is presented to allow the reader to make a judgement as to whether all participants receive same reference standard.

### **10. The index test results were interpreted without knowledge of the reference standard results**

Yes: The index test is clearly carried out prior to diagnostic confirmation OR it is stated that the individuals administering the index test are independent or 'blinded' to reference standard results

No: Index test carried out after reference standard and it is stated that person(s) administering index test are not 'blinded' to diagnosis, OR performance on reference standard

may form part of inclusion criteria OR additional clinical information may be available to the person(s) administering the index test.

Unclear: Insufficient information is presented so as to allow the reader to make a judgement.

### **11. The reference standard results were interpreted without knowledge of the index test results**

Yes: Clearly stated that diagnostic decision-making is made without reference to the index test AND/OR diagnostic decision-makers were independent of index test raters, OR it is clear that index test results could not have been involved in interpretation of diagnostic status if this is carried out prior to index test

No: Clear that index test results informed the reference standard, OR even if stated that index test results do not inform the reference standard, it may be clear that index test raters are involved in diagnostic decision-making.

Unclear: Insufficient information is presented to enable the reader to make a judgement.

### **12. Index test results were interpreted according to a pre-determined cut-off**

Yes: All versions of the test should be interpreted according to a pre-determined cut-off, whether this is the original cut-off for the English version, or whether sufficient justification is provided for another cut-off (e.g. translated versions with similar cultural/linguistic variations, or similar ethnic/cultural variation).

No: Only an optimal cut-off is calculated/reported, and participants are categorised according to this.

Unclear: Insufficient information is provided to enable the reader to make a judgement as to whether the cut-off used was calculated to be an optimal cut-off on the basis of the information gathered from study participants or whether this was pre-determined.

### **13. Any withdrawals or exclusions from the study were explained**

Yes: No withdrawals and/or exclusions, OR the number of withdrawals and/or exclusions are clearly stated and explained and the possible impact of this is taken into account.

No/Unclear: withdrawals and/or exclusions are referenced but not clearly described, and the reasons for this are not explained or accounted for in analysis.

### **14. Statistical methods used to calculate and/or compare measures of diagnostic accuracy were appropriate**

Yes: Appropriate methods include: receiver operating characteristic for area under the curve (ROC/AUC); sensitivity and specificity; Odds Ratio (OR) positive predictive value (PPV) and negative predictive value (NPV), Youden Index.

No: Clear absence of relevant diagnostic statistical data. Judgements of effectiveness of

index test are not based on above appropriate methods or are inaccurate

Unclear: Insufficient information is provided to enable the reader to make a judgement as to appropriateness.

**15. The results of statistical methods used to assess diagnostic accuracy were reported in full**

Yes: the results of all stated tests are reported. Where some tests present a range of results (i.e. Youden index, ROC/AUC graph), these are reported in full.

No: There is a clear absence of results for some statistical tests, OR tests which present a range of results are only partially reported.

Unclear: Insufficient information is presented to enable the reader to make a judgement.

**16. Clinical and demographic characteristics of the study population were clearly reported and any differences were accounted for in statistical analysis**

Yes: Relevant<sup>4</sup> clinical and demographic characteristics are reported in a clear format which enables comparison between groups (if more than one). Any population differences were reported and were accounted for in statistical analysis.

<sup>4</sup>Relevant characteristics include: diagnostic classification; score on index test/comparator test; age; gender; education; ethnicity (if this would be considered relevant on the basis of the ethnic and cultural background of the study population)

No: Clinical and demographic characteristics not reported in a clear format, OR key details are absent, OR significant group differences are present which are not accounted for in statistical analysis.

Unclear: Insufficient information is provided to enable the reader to make a judgement

**17. Index tests scores were appropriately adjusted for education level**

Yes: One additional point is added for groups with less than 12 years education (as directed for original version of test) OR for translated versions, education is adjusted for using another approach which the reader judges to be sufficiently justified OR the reader judges that there is sufficient justification for not adjusting for educational differences.

No: Education is not adjusted for using the instructions of the original test OR education is not adjusted for using an alternative method OR education is adjusted using a method which the reader would judge to be inappropriate or for which there is not an appropriate justification.

Unclear: Insufficient information is provided to enable the reader to make a judgement.

**18. Estimates of diagnostic accuracy included measures of statistical uncertainty (e.g. 95% confidence intervals)**

Yes: It is clear that all estimates of diagnostic accuracy (where appropriate) include measures of statistical uncertainty.

No: Results are clearly presented without measures of statistical uncertainty, OR these are incomplete OR only some tests include measures of statistical uncertainty.

Unclear: Insufficient information is presented to enable the reader to make a judgement.

### **19. Optimal cut-off values were calculated and reported**

Yes: An optimal cut-off score balancing sensitivity and specificity was reported.

No: only the pre-determined cut-off was used to report the sensitivity and specificity of the test with this population.

Unclear: Insufficient information was provided to enable the reader to make a judgement.

### **20. The clinical applicability of the study findings was discussed**

Yes: The discussion considers how the study findings might be applied in clinical practice.

No: The discussion does not consider how study findings might be applied in clinical practice AND/OR only considers implications for further research.

Unclear: Insufficient information is provided to enable the reader to make a judgement.

## **Appendix A2** Systematic Review Author Guidelines

Geriatrics and Gerontology International (available from:

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Each figure should be supplied as a separate file, with the figure number incorporated in the file name. For submission, low resolution figures saved as .jpg or .bmp files should be uploaded, for ease of transmission during the review process. Upon acceptance of the article, high resolution figures (at least 300 d.p.i.) saved as .eps or .tif files should be uploaded. Digital images supplied only as low resolution files cannot be used. Further instructions are available at the submission site.

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#### PARTS OF THE MANUSCRIPT

Manuscripts should be presented in the following order: (i) title page, (ii) abstract and key words, (iii) text, (iv) acknowledgments, (v) disclosure statement, (vi) references, (vii) figure legends, (viii) tables (each table complete with title and footnotes), (ix) figures. Footnotes to the text are not allowed and any such material should be incorporated into the text as parenthetical matter.

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Yamaya M, Yanai M, Ohru T, Arai H, Sasaki H. Interventions to prevent pneumonia among older adults. *J Am Geriatr Soc* 2001; 49: 85–90.

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Yamauchi J, Nakayama S, Ishii N. Effects of bodyweight based exercise training on muscle functions of leg multi-joint movement in elderly individuals. *Geriatr Gerontol Int* 2009. doi: 10.1111/j.14470594.2009.00530.x

**Book**

Ringsven MK, Bond D. *Gerontology and Leadership Skills for Nurses*, 2nd edn. Albany, NY: Delmar Publishers, 1996.

**Chapter in a Book**

Phillips SJ, Whisnant JP. Hypertension and stroke. In: Laragh JH, Brenner BM, eds. *Hypertension: Pathophysiology, Diagnosis, and Management*, 2nd edn. New York: Raven Press, 1995; 465–78.

**Journal article on the Internet**

Aboud S. Quality improvement initiative in nursing homes: the ANA acts in an advisory role. *Am J Nurs* [serial on the Internet]. 2002 Jun [cited 2004 Aug 12]; 102(6): [about 3 p.]. Available from: <http://www.nursingworld.org/AJN/2002/june/Wawatch.htm>.

**Monograph on the Internet**

Foley KM, Gelband H, editors. Improving palliative care for cancer [monograph on the Internet]. Washington: National Academy Press; 2001 [cited 2004 Jul 9]. Available from: <http://www.nap.edu/books/0309074029/html/>.

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These should be placed at the end of the paper, numbered in Roman numerals and referred to in the text. If written by a person other than the author of the main text, the writer's name should be included below the title.

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Tables should be self-contained and complement, but not duplicate, information contained in the text. Number tables consecutively in the text in Arabic numerals. Table should be double spaced and vertical lines should not be used to separate columns. Column headings should be brief, with units of measurement in parentheses; all abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and \*, \*\*, \*\*\* should be reserved for P values. The table and its legend/footnotes should be understandable without reference to the text.

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## **Appendix B – Empirical Paper**

**Appendix B1** Research ethics committee letter of ethical approval

**Appendix B2** NHS R&D letter of approval

**Appendix B3** Study protocol version 10 approved by REC and R&D

**Appendix B4** Participant information sheet – Clinic group version 8

**Appendix B5** Participant information – Casenote review group version 8

**Appendix B6** Invitation letter - clinic group version 5

**Appendix B7** Invitation letter - casenote review group version 5

**Appendix B8** GP letter version 4

**Appendix B9** Consent form version 3

**Appendix B10** Study demographic questionnaire version 3

**Appendix B11** Author guidelines for the journal *Psychology and Aging*

## Appendix B1 Research ethics committee letter of ethical approval

### Lothian NHS Board

### South East Scotland Research Ethics Committee 02



Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
EH1 3EG  
Telephone 0131 536 9000  
Fax 0131 465 5789

[www.nhslotthian.scot.nhs.uk](http://www.nhslotthian.scot.nhs.uk)

Date 21 January 2014  
Your Ref  
Our Ref

Enquiries to: Joyce Clearie  
Extension: 35674  
Direct Line: 0131 465 5674  
Email: [Joyce.Clearie@nhslotthian.scot.nhs.uk](mailto:Joyce.Clearie@nhslotthian.scot.nhs.uk)

21 January 2014

Miss Amanda Stevenson  
Trainee Clinical Psychologist  
NHS Lothian/University of Edinburgh  
School of Health in Social Science  
University of Edinburgh  
Teviot Place  
EH8 9AG

Dear Miss Stevenson

**Study title:** Psychological adjustment to a diagnosis of mild cognitive impairment: the roles of illness perceptions, cognitive functioning and psychological flexibility.  
**REC reference:** 13/SS/0237  
**IRAS project ID:** 113930

Thank you for your letter of 18 January 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Ms Joyce Clearie, [joyce.clearie@nhslotthian.scot.nhs.uk](mailto:joyce.clearie@nhslotthian.scot.nhs.uk).

#### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

#### Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the



Headquarters  
Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG

Chair Mr Brian Houston  
Chief Executive Tim Davison  
*Lothian NHS Board is the common name of Lothian Health Board*

## Appendix B2 NHS R&D letter of approval

### University Hospitals Division

Queen's Medical Research Institute  
47 Little France Crescent, Edinburgh, EH16 4TJ

FM/TM/approval

12 March 2014

Miss Amanda Stevenson  
NHS Lothian  
Psychology Department  
St John's Hospital  
Livingston  
EH54 6PP

# NHS

## Lothian

Research & Development  
Room E1.12  
Tel: 0131 242 3330  
Fax: 0131 242 3343

Email:  
R&DOffice@nhslothian.scot.nhs.uk

Director: Professor David E Newby

Dear Miss Stevenson

**Lothian R&D Project No:** 2014/0032

**Title of Research:** Psychological adjustment to a diagnosis of mild cognitive impairment: the roles of illness perceptions, cognitive functioning and psychological flexibility

**REC No:** 13/SS/0237

**Patient Information Sheet –**

**Casenote Review Group, Clinic Group:**  
version 8 dated 16 January 2014

**Consent Form:**

version 3 dated 10 January 2014

**Protocol:** version 10 dated 18 January 2014

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for **NHS Lothian**.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian. This includes any changes made subsequent to management approval and prior to favourable opinion from the REC.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study and the MHRA where applicable.

Please inform this office when recruitment has closed and when the study has been completed

I wish you every success with your study

Yours sincerely



Ms Fiona McArdle  
Deputy R&D Director



**Study Protocol: Psychological adjustment to a diagnosis of mild cognitive impairment: the roles of illness perceptions, cognitive functioning and psychological flexibility.**

People with mild cognitive impairment (MCI) are said to be at increased risk of developing dementia. MCI is associated with cognitive difficulties similar to those experienced by people with dementia, such as memory problems, but at attenuated levels (Petersen et al., 1999). People with MCI also tend to have intact functional abilities (Petersen et al., 1999). Cognitive impairment can lead to perceptions of lower quality of life (QoL) and psychological wellbeing (Missotten et al., 2008; Selwood et al., 2005) but evidence is equivocal (Banerjee et al., 2009).

Receiving a diagnosis of MCI can mean an uncertain prognosis and can be anxiety-provoking, due to the increased risk of developing dementia. Recent research has indicated that the beliefs people hold about an illness can influence their quality of life (QoL) and psychological wellbeing (e.g. Jopson & Moss-Morris, 2003). People with MCI who hold negative beliefs about their diagnosis have been found to experience greater levels of emotional distress independently of their level of cognitive impairment (Lin et al., 2012; Lin & Heidrich, 2012). The impact on QoL is not currently understood.

Evidence from studies evaluating the recently developed psychological intervention, Acceptance and Commitment Therapy (ACT; Hayes et al., 2006), indicates that how people stand towards their thoughts and beliefs, conceptualised here as psychological flexibility (PF), may play a role in how people respond to their thoughts. Thus, rather than reducing negative thinking overall, PF may act to reduce the impact of negative thoughts. For people with MCI who have negative perceptions about their illness, PF may therefore influence their perceived psychological wellbeing and QoL.

**Aims**

The current study aims to establish preliminary evidence for the possible utility of ACT for people with MCI by exploring (1) the relationship between illness perceptions of MCI,

psychological wellbeing and QoL in people with MCI (2) the relationship between level of cognitive impairment, psychological wellbeing and QoL in people with MCI and (3) whether illness appraisals are more strongly related to outcome variables than level of cognitive impairment and (4) whether these relationships are mediated by individual differences in PF.

### Research Questions

- Do individual differences in PF have an effect on the relationships between illness appraisals, level of cognitive impairment, QoL and psychological wellbeing in people with MCI?
- What is the nature of the relationship between appraisals of illness, QoL and psychological wellbeing in people with MCI?
- What is the nature of the relationship between level of cognitive impairment, QoL and psychological wellbeing in people with MCI?
- To establish whether illness appraisals are more strongly related to outcome variables than level of cognitive impairment.

### Hypotheses

The null hypotheses for the study will be:

- There will be **no** significant relationships between: illness appraisals, QoL and psychological wellbeing, or between level of cognitive impairment, QoL and psychological wellbeing.
- There will be **no** difference in the strength of relationships with outcome variables for illness appraisals and level of cognitive impairment.
- Individual differences in PF **will not** mediate the relationships between illness appraisals, level of cognitive impairment, QoL and psychological wellbeing.

The alternative hypotheses will therefore be:

- There **will** be a significant relationship between: illness appraisals, QoL and psychological wellbeing and between level of cognitive impairment, QoL and psychological wellbeing.
- Illness appraisals **will** be more strongly related to outcome variables than level of cognitive impairment.
- Individual differences in PF **will** significantly influence the relationships between illness appraisals, level of cognitive impairment, QoL and psychological wellbeing.

## **Method of investigation**

### *Participants*

Participants will be 53 individuals with mild cognitive impairment diagnosed within the past three to six months. Inclusion and exclusion criteria are outlined below:

### **Inclusion criteria:**

- ⤴ Diagnosis of MCI within the past 3-6 months
- ⤴ Able to provide informed consent
- ⤴ Over the age of 60
- ⤴ Able to speak, read and write fluently in English
- ⤴ Absence of significant physical health problems (e.g. cancer)
- ⤴ No past history of brain injury (e.g. stroke, head trauma)
- ⤴ No current psychiatric diagnosis (e.g. psychosis)

### **Exclusion criteria**

- ⤴ Premorbid cognitive difficulties (e.g. Learning disability)
- ⤴ Current residential or nursing care placement
- ⤴ Sensory impairment (e.g. blindness, deafness)
- ⤴ Current or past history of substance misuse
- ⤴ Current significant health problems

### *Design*

A within-subjects, cross-sectional, questionnaire-based design will be employed to analyse the relationships between independent variables and outcome variables using statistical mediation analysis. All participants will complete seven questionnaires: a brief demographic questionnaire; the Montreal Cognitive Assessment (MoCA; Nasreddine *et al.*, 2005); the Illness Perception Questionnaire – Mild Cognitive Impairment (IPQ-MCI; Lin *et al.*, 2012); the Acceptance and Action Questionnaire-II (AAQ-II; Bond *et al.*, 2011); the Geriatric Depression Scale-5 (GDS-5; Hoyle *et al.*, 1999); the Geriatric Anxiety Inventory – Short Form (GAI-SF; Byrne & Pachana, 2011) and the Quality of Life in Alzheimer's Disease Scale (QOL-AD; Logsdon *et al.*, 2002).

### *Measures*

The following measures will be used in this study:

#### *Demographic Questionnaire (created by principal researcher)*

All participants will complete a short questionnaire in order to gather basic information regarding sample population demographics. No personal information will be gathered.

### *AAQ-II*

This is a measure of PF, a central tenet of ACT. It is a 7-item questionnaire containing statements to which participants assign a response based on a 7-point Likert scale ranging from: *never true* to *always true*. This scale has not been validated for use by people with MCI, though the original version of the AAQ has been used successfully with a sample of older people (Butler & Ciarrochi, 2007).

### *Geriatric Depression Scale-5*

The GDS-5 is one of a number of shortened versions of the original GDS (GDS-30; Yesavage et al., 1983), providing a briefer administration time whilst maintaining high levels of sensitivity, specificity, accuracy and predictive ability (Hoyl et al., 1999). The GDS-5 has been successfully used by people with mild to moderate dementia (e.g. Lach et al., 2010). The scale consists of 5 items which respondents either endorse or reject by answering yes or no.

### *Geriatric Anxiety Inventory-SF*

The GAI-SF is a shortened form of the original Geriatric Anxiety Inventory (GAI; Pachana et al., 2007). Though the longer GAI is argued to have more robust psychometrics (Byrne & Pachana, 2011), the use of the GAI-SF in this case is to minimise fatigue and item burden to participants. The GAI-SF has not been employed with a population of people with MCI; however, the longer GAI has been employed with a sample of memory clinic attendees (Byrne et al., 2008). The GAI-SF consists of 5 items to which respondents indicate their agreement or disagreement by answering yes or no.

### *Quality of Life in Alzheimer's Disease*

The QoL-AD was identified as a reliable and valid self-report tool (Logsdon et al., 2002) that has been utilised widely as an outcome measure in research with people with dementia and cognitive impairment. This is a 13-item scale assessing various QoL contributors, such as living situation, and ability to do things for fun. Respondents rate each factor on a 4-point Likert scale ranging from *poor* to *excellent*.

### *IPQ-MCI*

The IPQ-MCI is a version of the revised Illness Perception Questionnaire (IPQ-R; Moss-Morris et al., 2002) developed and piloted for use with people with MCI comprising 8 subscales and 88 items in total. Participants are given a range of possible symptoms and asked to tick which ones they have experienced as a result of their MCI. They then rate a number of statements about their illness beliefs from a five point Likert scale ranging from *Strongly agree* to *Strongly disagree*.

### *MoCA*

The MoCA is a brief cognitive screening tool taking approximately 10 minutes to administer. Participants are scored out of 30 on tasks purporting to measure a number of cognitive domains, including memory, attention, visuospatial functioning, language and executive functioning. The MoCA was developed in order to produce a cognitive screen with greater sensitivity to MCI and early dementia than more commonly used tools such as the Mini-Mental State Examination (MMSE; Folstein et al., 1975), supported by findings from recent studies (e.g. Freitas et al., 2013).

### *Recruitment*

#### *NHS staff:*

Participants identified as meeting inclusion/exclusion criteria by NHS clinical staff (Psychiatry, Clinical Psychology, Community Psychiatric Nursing) will be approached within the context of clinical appointments by their named clinician, who will provide a verbal outline of the study and invite them to participate. If participants indicate an interest in becoming involved in the study, their named clinician will provide them with a participant information sheet (PIS) and an invitation letter. At this time the clinician will also inform them that the Chief Investigator will contact them by telephone to discuss the study further and to arrange an appointment following a minimum of twenty four hours.

#### *Casenote review:*

The Chief Investigator (who will be employed as a Trainee Clinical Psychologist within the service) will conduct a casenote review of patients recently diagnosed with MCI to identify possible participants who meet inclusion/exclusion criteria. Where possible, when such patients have a caseholder, their named clinician will approach them to invite them to participate. They will then be provided with a PIS and invitation letter. Where patients do not have an active caseholder, they will be sent an invitation letter and PIS. The PIS will include a reply slip to enable participants to register their interest in taking part and to opt in to receiving contact from the researcher. Participants will be informed that once their reply slip has been received, the Chief Investigator will contact them by telephone to discuss the study further and to arrange an appointment.

### *Procedure*

Once participants have agreed to be contacted, the Chief Investigator will contact them by telephone to discuss the study further and to arrange an interview appointment. All appointments will take place at NHS [REDACTED] sites, at the [REDACTED]. Interview appointments will last approximately one hour. Each appointment will consist of the following:

- ▲ Seeking informed consent (5 minutes)



Should participants wish to take a short break, they will be offered the opportunity to do so. If participants become distressed or feel fatigued, they will have the option of rescheduling the appointment or discontinuing their involvement in the study. Appropriate steps will be taken to minimise risk of harm should participants report distress. The Chief Investigator, as a Trainee Clinical Psychologist, is competent in the core skills necessary to provide immediate comfort and psychological support, and participants will be advised to seek further advice from their GP should they have any concerns about their mental and/or cognitive health. If significant concerns are raised regarding a participant's mental health, the Chief Investigator will seek advice from the project clinical supervisor and will provide immediate support, the participant's GP will be informed and they will be removed from the study. The Chief Investigator will be working under the supervision of a qualified Clinical Psychologist, and will be able to seek further advice from them if necessary. In addition, as part of the clinical team, the Chief Investigator will be able to facilitate access to psychological support and other treatments from the wider [REDACTED] Service for participants if necessary.

### *Statistical Analysis*

Initial correlational analyses will be carried out in order to establish the relationships between variables in the statistical model. Any variables not correlated will be removed from the model. The main research questions and objectives will be examined through mediation analysis, calculated using bias-corrected bootstrapping techniques, with separate analyses being carried out for each independent and dependent variable. Therefore, a total of six mediation analyses will be calculated. The independent variables are: level of cognitive impairment and illness perceptions. The mediator variable is PF, and the dependent variables are: QoL, depression and anxiety.

### *Dissemination*

The study will be written up as a doctoral thesis in line with the requirements of the University of Edinburgh Doctorate in Clinical Psychology. The thesis will also include a write up of the study in peer-reviewed journal format which will be prepared for publication in a relevant journal. A brief summary of the findings of the study will also be compiled and sent out to any participants who indicated their interest in receiving this on the consent form. Presentations will also be delivered to interested stakeholders and at relevant conferences and CPD events.



## **PARTICIPANT INFORMATION SHEET**

### **STUDY TITLE: Psychological adjustment to mild cognitive impairment**

You are being invited to take part in a research study. Before you decide if you would like to participate, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully, and talk to others about the study if you wish. If there is anything that is unclear, or if you have any questions, please do not hesitate to ask the Chief Investigator (Amanda Stevenson). You can also contact them using the details at the end of this sheet.

### **WHAT IS THE RESEARCH ABOUT?**

This study is examining how people adjust to receiving a diagnosis of mild cognitive impairment (sometimes referred to as memory and thinking difficulties). We know that how people view their diagnosis or condition can affect their sense of wellbeing, but the ways in which psychological factors influence the relationship between views about a condition and wellbeing are not well understood.

### **WHY HAVE I BEEN INVITED?**

We are inviting people who have received a diagnosis of mild cognitive impairment within the past three to six months to take part. We are aiming to recruit between 50 and 60 participants.

### **DO I HAVE TO TAKE PART?**

No. It is up to you to decide whether or not to join this study.

If you do decide to participate, you will be asked to sign a consent form, and you will be able to keep this information sheet for reference. If you decide to take part you will still be able to withdraw from the study at any point and you do not have to give a reason.

Involvement with the study will not affect the care you receive from any NHS service, now, or in the future (whether or not you decide to participate).

### **WHAT WILL HAPPEN TO ME IF I TAKE PART?**

If you choose to take part in this study, you will be asked to meet with the Chief Investigator on **one occasion** to participate in an individual interview lasting approximately **one hour**. The appointment will take place at one of the following locations: [REDACTED]

[REDACTED]. You will be able to choose which one would be most convenient for you, along with a time and date which is suitable for you. Please note that unfortunately we are unable to reimburse your travel expenses.

During the appointment you will have a further opportunity to ask questions and to discuss your involvement in the study. If you still wish to participate, you will be asked to sign a consent form stating that you agree to participate and that you understand what your participation will entail. We will also inform your GP (General Practitioner) by letter that you are taking part in the study.

You will then be asked to complete a series of questionnaires with the assistance of the Chief Investigator including:

- A brief test of mental functioning, such as memory
- Your views regarding your diagnosis of mild cognitive impairment and your current mental health

If at any point during the appointment you no longer wish to take part, you may withdraw from the study without having to give a reason.

### **WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?**

It is likely that there will not be an immediate benefit to you, but your participation will aid in our understanding of how people adjust to mild cognitive impairment. This may inform the development of future psychological treatments and interventions for people with mild cognitive impairment.

### **WHAT ARE THE POSSIBLE RISKS AND DISADVANTAGES OF TAKING PART?**

You will be asked to complete a set of seven tasks and questionnaires over a period of approximately one hour, which can leave some people feeling tired. In addition, some questions will ask you about sensitive topics, particularly regarding your current mental health, and your views about your diagnosis of mild cognitive impairment. It is possible that thinking about these issues may cause some to feel upset or distressed.

If you should experience either of these then you should inform the Chief Investigator, who will offer you support and ask whether you would like to take a break or to reschedule a later appointment. If you should become upset, or have any concerns, the Chief Investigator will be able to provide you with immediate comfort and support. We may also need to inform your GP or involve someone else who can help, such as a Psychiatrist.

### **WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?**

Consent forms and identifiable information will be destroyed, but your anonymous data may be held for future authorised research.

### **WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?**

All the information we collect from you will be kept confidential. We will keep your data anonymous during the research by assigning it a unique reference number. This reference number will be the only link between your data and your consent form. Once the study has been completed, your consent form will be destroyed. Your data will be securely stored on an NHS site and will be kept separately from consent forms.

Your data will only be accessible to the Chief Investigator, study supervisors, and anyone appointed by the Sponsor (NHS [REDACTED]/University of Edinburgh) to ensure the study is being carried out correctly.

We will inform your GP of your participation in the study by letter; however, we will not provide details to your GP regarding your performance on the assessment task or of your responses to questionnaires, unless you report any significant difficulties with your mood or functioning.

If you report anything that makes the Chief Investigator consider that you, or someone you know, are at risk of harm, your GP would need to be informed and we may need to involve someone else who can help, such as a Psychiatrist. Similarly, if you report information that relates to the prevention or detection of crime, the Chief Investigator may be required to disclose this information to relevant agencies (eg. Police). In each case, the Chief Investigator would discuss with you how this might be addressed.

### **WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?**

The results of the study will be written up and reported in a doctoral thesis format in part fulfilment of the requirements of the University of Edinburgh Doctorate in Clinical Psychology. We also hope to submit this thesis project to relevant academic journals for publication. All the information we collect from you will be kept anonymous, and will only be identifiable to the Chief Investigator and study supervisors.

If you would like to be informed of the results of the study, you may indicate your preference when signing the study consent form. You will then be provided with a written summary following completion of the study in May 2014.

### **WHO IS ORGANISING AND FUNDING THE RESEARCH?**

The study is being organised by Amanda Stevenson, Trainee Clinical Psychologist, under the supervision of Dr. David Gillanders (University of Edinburgh), Dr. Nuno Ferreira (University of Edinburgh) and Dr. Donna Gilroy (NHS [REDACTED]). The study is being supported by both NHS [REDACTED] and the University of Edinburgh.

### **WHO HAS REVIEWED THE STUDY?**

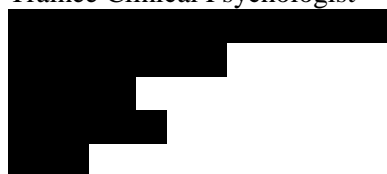
The project proposal has been reviewed and accepted by the University of Edinburgh Doctorate in Clinical Psychology, and by my supervisors: Dr. David Gillanders (Academic Director, Doctorate in Clinical Psychology), Dr. Nuno Ferreira (Lecturer in Clinical Psychology) and Dr. Donna Gilroy (Clinical Psychologist). Ethical approval has been granted by South East Scotland Research Ethics Committee on 21/01/14.

### **WHAT TO DO NOW?**

Since you have indicated to a member of staff that you are interested in participating, **the Chief Investigator will contact you by telephone** in the coming weeks to discuss the study with you and to arrange an interview appointment.

Alternatively, you may contact the Chief Investigator using the below details:

Amanda Stevenson  
Trainee Clinical Psychologist



### **FURTHER INFORMATION**

If you would like to speak to someone else about the study, please contact:

Dr Heather Wilkinson  
Research Director  
School of Health in Social Science  
University of Edinburgh  
Teviot Place  
Edinburgh  
EH8 9AG

## WHAT IF SOMETHING GOES WRONG?

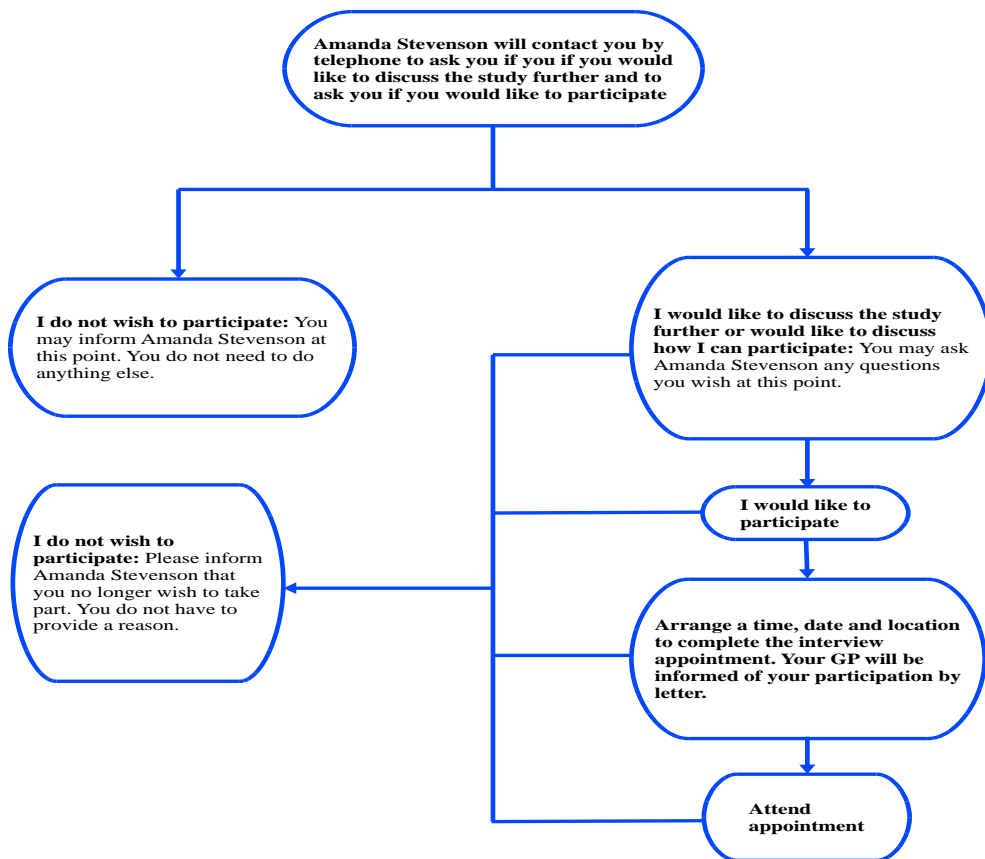
If you should wish to make a formal complaint regarding the study, please contact:

NHS [REDACTED] Complaints Team

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

email: [REDACTED]

Fig. 1: Flow chart explaining participation process



Thank you for taking the time to read this information sheet

Amanda Stevenson, Trainee Clinical Psychologist



## **PARTICIPANT INFORMATION SHEET**

### **STUDY TITLE: Psychological adjustment to mild cognitive impairment**

You are being invited to take part in a research study. Before you decide if you would like to participate, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully, and talk to others about the study if you wish. If there is anything that is unclear, or if you have any questions, please do not hesitate to ask the Chief Investigator (Amanda Stevenson). You can also contact them using the details at the end of this sheet.

### **WHAT IS THE RESEARCH ABOUT?**

This study is examining how people adjust to receiving a diagnosis of mild cognitive impairment (sometimes referred to as memory and thinking difficulties). We know that how people view their diagnosis or condition can affect their sense of wellbeing, but the ways in which psychological factors influence the relationship between views about a condition and wellbeing are not well understood.

### **WHY HAVE I BEEN INVITED?**

We are inviting people who have received a diagnosis of mild cognitive impairment within the past three to six months to take part. We are aiming to recruit between 50 and 60 participants.

### **DO I HAVE TO TAKE PART?**

No. It is up to you to decide whether or not to join this study.

If you do decide to participate, you will be asked to sign a consent form, and you will be able to keep this information sheet for reference. If you decide to take part you will still be able to withdraw from the study at any point and you do not have to give a reason.

Involvement with the study will not affect the care you receive from any NHS service, now, or in the future (whether or not you decide to participate).

### **WHAT WILL HAPPEN TO ME IF I TAKE PART?**

If you choose to take part in this study, you will be asked to meet with the Chief Investigator on **one occasion** to participate in an individual interview lasting approximately **one hour**. The appointment will take place at one of the following locations:

[REDACTED]. You will be able to choose which one would be most convenient for you, along with a time and date which is suitable for you. Please note that unfortunately we are unable to reimburse your travel expenses.

During the appointment you will have a further opportunity to ask questions and to discuss your involvement in the study. If you still wish to participate, you will be asked to sign a consent form stating that you agree to participate and that you understand what your participation will entail. We will also inform your GP (General Practitioner) by letter that you are taking part in the study.

You will then be asked to complete a series of questionnaires with the assistance of the Chief Investigator including:

- A brief test of mental functioning, such as memory
- Your views regarding your diagnosis of mild cognitive impairment and your current mental health

If at any point during the appointment you no longer wish to take part, you may withdraw from the study without having to give a reason.

### **WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?**

It is likely that there will not be an immediate benefit to you, but your participation will aid in our understanding of how people adjust to mild cognitive impairment. This may inform the development of future psychological treatments and interventions for people with mild cognitive impairment.

### **WHAT ARE THE POSSIBLE RISKS AND DISADVANTAGES OF TAKING PART?**

You will be asked to complete a set of seven tasks and questionnaires over a period of approximately one hour, which can leave some people feeling tired. In addition, some questions will ask you about sensitive topics, particularly regarding your current mental health, and your views about your diagnosis of mild cognitive impairment. It is possible that thinking about these issues may cause some to feel upset or distressed.

If you should experience either of these then you should inform the Chief Investigator, who will offer you support and ask whether you would like to take a break or to reschedule a later appointment. If you should become upset, or have any concerns, the Chief Investigator will be able to provide you with immediate comfort and support. We may also need to inform your GP or involve someone else who can help, such as a Psychiatrist.

### **WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?**

Consent forms and identifiable information will be destroyed, but your anonymous data may be held for future authorised research.

### **WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?**

All the information we collect from you will be kept confidential. We will keep your data anonymous during the research by assigning it a unique reference number. This reference number will be the only link between your data and your consent form. Once the study has been completed, your consent form will be destroyed. Your data will be securely stored on an NHS site and will be kept separately from consent forms.

Your data will only be accessible to the Chief Investigator, study supervisors, and anyone appointed by the Sponsor (NHS [REDACTED]/University of Edinburgh) to ensure the study is being carried out correctly.

We will inform your GP of your participation in the study by letter; however, we will not provide details to your GP regarding your performance on the assessment task or of your

responses to questionnaires, unless you report any significant difficulties with your mood or functioning.

If you report anything that makes the Chief Investigator consider that you, or someone you know, are at risk of harm, your GP would need to be informed and we may need to involve someone else who can help, such as a Psychiatrist. Similarly, if you report information that relates to the prevention or detection of crime, the Chief Investigator may be required to disclose this information to relevant agencies (eg. Police). In each case, the Chief Investigator would discuss with you how this might be addressed.

#### **WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?**

The results of the study will be written up and reported in a doctoral thesis format in part fulfilment of the requirements of the University of Edinburgh Doctorate in Clinical Psychology. We also hope to submit this thesis project to relevant academic journals for publication. All the information we collect from you will be kept anonymous, and will only be identifiable to the Chief Investigator and study supervisors.

If you would like to be informed of the results of the study, you may indicate your preference when signing the study consent form. You will then be provided with a written summary following completion of the study in May 2014.

#### **WHO IS ORGANISING AND FUNDING THE RESEARCH?**

The study is being organised by Amanda Stevenson, Trainee Clinical Psychologist, under the supervision of Dr. David Gillanders (University of Edinburgh), Dr. Nuno Ferreira (University of Edinburgh) and Dr. Donna Gilroy (NHS [REDACTED]). The study is being supported by both NHS Lothian and the University of Edinburgh.

#### **WHO HAS REVIEWED THE STUDY?**

The project proposal has been reviewed and accepted by the University of Edinburgh Doctorate in Clinical Psychology, and by my supervisors: Dr. David Gillanders (Academic Director, Doctorate in Clinical Psychology), Dr. Nuno Ferreira (Lecturer in Clinical Psychology) and Dr. Donna Gilroy (Clinical Psychologist). Ethical approval has been granted by South East Scotland Research Ethics Committee on dd/mm/yy.

#### **WHAT TO DO NOW?**

If you would like to know more about the study or are interested in participating, please contact the Chief Investigator using the reply slip at the end of this sheet. Amanda Stevenson will then contact you by telephone to discuss the study with you and to arrange an appointment should you decide to participate.

#### **FURTHER INFORMATION**

If you would like to speak to someone else about the study, please contact:

Dr Heather Wilkinson  
Research Director  
School of Health in Social Science  
University of Edinburgh  
Teviot Place  
Edinburgh  
EH8 9AG

## WHAT IF SOMETHING GOES WRONG?

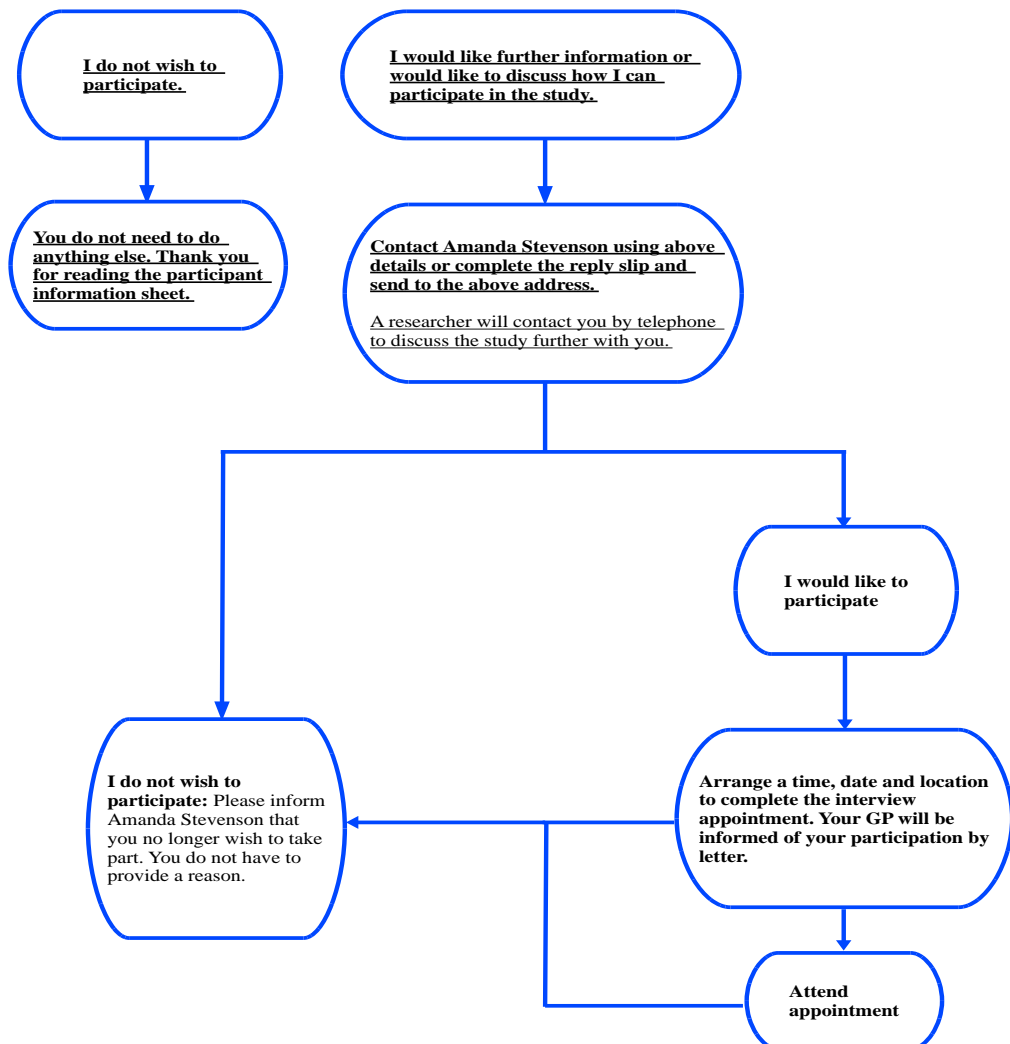
If you should wish to make a formal complaint regarding the study, please contact:

NHS [REDACTED] Complaints Team

[REDACTED]

email: [REDACTED]

Fig. 1: Flow chart explaining participation process



Thank you for taking the time to read this information sheet. Amanda Stevenson, Trainee Clinical Psychologist

**If you would like to participate in the study, or would like a researcher to contact you to discuss the study, please complete the tear off slip below and send it to:**

Amanda Stevenson  
Trainee Clinical Psychologist



---

Tear off slip here

*Reply Slip*

**“Psychological adjustment to mild cognitive impairment”**



I would like further information regarding the above study

I would like to participate in the above study

My preferred location for an appointment is:









Please contact me by telephone using the following details:

Name:

Contact

Number:

## Appendix B6 Invitation letter - clinic group version 5

dd/mm/yyyy

Address

Address



### Psychological adjustment to mild cognitive impairment

Dear *Name of potential participant*,

My name is Amanda Stevenson, I am a Trainee Clinical Psychologist with NHS [REDACTED] and am currently a doctoral student of Clinical Psychology at the University of Edinburgh. In line with the requirements of my training, I am conducting a study to investigate the process of psychological adjustment to a diagnosis of mild cognitive impairment.

I am writing to inform you of the study and to invite you to take part because you have been diagnosed with mild cognitive impairment within the past three to six months and because you have indicated to a clinician that you would like to hear more about the study.

Enclosed is a Participant Information Sheet which will tell you why the study is being carried out and what would be required from you if you decide to take part.

Please take some time to read and consider the following information carefully. You might find it helpful to show it to family and friends and to discuss it with them. I would like to make you aware that you are not obliged to participate in this study, and that this will not affect your current or future care in any way whether you decide to join the study or not. If you do decide to take part, you will still be able to end your participation at any time without having to give a reason.

I will contact you by telephone within the next **two weeks** to ask you whether or not you wish to be involved and to answer any questions you might have. Alternatively, you may contact me using the details on the information sheet.

Thank you for taking the time to read this letter.

Yours sincerely,

Amanda Stevenson  
Trainee Clinical Psychologist

Supervised by Dr. Donna Gilroy  
Clinical Psychologist

## Appendix B7 Invitation letter – casenote review group version 5

dd/mm/yyyy

Address  
Address



### Psychological adjustment to mild cognitive impairment

Dear *Name of potential participant*,

My name is Amanda Stevenson, I am a Trainee Clinical Psychologist with NHS [REDACTED] and am currently a doctoral student of Clinical Psychology at the University of Edinburgh. In line with the requirements of my training, I am conducting a study to investigate the process of psychological adjustment to a diagnosis of mild cognitive impairment.

I am writing to inform you of the study and to invite you to take part because a recent review of memory clinic attendance indicated that you were diagnosed with mild cognitive impairment within the past three to six months.

Enclosed is a Participant Information Sheet which will tell you why the study is being carried out and what would be required from you if you decide to take part.

Please take some time to read and consider the following information carefully. You might find it helpful to show it to family and friends and to discuss it with them. I would like to make you aware that you are not obliged to participate in this study, and that this will not affect your current or future care in any way whether you decide to join the study or not. If you do decide to take part, you will still be able to end your participation at any time without having to give a reason.

If you would like to take part, or would like to discuss the study in more detail, please complete the reply slip at the bottom of the Participant Information Sheet. You will then be contacted by telephone to answer any questions you might have and to arrange an appointment should you decide to take part.

Thank you for taking the time to read this letter.

Yours sincerely,

Amanda Stevenson  
Trainee Clinical Psychologist

Supervised by Dr. Donna Gilroy  
Clinical Psychologist

## Appendix B8 GP letter version 4



dd/mm/yyyy

Address  
Address

Dear *name of General Practitioner*,

**RE: Name, DOB, CHI, Address of patient.**

I am writing to inform you that the above named patient has consented to be take part in my research project. The study is investigating various cognitive and psychological factors that may affect how well an individual adjusts to a diagnosis of mild cognitive impairment. I am conducting this project in part fulfilment of the Doctorate in Clinical Psychology at the University of Edinburgh. It has been granted ethical approval by South East Scotland Research Ethics Committee (21/01/14).

The above named patient has been invited to take part in the study through their involvement with memory clinic services across NHS [REDACTED]. They may have been approached because they have indicated to a service clinician that they are interested in participating or because they have been identified as meeting study inclusion/exclusion criteria through casenote review. We are recruiting individuals with a diagnosis of mild cognitive impairment given in the past three to six months.

Involvement in the research will require participants to complete a series of measures assessing cognitive functioning and various psychological factors, including mood. Participants will attend an appointment lasting up to one hour; however, in order to reduce the potential for fatigue, they will be offered the opportunity to take breaks if they should wish.

I will not inform GPs of patients' performance on study measures as a matter of routine; however, should any concerns be raised regarding mood, anxiety, further cognitive impairment or risk of harm to self or others, you will be contacted directly.

Please do not hesitate to contact me should you have any comments or queries about the study.

Yours sincerely,

Amanda Stevenson  
Trainee Clinical Psychologist

Supervised by Dr Donna Gilroy  
Clinical Psychologist

## Appendix B9 Participant consent form version 3



### Psychological adjustment to mild cognitive impairment

#### Participant consent form

Please initial box

I have read and understood the Participant Information Sheet [date and version]	<input type="checkbox"/>
I have have been able to discuss the study with the Chief Investigator and I have had any questions answered to my satisfaction	<input type="checkbox"/>
I am aware that my participation in this study is voluntary and that I may terminate my involvement at any stage without having to provide a reason	<input type="checkbox"/>
I am aware that, whether or not I decide to participate, my involvement with the study will not affect the care I receive from any current, or future, NHS service	<input type="checkbox"/>
I understand that my General Practitioner (GP) will be informed by letter of my participation in the study	<input type="checkbox"/>
I am aware of the potential risks of participating in this study (if any)	<input type="checkbox"/>
I understand that my GP will be directly informed should any concerns be raised regarding my mental and/or cognitive health.	<input type="checkbox"/>
I understand that my GP will be directly informed should any concerns be raised regarding my own or someone else's safety	<input type="checkbox"/>
I understand that all my information will be kept confidential and will only be accessible to the Chief Investigator and study supervisors	<input type="checkbox"/>
I would like to be informed of study findings by post	<input type="checkbox"/>
I understand that relevant sections of my medical notes and data collected during the study may be looked at by the study researchers and individuals from the Sponsor, the University of Edinburgh, or from NHS Lothian, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my record.	<input type="checkbox"/>

I **agree** to take part in this study

Participant Name: .....

Signature: .....

Date: .....

Researcher Name: .....

Signature: .....

Date: .....

## Appendix B10 Demographic Questionnaire version 3



### Psychological adjustment to mild cognitive impairment

#### Demographic Information

Please answer the following questions:

<b>Participant code</b> (researcher only)			
<b>Date of birth</b>		<b>Age</b>	
<b>Gender</b>		<b>Marital status</b>	
<b>Wearing glasses if needed?</b>		<b>Wearing hearing aid(s) if needed?</b>	
<b>Any sight/hearing difficulties?</b>		<b>Years of education</b>	
<b>Working/Retired</b>		<b>Current/Previous employment</b>	
<b>Age at retirement</b>			
<b>Years since memory and thinking difficulties began</b>		<b>Date of MCI diagnosis</b>	
<b>Any other physical health problems?</b>			
<b>Any other physical health symptoms?</b>			

## **Appendix B11** Empirical paper author guidelines

Author guidelines for the journal *Psychology and Aging* (available from:  
<http://www.apa.org/pubs/journals/pag/index.aspx>)

### **Submission**

Submit manuscripts electronically through the Manuscript Submission Portal (.rtf, .doc, or .pdf files).

Ulrich Mayr  
Department of Psychology  
University of Oregon  
Eugene, OR

General correspondence may be directed to the Editor's Office.

In addition to addresses and phone numbers, please supply email addresses and fax numbers, if available, for potential use by the editorial office and later by the production office.

#### Masked review

Masked reviews are optional, and authors who wish masked reviews must specifically request them at submission. Authors requesting masked review should make every effort to see that the manuscript itself contains no clues to their identities. Authors' names, affiliations, and contact information should be included only in the cover letter.

If your manuscript was mask reviewed, please ensure that the final version for production includes a byline and full author note for typesetting.

#### Length

Manuscripts should not exceed 8,000 words (approximately 27 double-spaced pages in 12-point Times New Roman font). Shorter manuscripts are equally welcomed.

The word count does not include references, tables, and figures. If you feel that you need extra space, please contact the editor. For example, you may have a complex methodology or statistical approach or a new theoretical framework that requires more text.

Please include the word count for the main text below the keywords.

#### Brief reports

The Brief Report format is designated for particularly "crisp," theoretically noteworthy contributions that meet highest methodological standards. Use 12-point Times New Roman type and 1-inch (2.54-cm) margins; include an abstract of 75–100 words; do not exceed 265 lines of text, not including references; and typically include no more than two tables or figures.

#### Manuscript preparation

Prepare manuscripts according to the Publication Manual of the American Psychological Association (6<sup>th</sup> edition). Manuscripts may be copyedited for bias-free language (see Chapter 3 of the *Publication Manual*).

Review APA's Checklist for Manuscript Submission before submitting your article.

Double-space all copy. Other formatting instructions, as well as instructions on preparing tables, figures, references, metrics, and abstracts, appear in the *Manual*.

Below are additional instructions regarding the preparation of display equations, computer code, and tables.

#### Display equations

We strongly encourage you to use MathType (third-party software) or Equation Editor 3.0 (built into pre-2007 versions of Word) to construct your equations, rather than the equation support that is built into Word 2007 and Word 2010. Equations composed with the built-in Word 2007/Word 2010 equation support are converted to low-resolution graphics when they enter the production process and must be rekeyed by the typesetter, which may introduce errors.

To construct your equations with MathType or Equation Editor 3.0:

- Go to the Text section of the Insert tab and select Object.
- Select MathType or Equation Editor 3.0 in the drop-down menu.

If you have an equation that has already been produced using Microsoft Word 2007 or 2010 and you have access to the full version of MathType 6.5 or later, you can convert this equation to MathType by clicking on MathType Insert Equation. Copy the equation from Microsoft Word and paste it into the MathType box. Verify that your equation is correct, click File, and then click Update. Your equation has now been inserted into your Word file as a MathType Equation.

Use Equation Editor 3.0 or MathType only for equations or for formulas that cannot be produced as Word text using the Times or Symbol font.

#### Computer code

Because altering computer code in any way (e.g., indents, line spacing, line breaks, page breaks) during the typesetting process could alter its meaning, we treat computer

code differently from the rest of your article in our production process. To that end, we request separate files for computer code.

### **In Online Supplemental Material**

We request that runnable source code be included as supplemental material to the article. For more information, visit [Supplementing Your Article With Online Material](#).

### **In the Text of the Article**

If you would like to include code in the text of your published manuscript, please submit a separate file with your code exactly as you want it to appear, using Courier New font with a type size of 8 points. We will make an image of each segment of code in your article that exceeds 40 characters in length. (Shorter snippets of code that appear in text will be typeset in Courier New and run in with the rest of the text.) If an appendix contains a mix of code and explanatory text, please submit a file that contains the entire appendix, with the code keyed in 8-point Courier New.

### Tables

Use Word's Insert Table function when you create tables. Using spaces or tabs in your table will create problems when the table is typeset and may result in errors.

### Supplemental materials

APA can place supplemental materials online, available via the published article in the PsycARTICLES<sup>®</sup> database. Please see [Supplementing Your Article With Online Material](#) for more details.

### Abstract and key words

All manuscripts must include an abstract containing a maximum of 250 words typed on a separate page. After the abstract, please supply up to five keywords or brief phrases.

### References

List references in alphabetical order. Each listed reference should be cited in text, and each text citation should be listed in the References section.

Examples of basic reference formats:

- **Journal Article:**  
Hughes, G., Desantis, A., & Waszak, F. (2013). Mechanisms of intentional binding and sensory attenuation: The role of temporal prediction, temporal control, identity prediction, and motor prediction. *Psychological Bulletin*, *139*, 133–151. <http://dx.doi.org/10.1037/a0028566>

- **Authored Book:**  
Rogers, T. T., & McClelland, J. L. (2004). *Semantic cognition: A parallel distributed processing approach*. Cambridge, MA: MIT Press.
- **Chapter in an Edited Book:**  
Gill, M. J., & Sypher, B. D. (2009). Workplace incivility and organizational trust. In P. Lutgen-Sandvik & B. D. Sypher (Eds.), *Destructive organizational communication: Processes, consequences, and constructive ways of organizing* (pp. 53–73). New York, NY: Taylor & Francis.

## Figures

Graphics files are welcome if supplied as Tiff or EPS files. Multipanel figures (i.e., figures with parts labeled a, b, c, d, etc.) should be assembled into one file.

The minimum line weight for line art is 0.5 point for optimal printing.

For more information about acceptable resolutions, fonts, sizing, and other figure issues, please see the general guidelines.

When possible, please place symbol legends below the figure instead of to the side.

APA offers authors the option to publish their figures online in color without the costs associated with print publication of color figures.

The same caption will appear on both the online (color) and print (black and white) versions. To ensure that the figure can be understood in both formats, authors should add alternative wording (e.g., "the red (dark gray) bars represent") as needed.

For authors who prefer their figures to be published in color both in print and online, original color figures can be printed in color at the editor's and publisher's discretion provided the author agrees to pay:

- \$900 for one figure
- An additional \$600 for the second figure
- An additional \$450 for each subsequent figure

## Permissions

Authors of accepted papers must obtain and provide to the editor on final acceptance all necessary permissions to reproduce in print and electronic form any copyrighted work, including test materials (or portions thereof), photographs, and other graphic images (including those used as stimuli in experiments).

On advice of counsel, APA may decline to publish any image whose copyright status is unknown.

- [Download Permissions Alert Form \(PDF, 13KB\)](#)

## Publication policies

APA policy prohibits an author from submitting the same manuscript for concurrent consideration by two or more publications.

See also [APA Journals® Internet Posting Guidelines](#).

APA requires authors to reveal any possible conflict of interest in the conduct and reporting of research (e.g., financial interests in a test or procedure, funding by pharmaceutical companies for drug research).

- [Download Disclosure of Interests Form \(PDF, 38KB\)](#)

Authors of accepted manuscripts are required to transfer the copyright to APA.

- For manuscripts **not** funded by the Wellcome Trust or the Research Councils UK  
[Publication Rights \(Copyright Transfer\) Form \(PDF, 83KB\)](#)
- For manuscripts funded by the Wellcome Trust or the Research Councils UK  
[Wellcome Trust or Research Councils UK Publication Rights Form \(PDF, 34KB\)](#)

## Ethical principles

It is a violation of APA Ethical Principles to publish "as original data, data that have been previously published" (Standard 8.13).

In addition, APA Ethical Principles specify that "after research results are published, psychologists do not withhold the data on which their conclusions are based from other competent professionals who seek to verify the substantive claims through reanalysis and who intend to use such data only for that purpose, provided that the confidentiality of the participants can be protected and unless legal rights concerning proprietary data preclude their release" (Standard 8.14).

APA expects authors to adhere to these standards. Specifically, APA expects authors to have their data available throughout the editorial review process and for at least 5 years after the date of publication.

Authors are required to state in writing that they have complied with APA ethical standards in the treatment of their sample, human or animal, or to describe the details of treatment.

- [Download Certification of Compliance With APA Ethical Principles Form \(PDF, 26KB\)](#)

The APA Ethics Office provides the full [Ethical Principles of Psychologists and Code of Conduct](#) electronically on its website in HTML, PDF, and Word format. You may also request a copy by [emailing](#) or calling the APA Ethics Office (202-336-5930). You

may also read "Ethical Principles," December 1992, *American Psychologist*, Vol. 47, pp. 1597–1611.

## **Appendix C – Empirical Paper Documents for Amended Ethical Approval March 2014**

**Appendix C1** Letter of ethical approval for substantial amendment

**Appendix C2** Letter of NHS R&D approval for substantial amendment

**Appendix C3** Amended protocol version 12

**Appendix C4** Amended PIS version 12 – Clinic group version

**Appendix C5** Amended PIS version 12 – Casenote review group version

## Appendix C1 Letter of ethical approval for substantial amendment

**Lothian NHS Board**

**South East Scotland Research  
Ethics Committee 02**



Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
EH1 3EG  
Telephone 0131 536 9000  
Fax 0131 465 5789

[www.nhslothian.scot.nhs.uk](http://www.nhslothian.scot.nhs.uk)

Date 13 March 2014  
Your Ref  
Our Ref

Enquiries to: Joyce Clearie  
Extension: 35674  
Direct Line: 0131 465 5674  
Email: [Joyce.Clearie@nhslothian.scot.nhs.uk](mailto:Joyce.Clearie@nhslothian.scot.nhs.uk)

13 March 2014

Miss Amanda Stevenson  
Trainee Clinical Psychologist  
NHS Lothian/University of Edinburgh  
School of Health in Social Science  
University of Edinburgh  
Teviot Place  
EH8 9AG

Dear Miss Stevenson

Study title: Psychological adjustment to a diagnosis of mild cognitive impairment: the roles of illness perceptions, cognitive functioning and psychological flexibility.

REC reference: 13/SS/0237  
Amendment number: AMO1 SA1  
Amendment date: 11 March 2014  
IRAS project ID: 113930

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

No significant ethical issues but comment made that mentioning the possibility of home visits in the PIS, since many who needn't may take up the offer... Not a real problem though.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	12	10 March 2014
Participant Information Sheet: PIS Clinic Group	10	10 March 2014



Headquarters  
Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG

Chair Mr Brian Houston  
Chief Executive Tim Davison  
*Lothian NHS Board is the common name of Lothian Health Board*

## Appendix C2 Letter of NHS R&D approval for substantial amendment

University Hospitals Division

Queen's Medical Research Institute  
47 Little France Crescent, Edinburgh, EH16 4TJ



SS/NM

07 April 2014

Miss Amanda Stevenson  
NHS Lothian  
Psychology Department  
St John's Hospital  
Livingston  
EH54 6PP

RESEARCH & DEVELOPMENT  
Room E1.12  
Tel: 0131 242 3330  
Fax: 0131 242 3343  
Email:  
R&DOffice@nhslothian.scot.nhs.uk

Director:  
Professor David E Newby

Dear Miss Stevenson

**REC No:** 13/SS/0237  
**R&D Project ID No:** 2014/0032  
**Amendment:** Substantial amendment No.1 dated 10 March 2014  
**Title of Research** Psychological adjustment to a diagnosis of mild cognitive impairment: the roles of illness perceptions, cognitive functioning and psychological flexibility

I am writing in reply to recent correspondence in relation to an amendment(s) to the above project and the subsequent updated documents as follows.

- Appointment Letter version 5 - dated 10 March 2014
- Patient Information Sheet Case note review group version 10 - dated 10 March 2014
- Patient Information Sheet Clinic Group Version 10 – dated 10 March 2014
- Protocol Version 12 - dated 10 March 2014

We have now assessed any consequential changes and can confirm that NHS Lothian management approval is extended to cover the specific changes intimated.

Yours sincerely

A handwritten signature in black ink that reads 'Susan Shepherd'.

**Mrs Susan Shepherd**  
Head of Research Governance



**Study Protocol: Psychological adjustment to a diagnosis of mild cognitive impairment: the roles of illness perceptions, cognitive functioning and psychological flexibility.**

People with mild cognitive impairment (MCI) are said to be at increased risk of developing dementia. MCI is associated with cognitive difficulties similar to those experienced by people with dementia, such as memory problems, but at attenuated levels (Petersen et al., 1999). People with MCI also tend to have intact functional abilities (Petersen et al., 1999). Cognitive impairment can lead to perceptions of lower quality of life (QoL) and psychological wellbeing (Missotten et al., 2008; Selwood et al., 2005) but evidence is equivocal (Banerjee et al., 2009).

Receiving a diagnosis of MCI can mean an uncertain prognosis and can be anxiety-provoking, due to the increased risk of developing dementia. Recent research has indicated that the beliefs people hold about an illness can influence their quality of life (QoL) and psychological wellbeing (e.g. Jopson & Moss-Morris, 2003). People with MCI who hold negative beliefs about their diagnosis have been found to experience greater levels of emotional distress independently of their level of cognitive impairment (Lin et al., 2012; Lin & Heidrich, 2012). The impact on QoL is not currently understood.

Evidence from studies evaluating the recently developed psychological intervention, Acceptance and Commitment Therapy (ACT; Hayes et al., 2006), indicates that how people stand towards their thoughts and beliefs, conceptualised here as psychological flexibility (PF), may play a role in how people respond to their thoughts. Thus, rather than reducing negative thinking overall, PF may act to reduce the impact of negative thoughts. For people with MCI who have negative perceptions about their illness, PF may therefore influence their perceived psychological wellbeing and QoL.

**Aims**

The current study aims to establish preliminary evidence for the possible utility of ACT for people with MCI by exploring (1) the relationship between illness perceptions of MCI, psychological wellbeing and QoL in people with MCI (2) the relationship between level of cognitive impairment, psychological wellbeing and QoL in people with MCI and (3) whether illness appraisals are more strongly related to outcome variables than level of cognitive impairment and (4) whether these relationships are mediated by individual differences in PF.

## Research Questions

- Do individual differences in PF have an effect on the relationships between illness appraisals, level of cognitive impairment, QoL and psychological wellbeing in people with MCI?
- What is the nature of the relationship between appraisals of illness, QoL and psychological wellbeing in people with MCI?
- What is the nature of the relationship between level of cognitive impairment, QoL and psychological wellbeing in people with MCI?
- To establish whether illness appraisals are more strongly related to outcome variables than level of cognitive impairment.

## Hypotheses

The null hypotheses for the study will be:

- There will be **no** significant relationships between: illness appraisals, QoL and psychological wellbeing, or between level of cognitive impairment, QoL and psychological wellbeing.
- There will be **no** difference in the strength of relationships with outcome variables for illness appraisals and level of cognitive impairment.
- Individual differences in PF **will not** mediate the relationships between illness appraisals, level of cognitive impairment, QoL and psychological wellbeing.

The alternative hypotheses will therefore be:

- There **will** be a significant relationship between: illness appraisals, QoL and psychological wellbeing and between level of cognitive impairment, QoL and psychological wellbeing.
- Illness appraisals **will** be more strongly related to outcome variables than level of cognitive impairment.
- Individual differences in PF **will** significantly influence the relationships between illness appraisals, level of cognitive impairment, QoL and psychological wellbeing.

## Method of investigation

### *Participants*

Participants will be 53 individuals with mild cognitive impairment diagnosed within the past nine months. Inclusion and exclusion criteria are outlined below:

**Inclusion criteria:**

- Diagnosis of MCI within the past 9 months
- Able to provide informed consent
- Over the age of 60
- Able to speak, read and write fluently in English
- Absence of significant physical health problems (e.g. cancer)
- No past history of brain injury (e.g. head trauma)
- No current psychiatric diagnosis (e.g. psychosis)

**Exclusion criteria**

- Premorbid cognitive difficulties (e.g. Learning disability)
- Current residential or nursing care placement
- Sensory impairment (e.g. blindness, deafness)
- Current or past history of substance misuse
- Current significant health problems

*Design*

A within-subjects, cross-sectional, questionnaire-based design will be employed to analyse the relationships between independent variables and outcome variables using statistical mediation analysis. All participants will complete seven questionnaires: a brief demographic questionnaire; the Montreal Cognitive Assessment (MoCA; Nasreddine *et al.*, 2005); the Illness Perception Questionnaire – Mild Cognitive Impairment (IPQ-MCI; Lin *et al.*, 2012); the Acceptance and Action Questionnaire-II (AAQ-II; Bond *et al.*, 2011); the Geriatric Depression Scale-5 (GDS-5; Hoyl *et al.*, 1999); the Geriatric Anxiety Inventory – Short Form (GAI-SF; Byrne & Pachana, 2011) and the Quality of Life in Alzheimer's Disease Scale (QOL-AD; Logsdon *et al.*, 2002).

*Measures*

The following measures will be used in this study:

*Demographic Questionnaire (created by principal researcher)*

All participants will complete a short questionnaire in order to gather basic information regarding sample population demographics. No personal information will be gathered.

*AAQ-II*

This is a measure of PF, a central tenet of ACT. It is a 7-item questionnaire containing statements to which participants assign a response based on a 7-point Likert scale ranging from: *never true* to *always true*. This scale has not been validated for use by people with MCI, though the original version of the AAQ has been used successfully with a sample of older people (Butler & Ciarrochi, 2007).

### *Geriatric Depression Scale-5*

The GDS-5 is one of a number of shortened versions of the original GDS (GDS-30; Yesavage et al., 1983), providing a briefer administration time whilst maintaining high levels of sensitivity, specificity, accuracy and predictive ability (Hoyl et al., 1999). The GDS-5 has been successfully used by people with mild to moderate dementia (e.g. Lach et al., 2010). The scale consists of 5 items which respondents either endorse or reject by answering yes or no.

### *Geriatric Anxiety Inventory-SF*

The GAI-SF is a shortened form of the original Geriatric Anxiety Inventory (GAI; Pachana et al., 2007). Though the longer GAI is argued to have more robust psychometrics (Byrne & Pachana, 2011), the use of the GAI-SF in this case is to minimise fatigue and item burden to participants. The GAI-SF has not been employed with a population of people with MCI; however, the longer GAI has been employed with a sample of memory clinic attendees (Byrne et al., 2008). The GAI-SF consists of 5 items to which respondents indicate their agreement or disagreement by answering yes or no.

### *Quality of Life in Alzheimer's Disease*

The QoL-AD was identified as a reliable and valid self-report tool (Logsdon et al., 2002) that has been utilised widely as an outcome measure in research with people with dementia and cognitive impairment. This is a 13-item scale assessing various QoL contributors, such as living situation, and ability to do things for fun. Respondents rate each factor on a 4-point Likert scale ranging from *poor* to *excellent*.

### *IPQ-MCI*

The IPQ-MCI is a version of the revised Illness Perception Questionnaire (IPQ-R; Moss-Morris et al., 2002) developed and piloted for use with people with MCI comprising 8 subscales and 88 items in total. Participants are given a range of possible symptoms and asked to tick which ones they have experienced as a result of their MCI. They then rate a number of statements about their illness beliefs from a five point Likert scale ranging from *Strongly agree* to *Strongly disagree*.

### *MoCA*

The MoCA is a brief cognitive screening tool taking approximately 10 minutes to administer. Participants are scored out of 30 on tasks purporting to measure a number of cognitive domains, including memory, attention, visuospatial functioning, language and executive functioning. The MoCA was developed in order to produce a cognitive screen with greater sensitivity to MCI and early dementia than more commonly used tools such as the Mini-Mental State Examination (MMSE; Folstein et al., 1975), supported by findings from recent studies (e.g. Freitas et al., 2013).

## *Recruitment*

### *NHS staff:*

Participants identified as meeting inclusion/exclusion criteria by NHS clinical staff (Psychiatry, Clinical Psychology, Community Psychiatric Nursing) will be approached within the context of clinical appointments by their named clinician, who will provide a verbal outline of the study and invite them to participate. If participants indicate an interest in becoming involved in the study, their named clinician will provide them with a participant information sheet (PIS) and an invitation letter. At this time the clinician will also inform them that the Chief Investigator will contact them by telephone to discuss the study further and to arrange an appointment following a minimum of twenty four hours.

### *Casenote review:*

The Chief Investigator (who will be employed as a Trainee Clinical Psychologist within the service) will conduct a casenote review of patients recently diagnosed with MCI to identify possible participants who meet inclusion/exclusion criteria. Where possible, when such patients have a caseholder, their named clinician will approach them to invite them to participate. They will then be provided with a PIS and invitation letter. Where patients do not have an active caseholder, they will be sent an invitation letter and PIS. The PIS will include a reply slip to enable participants to register their interest in taking part and to opt in to receiving contact from the researcher. Participants will be informed that once their reply slip has been received, the Chief Investigator will contact them by telephone to discuss the study further and to arrange an appointment.

### *Procedure*

Once participants have agreed to be contacted, the Chief Investigator will contact them by telephone to discuss the study further and to arrange an interview appointment. All appointments will take place at NHS Lothian sites, [REDACTED], or in their own homes (only if this assessed as safe). Home visits will only be offered to those participants who are known to the NHS clinician (Psychology, Psychiatry, Nursing) who identifies that the patient meets inclusion criteria, and where the clinician has no concerns regarding risk to NHS staff lone workers. In the case of patients identified via casenote review, the possibility of home visits will be discussed with the project supervisor and with the patient's named clinician. For these participants, home visits will only be offered where no concerns are raised regarding risk to NHS staff lone workers. The NHS [REDACTED] Lone Worker policy and the department's own Safe and Well procedures will be followed at all times in order to minimise any potential risk during home visits.

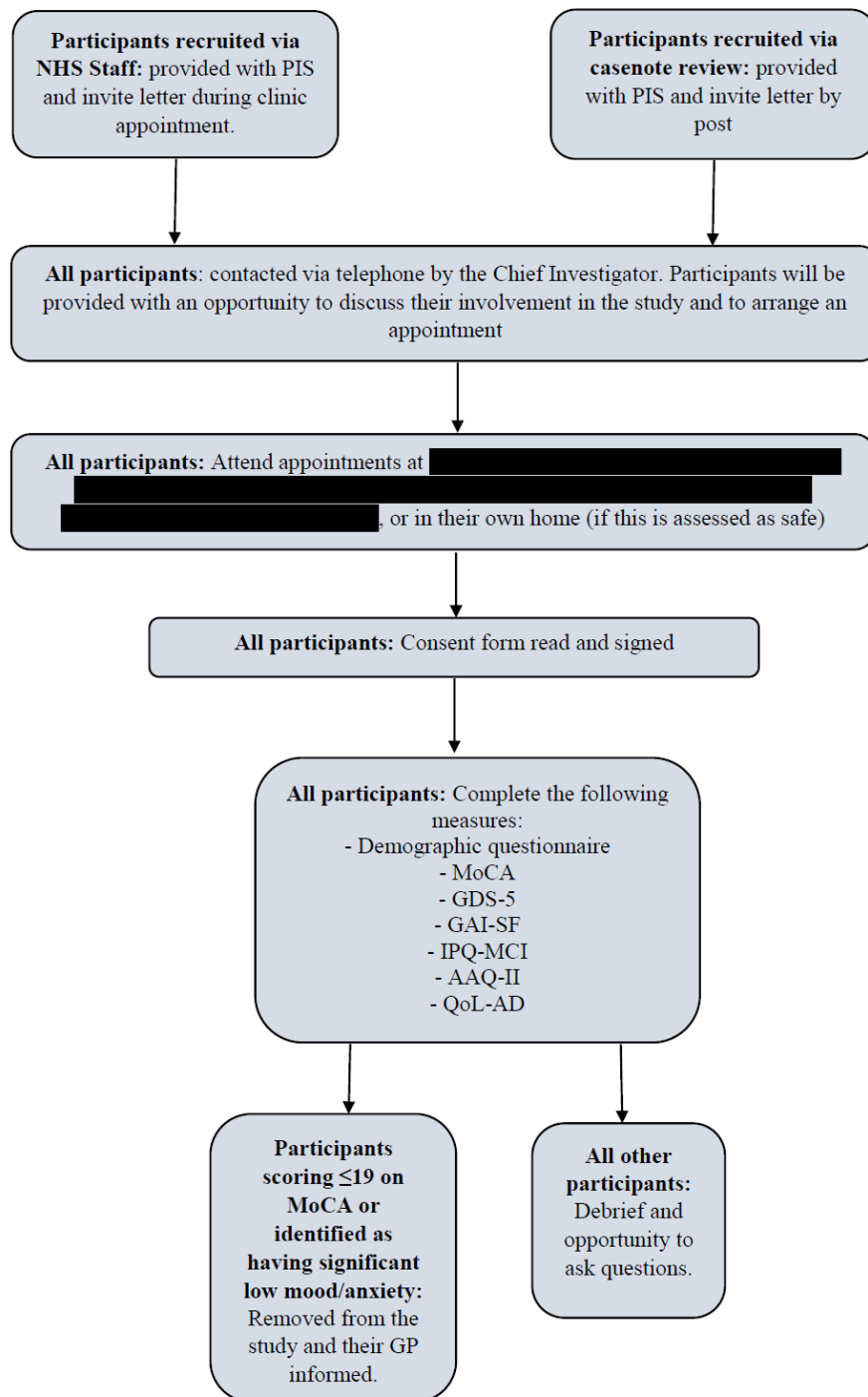
Interview appointments will last approximately one hour. Each appointment will consist of the following:

- Seeking informed consent (5 minutes)
- Completion of demographic questionnaire (5 minutes)
- Completion of cognitive screening measure – those scoring below clinical cut off for dementia on the MoCA will be removed from the study and their GP informed (10 minutes)
- Assessment of mood (5 minutes)

- Assessment of anxiety (5 minutes)
- Assessment of illness appraisals (10 minutes)
- Assessment of PF (5 minutes)
- Assessment of QoL (10 minutes)
- Participant questions/comments and debrief (5 minutes)

The process is illustrated in figure 1 below:

Figure 1:



Should participants wish to take a short break, they will be offered the opportunity to do so. If participants become distressed or feel fatigued, they will have the option of rescheduling the appointment or discontinuing their involvement in the study. Appropriate steps will be taken to minimise risk of harm should participants report distress. The Chief Investigator, as a Trainee Clinical Psychologist, is competent in the core skills necessary to provide

immediate comfort and psychological support, and participants will be advised to seek further advice from their GP should they have any concerns about their mental and/or cognitive health. If significant concerns are raised regarding a participant's mental health, the Chief Investigator will seek advice from the project clinical supervisor and will provide immediate support, the participant's GP will be informed and they will be removed from the study. The Chief Investigator will be working under the supervision of a qualified Clinical Psychologist, and will be able to seek further advice from them if necessary. In addition, as part of the clinical team, the Chief Investigator will be able to facilitate access to psychological support and other treatments from the wider Older Adult Mental Health Service for participants if necessary.

### *Statistical Analysis*

Initial correlational analyses will be carried out in order to establish the relationships between variables in the statistical model. Any variables not correlated will be removed from the model. The main research questions and objectives will be examined through mediation analysis, calculated using bias-corrected bootstrapping techniques, with separate analyses being carried out for each independent and dependent variable. Therefore, a total of six mediation analyses will be calculated. The independent variables are: level of cognitive impairment and illness perceptions. The mediator variable is PF, and the dependent variables are: QoL, depression and anxiety.

### *Dissemination*

The study will be written up as a doctoral thesis in line with the requirements of the University of Edinburgh Doctorate in Clinical Psychology. The thesis will also include a write up of the study in peer-reviewed journal format which will be prepared for publication in a relevant journal. A brief summary of the findings of the study will also be compiled and sent out to any participants who indicated their interest in receiving this on the consent form. Presentations will also be delivered to interested stakeholders and at relevant conferences and CPD events.



## **PARTICIPANT INFORMATION SHEET**

### **STUDY TITLE: Psychological adjustment to mild cognitive impairment**

You are being invited to take part in a research study. Before you decide if you would like to participate, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully, and talk to others about the study if you wish. If there is anything that is unclear, or if you have any questions, please do not hesitate to ask the Chief Investigator (Amanda Stevenson). You can also contact them using the details at the end of this sheet.

### **WHAT IS THE RESEARCH ABOUT?**

This study is examining how people adjust to receiving a diagnosis of mild cognitive impairment (sometimes referred to as memory and thinking difficulties). We know that how people view their diagnosis or condition can affect their sense of wellbeing, but the ways in which psychological factors influence the relationship between views about a condition and wellbeing are not well understood.

### **WHY HAVE I BEEN INVITED?**

We are inviting people who have received a diagnosis of mild cognitive impairment within the past nine months to take part. We are aiming to recruit between 50 and 60 participants.

### **DO I HAVE TO TAKE PART?**

No. It is up to you to decide whether or not to join this study.

If you do decide to participate, you will be asked to sign a consent form, and you will be able to keep this information sheet for reference. If you decide to take part you will still be able to withdraw from the study at any point and you do not have to give a reason.

Involvement with the study will not affect the care you receive from any NHS service, now, or in the future (whether or not you decide to participate).

## **WHAT WILL HAPPEN TO ME IF I TAKE PART?**

If you choose to take part in this study, you will be asked to meet with the Chief Investigator on **one occasion** to participate in an individual interview lasting approximately **one hour**. The appointment will take place at one of the following locations: [REDACTED]

[REDACTED]. We may be able to offer to visit you at home, in specific circumstances. You will be able to choose which one would be most convenient for you, along with a time and date which is suitable for you. Please note that unfortunately we are unable to reimburse your travel expenses.

During the appointment you will have a further opportunity to ask questions and to discuss your involvement in the study. If you still wish to participate, you will be asked to sign a consent form stating that you agree to participate and that you understand what your participation will entail. We will also inform your GP (General Practitioner) by letter that you are taking part in the study.

You will then be asked to complete a series of questionnaires with the assistance of the Chief Investigator including:

- A brief test of mental functioning, such as memory
- Your views regarding your diagnosis of mild cognitive impairment and your current mental health

If at any point during the appointment you no longer wish to take part, you may withdraw from the study without having to give a reason.

## **WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?**

It is likely that there will not be an immediate benefit to you, but your participation will aid in our understanding of how people adjust to mild cognitive impairment. This may inform the development of future psychological treatments and interventions for people with mild cognitive impairment.

## **WHAT ARE THE POSSIBLE RISKS AND DISADVANTAGES OF TAKING PART?**

You will be asked to complete a set of seven tasks and questionnaires over a period of approximately one hour, which can leave some people feeling tired. In addition, some questions will ask you about sensitive topics, particularly regarding your current mental health, and your views about your diagnosis of mild cognitive impairment. It is possible that thinking about these issues may cause some to feel upset or distressed.

If you should experience either of these then you should inform the Chief Investigator, who will offer you support and ask whether you would like to take a break or to reschedule a later appointment. If you should become upset, or have any concerns, the Chief Investigator will be able to provide you with immediate comfort and support. We may also need to inform your GP or involve someone else who can help, such as a Psychiatrist.

### **WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?**

Consent forms and identifiable information will be destroyed, but your anonymous data may be held for future authorised research.

### **WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?**

All the information we collect from you will be kept confidential. We will keep your data anonymous during the research by assigning it a unique reference number. This reference number will be the only link between your data and your consent form. Once the study has been completed, your consent form will be destroyed. Your data will be securely stored on an NHS site and will be kept separately from consent forms.

Your data will only be accessible to the Chief Investigator, study supervisors, and anyone appointed by the Sponsor (NHS [REDACTED]/University of Edinburgh) to ensure the study is being carried out correctly.

We will inform your GP of your participation in the study by letter; however, we will not provide details to your GP regarding your performance on the assessment task or of your responses to questionnaires, unless you report any significant difficulties with your mood or functioning.

If you report anything that makes the Chief Investigator consider that you, or someone you know, are at risk of harm, your GP would need to be informed and we may need to involve someone else who can help, such as a Psychiatrist. Similarly, if you report information that relates to the prevention or detection of crime, the Chief Investigator may be required to disclose this information to relevant agencies (eg. Police). In each case, the Chief Investigator would discuss with you how this might be addressed.

### **WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?**

The results of the study will be written up and reported in a doctoral thesis format in part fulfilment of the requirements of the University of Edinburgh Doctorate in Clinical Psychology. We also hope to submit this thesis project to relevant academic journals for publication. All the information we collect from you will be kept anonymous, and will only be identifiable to the Chief Investigator and study supervisors.

If you would like to be informed of the results of the study, you may indicate your preference when signing the study consent form. You will then be provided with a written summary following completion of the study in May 2014.

### **WHO IS ORGANISING AND FUNDING THE RESEARCH?**

The study is being organised by Amanda Stevenson, Trainee Clinical Psychologist, under the supervision of Dr. David Gillanders (University of Edinburgh), Dr. Nuno Ferreira (University of Edinburgh) and Dr. Donna Gilroy (NHS [REDACTED]). The study is being supported by both NHS Lothian and the University of Edinburgh.

### **WHO HAS REVIEWED THE STUDY?**

The project proposal has been reviewed and accepted by the University of Edinburgh Doctorate in Clinical Psychology, and by my supervisors: Dr. David Gillanders (Academic Director, Doctorate in Clinical Psychology), Dr. Nuno Ferreira (Lecturer in Clinical Psychology) and Dr. Donna Gilroy (Clinical Psychologist). Ethical approval has been granted by South East Scotland Research Ethics Committee on 21/01/14.

### **WHAT TO DO NOW?**

Since you have indicated to a member of staff that you are interested in participating, **the Chief Investigator will contact you by telephone** in the coming weeks to discuss the study with you and to arrange an interview appointment.

Alternatively, you may contact the Chief Investigator using the below details:

Amanda Stevenson  
Trainee Clinical Psychologist

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

### **FURTHER INFORMATION**

If you would like to speak to someone else about the study, please contact:

Dr Heather Wilkinson  
Research Director  
School of Health in Social Science  
University of Edinburgh  
Teviot Place

Edinburgh  
EH8 9AG

**WHAT IF SOMETHING GOES WRONG?**

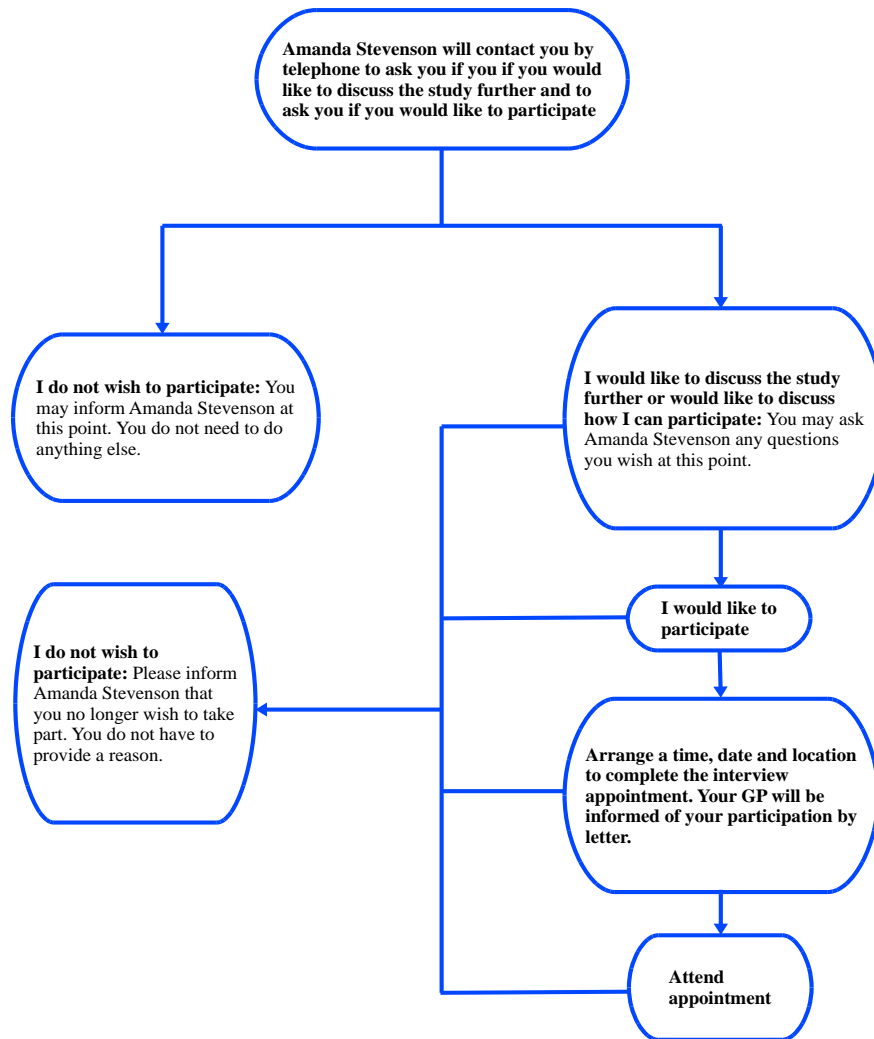
If you should wish to make a formal complaint regarding the study, please contact:

NHS [REDACTED] Complaints Team

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

email: [REDACTED]

Fig. 1: Flow chart explaining participation process



Thank you for taking the time to read this information sheet

Amanda Stevenson, Trainee Clinical Psychologist

Amanda Stevenson, Trainee Clinical Psychologist



## PARTICIPANT INFORMATION SHEET

### **STUDY TITLE: Psychological adjustment to mild cognitive impairment**

You are being invited to take part in a research study. Before you decide if you would like to participate, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully, and talk to others about the study if you wish. If there is anything that is unclear, or if you have any questions, please do not hesitate to ask the Chief Investigator (Amanda Stevenson). You can also contact them using the details at the end of this sheet.

### **WHAT IS THE RESEARCH ABOUT?**

This study is examining how people adjust to receiving a diagnosis of mild cognitive impairment (sometimes referred to as memory and thinking difficulties). We know that how people view their diagnosis or condition can affect their sense of wellbeing, but the ways in which psychological factors influence the relationship between views about a condition and wellbeing are not well understood.

### **WHY HAVE I BEEN INVITED?**

We are inviting people who have received a diagnosis of mild cognitive impairment within the past three to six months to take part. We are aiming to recruit between 50 and 60 participants.

### **DO I HAVE TO TAKE PART?**

No. It is up to you to decide whether or not to join this study.

If you do decide to participate, you will be asked to sign a consent form, and you will be able to keep this information sheet for reference. If you decide to take part you will still be able to withdraw from the study at any point and you do not have to give a reason.

Involvement with the study will not affect the care you receive from any NHS service, now, or in the future (whether or not you decide to participate).

### **WHAT WILL HAPPEN TO ME IF I TAKE PART?**

If you choose to take part in this study, you will be asked to meet with the Chief Investigator on **one occasion** to participate in an individual interview lasting approximately **one hour**. The appointment will take place at one of the following locations:

**We may be able to offer to visit you at home, in specific circumstances.** You will be able to choose which one would be most convenient for you, along

with a time and date which is suitable for you. Please note that unfortunately we are unable to reimburse your travel expenses.

During the appointment you will have a further opportunity to ask questions and to discuss your involvement in the study. If you still wish to participate, you will be asked to sign a consent form stating that you agree to participate and that you understand what your participation will entail. We will also inform your GP (General Practitioner) by letter that you are taking part in the study.

You will then be asked to complete a series of questionnaires with the assistance of the Chief Investigator including:

- A brief test of mental functioning, such as memory
- Your views regarding your diagnosis of mild cognitive impairment and your current mental health

If at any point during the appointment you no longer wish to take part, you may withdraw from the study without having to give a reason.

#### **WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?**

It is likely that there will not be an immediate benefit to you, but your participation will aid in our understanding of how people adjust to mild cognitive impairment. This may inform the development of future psychological treatments and interventions for people with mild cognitive impairment.

#### **WHAT ARE THE POSSIBLE RISKS AND DISADVANTAGES OF TAKING PART?**

You will be asked to complete a set of seven tasks and questionnaires over a period of approximately one hour, which can leave some people feeling tired. In addition, some questions will ask you about sensitive topics, particularly regarding your current mental health, and your views about your diagnosis of mild cognitive impairment. It is possible that thinking about these issues may cause some to feel upset or distressed.

If you should experience either of these then you should inform the Chief Investigator, who will offer you support and ask whether you would like to take a break or to reschedule a later appointment. If you should become upset, or have any concerns, the Chief Investigator will be able to provide you with immediate comfort and support. We may also need to inform your GP or involve someone else who can help, such as a Psychiatrist.

#### **WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?**

Consent forms and identifiable information will be destroyed, but your anonymous data may be held for future authorised research.

#### **WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?**

All the information we collect from you will be kept confidential. We will keep your data anonymous during the research by assigning it a unique reference number. This reference number will be the only link between your data and your consent form. Once the study has been completed, your consent form will be destroyed. Your data will be securely stored on an NHS site and will be kept separately from consent forms.

Your data will only be accessible to the Chief Investigator, study supervisors, and anyone appointed by the Sponsor (NHS [REDACTED]/University of Edinburgh) to ensure the study is being carried out correctly.

We will inform your GP of your participation in the study by letter; however, we will not provide details to your GP regarding your performance on the assessment task or of your responses to questionnaires, unless you report any significant difficulties with your mood or functioning.

If you report anything that makes the Chief Investigator consider that you, or someone you know, are at risk of harm, your GP would need to be informed and we may need to involve someone else who can help, such as a Psychiatrist. Similarly, if you report information that relates to the prevention or detection of crime, the Chief Investigator may be required to disclose this information to relevant agencies (eg. Police). In each case, the Chief Investigator would discuss with you how this might be addressed.

#### **WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?**

The results of the study will be written up and reported in a doctoral thesis format in part fulfilment of the requirements of the University of Edinburgh Doctorate in Clinical Psychology. We also hope to submit this thesis project to relevant academic journals for publication. All the information we collect from you will be kept anonymous, and will only be identifiable to the Chief Investigator and study supervisors.

If you would like to be informed of the results of the study, you may indicate your preference when signing the study consent form. You will then be provided with a written summary following completion of the study in August 2014.

#### **WHO IS ORGANISING AND FUNDING THE RESEARCH?**

The study is being organised by Amanda Stevenson, Trainee Clinical Psychologist, under the supervision of Dr. David Gillanders (University of Edinburgh), Dr. Nuno Ferreira (University of Edinburgh) and Dr. Donna Gilroy (NHS [REDACTED]). The study is being supported by both NHS [REDACTED] and the University of Edinburgh.

#### **WHO HAS REVIEWED THE STUDY?**

The project proposal has been reviewed and accepted by the University of Edinburgh Doctorate in Clinical Psychology, and by my supervisors: Dr. David Gillanders (Academic Director, Doctorate in Clinical Psychology), Dr. Nuno Ferreira (Lecturer in Clinical Psychology) and Dr. Donna Gilroy (Clinical Psychologist). Ethical approval has been granted by South East Scotland Research Ethics Committee 2 on 21/01/14.

#### **WHAT TO DO NOW?**

If you would like to know more about the study or are interested in participating, please contact the Chief Investigator using the reply slip at the end of this sheet. Amanda Stevenson will then contact you by telephone to discuss the study with you and to arrange an appointment should you decide to participate.

#### **FURTHER INFORMATION**

If you would like to speak to someone else about the study, please contact:

Dr Heather Wilkinson  
Research Director  
School of Health in Social Science  
University of Edinburgh

Teviot Place  
Edinburgh  
EH8 9AG

**WHAT IF SOMETHING GOES WRONG?**

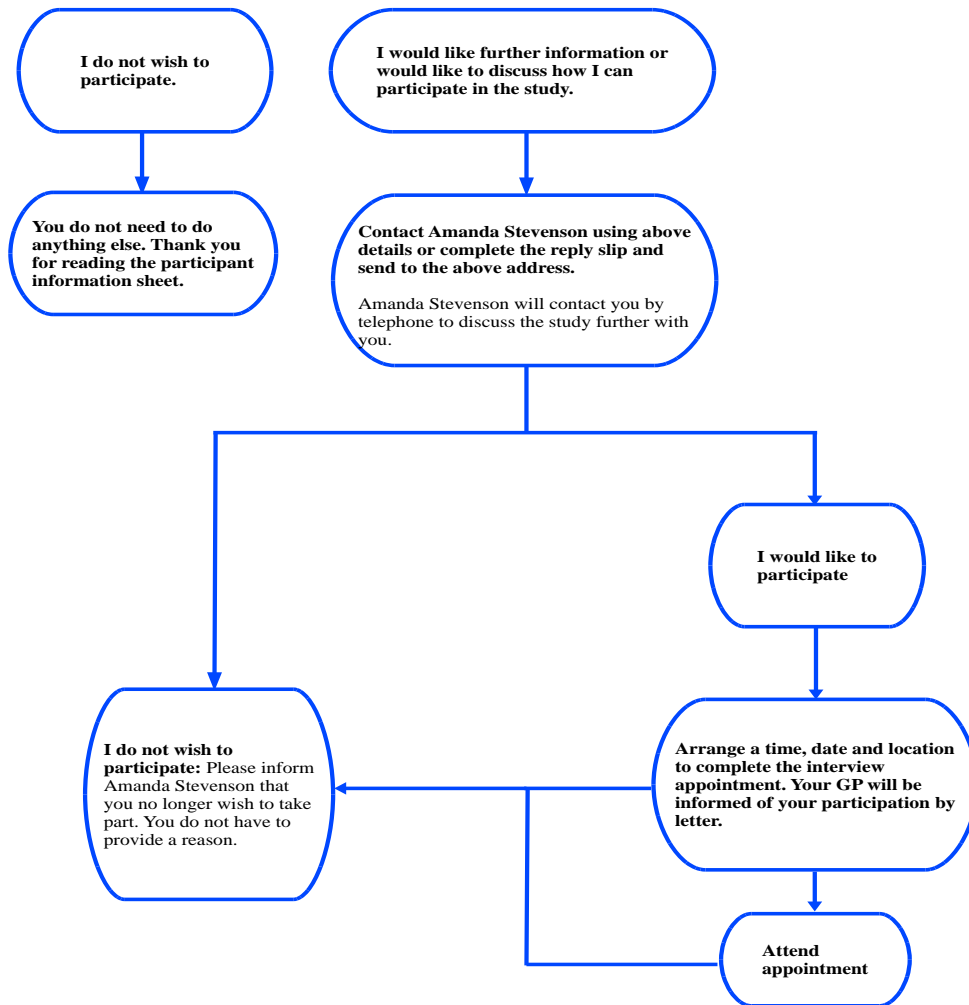
If you should wish to make a formal complaint regarding the study, please contact:

NHS [REDACTED] Complaints Team

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

email: [REDACTED]

Fig. 1: Flow chart explaining participation process



**Thank you for taking the time to read this information sheet**

**Amanda Stevenson, Trainee Clinical Psychologist**

**If you would like to participate in the study, or would like a researcher to contact you to discuss the study, please complete the tear off slip below and send it to:**

Amanda Stevenson  
Trainee Clinical Psychologist

[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]

Tear off slip here

*Reply Slip*

**“Psychological adjustment to mild cognitive impairment”**



I would like further information regarding the above study

I would like to participate in the above study

My preferred location for an appointment is:

[Redacted]

[Redacted]

[Redacted]

[Redacted]

**In my own home (only in specific circumstances)**

Please contact me by telephone using the following details:

Name:

Contact

Number: