

Mindfulness ability in people with mild to moderate dementia

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Thesis declaration form

UCL Doctorate in Clinical Psychology

Thesis declaration form

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Overview

This thesis focuses on research with people with dementia (PWD).

Part 1 is a literature review exploring factors identified or endorsed by PWD and their carers as influencing whether or not the person with dementia would participate in research. A total of 16 papers were included. The quality of papers was variable, and limitations frequent. The most prominent motivators identified for research participation were direct health benefit and altruism. The most prominent barriers were concerns about risks and side effects of drugs and procedures, and the practical burden of participation. The discussion highlights key considerations for future recruitment.

Part 2 is an empirical study examining the performance of 34 PWD on an experience-sampling measure of mindful attention. The study aimed to develop the evidence base for future mindfulness-based interventions (MBIs) for depression in dementia. No significant results were found for the main hypotheses, that people with dementia would perform significantly more poorly than a comparison group of older adults without dementia on the measure of mindful attention, and that performance on this measure would positively correlate with measures of executive function and overall cognition.

Possible reasons for the findings are discussed, along with limitations of the study, and implications for future research and clinical practice. The comparison group data is shared with Habib (2016). The study is a substudy of an ongoing PhD project by Joshua Stott.

Part 3 is a critical appraisal of the research process. It reflects on particular challenges that arose in the recruitment, consent and data collection processes with the PWD sample, outlining how these were dealt with during the study, and making recommendations for future research.

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Part 1: Literature review

What factors do people with dementia and their carers see as influencing whether or not they choose to participate in research?

Abstract

Aims

This review explored motivators and barriers to participation in dementia research, where these had been endorsed or volunteered by people with dementia and/or their carers.

Method

PsycInfo and Medline databases, and the Alzheimer's Society online library catalogue, were searched for papers published up to October 2015. Further papers were identified through hand and online search and expert recommendation. The quality of studies was assessed using the QualSyst tool (Kmet, Lee, & Cook, 2004) and overall ratings assigned as per NICE recommendations (NICE, 2014).

Results

Sixteen papers were identified as meeting eligibility criteria, comprising a range of methodologies. Quality was variable and methodological limitations common. Data from carers were more common than from people with dementia. Narrative synthesis revealed the most common motivators were direct benefit to the person with dementia, and altruism. The most common barriers were concern about risks of drugs and procedures, and practical burden. Additional factors were identified specific to brain donation research and participation by minority ethnic populations. Findings were tentative, and more detailed analysis difficult, due to limitations in the identified literature.

Conclusion

The views of people with dementia and their carers on motivators and barriers to research were generally consistent with the wider literature. Further high quality research is needed to develop our understanding of these factors to aid the recruitment process for dementia research studies.

Introduction

Increasing acknowledgement of the economic, social and psychological costs of dementia in recent years has led to a growing international emphasis on dementia research. UK government policy (Department of Health, 2015) highlights the importance of research infrastructure, activity and participation. Research priorities reflect the biopsychosocial nature of dementia by addressing hopes for prevention, identification and cure, while also aiming to help people affected by dementia – both those diagnosed, and those supporting them – live well with the condition (Alzheimer's Society, 2014).

The feasibility and success of research activity depends on the recruitment of suitable participants. There are now several large-scale projects internationally to support this, including the Join Dementia Research hub in the UK (<https://www.joindementiaresearch.nihr.ac.uk>) and the Recruiting Older Adults into Research (ROAR) project in the US (Global Action Against Dementia, 2015). The Prime Minister's 'Challenge on Dementia' (2015) aspired to research involvement by 10% of people with dementia by 2020. A systematic review and meta-analysis estimated that this could be realistic for pharmacological trials, if everyone diagnosed with Alzheimer's were invited to join a research register (Cooper, Ketley, & Livingston, 2014), and noted the potential for recruitment to non-pharmacological trials to be even higher (Cohen-Mansfield, 2002, cited in Cooper, Ketley & Livingston, 2014).

Yet the challenges involved in the recruitment stage of dementia research alone are well established. These include the difficulty in obtaining representative cohorts of patients from primary care and the lack of awareness of research opportunities for potential participants (Alzheimer's Disease International, 2014), negotiating issues of capacity and consent (Howe, 2012) and the often essential requirement to recruit a study partner in addition to the person with dementia (hereafter abbreviated as PWD) (Grill & Karlawish, 2010). Physical comorbidities may mean participants, even

if willing, require additional practical support to participate (such as home visits) (Jefferson et al., 2011), and there may be socio-cultural issues around research within minority ethnic contexts which indicate a need for substantial work building trust and communication if the research is to gain a foothold with underrepresented groups (Olin, Dagerman, Fox, Bowers, & Schneider, 2002; Rabinowitz & Gallagher-Thompson, 2010; Valle, 2005).

Researchers have extrapolated experiences from specific research projects in order to make suggestions for improvements to future studies (Cohen-Mansfield, 2003; Watson, Ryan, Silverberg, Cahan, & Bernard, 2014). Such recommendations tend (understandably) to be problem-focused, and to foreground the barriers to participation in those who decline, or are unable to engage in the research process, rather than factors motivating those who do take part. However some have highlighted the need to develop our understanding of why a patient might choose to participate in a study – as well as why they might decline (Vellas et al., 2012).

At the time of writing, there has not been a systematically based review of the literature which explores both motivators and barriers to research participation from the perspective of people with dementia. It may be assumed that the factors such a review would identify would be similar to those noted previously by researchers, but that assumption needs to be tested.

If such a review can provide a clearer understanding of both the pushes and pulls of dementia research participation (and non-participation) for those directly affected by the condition, this could aid researchers in designing more effective, efficient recruitment strategies for their studies.

It would also reflect the growing emphasis on involving people with dementia in all stages of research (Alzheimer's Society, 2016), and be congruent with a position of respect for the personhood of people with dementia (Kitwood & Bredin, 1992) in the research process more generally (Cowdell, 2006), by privileging evidence which includes their voices.

The current review addresses this gap, and acknowledges the often essential role of carers in supporting the research involvement of people with dementia, by asking the following questions:

1) What factors have people with dementia identified or endorsed as motivators or barriers to their participation in research?

2) What factors have carers for people with dementia identified or endorsed as motivators or barriers to the involvement of the people they care for in research?

Method

Inclusion/exclusion criteria

An initial scoping search indicated there was not a substantial existing literature on these questions. Therefore inclusion criteria were broad.

Inclusion criteria:

a) the article contained empirical material on motivators/barriers to people with dementia participating in research, directly provided by people with dementia and/or their carers

b) the relevant full text article was published in a peer-reviewed journal, accessible, and written in English

Exclusion criteria:

a) the article focused only on issues of capacity/consent/proxy decision making as barriers or motivators to participation in research by people with dementia (since there are recent reviews of this general area, including the systematic review by Lord, Livingston, and Cooper (2015))

b) the article focused only on carers' own participation in research, rather than carers' views on the involvement in research of the people with dementia for whom they cared

Search strategy

PsycInfo and Medline databases, and the Alzheimer's Society online library catalogue, were searched for papers published up to 5 October 2015. The following

search terms were derived from an initial review of criterion papers, and were used in combination depending on the specific requirements of each search engine.

dementia OR Alzheimer*

AND

research OR experimentation OR clinical trial*

AND

client participation OR participa* OR taking part OR involvement

Further potential papers were identified by a hand search of the reference lists of eligible papers, through recommendation by experts working in dementia research, and via a search of the first twenty pages of Google Scholar, applying key search terms. Grey literature was not searched. A search of reviews of recent research published by the Alzheimer's Society did not result in further papers for screening.

Figure 1 summarises the search and screening process in a PRISMA flowchart (Moher, Liberati, Tetzlaff, Altman/The PRISMA Group, 2009). After initial screening, 97 papers were read in full with 16 included in the final review.

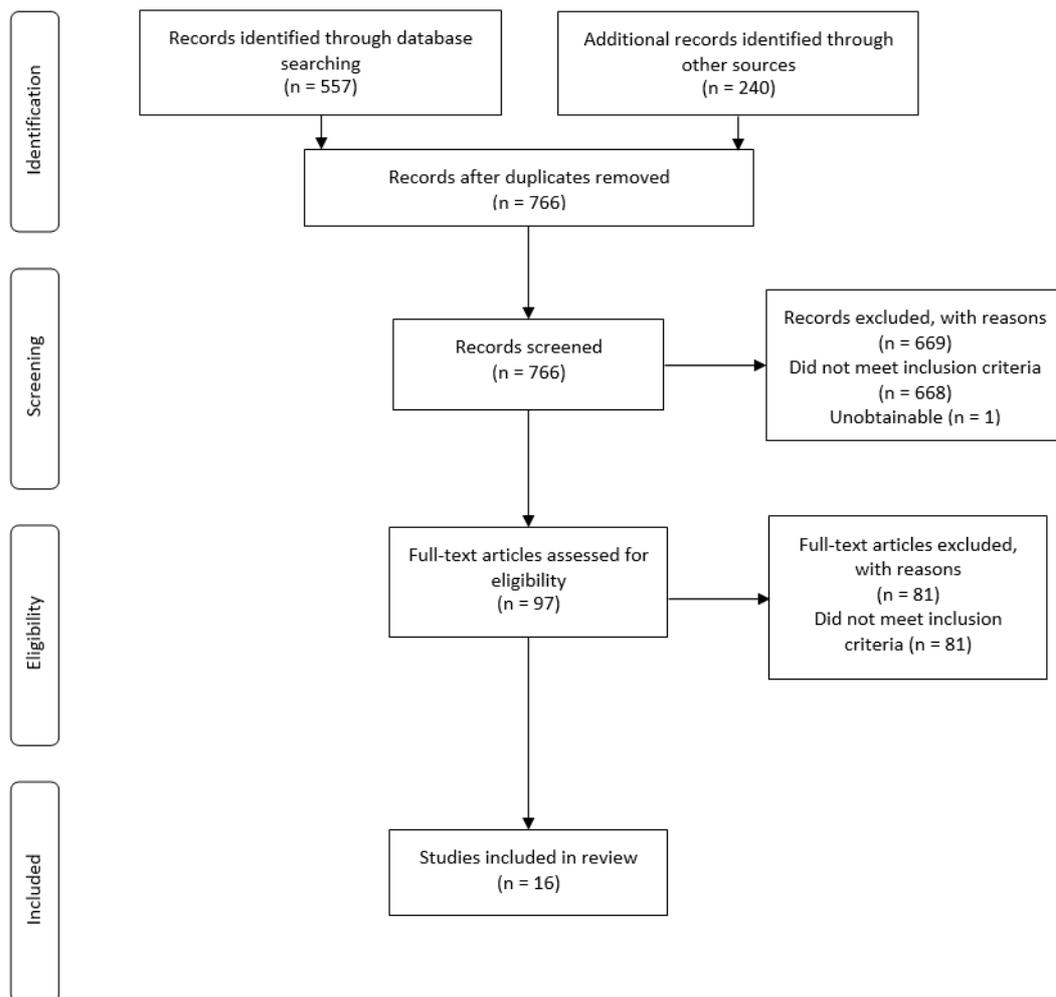


Figure 1: PRISMA flowchart of search and study selection.

Procedure

Given the low numbers of papers meeting the eligibility criteria, all which did so were included, whether they related to completed, ongoing, or future/hypothesised research with people with dementia, and whatever the methodology used (qualitative, quantitative, mixed-method or descriptive/survey studies).

Summaries of each paper were created, and data tabulated under the following headings: authors/date, country, design, sample/N, nature of research, key objectives, outcomes, strengths, and limitations, and quality (see Table 1, p.19).

Authors of individual papers used different terms (proxy, surrogate, carer/caregiver, study partner) to describe people with the same role. For ease of reading, it was decided to use the term 'carer' as inclusive of all these titles, unless a title had a particular significance (e.g. 'proxy' as a legal term in the context of proxy decision-making).

As papers varied widely in method, content, and quality, a narrative synthesis was carried out, with iterative clustering of key relevant findings from each paper. A structure was then identified into which all the main themes were incorporated.

Assessing study quality

All studies included in the review were quality assessed (as recommended by NICE, 2014) using the QualSyst (Kmet et al., 2004), a widely used tool which allows appraisal of a range of designs.

Quantitative/survey designs were assessed using the 14-item QualSyst quantitative checklist. Each study was rated by summing scores for each study across the 14 checklist criteria (where 0 = no, 1 = partially met, 2 = yes, and n/a = not relevant to this article), then dividing each score by the total possible score for that study (based on relevant items only, i.e. total possible score = 28 – (number of 'n/a'*2)).

Qualitative studies were evaluated using the 10-item QualSyst qualitative checklist (Kmet et al., 2004). Under this checklist, all items must be completed for

every study (with 'yes' = 2, 'partial' = 1, 'no' = 0), then totalled, and a summary score provided (consisting of total score/20). As the mixed method study had a predominantly qualitative focus, this was also evaluated using the qualitative checklist.

As recommended by NICE (2014), rather than presenting raw scores, an overall quality rating for each study was derived from the relevant appraisal checklist criteria. This reflected the completeness of checklist criteria for each study and how likely any missing criteria were to have biased the study's main conclusions. The three rating levels are:

- '++' (most criteria fulfilled, study conclusions unlikely to alter where these have not been fulfilled; described in the current review as 'high quality')
- '+' (some criteria fulfilled, study conclusions unlikely to alter where criteria unfulfilled/inadequately described; described in the current review as 'medium quality')
- '-' (few/no checklist criteria fulfilled, conclusions likely or very likely to alter; described in the current review as 'low quality')

Table 1: Summary of study findings

Authors/ date	Country	Design	Sample/n	Nature of research	Key objectives	Key outcomes	Key strengths	Key limitations	Quality
Avent et al. (2013)	UK	Survey	People with dementia (PWD) (33), carers (29).	Unspecified future studies.	Understand motivation of patients and carers for joining a dementia research register.	Helping others and helping oneself were the leading motivators.	Participants had opportunity to provide open responses as well as select from closed set. Included both PWD and carers. High (80%) participation rate.	Presentation of data means not possible to separate/ compare PWD and carer responses. Only sampled existing registrants. Assesses motivation to join register – not an actual study.	+
Black et al. (2013)	USA	Qualitative	PWD (39), carers (46).	Current drug and non- drug studies, unspecified future studies.	Explore decision-making process of those who consented to participate in research.	Helping the person with dementia was the most common motivator. Altruism/helping others second most common.	Included both PWD and carers. Real studies. Records differences in response by study type. Rigorous methodology.	All bar one respondent had consented to a study – those who declined may have held different attitudes. Data mainly retrospective. Most studies low risk/non- intervention.	++
Cohen- Mansfield et al. (2002)	Israel	Survey	PWD/carers (53).	Completed drug study.	Reasons for refusing to join a drug study.	Potential harm/lack of benefit were key in refusal.	Included both PWD and carers. No apparent limitation on response options.	Presentation of data – cannot distinguish PWD from carer responses. Limited focus (reasons for refusal of a drug study). Unclear methodology. Retrospective data.	-

Authors/ date	Country	Design	Sample/n	Nature of research	Key objectives	Key outcomes	Key strengths	Key limitations	Quality
Connell et al. (2001)	USA	Qualitative	Carers (50)	Longitudinal research programme with varied elements.	Examine white and African- American carer attitudes towards research participation.	Key themes identified: benefits, barriers and resources relevant to participation.	Rigorous methodology. Real (current) research programme.	Sampled carers only. All participants had already consented to the research programme. Retrospective data.	++
Dunn et al. (2011)	USA	Mixed method	Carers (82)	Hypothetical drug and non-drug studies.	Explore decision making for three hypothetical research studies.	Main motivators included altruism and direct benefit to PWD. Barriers included inconvenience, risk, and patient's lack of interest. Answers varied by study type.	Explored different study types. Incorporated both open and more structured questioning. Explored both motivators/ barriers, not biased by existing participation.	Sampled carers only. Hypothetical studies only. Process of content analysis unclear.	+
Elad et al. (2000)	Israel	Survey	Carers (29)	Current drug trial.	Explore factors affecting carers' decisions to allow/refuse participation by PWD.	Key motivators: hope for direct benefit to PWD, altruism, recommendation by physician/ family. Leading barriers: concerns re drug risk/ efficacy, burden on PWD/carer.	Real study (current). Sampled carers who had either enrolled or declined a study.	Sampled carers only. Unclear whether questionnaire allowed open responses, or extent of any limits on possible responses.	+

Authors/ date	Country	Design	Sample/n	Nature of research	Key objectives	Key outcomes	Key strengths	Key limitations	Quality
Guerrero- Austrom et al. (2011)	USA	Qualitative	Carers (30)	Ongoing brain donation programme (FTD).	Identify attitudes about brain donation in carers, to aid understanding of variables that may improve or act as barriers to participation.	Key themes: motivations included direct, indirect and altruistic benefit for PWD and family. Barriers included lack of effective communication with the research team.	Real study. Rigorous methodology. Included both carers who had consented to and declined studies – less chance of positive bias.	Sampled carers only.	++
Hinton et al. (2000)	USA	Qualitative	Carers and PWD from 25 families	Study of dementia caregiving (recruitment stage).	Identify socio- cultural barriers to recruiting PWD and their families to a research project.	Three key themes: dementia seen as normal aging, not warranting clinical/research attention; fear of research causing worry; stigma of dementia diagnosis.	Rigorous methodology. Real study (current).	Study focuses on one minority ethnic population which may affect generalisability.	++
Karlawish et al. (2001)	USA	Qualitative	Carers (22)	Current drug trial.	Explore decision-making factors for carers and differences between those who consented/ declined research participation for PWD.	Main motivators: potential direct benefit, trust in institutions, altruism, desperation. Main barriers: perception of practical burdens, possible harm. Emphasis on interdependence of risks/benefits for carer/PWD.	Real (current) study. Rigorous methodology. Potentially less chance of positive bias as sample included those who'd enrolled, declined, or been judged ineligible.	Sampled carers only.	++

Authors/ date	Country	Design	Sample/n	Nature of research	Key objectives	Key outcomes	Key strengths	Key limitations	Quality
Karlawish et al. (2002)	USA	Survey	PWD (15), carers (15)	Hypothetical drug trials.	Reasons for enrolling for PWD and their carers in an early phase clinical trial.	Main motivators: direct health benefit to PWD, altruism. Main barriers: burden of participation.	Includes both PWD and carers.	Hypothetical study only, fewer details supplied to participants than for real studies. Does not differentiate between PWD and carer responses. Does not quantify responses. All were existing participants in research studies.	+
Karlawish et al. (2008)	USA	Quantitative	Carers (108)	Hypothetical future clinical trials.	Explore how varying four practical elements of a study affects carers' willingness to participate.	Highest utility assigned to home visits (balancing out disutility of high risk). Value of reducing travel inconvenience positively correlated with dementia severity.	Range of options available to respondents allowed deeper exploration of practical barriers. Rigorous methodology/ statistical analysis.	Sampled carers only. Hypothetical studies only.	++
Lynöe et al. (1998)	Sweden	Survey	Carers (19)	Completed study - blood sample/ health record check.	Reasons for allowing PWD to participate.	Altruistic reasons most frequently/ strongly endorsed (but only limited range of response options provided).	Real study.	Sampled carers only, all had already participated. Limited response choices apparently offered, methodology of questionnaire unclear. Retrospective data only.	-

Authors/ date	Country	Design	Sample/n	Nature of research	Key objectives	Key outcomes	Key strengths	Key limitations	Quality
Mastwyk et al. (2002)	Australia	Survey	Carers (25)	Completed drug trials.	Determine why carers seek participation of PWD in clinical trials.	Dominant factors endorsed were direct health benefits to patient and altruistic motives.	Real (completed) studies.	Carers only, and only sampling those who had taken part in the study. Limited response choices offered re motivators only. Questionnaire methodology unclear. Retrospective data only.	-
Mastwyk et al. (2003)	Australia	Survey	Carers (44)	Completed drug trial.	Explore carer motivations for seeking participation of PWD in drug trial.	Main motivators: direct benefits and altruism. Other factors included recommendation by others and non-health benefits.	Real (completed) study. Included carers who had not been accepted to the study (screening only group).	Carers only. Limited response choices offered re motivators only. Questionnaire methodology unclear. Retrospective data only.	+
Sugarman et al., (2001)	USA	Qualitative	Carers (49)	Variety of current/ completed drug and non-drug studies.	Explore how carers make decisions about research for PWD.	Drug trials: main motivators were direct benefit/lack of options/ desperation, altruism also prominent. Non- drug studies: main motivators were altruism and hope of better care. Trust in doctor/ institution important.	Real studies (completed and current, range of types). Rigorous methodology.	Sampled carers only, all of whom had already consented to a study. Retrospective data only.	++

Authors/ date	Country	Design	Sample/n	Nature of research	Key objectives	Key outcomes	Key strengths	Key limitations	Quality
Williams et al., (2001)	USA	Qualitative	Family members/ carers – numbers unclear.	Current exercise intervention study (recruitment stage).	Exploration of reasons for high refusal rate in Cuban American nursing home residents with aim of improving recruitment.	Main themes: perception of PWD's need for contentment and solitude, and the futility of intervening.	Part of a real study with PWD.	Study focuses on one minority ethnic population which may affect generalisability. Unclear methodology.	-

Note: The eligibility of some papers was based on a subsection of a wider study. For these papers, the design selected, and quality rating assigned, applies to the subsection only.

Results

Overview of included studies and limitations

Sixteen studies met the eligibility criteria. Ten were from the USA, one from the UK, two from Australia, two from Israel, and one from Sweden. Seven were assessed as high quality (six qualitative papers, and one quantitative), five as medium quality (four surveys and one mixed-method paper), and four as low quality (three surveys and one qualitative paper). Overall, the review comprises seven qualitative studies, seven surveys, one mixed-method study and one quantitative study.

Eleven papers included data from carers only, and five included data from people with dementia and carers. Unfortunately papers did not always clearly distinguish their responses, reducing the utility of the studies to the current review.

Studies focused on a diverse range of research types. Pharmacological studies were most common, but papers also covered joining a research register, physical intervention, longitudinal studies comprised of various elements, diagnostic/medical studies and brain donation.

Across the included studies, the majority of interviewees/respondents were white, and carers were predominantly female. Small sample sizes and limited sample sites were standard. Studies varied in whether they assessed real or hypothetical scenarios. Data for real studies were frequently retrospective.

Motivators

Twelve of the sixteen papers included discussion of factors motivating research participation.

Direct benefit to the PWD

Ten studies mention direct benefit to the PWD as a leading motivator for research participation. These comprised four high quality qualitative studies (Black, Wechsler, & Fogarty, 2013; Connell, Shaw, Holmes, & Foster, 2001; Karlawish, Casarett, Klocinski, & Sankar, 2001; Sugarman, Cain, Wallace, & Welsh-Bohmer,

2001), one medium quality mixed-method paper (Dunn, Hoop, Misra, Fisher, & Roberts, 2011), four medium quality survey studies (Avent et al., 2013; Elad et al., 2000; Karlawish, Casarett, & James, 2002; Mastwyk, Macfarlane, LoGiudice, & Sullivan, 2003), and one low quality survey study (Mastwyk, Ritchie, LoGiudice, Sullivan, & Macfarlane, 2002). This hoped-for benefit was framed both generically and specifically.

Three papers mention non-specific direct benefit to the PWD. Black et al. (2013) interviewed 39 people with dementia and 46 carers about how they decided whether to consent to a range of drug and non-drug studies. The leading motivator in both groups was the desire to help the PWD, mentioned by 74% of people with dementia (25/34) and 80% of carers (36/45). Strengths of this study include incorporating detailed qualitative interview data from both carers and people with dementia relating to a range of real research studies (current and future), as well as providing descriptive data for interview themes, allowing more detailed analysis of findings. Limitations include data being retrospective, and the fact that most participants had already consented to research.

Direct benefit was the second most frequently mentioned motivator to enrol in Dunn et al. (2011), being mentioned by 18% of carers (15/82, 13 of whom said they would enrol) across study types. This paper explored motivators and barriers to participation across three hypothetical studies (MRI/imaging, a drug trial, and a vaccine trial). The methodology made it possible to explore responses to a range of research scenarios, while avoiding the issue of potential bias linked to respondents having consented to participation in a genuine study. However the fact that all studies were hypothetical may have affected responses.

In Avent et al.'s 2013 survey of reasons for joining a dementia research register, 27% (28/102) mentioned 'Research might help me/patient I care for' as a motivator in the free text response section, with 81% (81/100) endorsing this as important in the closed response section. It was selected as 'most important' by 29%

(26/91), making it the second most valued motivator overall. The survey did not explore views about a specific study, but asked people with dementia and carers about motivations for joining a research register. As all respondents were already registered, data may have been positively biased. The sample included people with dementia, carers (who had registered in their role as proxy for a PWD), and carers who had registered in their own right. Views of groups are not clearly distinguished in the results, reducing the utility of the data to the current review.

Specific health benefit

Seven of the ten studies gave specifics about the health benefit carers hoped people with dementia would experience via research involvement.

Connell et al. (2001) summarised interview data from 50 carers under three key themes: one of these was 'Benefits' (of participation), with the subtheme of 'Access to Diagnosis, Care, and Treatment' including the hope for slowing of disease progression. The study benefited from a rigorous methodology, exploring both motivators and barriers to participating in a real research programme, and having an additional focus on the experience of African American research participants. However only carers were interviewed, all data is retrospective, and the interviewees were already involved with an existing programme.

Karlawish et al. (2001) interviewed 22 carers who had been prospective study partners in a drug study (nine enrolled, eight declined, and five were found ineligible), exploring reasons for/against enrolment. Potential for direct medical benefit to the PWD was the leading motivator, volunteered by 100% of carers who enrolled in the study (9/9). Though data were retrospective, and only carers were interviewed, strengths included the study being a genuine one, and views being sampled from those who had declined/been found ineligible as well as those who participated.

Sugarman et al. (2001) interviewed 49 carers of people who had supported PWD participation in a range of study types (32 in a genetic study, 20 in drug trials,

10 in an imaging study, two in a cognitive intervention, two in an epidemiological study, with some enrolled in more than one). For those involved in drug studies, researchers found 'hope for direct benefit' as one of four key themes in participant interviews, specifying that this incorporated slowed progression, increased life span, and improved quality of life. Strengths of the study included the research being genuine, and the methodology allowing for a broad exploration of both motivators and barriers to participation across different study types. Limitations included only carers who had already consented to participation being interviewed, and data being retrospective.

Elad et al. (2000) sampled 29 carers, 10 of whom had declined and 19 who had enrolled in a drug trial. Sixty-three per cent (12/19) of those who enrolled endorsed 'hope for improvement in condition' as the leading reason for their participation, with 47% (9/19) mentioning hope for 'stabilisation/maintenance' in the dementia. Strengths of the study include that it involved both those who joined the study and those who declined it, and that the study was real. Limitations included only carers being sampled, data being retrospective, and the methodology of the survey component being unclear (e.g. whether answers were given in the context of open questioning or limited response options).

Karlawish et al. (2002) described potential benefit to the patient's health or wellbeing as 'typically featuring' in reasons to enrol in a hypothetical drug trial by 47% of PWD (7/15) and 40% of carers (6/15). The study benefits from incorporating data from both people with dementia and carers, and exploring both motivations and barriers to participation. However the trial was hypothetical, the study did not distinguish patient and carer responses, and all respondents were already involved in research.

Mastywk et al. (2003) surveyed 44 carers of people with dementia who had completed a drug trial. Ninety-six per cent (26/27 who responded) of carers of the 29 people in the treatment group endorsed 'Help relative feel better' as the leading

reason for participation, with 73% (19/26 who responded) endorsing 'Help relative live longer' as the second most important reason. These were also the most popularly endorsed motivators to participation among the 15 carers who were screened only, with 93% (14/15) agreeing with both statements. The paper's strengths included being based on a real study and including data both from those judged ineligible for a study and those who had participated. It was limited in offering a restricted range of options for response (focused on motivating factors only) and data being retrospective.

Mastwyk et al. (2002) received responses sufficient for analysis from 25/ 31 carers who had supported the people they cared for to participate in a drug trial (though not all carers appear to have responded to every item). All 21 people (100%) who responded endorsed the item 'Help relative feel better', identifying it as the leading reason for their participation, with 81% (17/21) endorsing 'Help relative live longer', making it the joint third most popular reason. The survey shared the strength of Mastwyk et al. (2003) in being based on real research, but also shared its limitations. Unlike Mastwyk et al. (2003) it sampled only those included in the drug trial.

Diagnosis

Specific hopes that research participation would help with diagnosis were found in two studies.

Black et al. (2013) found that that 'desire to get a diagnosis' was one of the most common factors underlying the leading motivator for participation, to help the PWD, while Connell et al. (2001) identified the hope for definitive diagnosis under the subtheme of 'Access to diagnosis, care and treatment'.

Most papers which did not include diagnosis as a motivating factor focused on drug trials. This may be because having an existing diagnosis of dementia would be a prerequisite for entering the study, and therefore the hope of diagnosis could not be a motivator to do so.

Monitoring/treatment

Six of the ten studies mentioning direct benefit specified monitoring and/or treatment as a motivator.

Black et al. (2013) noted that 6% of interviewees with dementia (2/34) and 11% of carers (5/45) mentioned 'being informed of new treatments or other studies' as a motivator for participation.

Connell et al. (2001) identified the hope of receiving better care, and access to medications and potential cures, as part of the subtheme of 'Access to Diagnosis, Care, and Treatment' (under 'Benefits', one of three headline themes).

Sugarman et al. (2001) records hopes from two interviewees that participation could gain their relative experimental or 'leading edge' treatment.

Seventy-five per cent (75/100) of respondents in the forced choice response section of Avent et al.'s 2013 survey endorsed as 'important' the statement that research involvement might help with monitoring a person's dementia. None mentioned it in the free response section, and only 10% (9/91) saw it as the most important motivator to their registration with the research database. Forty-eight per cent of respondents (48/100) agreed that the possibility of accessing treatment not available on the NHS was 'important' in the forced choice section (though no-one identified it in free response), and only 8% (7/91) agreed it was the most important motivator.

In Mastwyk et al. (2003), 93% (25/27 respondents of the treatment group of 29) rated the hope that the drug would cure their relative as extremely/moderately important, with 85% (11/13) of respondents from the screening only group (N = 15) agreeing. Receiving 'Free specialist care and attention' was rated as extremely/moderately important by 17% (4/23) of the 29 respondents in the treatment group, with 39% (5/13) of the screening only group agreeing.

Ninety per cent of respondents (18/20, of 25 sampled) to the survey by Mastwyk et al. (2002) endorsed 'The hope the drug would cure' as extremely or

moderately important, making this a key motivator for participation, with 'Free specialist care or tablets' seen as extremely/moderately important by 41% (7/17) respondents.

Social/emotional benefit

This was included in only two studies.

Black et al. (2013) notes that people with dementia were less motivated than carers by the hope of emotional support, though how many times this was expressed is not stated.

The carer's hope for social benefit for the PWD was noted in Dunn et al. (2011). Two of 82 carer interviewees who consented to hypothetical MRI/behavioural or drug studies gave 'socialisation for patient' as a motivator to enrolment (making it one of least frequent responses).

Financial benefit

Only two studies directly mention financial benefit, though one may make implicit reference to this.

Black et al. (2013) notes 'financial reasons' were mentioned by 6% (20/34) of people with dementia and 4% (2/45) of carers as a motivator for research participation, though this was among the lowest priority reasons volunteered.

Though none of the respondents in Avent et al. (2013) volunteered payment as a motivator in the free response section of the survey, when offered it as an option in the forced choice section, 8% (8/100) agreed it was 'important'. Only 1% (1/91) agreed it was the most important factor in their participation in a research register, a rate the authors note is less than chance. It is not possible to tell from the study whether respondents were carers or people with dementia, and the question did not relate to a real study, or specify an amount.

While carer interviewees in Sugarman et al. (2001) did not report financial compensation as a likely motivator, their responses were given in the context of receiving \$25 for each telephone interview they completed.

Summary

Direct benefit for the PWD was a leading motivator for research participation in the majority of papers. These benefits were most commonly identified as hoped-for positive medical impact on the PWD's condition, or better condition management/future treatment. Non-medical (social or financial) direct benefits were infrequently mentioned.

Benefit to carers

Nine of the 12 papers discussing motivators mention benefit to carers: three high quality qualitative studies (Black et al., 2013; Guerriero-Austrom et al., 2011, Sugarman et al., 2001), one high quality quantitative survey (Karlavish et al., 2001), one medium quality quantitative study (Dunn et al., 2011), three medium quality surveys (Avent et al., 2013, Mastwyk et al., 2003, Elad et al., 2000) and one low quality survey (Mastwyk et al., 2002). Such benefits were framed both generally and more specifically.

In Black et al. (2013), 40% of carers (18/45) and 18% of people with dementia (6/34) mentioned being motivated by potential benefit to the carer, or family. It is not possible to tell from the data as presented whether 'carer' and 'family' are intended to represent different concepts.

As also noted under 'Direct benefit to the PWD' (p.26), Avent et al. (2013) noted 'Research might help me [i.e. the carer]/patient I care for' as the second most important motivator in joining a research register. As the study did not distinguish responses of carers and people with dementia, it is unclear how often this response related to carer benefit rather than benefit to the PWD.

Diagnosis

Guerriero-Austrom et al. (2011) explored barriers and motivators to participation in a brain donation programme in focus group interviews with 30 carers of people with frontotemporal dementia (FTD). Getting a definitive post-mortem diagnosis was the leading motivating factor to participation identified by carers. This can be

understood in the context of the higher familial risk of this form of dementia. Though the study was limited by sampling carers only, and data being retrospective, it may have been at less risk of positive bias since it included both people who had declined and those who had consented to involvement in a research programme, was based on real research, and had a rigorous methodology.

Emotional support

As noted above under 'Social/emotional benefit' for people with dementia (p.31), carers in Black et al. (2013) were more motivated than people with dementia by the hope of receiving emotional support, though how many times this was expressed is not stated.

In Mastwyk et al.'s 2002 survey, 58% (11/19) of carers endorsed 'Having someone to talk to' as 'extremely' or 'moderately' important. In Mastwyk et al. (2003), 63% (15/23) in the treatment group endorsed this item, vs 36% (4/11) in the screening-only group.

Desperation, hope, and agency

Karlawish et al. (2001) found that desperation was the fourth most common motivator to enrolment among those who consented (cited by 44%, 4/9). The study was unusual in sampling carers who had either consented to, declined, or been judged ineligible for a current drugs trial, and was able to explore differences and similarities between these groups.

The sense of there being nothing to lose emerged as a theme for several interviewees in Dunn et al. (2011), though the number mentioning this is not recorded. One interviewee specifically mentioned 'desperation' as a motivator for participation. Two interviewees mentioned that a 'feeling of taking action' would motivate participation in the hypothetical studies discussed.

In Sugarman et al. (2001), themes of nothing else being available, and desperation, represented two of the four areas seen as key in the complex process of deciding to participate in research. These themes were more frequently

mentioned by carers partnering people with dementia involved in drug trials, and where the person's dementia was more severe.

Elad et al. (2001) found that maintenance of hope was the third most frequently mentioned motivator, given by 21% (4 of 19 respondents) who had joined a drug study).

Summary

Two-thirds of studies mention benefits to carers as motivating research participation, though not generally as a leading factor. The exception was the brain donation study. Such benefit comprised diverse elements; one of the most frequently cited was desperation/need to maintain hope.

Altruistic motivators

Helping others/advancing science.

These general altruistic motivators were mentioned in all 12 papers discussing motivators, and frequently appeared in the top three reasons for participation mentioned by both people with dementia and carers.

In Black et al. (2013), 62% (21/34) of people with dementia and 53% of carers (24/45) mentioned the wish to 'help people in the future' – making it the second most popular motivator.

Connell et al. (2001) found 'Helping others' to be one of three key motivational subthemes identified from interview data, under a major theme of 'Benefits' to participating in research.

A study of barriers/motivators to participating in a brain donation programme for people with FTD (Guerriero-Austrom et al., 2011) describe 'advancing scientific knowledge' as one of the three primary motivators to participation.

Karlawish et al. (2001) found the desire to benefit other patients with Alzheimer's disease was mentioned by 56% (5/9) of carers who agreed to enrolment in a drug study, making it one of the top four motivating factors, though most of these carers said this reason was more important to the PWD than it was to them.

Altruism was identified as a primary motivator for participation in Sugarman et al.'s 2001 interviews when the trials were non-pharmacological; for drug studies, altruism was a secondary motivator (after direct benefit to the PWD).

Thirty-five per cent (29/82) of interviewees in Dunn et al. (2011) mentioned 'altruism' as their main motivation for consenting to drug or non-drug studies, making this the leading motivator overall.

Forty-seven per cent (48/102) of respondents to the free response section of Avent et al.'s 2013 survey stated 'research might help others' had been the most important motivator for joining the research register. Eighty-six per cent (86/100) of respondents in the forced choice section agreed it was important, with 44% (40/91) agreeing it was the most important reason for registration. This made it the leading motivator for respondents.

Elad et al. (2000) found that 11% (2/19) of those who enrolled in a drug study mentioned contributing to science as a motivator, though this trailed the primary motivator of direct benefit.

Karlawish et al. (2002) state that reasons for enrolling in (hypothetical) drug trials 'typically featured' helping others/one's family/contributing to scientific knowledge.

In Mastwyk et al. (2003), altruistic motives were among the highest rated, with 96% of carer respondents (23/24) from the treatment group endorsing 'Improve the health of others' as extremely/moderately important, with 85% (12/14) of the screening-only group agreeing. Ninety-two per cent (23/26) in the treatment group also endorsed 'Contribute to science', with 80% (12/15) of the screening-only group agreeing.

In a low quality survey study (Lynöe, Sandlund, & Jacobsson, 1998), 71% (15/21) ranked 'the benefit of future patients' as of first or second importance in their decision to participate, while 43% (9/21) ascribed the same importance to 'the benefit of science'. Strengths of this paper included being based on a real study

(blood test and health records check), but it had extensive limitations – survey response options were restricted to indirect motivating factors, methodology was unclear, and only carers who had consented to the study were sampled.

Ninety-five per cent (20/21) of respondents in Mastwyk et al. (2002) endorsed 'Contribute to medical science' as an extremely/moderately important motivation, while 94% (17/18) similarly endorsed 'Improve the health of others'.

Altruistic motivations were framed as matters of morality/obligation in two studies. In Lynöe et al. (1998), 2/21 carers endorsed the item, 'To participate is a way for the Alzheimer patient to be useful'. Carer interviewees in Sugarman et al. (2001) commented (for non-pharmacological studies) on the motivation of being a good citizen and the obligation to help others.

Altruism/benefit to wider family

The altruistic wish to benefit family members was mentioned in six papers; four high quality qualitative studies (Black et al., 2013; Connell et al., 2001; Sugarman et al., 2001; Guerriero-Austrom et al., 2011), one medium quality mixed-method study (Dunn et al., 2011), and one medium quality survey study (Karlavish et al., 2002).

In Black et al. (2013), 18% of people with dementia (6/34) and 40% of carers (18/45) mentioned being motivated by potential benefit to the family (or carer), as opposed to direct benefit to the PWD. Helping one's family was one of the 'typically featuring' motivators for consenting to a (hypothetical) drug trial in Karlavish et al. (2002), and was stated as a reason for joining a (non-drug) study by three carer interviewees in Dunn et al. (2011).

Helping family formed part of the subtheme of 'helping others' identified under the headline themes of 'Benefits' to research participation in Connell et al. (2001), and interviewees in Sugarman et al. (2001) volunteered helping children/grandchildren as one aspect of the altruistic motivations which were the main reason for consenting to non-drug studies, and also represented a secondary reason for consenting to other study types.

The wish to benefit family members may be a particular driver when there is a potential for inherited risk of a particular dementia. Providing risk information for family members was one of three primary motivators (along with getting a definitive diagnosis, and advancing knowledge) mentioned by carers in Guerriero-Austrom et al. (2011).

Summary

Altruistic factors were always among the leading motivators for research participation, and were mentioned across all 12 papers. Half of these specifically mentioned future benefit to the PWD/carer's family.

Relationship with clinician/institution

The relationship with the sponsoring clinician or institution was mentioned in eight studies: three high quality qualitative studies (Black et al., 2013; Karlawish et al., 2001; Sugarman et al., 2001), one medium quality mixed-method study (Dunn et al., 2011), three medium quality survey studies (Elad et al, 2000; Avent et al, 2013; Mastwyk et al., 2003, and one low quality survey study (Mastwyk et al., 2002).

In Black et al. (2013), 35% (12/34) of people with dementia and 16% (7/45) of carers expressed trust in the clinician or the university hosting the study as a motivator. This was the third most popular motivator mentioned by people with dementia, and the fourth most popular with carers.

'Trust' was one of the top four reasons for enrolment in a drug trial, mentioned by 56% of carers (5/9) who consented to the study in Karlawish et al. (2001). The researchers identified three separate 'domains of trust' for respondents – in the principal investigator/clinic, the hosting university, and the sponsoring pharmaceutical company, and understood these as helping participants overcome uncertainty about their scientific understanding of the project, and manage their feelings of desperation.

Sugarman et al. (2001) identified 'trust in physician or institution' as a theme in some responses (for those who had consented to non-drug studies), with

interviewees explaining that this trust made it easier to override the need to fully understand the research, as if the doctor had asked for their involvement, 'it must be worthwhile'.

Institutional trust (in terms of safeguards/monitoring) was mentioned by 61% (5/82) interviewees in Dunn et al. (2011). This made it the third highest motivator recorded, through it trailed the top two motivators of altruism and potential direct benefit to the patient.

Trust in/recommendation from a professional was also expressed as a motivator in Elad et al. (2000) (by 11%/2/19 respondents who had enrolled in a drug study).

In Mastwyk et al. (2003), 'Doctor recommended' was endorsed as extremely/moderately important by endorsed by 18% (3/17) of the treatment group, and 54% (6/11) of the screening-only group; the item was similarly endorsed by 56% (9/16) of those who responded in Mastwyk et al. (2003).

Summary

Trust in a clinician or institution connected with the research was consistently mentioned as a high-ranking motivator in studies, though never the leading one.

Barriers

Eleven of the 16 papers included some discussion of barriers to participation. Two of these focused on specific cultural groups (Hinton, Guo, Hillygus, & Levkoff, 2000; Williams, Tappen, Buscemi, Rivera, & Lezcano, 2001) and are incorporated in a separate section below, along with Connell et al.'s African American interviewee data, so as not to dilute the specificity and thematic importance of these findings.

Lack of direct benefit

Concern about lack of direct benefit to the PWD was mentioned as a barrier in four studies – one high quality qualitative study (Connell et al., 2001), one medium quality mixed-method study (Dunn et al., 2011), one medium quality survey study (Elad et al., 2000), and a low quality survey study (Cohen-Mansfield, 2002). All

sampled participants where joining a drug trial (real or hypothetical) had been suggested.

The idea of participation offering 'no direct benefit' to the PWD was the primary barrier raised by carers in Connell et al. (2001), with one interviewee expressing concern that 'it would all be for nothing' if the person they cared for was put in the placebo condition. It should be noted that all carer interviewees in Connell were already enrolled in research, so it is not unclear if the potential lack of direct benefit had actually acted as a barrier to participation.

An interviewee in the study by Dunn et al. (2011) stated that she felt her partner needed 'real medicine' not a placebo, and 4% (3/82) of interviewees (all from the group who had declined a hypothetical vaccine study) gave 'possible lack of benefit' as a reason.

Fifty per cent (5/10) carer respondents in Elad et al. (2001) who had declined consent to a drug trial mentioned concern that the drug involved would not work.

Six per cent (3/53) of respondents in Cohen-Mansfield et al. (2002) mentioned lack of direct benefit as a reason for declining a drug trial. The study sampled both carers and people with dementia who had declined to participate in the trial, asking for their reasons. This open questioning on reasons for declining the study facilitated a wide range of different responses, and both carers and people with dementia were questioned. However the methodology is unclear, and responses from people with dementia and carers are not distinguished.

Summary

Several studies note the possibility of lack of direct benefit, in the form of ineffective or placebo medications being provided in a drug trial, as a barrier to participation. This was rarely a primary concern.

Fear of negative impact

Six papers of the 16 including coverage of barriers noted fear of negative impact on the PWD in various forms, including two high quality qualitative studies

(Connell et al., 2001; Karlawish et al., 2001), one medium quality mixed-method study (Dunn et al., 2011), two medium quality survey studies (Elad et al., 2001; Karlawish et al., 2002), and one low quality survey study (Cohen-Mansfield et al., 2002).

Risks of drugs and procedures

Five papers discussed concern about the risks of the drugs or procedure to the PWD as a barrier to research participation.

Concern about the potential negative impact of research procedures and tests was identified in Connell et al. (2001) as one of six subthemes under a headline theme of 'Barriers'.

The potential side effects of the study drug were one of the three most common barriers mentioned by carers in Karlawish et al. (2001), mentioned by 38% (3/8) who declined to enrol in the study.

Worry about potential risks from drugs were mentioned by 27% (22/82) of interviewees in Dunn et al. (2011), and was the second most common barrier identified. Nine per cent (7/82) specifically mentioned concern about the impact of procedures on the PWD.

In Elad et al. (2001), 60% (6/10) of carers who refused to participate in a drug trial gave concern about side effects as a reason, and this was the most frequently expressed barrier.

In Karlawish et al. (2002) 20% of carers (3/15) and 13% of people with dementia (2/15) mentioned potential medication risks, physical or mental discomfort as a barrier to enrolment in a hypothetical early phase clinical trial, though the author does not include these in the group of 'typically featuring' reasons.

Concerns re participants' health

Three papers found other concerns about how the PWD's health would be affected by participation, or affect their ability to participate.

In Karlawish et al. (2001), the wish not to alter the patient's vitamin dosage for a specific trial was mentioned by 38% (3/8) who had declined a drug trial.

Nine per cent of interviewees (7/82) in Dunn et al. (2011) expressed concerns about other medical conditions, and 7% (6/82) referenced the persons' current severity of dementia, as barriers to participation – interviewee quotes suggest that this was related to the perception that no direct benefit was possible and thus risks would outweigh benefits, or because the PWD was seen as not being fit to participate.

In Cohen-Mansfield et al. (2002), concern about threat to the patient's stability was the most frequently given reason for refusing participation in a drug trial, being mentioned by 66% of interviewees (35/53). Concern about increased agitation was the second most frequently mentioned (by 45%, 24/53). As previously noted, the utility of the data is restricted by the limited detail provided and the lack of distinction between carer and PWD responses. In the same study, 38% (20/53) gave the reason that the person's existing medication was working. The PWD currently being 'psychotic/delusional' (mentioned by 17%, 9/53) or psychologically unable in some other way to take part (mentioned by 8%, 4/53) were among less frequent reasons for declining the study.

Summary

Concerns about risks and side effects of a drug as a barrier to participation, as well as the impact of procedures, were highly ranked concerns in four studies. The same number mentioned more general concerns about the PWD's health and wellbeing as a barrier to participation, though generally ranking this less highly.

Practical burden of participation

The burden on participants of involvement in dementia research appeared as a barrier in six papers. These were made up of two high quality qualitative studies (Karlawish et al., 2001; Connell et al., 2001), one high quality quantitative study

(Karlawish et al., 2008), one medium quality mixed-method study (Dunn et al., 2011) and two medium quality survey studies (Elad et al., 2001; Karlawish et al., 2002).

In Karlawish et al. (2001), general hassles and burden, including travel, was the main reason given by carers who declined enrolment in a drug study (mentioned by 50%, 4/8). The study suggested that this concern may have interacted with other care-related factors, since those citing it as a barrier to participation did not have longer journeys than those who did not mention travel as an issue. One carer specified concern that participation could increase her mother's stress levels, making it more difficult for her and her father to maintain their caring roles.

'Insufficient time and resources' was identified as one of six subthemes under a headline theme of 'Barriers' in Connell et al. (2001).

Karlawish et al. (2008), explored how much utility/disutility carers assigned to different practical elements of research participation. The study concluded that clinical trials that reduce travel inconvenience (for example by arranging transport) may offset the barriers of factors such as the risk of a clinical intervention, and thereby increase participation. Although the study sampled carers only, and related to hypothetical research, its large sample size (108 carers) allowed for detailed parametric analysis of the data.

'Inconvenience' was the most frequently mentioned barrier to participation in Dunn et al. (2011), given by 38% (31/82) interviewees across hypothetical study types (MRI/imaging, drug trial, vaccine trial).

Thirty per cent (3/10) of carers who refused consent to a drug study (Elad et al., 2001) gave physical burden on the patient as a reason, and 20% (2/10) mentioned physical burden on the carer.

Burden of participation (such as overnight stay in a research unit, or frequent study visits) was noted as a typical reason volunteered by carers and people with dementia for refusing to participate in a hypothetical drug trial in Karlawish et al. (2002).

Summary

Inconvenience and practical burden were frequently identified as barriers to research participation, and sometimes as the primary barrier.

Cultural factors

Specific intra-cultural barriers to participation were a focus in three studies: two high quality qualitative studies (Connell et al., 2001; Hinton et al., 2000) and one low quality qualitative study (Williams et al., 2001). These provide more in-depth material on barriers to recruitment among three minority ethnic groups in the USA.

African American recruitment

Focus groups in Connell et al. (2001) included 12 African-American participants, who were asked additional questions about any specific concerns they held about the research process. These questions elicited two primary themes regarding barriers to participation. The first was strongly-held beliefs on helpseeking, incorporating a preference for taking care of oneself without reference to outside medical support, and fatalism about health outcomes. The second was scepticism and suspicion about research and the procedures involved.

Chinese American recruitment

Hinton et al. (2000) report a detailed qualitative investigation of barriers to recruiting Chinese American people with dementia and their carers to a study of dementia caregiving. Themes identified included carers' beliefs that a relative's dementia-related cognitive and behavioural changes were a normal and expected part of aging, not a symptom warranting clinical or research scrutiny. Some carers viewed research participation as potentially harmful because it might cause excessive worry. The perceived stigma of Alzheimer's also acted as a barrier. Data may be seen as having increased validity from being gathered during an actual study. Further strengths included a rigorous methodology, and inclusion of data from those who had declined a study.

Cuban American recruitment

Williams et al. (2001) drew on contemporaneous notes from researchers who had attempted recruitment to an exercise intervention in residential homes, and had found a high rate of refusal among Cuban-American family carers. The most frequent barrier identified was the desire not to disturb the person's comfort (*tranquilidad*), this being seen as a right for people nearing the end of their lives. Likewise, carers believed in the principals of solitude (*soledad*) – that the older person should be left alone, and of futility (*futilidad*) – that there was no point in intervening with their relative, and interfering with the natural course of things. They also seemed to hold misperceptions of their relatives' level of functional ability, underestimating the amount they could still do. Strengths of the study include culturally-informed exploration of factors involved in declining a study in a particular population. Limitations include lack of clarity and detail in the description of study design/methodology.

Summary

Three studies had a primary focus on cultural factors, identifying specific beliefs and attitudes in different communities which acted as barriers to research participation.

Difficulties in communication

This area was specifically covered in two papers. Guerriero-Austrom et al. (2011) comment on how communication difficulties affected carer engagement with the possibility of brain donation for their relative. These difficulties included perceived lack of sensitivity around how the topic was introduced, the challenge of developing a positive relationship between researcher and family, and the problem of the researcher not understanding relevant family dynamics. Carers also commented that they were not given the research information they needed, that they felt their questions were not always answered, and that they lacked clarity on their involvement in ongoing research. An interviewee in Connell et al. (2001) specifically

commented that the lack of opportunity to communicate with researchers without their family member present acted as a barrier to participation.

Summary

Though communication issues were mentioned as a barrier in only two studies, it is notable that both related to the sensitive issue of brain donation.

Discussion

Main findings

The main motivators for dementia research participation identified or endorsed by people with dementia or their carers were direct health benefit and altruism. Trust in the sponsoring clinician or institution was also important. The main barriers were concerns about risks/side effects of drugs and procedures, and the practical burden of participation.

Less frequently identified barriers (in part due to fewer papers on these areas being eligible for inclusion) were those specific to cultural groups (beliefs around healthcare, the research process and dementia more generally), and those related to brain donation (specifically, concerns about communication on this sensitive topic).

Due to the wide variation in methodology, quality, and types of research explored in the included studies, and the fact that not all studies explored both motivators and barriers, or ranked these, it was not possible to provide overall ranking of motivators or barriers, or claim with certainty that the findings are generalisable across different study types.

Nevertheless, they are congruent with other summaries of factors affecting dementia research recruitment and participation such as Knebl and Patki (2010), Watson et al. (2014), and Cohen-Mansfield (2003). The findings from specific minority ethnic populations are also consistent with existing work on this area (such as Ballard, Gwyther, & Edmonds, 2010; Schnieders, Danner, McGuire, Reynolds, &

Abner, 2013). Likewise, the difficulties around communicating over the issue of brain donation have been previously described (Stevens, 1998).

Such papers sometimes draw on the same literature as the current review (meaning some similarity would be expected). However as they also place their findings in a wider context of clinical and research evidence, and draw on the broader research participation literature, it may tentatively be argued that the reliability and validity of the current findings are enhanced through this congruence.

Limitations of the review

Robustness of the search process

Within each paper included in the review, the focus of interest (opinions volunteered or endorsed by people with dementia or their carers) was not always the primary focus of the paper. Eligibility for inclusion was frequently not reliably signalled by the paper title or abstract, and more detailed screening was required.

While the search strategy detailed above (p.14) attempted to allow for this by using sufficiently inclusive search terms, additional resources would have allowed for a more exhaustive search process, and may have identified further relevant papers. When a broader search leads to an increase in the number of papers identified for a review, this can increase the robustness of the subsequent narrative synthesis (Ryan & Cochrane Consumers and Communication Review Group, 2013).

Potential for bias in quality assessment

Detailed scrutiny of quality both within and between the selected papers is required to ensure that, as far as possible, the most methodologically sound papers make the greatest contribution to the conclusions of the review (Pettigrew and Gilbody, 2002).

In the current review, this scrutiny was based in the use of a quality appraisal tool designed for a range of methodologies (see above, p.17, and Kmet et al., 2004). This was employed to identify variations in quality between papers, and key quality issues are highlighted in Table 1 (p.19, above) and paper summaries.

It should be acknowledged that the quality ratings derived from this process were assigned by a single rater (the review author). Kmet et al. (2004) acknowledge that there is some subjectivity inherent in scoring using their assessment tools. This is also the case for the assignment of overall quality ratings (as described above, p.18).

To reduce the potential for bias, it would have been preferable to have two people assessing quality, and to establish the level of inter-rater agreement both on the assessment tool items and the derived overall quality ratings. This process could then have been documented within the review as a support to readers in scrutinising the findings.

Challenge of combining disparate methodologies

The possibility of confining the review to papers drawing on a single methodology was considered. This would have supported quality comparison across papers. However the scarcity of eligible literature was apparent at an early stage, and to restrict inclusion to papers from a single methodology would have exacerbated this further. The author considered that it was important to represent the fullest possible range of views from people with dementia and carers, and thus to include all eligible papers.

This did however compromise the comparability of papers in terms of quality, given their fundamental methodological differences. It was hoped that the open discussion of quality issues and ratings within the review would support readers in making their own assessment of the validity of the search, selection and quality appraisal process used, and of the relative value of each included paper in answering the review questions.

Limitations of the literature

As already acknowledged ('Procedure', p.17), the number of eligible papers identified was limited, and quality, potential bias and focus of coverage varied substantially.

Potential for bias within eligible studies

There was variation in whether papers addressed genuine (concluded, ongoing, or yet to commence) or hypothetical studies. For concluded and ongoing studies, only retrospective data were possible on factors influencing the decision whether to participate. Recall bias may have been present (Hassan, 2005), with the already-taken decision to participate, and subsequent investment in the process, affecting the identification and weighting of factors underlying that decision. Additionally, multiple factors may influence decision-making in hypothetical vs real research situations (Kühberger, Schulte-Mecklenbeck, & Perner, 2002), making unclear the extent to which we can rely on responses to a hypothetical scenarios mirroring a real world situation.

Gathering data from both participants and those who declined studies occurred only in Elad et al. (2000) and Karlawish et al. (2001). Had this been a more common approach, it could have provided a more representative picture of how both motivations and barriers influenced participation decisions across different research situations.

Differences across research types

It was not possible in the current review reliably to establish differences between themes emerging across different types of research (such as pharmacological studies and psychological or behavioural interventions). More detailed exploration of motivators and barriers which may be specific to each area could be a fruitful research direction.

One such area is non-pharmacological studies. Cooper et al. (2014) noted the lack of good quality data from such studies about factors influencing recruitment of

people with dementia as participants. This remains the case, though at the time of writing the current review, a protocol for a forthcoming systematic review and meta-analysis which aimed to include data on factors associated with successful recruitment of people with dementia to studies of psychological interventions had recently been published (Farrand, Matthews, Dickens, Anderson, & Woodford, 2016).

Imbalance in international coverage

Given that the majority of included papers came from the US (and only 1 or 2 from each of the UK, Israel, Sweden and Australia), we cannot assume that the tentative findings are generalisable across all these countries, or to countries not represented in the eligible literature – further work would be needed to establish this.

Considerations for future recruitment

As highlighted in the introduction, recruitment remains a major difficulty in dementia research. The findings of the current review tentatively support the idea that direct health benefit (and/or improved care opportunities) for the person with dementia is a leading motivator for clinical trial participation and, conversely, concerns about the risks to the person's health and wellbeing are a leading barrier. It would not be ethical to encourage belief in the likelihood of direct medical benefit for trial participants where this is not supported by evidence. Yet it could be reasonable to convey benefits of participation such as additional health checks/condition monitoring to potential recruits, as long as this information is not overprivileged in comparison to possible risks.

The review findings also suggest that there are several broader motivations, beyond the hope of direct benefit, which may incentivise participants and carers. One way of helping people connect with such motivations could be to share service user and carer testimony on these factors (such as altruism, social and emotional benefit, and the maintenance of hope and agency). As Grill and Karlawish (2010) suggest, if prospective participants can connect with a range of motivations for

enrolment, they may be more likely both to consent to a study and to persist with it through the research process.

Given that practical burden was also identified as a leading barrier to participation, consideration should also be given at an early stage in the research planning process as to how best to mitigate this – for example, through offering home visits or arranging transport for participants and carers. Highlighting this when recruiting may increase participation rates.

Finally, the findings suggest that communication may be a particular challenge when attempted to recruit to brain donation studies. This implies that early consideration of how to facilitate sensitive communication with potential donor families may be beneficial in relationship-building and subsequent successful recruitment in this area of research.

Recruitment from minority ethnic groups

The three papers which focused on barriers (or motivators) identified by specific minority ethnic groups (African Americans, Cuban Americans and Chinese Americans) include detailed data on barriers to research participation within each group, and highlight practice which may best address these – including employing researchers with relevant language and cultural knowledge, and developing relationships with local communities to support trust and involvement in the research process.

It is possible that the lack of culturally specific themes emerging in other papers is an artefact of demographic imbalance in the samples recruited, rather than an indication that cultural factors are not an important aspect of participation decisions for people from minority ethnic communities. If this is the case, it would be consistent with a known difficulty in dementia research about which future recruiters should be vigilant. As demonstrated in Cooper, Tandy, Balamurali and Livingston's systematic review and meta-analysis (2010), people from minority ethnic communities are less likely to access dementia research trials. They also tend to

present later for diagnosis and to access less care and treatment, although they are at greater risk of Alzheimer's than the Caucasian population (Grill & Karlawish, 2010). There is a general need (highlighted by Cooper et al., 2010), for better understanding of the factors underlying differential rates of access to dementia services and research by specific cultural groups in different countries, and ongoing work to support and bring together evidence and tailored recommendations to support equity of access and outcome (such as those suggested in Connell et al. (2010) and Dilworth-Anderson, Thaker, and Burke (2005)).

In terms of future work to develop the current review's focus on motivations and barriers to research participation, the same issues apply: more research is needed in countries beyond the USA in order to identify the factors identified as influencing research participation by people with dementia and their carers from different minority ethnic groups within those countries. This would allow recruitment interventions to be targeted accordingly, and these under-represented groups more effectively encouraged to access relevant studies.

Including the voice of people with dementia

Given the often essential role of a carer/study partner in facilitating the PWD's research involvement (Grill & Karlawish, 2010), it is perhaps unsurprising that many papers in the review focused on carers' views. These may also be seen as simpler to access, especially where the PWD is more severely impaired. Yet this may lead to an overgeneralised exclusion of people with dementia from research into influences on participation.

However there is an ethical expectation that assent will be sought from the PWD (Overton et al., 2013; Slaughter, Cole, Jennings, & Reimer, 2007) for research, even when a proxy has responsibility for consent. Evidence suggests that proxies do involve the PWD in their decision-making process (Sugarman et al., 2001). It would be preferable in future research on this area to include both the PWD and the carer/proxy wherever possible, pragmatically reflecting that both may

influence the participation decision, and both have views of value. While this may present challenges, existing studies suggest some potential avenues (Beuscher & Grando, 2009; Cowdell, 2006, 2008), and such an approach would be consistent with honouring the personhood of people with dementia.

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Part 2: Empirical paper

Mindfulness ability in people with mild to moderate dementia

Abstract

Background

People with dementia (PWD) experience high rates of depression, but it is unclear whether they can benefit from mindfulness-based interventions (MBIs).

Aims

The study's primary aim is to compare the performance of older people with and without dementia on an experience-sampling measure of mindful attention. This is a step towards exploring whether PWD can benefit from the mindfulness component of MBIs. The secondary aim is to further develop the mindful attention measure for use with PWD, by exploring convergent validity with a self-report mindfulness measure.

Design

Thirty-four participants with dementia were recruited through memory services, and tested face-to-face. A cross-sectional between groups design was used to investigate the primary aim, with a cross-sectional correlational design for the secondary aim. Comparison older adult data were taken from the DClinPsy thesis of Noor Habib (Habib, 2016).

Measures

Measures of mindfulness (Meditation Breath Attention Task/MBAT, Cognitive and Affective Mindfulness Scale (Revised)/CAMS-R), cognitive flexibility and cognition (Trail Making Test/TMT, Addenbrooke's Cognitive Examination III/ACE III), and potential confounding variables (Hospital Anxiety and Depression Scale/HADS, Test of Premorbid Functioning/TOPF) were administered.

Results

There were no significant findings for the main hypotheses, that people with dementia would perform significantly more poorly than a comparison group of older adults without dementia on the MBAT, and that performance on the MBAT would positively correlate with measures of executive function and overall cognition. The

groups differed significantly on a range of demographic characteristics and some neuropsychological and mood measures.

Conclusions

Reasons for the null findings are unclear. Findings are considered in the context of previous research and with reference to study limitations. Implications for future research and practice are discussed.

Introduction

Dementia and depression

Dementia is a progressive and chronic syndrome, with varying patterns of impairment in cognitive and executive function, as well as emotional and behavioural changes (World Health Organization, 2016). It is estimated that 46.8 million people worldwide are living with the condition (Prince et al., 2015), with an estimated 850,000 in the UK alone (Prince et al., 2014). The economic cost of the condition is high (estimated at £26.3 billion a year in the UK alone (Prince et al., 2014)), as is the biopsychosocial impact on people living with dementia, and those who care for them.

People with dementia tend to experience depression at far higher rates than the non-dementia population (Winblad et al., 2004, cited in Enache, Winblad, & Aarsland, 2011). It is estimated that 50% of people with dementia experience some symptoms of depression, which increase functional impairment (Kales, Chen, Blow, Welsh, & Mellow, 2005), decrease quality of life (Shin, Carter, Masterman, Fairbanks, & Cummings, 2005), increase speed of cognitive decline (Rapp et al., 2011), are associated with higher mortality rates (Suh & Yeon, 2005) and increase carer stress (González-Salvador, Arango, Lyketsos, & Barba, 1999) and healthcare costs (Kunik et al., 2003). Anxiety is also common and has a deleterious impact (Orgeta, Qazi, Spector, & Orrell, 2015).

Mindfulness and depression

MBIs are already included within the evidence-based psychological interventions for depression within the NHS. While cognitive behaviour therapy (CBT) or interpersonal therapy (IPT) are the NICE-approved interventions for first episodes of moderate to severe depression (in conjunction with medication if appropriate), with CBT also recommended for people who have relapsed, mindfulness-based cognitive therapy (MBCT) is recommended for those who have experienced three or more depressive episodes (NICE, 2009).

Mindfulness practice can be seen as helping avert or mitigate depressive episodes through giving the practitioner a different relationship to difficult thoughts, emotions and physical sensations. Repeated practice in noticing these, with compassionate acceptance, means the person becomes more able to allow these experiences to come and go without being drawn further into low mood, through reducing engagement with unhelpful strategies such as depressive rumination (J. M. G. Williams & Kuyken, 2012). While MBIs are not a standard intervention for people with current depressive symptoms, there is a growing body of evidence for their use in this context. The first meta-analysis of RCTs of MBIs with people currently experiencing anxiety or depression found a positive impact for people with symptoms of a current depressive disorder, concluding that MBIs might be considered as an intervention for this population (Strauss, Cavanagh, Oliver, & Pettman, 2014).

Treating depression in dementia

There is no good evidence for antidepressant use in dementia (Banerjee et al., 2013), increasing the importance of exploring possible psychological interventions for this population.

There is a small but increasing number of studies in this area, with some promising initial findings, such as a pilot RCT (Spector et al., 2015) which found that a tailored CBT intervention for anxiety in dementia was both feasible and effective.

In addition, Dr Joshua Stott's ongoing PhD project is currently investigating whether people with dementia are able to demonstrate capacities seen as key in the use of cognitive behavioural therapy (CBT) for depression and anxiety. The current study is a substudy of this project.

Mindfulness and dementia

Exploration of MBIs for people with dementia is also at an early stage. A small pilot study (Leader, Litherland, Mason, Pilchick, Sansom, & Robertson, 2013) suggested that mindfulness interventions (specifically mindfulness-based stress

reduction, MBSR) could be taught to some people with dementia, especially in the earlier stages, and that those who were able to learn and practice it found it beneficial. The study nevertheless stated that the sample was too small to generalise its conclusions and the researchers could not exclude the influence of non-specific factors. More recent work (M. Y. Chan, 2015; Churcher-Clarke, 2015) has found that people with dementia living in care homes experienced a significant improvement in quality of life (as measured by the QoL-AD, (Logsdon, Gibbons, McCurry, & Teri, 1999)) following a pilot group mindfulness intervention. Preliminary work has also indicated the possible benefits of mindfulness-based stress reduction for people with mild cognitive impairment (MCI) (Wells et al., 2013) which shares some characteristics of dementia and confers an increased risk of developing dementia.

Yet while the existing research does indicate that MBIs may have some utility in dementia, the mechanisms remain unclear. The care-home based studies cited above compared a group intervention to treatment as usual (continuing with normal activities). As Chan (2015) notes, it is not possible confidently to attribute the improvements seen to the specific therapeutic impact of mindfulness practice rather than non-specific therapeutic effects of being in a regular group. The question remains open as to whether people with dementia can engage with (and therefore potentially benefit from) specific elements of mindfulness practice to the same level as people without dementia, and thus whether further research and intervention development in this area could be helpful.

There are also some *prima facie* reasons to believe that people with dementia may find certain elements of mindfulness practice more difficult than people without dementia.

Cognitive flexibility

The ability to attend (and to self-regulate attention) has been identified as one of the two core components of mindfulness practices (the other being approaching

present-moment experience with an orientation of curiosity, openness, and acceptance (Bishop et al., 2006)). A study by Moore and Malinowski (2009) demonstrated that these abilities (attentional performance and self-regulation of attention, in the form of cognitive flexibility) are positively related to meditation practice and levels of mindfulness. That study also suggested that mindfulness ability and cognitive flexibility may be connected independently of meditation practice, as the correlations between these two factors were also significant in a non-meditating control group.

As deficit in executive function (encompassing cognitive flexibility) is a diagnostic criterion for Alzheimer's disease (World Health Organization, 2016), we might therefore tentatively expect people with dementia to perform more poorly on a task measuring mindful attention than people who do not have dementia (where both groups are naïve to meditation). The current study focuses on the attentional element in mindfulness practice.

Overall cognition

People with dementia also have impaired overall cognition (as measured by screening tools such as the ACE III (Hsieh, Schubert, Hoon, Mioshi, & Hodges, 2013). Overall cognition has previously been shown to predict ability to engage in a task of metacognition (cognitive restructuring) in older adults (Johnco, Wuthrich, & Rapee, 2013), and the ability to metacognise (to think about one's own thoughts) is arguably fundamental to engaging in mindfulness practice (Teasdale, 1999). Therefore impairment in this area may tentatively be expected to influence the ability of people with dementia to perform well on a measure of mindful attention.

Methodological challenges in measuring mindfulness

Existing research has highlighted generic difficulties in researching mindfulness. Bergomi, Tschacher, and Kupper (2012) provide an overview of some of the existing validated measures, highlighting that all displayed flaws and specificities which meant they were not generalisable across populations, or valid as a measure of a

holistic concept of mindfulness. The majority of measures assessing mindfulness are self-report in format, and in the same paper, the authors also enumerate the difficulties of using self-report methods to assess mindfulness. Grossman (2008) also details a number of systematic biases in using self-report measures in this context, including the Hawthorne effect, the overconfidence effect, social desirability responding, and cognitive dissonance.

Measuring mindfulness in dementia

The use of self-report measures may be additionally problematic for people with a diagnosis of dementia, depending on their current severity. Smith et al. (2005) highlight the 'unique methodological challenges' presented by the use of self-report when attempting to assess a different variable in people with dementia, health-related quality of life. These include disorders of memory, attention, expressive and receptive language, judgment and behaviour. The authors do not completely exclude the use of self-report in people with dementia, since competencies and abilities will vary widely between individuals.

Therefore given the potential difficulties of self-report, particularly for people with dementia, selecting a methodology which could reduce these possible challenges in measuring mindfulness performance is an important consideration. One possible alternative is the use of experience sampling methodology. This is a means of tapping into a participant's present-moment experience, and is therefore less likely to be subject to self-report biases such as recall effects as well as having increased ecological validity over a laboratory-based assessment (Scollon, Kim-Prieto, & Diener, 2009). Experience sampling also has the benefit of reducing demands on many aspects of cognition involved in delayed self-report, which, as Smith et al. (2005) notes, may be additionally difficult for people with dementia (including executive demands, sustained attention and prospective memory). One such measure, developed specifically to measure mindful attention, is the Meditation Breath Attention Task (MBAT) (Frewen, Evans, Maraj, Dozois, & Partridge, 2008).

The MBAT also benefits from the ecological and face validity inherent in its close approximation of a common element of meditation practice, mindfulness of breathing.

Aims

The current study's first aim is to establish whether, as is tentatively expected, a group of higher-functioning people with dementia perform more poorly than a comparison group of older people without dementia on the MBAT. This is a key step towards establishing whether higher-functioning people with dementia could engage with and benefit from the mindfulness component of MBIs for depression, as opposed to their social interaction component.

As there is reason to expect that some core deficits of dementia (cognition and executive function) might influence the performance of people with dementia, discussion of the study findings will be aided by measuring these areas, as well as the possible confounding factors of mood and premorbid IQ, and by exploring correlations between these measures and the MBAT. Differences between the group of people with dementia and the comparison group will also be explored.

The study's second aim is to develop the evidence base for the MBAT in people with dementia, to support future research in this population. This will be done by exploring whether correlational analysis supports convergent validity of the MBAT with a brief self-report measure of mindfulness, while acknowledging the challenges of self-report.

Hypotheses

Hypotheses (tentative):

- 1) People with dementia will perform significantly more poorly than a comparison group of older adults without dementia on the MBAT.
- 2) Performance on this measure will positively correlate with measures of executive function and overall cognition. If these correlations are present it will be

expected that performance on these measures predicts mindfulness performance over and above mood and premorbid IQ.

Exploratory (convergent validity):

3) The study will explore whether there is an association between the performance of people with dementia on the MBAT, and their score on a brief self-report measure of mindfulness.

Method

Design

A cross-sectional between groups design was used to compare the performance of the sample of people with dementia (PWD) and an older adult (OA) comparison group on the MBAT. A cross-sectional correlational design was used to explore the possibility of convergent validity between the mindful attention measure and a self-report measure of mindfulness, and of associations between the mindful attention measure and measures of core mindfulness-related cognitive and executive deficit in dementia.

Setting

The dementia sample was collected across four memory services within two foundation trusts in London, and their embedded dementia adviser services. To reduce participant burden and facilitate attendance, most assessments were conducted at participants' homes.

Participants

Inclusion/exclusion criteria

Any patient on the memory service or dementia adviser caseloads, with a dementia diagnosis, was potentially eligible for the study. The decision to contact the patient to invite them to participate was based on further inclusion/exclusion criteria, assessed by review of clinical notes and discussion with memory service staff.

A key screening criterion was a score of >70 on the ACE (or MMSE >24) in the patient's most recent diagnostic assessment. This threshold was selected as representing a mild to moderate level of dementia such that prospective participants were more likely to be able to give informed consent to participate, and be able to functionally engage in the research tasks. Where this was uncertain, the clinical judgement of the most closely involved memory service practitioner was followed. Among participants who had completed the ACE some time previously, some were found to have deteriorated in performance to below 70 on retesting. It was decided not to exclude these participants from the study since they had demonstrated their ability to give informed consent, and had been able to engage with the research tasks during the appointment (these being pragmatic markers of being a higher-functioning group). Had this not been the case they would have been excluded from the study.

Exclusion criteria included the need for an interpreter, current significant mood/anxiety disorders or psychotic symptoms, substance misuse problems or premorbid learning disability, and sensory or physical disabilities or impairments which would make engagement with the research measures difficult. Some patients had previously stated they did not want to be contacted for research, or had previously participated in a similar study, and were therefore excluded.

Participants were also excluded from the study if notes indicated previous experience of mindfulness meditation, since the study was interested in naïve performance on the mindfulness measure. Previous experience of cognitive behavioural therapy (CBT) was also an exclusion factor, since the associated project of the current study was interested in naïve performance on CBT-relevant measures.

Ethics

Ethical approval for the study, and subsequent amendment (Appendices A and B), was granted by the City Road and Hampstead National Research Ethics Service

Committee. The study was also registered with research and development departments local to the memory services involved.

Sample size

Although no previous study has used the full MBAT with comparable populations, either as a within or between groups measure, medium to large effect sizes have been found in a study with several parallels to the current research. In Hebblethwaite, Jahoda, and Dagnan (2011), a different cognitively compromised group (people with intellectual disability) was compared with controls with normal IQ, on tasks which (like mindfulness) involved metacognitive ability, with $N = 19$ in each group.

Due to the differences between Hebblethwaite et al. (2011) and the current study, it was felt prudent to power the current study to detect a medium (rather than large) effect, while aiming for the largest possible group sizes.

Power was calculated using G*Power (Kiel, 2007) for an independent groups t-test for the primary hypothesis, that there would be a significant difference in performance on the MBAT between PWD and the OA comparison group. (The MBAT was treated as an interval variable, as had been the case in a study led by the originator of the measure (Frewen, Lundberg, MacKinley, & Wrath, 2011)).

G*Power produced a requirement for a minimum $N = 102$ (51 participants in each group) to detect a medium effect size ($d = 0.5$, with $\beta = 0.8$ and $\alpha 0.05$), for a study involving equal size groups.

Measures

Neuropsychological, mood and mindfulness measures and demographic questions were therefore administered along with measures specific to that study (measuring CBT abilities), which are not reported here. The same measures were used in the OA and dementia samples, with the exception of the CAMS-R which was only used in the dementia sample.

Demographic questions were always administered first, with the order of presentation for mindfulness and neuropsychological measures counterbalanced. The order of neuropsychological measures was always randomised to avoid order effects. For the mindfulness measures, the self-report measure was always presented before the experience-sampling measure. This was to reduce the possibility of naïve participants' response to the mindfulness exercise affecting their subsequent self-report on the CAMS-R.

Mindfulness measures

Meditation Breath Attention Task (MBAT)

The MBAT, the development of which is described in Frewen et al. (2008), was used to assess ability to mindfully attend to the breath. The MBAT is based on the experience sampling method, and was selected for the current study to address the need for a methodology more likely to avoid the difficulties of standard self-report. The measure has strong ecological and face validity as 'the ringing of bells during silent meditation sittings as a form of reminding practitioners to return their attention toward their breathing (if their attention has wandered) is a common practice at mindfulness meditation retreats' [and in both group and individual sitting meditation practice] (Frewen et al., 2008).

In the task (see Appendix C), a ten minute practice period is followed by a 15 minute exercise in which participants are instructed to keep their attention on their breath, noticing without judgement if their attention wanders, but then returning their attention to the breath. A bell is rung at three minute intervals, with participants instructed to raise one hand if their attention is on the breath, and the other hand if it is elsewhere (the hand specified was counterbalanced across the sample to reduce the potential impact of the dominant hand on responses). The number of times each participant indicates that they were focused on the breath at the bell is recorded (with a maximum possible score of five).

Validity and reliability of the MBAT with adults has been demonstrated in several studies. Frewen et al. (2008) demonstrated convergent validity in studies with adult volunteers, finding MBAT scores to be significantly correlated with relevant elements of the MAAS (Mindful Attention Awareness Scale), and three of four subscales of the Kentucky Inventory of Mindfulness Skills (KIMS), both well validated multidimensional measures of mindfulness (Baum et al., 2010). Further evidence for convergent validity with the Five-Facet Mindfulness Questionnaire (FFMQ) was supplied subsequently by Liu et al. (2013). Construct validity for the measure has also been demonstrated (Lai, MacNeil, & Frewen, 2015; Frewen, Lundberg, MacKinley, & Wrath, 2011), and a further study indicated good test-retest reliability (Frewen, Unholzer, Logie-Hagan, & MacKinley, 2014).

Consideration was given to using a shorter version of the MBAT which involves additional visual cues and verbal support from the researcher. This version was used in the care home pilot study cited above (M. Y. Chan, 2015; Churcher-Clarke, 2015) to reduce task demands and increase acceptability and feasibility for people with dementia. However the participants in that study were more impaired (the mean MMSE score of 15.85 in the intervention group would have rendered them ineligible for the current study, with its minimum MMSE of 24).

The author had also piloted the shorter measure in a memory service group of higher-functioning people with dementia (who would have been eligible for the current study), and found a ceiling effect in responses. It was therefore decided to use the unadapted measure.

For the current study, a recorded version of the task was used to ensure consistency of delivery for each participant (this was also used in the OA comparison sample).

Cognitive and Affective Mindfulness Scale (Revised) (CAMS-R)

The CAMS-R (Feldman, Hayes, Kumar, Greeson, & Laurenceau, 2006, Appendix D) is a brief (12-item) self-report measure sampling four domains of

mindfulness – attention, present focus, awareness and acceptance/non-judgement. It was used to assess convergent validity with the MBAT. Feldman et al. (2006) previously demonstrated that the CAMS-R has acceptable internal consistency and evidence of convergent and discriminant validity with concurrent measures of mindfulness, distress, well-being, emotion-regulation, and problem-solving approaches in three samples of university students, as well as finding that scores were positively correlated with cognitive flexibility ($p < 0.1$). As there is no existing self-report measure of mindfulness validated for use with people with dementia, the CAMS-R was selected as the briefest and least burdensome option available. While some difficulties were reported with measure completion in the care home pilot study mentioned above (J. Chan, personal communication, 5 December 2014), it was anticipated that the current study's higher-functioning population would encounter fewer challenges in this regard. A focus group of higher-functioning memory service patients had previously found the CAMS-R to be an acceptable measure (J. Chan, personal communication, 11 March 2015).

Neuropsychological measures

Trail Making Test (TMT)

Cognitive flexibility was measured using the TMT (Appendix E), a two-part, frequently used and acceptable measure for people with dementia, with excellent inter-rater reliability (Bowie & Harvey, 2006), in which participants are asked to 'join the dots' on a series of targets. In Trails A, this is a series of sequential numbers; in part B, a series of alternating sequential numbers and letters. Trails B has support as a measure of executive function (specifically, cognitive flexibility) (Kortte, Horner, & Windham, 2002), and has been shown to significantly discriminate subjects with and without dementia (Heun, Papassotiropoulos, & Jennssen, 1998).

Participants' levels of cognitive flexibility is understood to be best represented by using a score derived by combining Trails A and B scores (which reduces the impact of other factors such as reduced motor and visual scanning speed on the

Trails B set-switching task). It has been argued that the ratio score (Trails B score divided by Trails A score) may be the preferred derived score as it correlates more strongly with other measures of set-switching than the constituent scores (Arbuthnott and Frank, 2000; Lamberty, 1994, cited in Hester, Kinsella, Ong, and McGregor 2005). However more recent data (Sanchez-Cubillo et al., 2009) suggests that the difference score (Trails B score minus Trails A score) could be a more accurate reflection of set-switching ability. The difference score is used in the current study.

Addenbrooke's Cognitive Examination III (ACE III).

The ACE III (Appendix F) was used to assess overall cognition. It is a widely used and acceptable measure with people with dementia and is frequently used as a screening tool within memory services. It has been validated against its predecessor the ACE-R and other standardised tests of neurological functioning in early dementia (Hsieh et al., 2013), and has been shown to have high internal reliability (Cronbach's $\alpha = 0.88$, (Velayudhan et al., 2014)).

Measures of potentially confounding variables

Hospital Anxiety and Depression Scale (HADS)

The HADS (Appendix G) was used to identify whether clinically relevant levels of anxiety and/or depression may be acting as a confounding factor in data analysis of the main hypotheses. Anxiety and depression can influence cognition (Austin, 2001; Derakshan & Eysenck, 2009) which, as noted above ('Overall cognition', p.67), may influence performance on a mindfulness task. In addition, depression may affect motivation and effort to perform optimally during testing (Lezak, Howieson, Bigler, & Tranel, 2012).

The HADS was developed to identify anxiety and depression among patients in a hospital medical outpatient setting (Snaith & Zigmond, 1983). It has also been used in community and outpatient settings (Dunbar, Ford, Hunt, & Der, 2000; Cacia et al., 2003), and is recommended for the identification of mood difficulties in primary

care settings (NICE, 2009). It is an easy-to-administer, well accepted questionnaire measure with acceptable internal consistency (Samaras et al., 2013), consisting of 14 self-report items equally contributing to two seven-item subscales assessing depression and anxiety. Symptoms in the preceding week are rated by the respondent on a four point Likert scale, with a maximum score of 21 on each subscale. Higher scores correspond to higher disease severity (Johnston, Pollard, & Hennessey, 2000; Herrero et al., 2003).

The HADS has been used in research settings in patients with dementia (Samaras et al., 2013) where it was found to be a feasible measure. It has demonstrated good validity in assessing symptom severity and caseness of anxiety and depression in medical, psychiatric and primary care patients and in the general population (Bjelland, Dahl, Haug, & Neckelmann, 2002). As it does not assess somatic symptoms of depression (which can overlap with the physical impact of illness/frailty), it reduces the chance of false positives for depression in screening populations whose physical health is poorer.

Test of Premorbid Functioning (TOPF)

Estimated premorbid IQ was also considered to have the potential to act as a confound in the data. There is evidence that for people with intellectual disability, IQ level is related to poorer metacognitive ability (Hebblethwaite et al., 2011). It might therefore also be suspected that in people with dementia, lower premorbid IQ level would affect their ability to perform on a mindfulness task, beyond the potential impact of dementia-related deficits. As this could reduce the confidence that might be placed in any association found between membership of the dementia sample and poorer performance on the MBAT, it was felt to be important to include a separate measure of premorbid IQ.

Premorbid IQ estimates were derived from the score on the TOPF (Appendix H, Wechsler, 2011), along with demographic information (gender, years of education). The TOPF requires the reading and pronunciation of words with irregular grapheme-

to-phoneme translation (which is relatively well preserved in early dementia (Holdnack, Schoenberg, Lange, & Iverson, 2013), but not comprehension or knowledge of word meaning. The TOPF was validated as part of the wider WAIS-IV/WMS-IV UK validation process, which included a group study of people with probable Alzheimer's disease. Results were in line with the prediction that TOPF-predicted IQ and memory would be higher than the obtained WMS and WAIS scores, suggesting it has some utility as a measure of premorbid IQ in this population.

Procedure

For the dementia sample, participants were recruited and assessed by three researchers (the author and two research assistants), Recruitment was done via three routes:

- In two services, a regularly updated database of people seen within the service who had consented to research contact was reviewed at intervals. Patients meeting key inclusion criteria were contacted directly for further screening. Staff caseloads were also screened for patients who appeared to be eligible for the study but who had not previously agreed to research contact. The researcher asked the staff member to request consent to research contact from the patient.
- In one service, recruitment was done by screening of caseloads and of the waiting list for the cognitive stimulation therapy group, which comprised a higher functioning group of patients.
- In one service, recruitment was led by clinicians, who contacted the researcher with details of eligible patients who had consented to contact.

Following this initial stage, patients were contacted by telephone. Information about the study was provided (summarising key points of the participant information sheet, Appendix I) and any questions answered. If the patient consented to participate, an appointment was arranged.

Participant information material for the study was reviewed at the start of the appointment and written informed consent (Appendix J) obtained in line with the agreed ethical procedures. Measures were then administered, with data recorded in an online system, or on hard copy response forms and transferred to the electronic system as soon as possible following the appointment. Following completion of the measures, participants were asked for feedback on their experience of the research process, including the mindful attention task. Finally, participants were thanked and debriefed.

Data analysis

Data were analysed using SPSS version 22. Analyses were independent groups t-tests or correlations, with non-parametric equivalents used where data did not meet test assumptions.

OA comparison sample

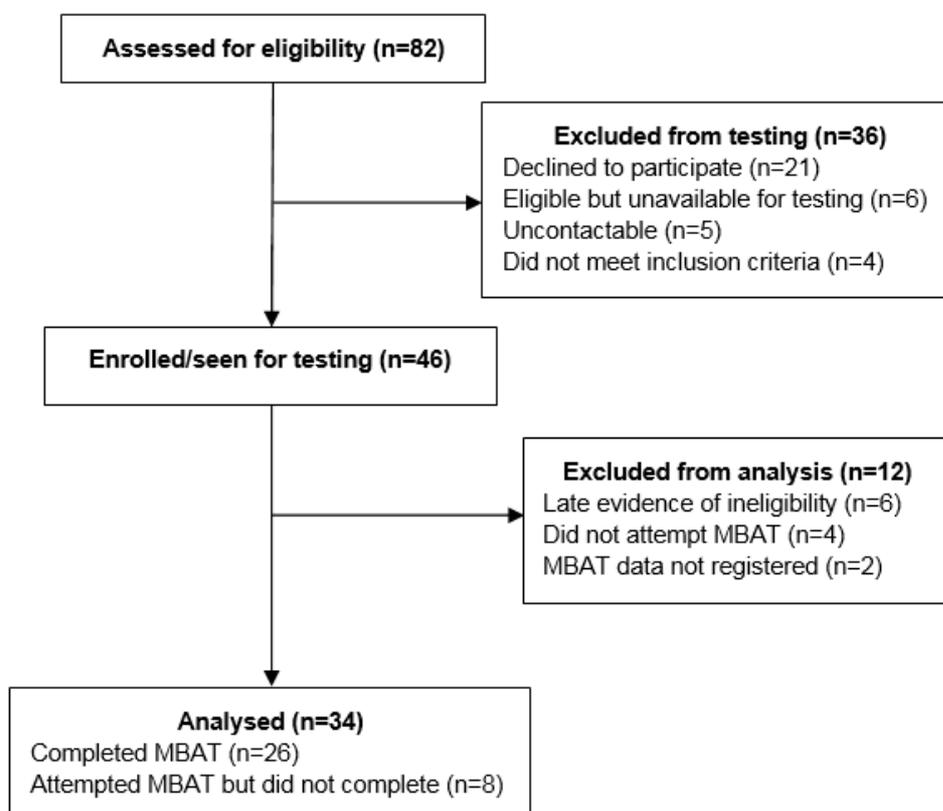
The OA sample consisted of 55 healthy people aged 65 and above, recruited to a parallel DClinPsy study which was also a substudy of Joshua Stott's PhD study. Participants were recruited via promotional activity in the University of the Third Age and Age UK in London, as well as through snowball sampling. Eligibility criteria were similar to the PWD sample, except that a diagnosis of dementia was an exclusion criterion. In addition, data for participants who scored below the threshold for identifying dementia on the ACE III on testing (which is 82) were excluded from analysis. Participants who met eligibility criteria were primarily tested within an academic setting.

The OA comparison sample were administered a similar battery of measures (not including the CAMS-R) and used the same recording of the MBAT as the current study. These data were used in the current study only to answer the primary hypothesis about difference in MBAT performance between the groups. Other analyses of the OA sample are reported in the DClinPsy thesis of Noor Habib (Habib, 2016).

Results

The flow of participants through the study is illustrated in Figure 1, below.

Figure 1: Flow of participants through the study



Demographic characteristics of the samples

Between groups analyses were carried out to assess any differences between the groups on demographic characteristics (see Table 1, p.81). Statistically significant differences (at the $p < .001$ level of significance) were found for age and years of education - members of the dementia sample were older and had fewer years of education than the OA sample. There were no statistically significant differences found between groups for gender, ethnicity or marital status.

Table 1: Demographic characteristics and results of between groups analyses for PWD and OA participants

Variable		Group		Test statistic		
		PWD (N = 34)	OA (N = 55)			
		M (SD)	M (SD)			
Age		82.84 (6.58)	72.96 (6.30)	t = 7.06*		
Years of education		11.91 ^a (3.82)	16.07 (3.59)	t = 5.14*		
		n (%) ^b	n (%) ^b			
Gender	Male	17 (50)	21 (38)	$\chi^2 = 0.83$		
	Female	17 (50)	34 (63)			
Ethnicity	White (English)	22 (65)	49 (89)	$\chi^2 = 10.25$		
	White (Irish)	1 (3)	2 (4)			
	White (Other)	5 (15)	3 (6)			
	Mixed (White and Black African)	1 (29)	0 (0)			
	Asian/Asian British (Chinese)	1 (3)	0 (0)			
	Black/African/Caribbean/Black British (Caribbean)	1 (3)	0 (0)			
	Black/African/Caribbean/Black British (Other)	2 (6)	0 (0)			
	Other ethnic group (Other)	1 (3)	1 (2)			
	Marital status	Single	5 (15)		7 (13)	$\chi^2 = 3.62$
		Married	12 (35)		29 (53)	
Separated		0 (0)	1 (2)			
Divorced		6 (18)	7 (13)			
Widowed		11 (32)	11 (20)			

* $p < .001$. ^aN = 33; ^bPercentages may not total 100 due to rounding.

Neuropsychological, mood and self-reported mindfulness variables

Data for neuropsychological and mood variables, and for self-reported mindfulness (CAMS-R) are shown in Table 2, below. All data for the MBAT are presented in Table 3 (p.86).

Table 2: *Data for neuropsychological, mood and self-reported mindfulness variables by group*

Variable	Group		Test statistic
	PWD (N = 34)	OA (N = 55)	
	M (SD) Min-Max	M (SD) Min-Max	
ACE (/100)	74 ^a (10.84) 45-98	95.11 (4.42) 82-100	t = 10.67*
Estimated IQ	101.92 ^{a, b} (14.00) 75.90-126.40	118.70 (9.02) 93.30-132.60	t = 6.16*
TMT difference score	166.58 ^a (76.36) 38-274	42.98 (35.94) 4-155	t = 8.80*
HADS (anxiety) (/21)	4.94 (2.76) 1-12	4.55 (2.89) 0-12	t = 0.64
HADS (depression) (/21)	5.35 (3.88) 0-14	2.47 (1.82) 0-7	t = 4.21*
CAMS-R (total) (/48)	32.88 (4.74) 24-44	n/a ^d	n/a ^d

*p<0.001. ^a N = 33; ^b IQ estimates relate to premorbid IQ in PWD group; ^c N = 26;

^d The CAMS-R was not administered to the OA group.

Strategy for missing data

Variables other than the MBAT

While the majority of these 34 participants completed all measures, there were some missing data. Before further analysis, Little's MCAR test was performed (Little, 1988). When this test has a significant result, data cannot be assumed to be missing completely at random (MCAR), which is a key assumption for using pairwise or listwise exclusion in analysis rather than imputation to deal with missing data (Graham, 2009). In this case, the p value was non-significant.

Graham (2009) advises the use of listwise rather than pairwise exclusion of cases for missing data when data is MCAR, while acknowledging the potential loss of power from excluding partial data from analysis. This was a consideration for the current study, given that it was already somewhat underpowered. However Graham comments that when the cases lost are not at a high percentage, both biases and loss of power are likely to be inconsequential, and states a number of additional reasons against pairwise deletion (Graham, p.554). Therefore it was decided to use listwise deletion of cases in analyses for the current study.

Missing data for the MBAT

The amount of missing or ambiguous data was higher for the MBAT than the other variables. While 26 of the 34 participants had completed the measure in full according to instructions, six had given one or more ambiguous responses (e.g. raising neither hand), and two did not complete the full exercise.

It was felt that listwise deletion, excluding 8/34 (24%) of cases from all analyses involving the MBAT, would have too great an effect on the power of the study and would further increase the risk of Type II error. Therefore for this variable only, missing/ambiguous responses were imputed. While several methods for doing this were considered (Gelman and Hill, 2006; Higgins and Green, 2011), the final decision was to impute an assumed outcome. If the participant had failed to respond clearly, or indicated they were not able to complete the task, the researcher saw this

as indicating distraction or difficulty with the task which could plausibly be equated with failure to attend to the breath. The missing or ambiguous responses were given a score of '0', as required in the MBAT for those who indicate they are not attending to the breath at the bell.

Hypotheses

Hypothesis (tentative):

- 1) People with dementia will perform significantly more poorly than a comparison group of older adults without dementia on the MBAT.

MBAT data were found not to meet the assumptions for parametric testing, as the data distribution showed extreme negative skew and platykurtosis. Attempts to transform the data were unsuccessful, therefore a non-parametric analysis was used (Mann Whitney U test).

The results are shown in Table 3 (p.86). No statistically significant difference was found between the groups ($p = .38$). The difference remained insignificant when imputed data were excluded ($p = .79$).

Therefore the null hypothesis (that the groups came from a population with the same median score) could not be rejected.

Considerations for further data analysis for the primary hypothesis

Consideration was then given to the possibility that the pre-existing group differences found on demographic factors (such as age and years in education) may have influenced this result by acting as covariates. Two main options were considered for exploring this. These are outlined below, along with the reasons for rejecting their use.

The first option considered was the application of ANCOVA as a way of controlling for potential covariates. This was discounted since, as summarised in Miller and Chapman (2001), the ANCOVA should not be used in naturally occurring groups (such as those in the current study) since data could violate the assumption of independence of observations within groups. It was felt that in the current study, it

was possible that the significant between-group differences found on demographic variables such as age and years of education were real group differences (i.e. related at some level to the state of having dementia or not), rather than random error (in which case attempting to control for the differences as covariates would be appropriate).

Another approach considered was to attempt to mitigate for the pre-existing group differences in age and years of education by selecting out cases from the OA comparison group which most closely matched the PWD group on these characteristics. However, this would have had the disadvantage of further reducing the power of the study.

It was also considered that the stark group differences observed on these demographic factors would be more likely to magnify any between-group difference on the MBAT rather than mask it, further challenging the rationale for using either of the above strategies. This view was based on findings such as those in Tombaugh (2004) which assessed the impact of age and years in education on performance on the TMT in 911 (non-cognitively impaired) adults aged 18-89. That study found that performance covaried (worsened) with increased age and reduced years in education. This would suggest that, were it possible to reduce the effect of age and years in education on the outcome of the primary hypothesis in the current study, the observed difference between groups would further reduce and no benefit would be gained.

Table 3: Results of Mann Whitney U tests with descriptive statistics for MBAT scores by group

Variable	Group						df	U	z	r
	PWD (N = 34)			OA (N = 55)						
	Median	Mode	Min-Max	Median	Mode	Min-Max				
MBAT (with imputed data)	3	5	0-5	4	4	0-5	87	1036.50*	0.88	0.09
MBAT (without imputed data) ^a	4	5	0-5	4	4	0-5	79	689.50**	-0.27	0.03

^aN = 26; *p=.38; **p=.79.

Hypothesis (tentative):

- 2) Performance on this measure will positively correlate with measures of executive function and overall cognition. If these correlations are present it will be expected that performance on these measures predicts mindfulness performance over and above mood and premorbid IQ.

As planned, further exploratory analyses were considered for the PWD sample, to assess whether there were associations between the MBAT score and the two putative influencing mechanisms of cognition and cognitive flexibility (plus the potential confounding variables of anxiety, depression and estimated premorbid IQ).

Spearman's rank order correlation was performed to assess the relationship between the MBAT and the TMT difference score. Though the correlation was statistically non-significant, the result displayed a trend towards significance ($r_s(31) = .323, p = .067$).

The same analysis was performed to assess the relationship between MBAT and HADS (anxiety) scores. The resulting correlation was statistically non-significant ($r_s(32) = .181, p = .306$).

Correlational analyses for the MBAT and the ACE, HADS (depression) and premorbid IQ were not performed, as assessment of bivariate scatterplots indicated the distribution assumptions of the test were not met.

Exploratory (convergent validity):

- 3) The study will explore whether there is an association between the performance of people with dementia on the MBAT, and their score on a brief self-report holistic measure of mindfulness.

The bivariate scatterplot for the MBAT and CAMS-R was assessed as meeting the distribution assumptions for Spearman's rank-order correlation. There was no statistically significant correlation between the measure of mindful attention to the breath and self-reported mindfulness ($r_s(32) = .006, p = .971$). This correlation

coefficient is very close to zero (where a result of zero would suggest no relationship between the ranks.)

Discussion

Summary of results

For the primary hypothesis, no statistically significant difference was found on the measure of mindful attention between the group of PWD and the comparison group of older adults. This was in spite of there being statistically significant differences between the groups on measures of overall cognition, estimated premorbid IQ, and executive ability, with PWD performing worse.

Further analysis aimed at exploring possible mechanisms influencing MBAT performance in PWD found a tentative trend towards significance in the association between cognitive flexibility (the TMT difference score) and score on the MBAT ($p = .067$).

For the exploratory hypothesis, no statistically significant relationship was found between the measure of mindful attention and the self-report measure of mindfulness for PWD. Therefore the current study does not support convergent validity for the MBAT with the CAMS-R in this sample.

These results were found in the context of the study being underpowered to detect small to medium effects. This is discussed in more detail below, under 'Limitations' (p.93).

The context of previous research

For the first hypothesis, it is not possible to place the findings in the context of directly parallel previous research, since there are no currently published studies comparing groups on naïve performance on the MBAT. However the tentative expectation that people with dementia would perform significantly worse than the comparison group on the MBAT was based in known and well established differences (also reflected in the findings of the current study) between people with and without dementia, in areas which have a plausible theoretical link to the skills

involved in engaging with the MBAT - cognition and cognitive flexibility. Possible reasons underlying the non-significant finding are discussed below, under 'Interpretation of findings' (p.90).

For the exploratory hypothesis, convergent validity of the MBAT with a self-reported measure of mindfulness (the CAMS-R) was not established in the current study. However, as noted under 'Measures' (above, p.74), convergent validity of the MBAT with several other well-validated measures of mindfulness has previously been demonstrated in studies with adults. These have included findings of significant correlations with the Mindful Attention Awareness Scale (MAAS), three of four subscales of the Kentucky Inventory of Mindfulness Skills (KIMS), and the Five-Facet Mindfulness Questionnaire (FFMQ) (Frewen et al., 2008; Lai et al., 2015).

Conversely, the CAMS-R has previously been found to have convergent validity with other mindfulness measures, including a statistically significant association ($p < .001$) with the MAAS (Feldman et al., 2006).

However a small number of previous studies using the MBAT report findings which suggest convergent validity for the measure with other measures of mindfulness is not always found. Frewen et al. (2011) did not find an association in students between self-reported difficulty in attending to the breath and lower MBAT score. The same study failed to replicate the Frewen et al. (2008) finding of a moderate correlation between MBAS and trait mindfulness (the 'Act with Awareness' subscale of the KIMS).

Given the substantial variation in design, methodology and participant characteristics across these studies, it is difficult to identify whether there are factors common to the non-significant finding for convergent validity in the current study, and in other studies with similarly non-significant findings for convergent validity.

Greater ease of comparison would have been possible had the current study used a self-report mindfulness measure already established as having convergent validity with the MBAT in an adult sample. However the CAMS-R was selected for

both practical and ethical reasons, as a reliable and valid measure likely to be least burdensome for participants to complete in the context of a substantial test battery.

Interpretation of findings

One possible explanation for the current null findings on the primary hypothesis, given that the PWD group was a relatively high-functioning, community-dwelling sample, is that there was in fact no significant difference between the PWD and OA group's underlying ability to pay sustained, mindful attention to the breath, as measured by the MBAT. However, given the significant differences between the groups on other measures of relevant skills in cognition and executive ability, it is perhaps more likely that other factors influenced the outcome. As discussed below, these may include a range of challenges to the validity and feasibility of the measure, or that there was a significant but small difference between groups on the MBAT which the study was underpowered to detect (Type II error).

Potential issues for validity and reliability of the MBAT

The current study was grounded in the existing evidence for the validity, reliability, and feasibility of the MBAT as an experience-sampling measure of mindful attention in adults (see above, p.73), and its merits in addressing some of the challenges to validity found in standard self-report measures of mindfulness. However, the MBAT still comprises elements which may lead to invalid, biased or incomplete responding at different levels of the task. A number of these are scrutinised further below.

Construct validity of the task

Researchers subscribing to a methodological behaviourist perspective (Pistrang, Barker, & Elliott, 2016) could argue that MBAT data is derived from introspection by participants, who must still self-report their locus of attention. From this perspective, even though the MBAT mitigates many problematic aspects of self-report, it still could not have construct validity as a measure of mindful attention.

Factors that may have affected valid responding

Social desirability bias

Even from a stance that valid self-report of an internal state is possible, participant responses to the MBAT could still be affected by social desirability factors (Paulhus, 1991). Participants could have intuited the desirable response pattern for the MBAT from pre-existing social learning (at its simplest level, the knowledge that paying attention is 'better' than being distracted). In such a circumstance, it would be possible for a participant to accurately introspect their attentional state but to misreport this (i.e., that they were 'attending to the breath' when their true state was of non-attention), in the hope of creating a more favourable impression (Tourangeau et al, 2007, cited in Kaminska & Foulsham, 2013).

Cognitive dissonance

Cognitive dissonance (Festinger, 1962) could also have influenced response choices. Participants with dementia frequently asked how well they had done on the test battery, with some indicating anxiety about this. It is possible that a person with dementia who wished to reassure themselves about their capacities might be biased towards giving the 'correct' answer on the MBAT, to reduce their discomfort about their cognitive difficulties, rather than carefully giving an accurate answer which might not be congruent with a more positive self-image. It is also possible that responses in the older adult comparison group could be affected through a similar process, if the respondents had concerns about cognitive deterioration.

Anxiety under observation

It should be acknowledged that the MBAT differs from standard experience-sampling measures, as, in the standard presentation of the measure, the researcher is physically present with the participant. Thus participants are asked to undertake an unfamiliar task, with their eyes closed, under close observation. As Frewen et al.

(2008) note, being aware of others' presence during such a task could increase anxiety, and affect the ability to focus and report on the breath accurately.

Depression

Given the known impact of depression on motivation/effort (Lezak et al., 2012) in testing, as well as on cognitive performance (Austin, 2001), low mood should be considered as a further potential influence affecting valid responding and task persistence. If this was the case, it may have differentially affected the PWD sample, since HADS depression scores were significantly higher for this group (reflecting higher rates in this population).

Inherent challenges of the task for the dementia sample

Though the task attempts to mitigate challenges of self-report, valid completion still demands competence in a range of cognitive and executive areas which are characteristically impaired in dementia. These are noted in Salmon and Bondi (2009), with problems of delayed recall (leading to abnormally rapid forgetting) foremost, as well as attention deficits which are most prominent in tasks requiring the disengagement and shifting of attention, and memory tasks which rely on self-control of attentional resources. Typical executive deficits include problems in cue-directed behaviour and the concurrent manipulation and retention of information.

The MBAT asks participants to use all these capacities. They are required to maintain attention to the breath for extended periods, and are then cued (by the bell) to disengage from that focus of attention, and to set-shift into attending to and processing the instructions being provided. They must simultaneously retain the memory of where their attention was at the point the bell rang and subsequently use this information in order to select the correct (accurate) response in terms of which hand to raise. These requirements (themselves potentially problematic in dementia) also necessitate a delay in responding once the bell has rung, which in itself could affect a participant's ability accurately to respond if they have impaired delayed recall.

Thus, although the MBAT may appear relatively simple to an observer, it could be challenging for a person who has deficits of cognition and executive function. The researcher hypothesised that this may explain some aspects of task performance observed in the PWD group, and potentially have affected the validity of their responses; a small number of participants responded impulsively (raising their hand before the instructions were given), incongruently (raising the attending hand but commenting later that they had not been attending), ambiguously (half raising a hand then putting it down), or not at all.

It is also possible that the lack of awareness of impairment ('anosognosia') typical of Alzheimer's (Lorenzo & Tamietto, 2008) could combine with the deficits detailed above to further problematise reliance on the validity of participant responses.

Potential validity issues for the CAMS-R

The CAMS-R (a self-report measure) was administered only to the dementia sample. The null finding for the exploratory hypothesis may have been influenced by the additional difficulty which may be experienced in self-report in this population (see above, p.68).

Limitations

Power issues and Type II error

Insufficient power may have affected the outcome of analyses in a number of ways. Required group size had been calculated to achieve sufficient power in an independent groups t-test to detect a medium effect. This had produced a requirement of 51 participants in each group. This had already been met for the OA comparison group, with 55 participants. Forty-six PWD were recruited and seen for the study, getting close to the required level. However as only 34 were included in

the analyses, for reasons covered above under 'Missing data for the MBAT' (see above, p.83), the study was underpowered to detect medium effects.

Type II error is also more likely to be present in the results of non-parametric tests (Field, 2013), which have lower power. As a non-parametric test (Mann Whitney U) was required for analysis of the main hypothesis due to the abnormal distribution of the data, this may also have contributed to the non-significant findings.

Scores between the two groups on the primary hypothesis (difference in performance on the MBAT) did differ in the tentatively expected direction (with PWD having a lower median score), and this was associated with a small effect size (of 0.9). It is possible that the non-significant finding for this analysis represents Type II error, with the effect being significant (though small), but with the study underpowered to detect it.

Testing situation

Although the MBAT has ecological validity as a task of mindfulness practice, the wider testing situation was less representative of a real world meditation setting. Care is taken in meditation courses to aid focus and concentration by reducing or removing sources of external distraction. Such a level of control was difficult to achieve in participants' homes, where the majority of testing for the PWD sample took place. Sometimes family members/partners were present, occasionally presenting a distraction to the participant. The researcher found some benefit from including family members in the process of socialising the participant to the testing situation (such as aiming for a quiet environment, with no prompting or intervention on the tasks), but this was not always wholly successful..

Additionally, participants were asked to complete a substantial testing battery immediately before the meditation task, which would not occur in the natural setting of an MBCT for depression group. The extended testing period may have

contributed to psychological fatigue, which has been shown to affect cognitive performance (van der Linden, Frese, & Meijman, 2003).

Implications for future research

Given the pattern of findings and the underpowered nature of the study, future research should aim to replicate the study with an adequate sample size, while reducing as far as possible factors which may have affected the validity of the testing process. This might include recruiting a more homogeneously high-functioning dementia sample (e.g. by requiring a recent, higher cut-off on the ACE).

It could be useful for future researchers to incorporate a more formal measure of task comprehension than was used in the current study, and for this feedback to be sought immediately after the MBAT is administered (rather than at the end of a longer battery of testing) to reduce the potential impact of dementia-related deficits on participant responses. Having more reliable information as to the participants' qualitative understanding of the measure could aid its future development for this population. This might include the incorporation of more scaffolding elements into the mindfulness task, such as shorter intervals and/or additional verbal and visual cues, as used with the more impaired care home sample studied by Chan (2015) and Churcher-Clarke (2015). This would still retain the face validity of the MBAT, as it would parallel the introductory mindfulness of breathing exercises often used in meditation courses.

Delivering the MBAT in the context of a more tightly focused battery of assessments could also reduce the potential for participant fatigue which may influence performance.

Acknowledging the problematic elements of any task involving self-report would also suggest the need to develop alternate measures of the current construct of interest (the attentional aspect of mindfulness as represented by attention to the breath) through an objectively observable behaviour, in line with a methodologically behaviourist stance. Another avenue would be to identify a different aspect of

mindfulness practice which could be operationalised and measured as an observable behaviour. A compromise approach might focus on retaining the introspective aspect of the MBAT but further establishing (or disproving) its construct validity. One element of this could be establishing convergent validity through association with an observable behaviour representing the same construct (some work has already been done in this area - see above, p.74). Frewen and colleagues have also suggested the possibility of functional neuroimaging to investigate the neural correlates of MBAT performance, based on the example of similar investigations done for the related concept of mind-wandering (Andrews-Hanna et al., 2010, cited in Frewen et al., 2011).

The current study was a cross-sectional study involving participants naïve to meditation. A future study could usefully incorporate a longitudinal element, to move beyond measuring baseline performance on the MBAT to exploring whether people with dementia are able to increase their level of mindful attention through practice (which would be a clinically relevant goal).

Clinical implications

The current study was aimed at developing the theoretical base for future mindfulness interventions for depression, rather than piloting a specific clinical intervention. However, it demonstrated that a majority of participants with dementia were able to engage with the task, and a substantial minority reported enjoying it and/or finding it relaxing.

We may therefore anticipate more generally that, since some higher-functioning people with dementia are able to engage in the mindfulness process, mindfulness may be seen as a potential mechanism of change for future clinical interventions with this population.

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Part 3: Critical appraisal

Introduction

This paper contains personal reflections on challenges that arose in my research process. I comment on how I dealt with these, as well as making suggestions that may aid future research. My focus is on issues and dilemmas related to recruitment, consent and data collection.

Recruitment issues

When originally proposed, my research project had been designed as a cross-sectional within-group study of people with dementia. That study was powered to detect a medium effect size in a regression analysis, producing a required sample size of 59. However it became apparent after several months of data collection that this sample size was unachievable. This led to a change of design, to a between-groups approach which meant that the study was less underpowered. The major impact that recruitment problems had on my research process led me to reflect on some of the key factors I experienced as contributing to this difficulty.

Unreliable self-report during screening

As I note in the 'Results' section of the empirical paper, 46 people with dementia were recruited for the study (which would have taken it close to achieving the planned sample size). One of the reasons that six participants' data had to be discounted from analysis, affecting power, was ineligibility due to previous experience of CBT or meditation being revealed at a late stage. This also meant that a substantial amount of data collection time was spent with participants who were ineligible for the study.

Retrograde amnesia is a recognised deficit of dementia (Salmon & Bondi, 2009), hence it is considered best practice when diagnosing the person not to rely on self-report alone, but to get collateral input from someone who has known the person well over a long period (Neugroschl, 2016). For future research, it is important to remain mindful that memory difficulties can affect responses at all stages of the recruitment and testing process, not only during formal testing.

Therefore in future research, it could also be prudent to seek collateral information during the screening process, if an accurate response is considered essential for the study. However it must also be acknowledged that this will not always be possible, as it relies on reliable collateral sources being available and accessible, which clinical experience suggests is not always the case.

Inclusion criteria

With hindsight, it is arguable that the decision completely to exclude prospective participants who disclosed past meditation experience could have been disproportionate. Previous studies have attempted to account for past experience by including a measure of the amount of previous meditation practice (Frewen, Hargraves, DePierro, D'Andrea, & Flodrowski, 2016). This could be sensible in future research.

Impact of health problems

The risk of dementia increases with age (with my sample having a mean age of 82), and with increasing age some level of physical change/deterioration is expected (Ricklefs & Finch, 1995), though the nature and impact of this will vary greatly, depending on a range of biopsychosocial factors. This can lead to a wide variation in physical health and frailty in this population, with a proportion of older people living with multiple comorbid conditions in addition to dementia (World Health Organization, 2012). This can have a major impact on recruitment to research (MacFarlane et al., 2015).

I saw at first hand the impact of this variability in the health of participants on my ability to recruit sufficient numbers to power my study. Several potential participants were excluded at an early stage either through screening their records, or by their self-report during telephone screening, as their physical health status meant that they would be unlikely to be able to engage with the research tasks, or might experience harm. One example was a prospective participant with a diagnosis of COPD, where research suggests that breath-focused meditation tasks could

increase anxiety (R. R. Chan, Giardino, & Larson, 2015). A further prospective participant died before being seen.

The burden of health conditions extended beyond the potential impact of symptoms on the testing process. I screened several participants who were involved in multiple services for their physical health and associated support needs, with regular appointments both at home and across different sites. It was common to hear in such cases that people did not wish to engage in an additional appointment to complete the research tasks, even if they supported the research aims in principle. Research supports the idea of perceived inconvenience and burden as deterrents to dementia research participation (Connell, Shaw, Holmes, & Foster, 2001; Dunn, Hoop, Misra, Fisher, & Roberts, 2011; Karlawish, Casarett, Klocinski, & Sankar, 2001).

Some participants consented to and began the research appointment, yet we agreed to end before the testing was complete due to their disclosure (or non-verbal communication) of tiredness or discomfort. Furthermore, some participants were seen across more than one session to allow for fatigue (which then had an effect on the time available to see additional participants).

I attempted to reduce attrition of potential recruits by maintaining intermittent contact (where consent for this was obtained) with those whose health was fluctuating, as they anticipated possible future improvement (and thus ability to engage in the study). This resulted in a small number of additional participants.

It seems inevitable that health-related difficulties will affect recruitment on a study of people with dementia, especially given that the dementia is more likely to be present in the context of existing health vulnerabilities and conditions including diabetes, obesity, smoking, and hypertension (Baumgart et al., 2015).

Allowing as much time as possible for data collection, expecting attrition among those who consent, and having access to a range of recruitment sources could all be useful preparation for future similar studies.

Over-research

All the memory services involved in the study were highly supportive of research, in line with Memory Services National Accreditation Programme (MSNAP) standards (Hodge, Hailey, & Orrell, 2016). This provided a supportive basis for recruitment.

There were nevertheless challenges present. When a service was very research-active (as were some of those in the current study) senior staff highlighted the need to be wary of potentially 'over-researching' prospective participants (<http://www.ethicsguidebook.ac.uk/Over-researched-groups-86>). Previous opinion from another review of recruitment challenges supports the idea that lack of competing studies can be a major influence on the ability to recruit, beyond the other inherent challenges within this population (Grill & Karlawish, 2010) .

I and the other data collectors attempted to manage this by prioritising approaches to those not involved in a current study. Where we did make tentative contact with patients involved in other studies, it was not uncommon for them to decline involvement while the current study was ongoing.

Personal qualms about recruitment

During the study I realised that I experienced qualms about approaching and seeking participation from people with dementia. This was particularly the case when the participant was someone I had assessed for dementia in my clinical work, where I had concerns that their positive experience of our contact might mean they felt obliged to help me, and where I felt, since their diagnosis was recent, they may still be going through a process of adjustment. Furthermore, cognitive testing has the potential to trigger emotional distress in vulnerable participants by reminding them of cognitive difficulties to which they have not adjusted (J. M. Lai, Hawkins, Gross, & Karlawish, 2008).

However I was also aware that being too tentative could hinder recruitment for a study which aimed to benefit people with dementia (and thus their carers) in the

future. I used research supervision to discuss these dilemmas, and to take a more balanced view. This developed further during my contact with participants as I gained more evidence on their actual responses to the research process.

I realised that it was helpful to remind myself that I was communicating sensitively and respectfully with potential participants, and providing information in an ethical way, in line with the guidance on 'Informed consent to dementia research' (Alzheimer Europe, n.d.). This always allowed people to decline participation, and it was more likely that the sense of 'pressuring' was a fear of mine rather than being perceived by the participant.

I also reflected that offering the opportunity for research participation was a way of respecting the personhood of a person with dementia (Kitwood & Bredin, 1992) – by not pre-assuming that they lacked the ability to make their own decision, but rather assessing this through our interaction. I also realised that for some participants, research involvement was very much in line with their personal values. Several told me about past careers in teaching and science which motivated them to assist; I felt this suggested that participation was an opportunity to reconnect with a valued part of their identity. It was also clear that some participants welcomed the stimulation and social contact involved in the research visit. It was heartening to have evidence that the process could be experienced as valuable in its own right for these participants.

Consent issues

Avoiding misunderstandings during screening calls

Some prospective participants expressed confusion on hearing from me. They had not retained the memory of their consent to research contact, and did not understand why someone from the memory service was contacting them. Others interpreted my summary of the study aims as suggesting that they themselves had depression, and were keen to assure me 'they were OK' and didn't need help in this regard.

Conversely, some participants, or their carers (if they had been delegated to make practical arrangements) seemed to want to book the appointment time in before I felt that they had received sufficient information to provide informed consent. My perception was that this was a response reflecting behaviours rehearsed in previous contact with clinical services. As I was calling from a service they had previous contact with and support from, they may have assumed I was offering a similar service. Were this the case, they would not have perceived a need for more information from me in order for them to agree to an appointment.

A further number, hearing I was based in the memory service for the research, were keen to participate as they felt it could help them with their memory problems.

Recruiting participants in such scenarios without correcting these assumptions would have been unethical, since the result would have been uninformed refusal to participate, or (more seriously) uninformed consent. Properly informed consent through appropriately communicated information is a prerequisite for ethical research (Alzheimer Europe, n.d.).

Such patterns of misunderstanding about my role and the possible benefit of the research were evident early in my recruitment process. I countered them by adapting the existing recruitment information further, and preparing a telephone script which, while being succinct (important when sharing information with people who are known to have some level of deficit in memory and possibly communication), also ensured that the prospective recruit was aware from the beginning of our conversation of the nature of my role and the purpose of my contact with them. This gave me additional confidence that participant consent was on an informed basis.

Ensuring direct consent from the participant

On a small number of occasions, a carer expressed that they were able to consent to involvement in research on behalf of the person with dementia. While having the support of the carers when arranging appointments was helpful, I was

mindful of the ethical requirement for the current study that the person with dementia themselves must understand and consent to involvement (and have capacity to do so).

Where practical reasons meant it was not possible to get such consent by phone at the time, this was dealt with by ensuring that the information and consent process was thoroughly revisited with the person with dementia on the day of the appointment. On one occasion where I felt the person's own preference might be conflicting with that of the carer, I used time alone with the person with dementia to ensure they understood their right not to take part.

Reseeking consent

On some occasions, participants' understandable difficulties in retaining information meant that I arrived for a research appointment to find that the person had forgotten our previous contact, and their previous agreement to participate.

To try and retain their involvement in an ethical way, I sought their permission to remind them of the purpose of the study, and then resought consent without assuming retention of any of our original discussion. It was clear that these participants retained their capacity to consent when given appropriate information, and wished to participate. Participants often welcomed the reminder calls we offered prior to the appointment, and wherever possible we also sent a reminder letter as an additional cue.

Challenges of data collection

Practicalities limiting volume of participants seen

Given the relatively limited time available for data collection, I had hoped to be able to see up to three participants a day. However this proved unrealistic. The length of time taken by each participant to complete the testing battery was hard to predict, being influenced by their level of functioning, communication style, and need for breaks. This made it impractical to book in testing appointments close together.

Collecting data across four boroughs also meant allowing for considerable travel time between participant visits.

Benefits and disadvantages of home visits

Being able to do home visits was essential to recruiting people with dementia to the study. Both the clinical experience of the study team and existing research on factors influencing dementia research participation (e.g. Karlawish, Cary, Rubright, & Tenhave, 2008) suggest that the convenience of a home visit can compensate for perceived disadvantages of research involvement, facilitating increased participation.

My experience on this study supported this view. Several persons ambivalent about participating were much keener to do so as soon as they understood that the researcher could come to see them at home – it was important to inform them of this at an early stage in the conversation. Pragmatically home visits can also benefit the researcher. While seeing people in clinic could be more efficient than travelling between home appointments, in a population with memory difficulties that may affect attendance at pre-arranged appointments, a home visit is more likely to facilitate the appointment successfully completing. As noted under 'Reseeking consent' (above, p.113), I experienced contact with participants who had forgotten our arrangement but were happy to continue when I arrived at their home and resought informed consent. Had these individuals been offered a clinic appointment, it is possible that they would not have attended and that a data collection opportunity would have been lost.

While the 'Limitations' section of the empirical paper acknowledges some difficulties that home visit settings may have imposed on the testing situation (such as increased distraction), overall it seemed that the benefits of home visits for both the participants and me outweighed the disadvantages.

Involvement of carers/family members

A family member or carer was frequently present during the research appointment. Research has demonstrated that carers (including formal study partners) can play an essential role in supporting people with dementia's involvement in research (Black, Taylor, Rabins, & Karlawish, 2014), and my own experience was that it was beneficial, both in helping the participant feel at ease, and in facilitating practical elements of the appointment (such as reminding the person about the appointment). However I also experienced some challenges through the presence of the carer, in the form of distraction, or their attempts to help the participant with the research tasks.

Once I had experienced the process several times, I started to develop ways of working which explicitly incorporated the carer – welcoming their involvement and socialising them to the testing process (for example, explaining why I asked them not to help their family member answer questions). In effect I was pragmatically seeking informed agreement from the carer as well as consent from the person with dementia, recognising the role of the carer within the research process.

On a minority of occasions, the carer was present in the home but not consistently in the same room, and happy to 'let us get on with it'. However given that testing extended over at least 1.5 hours, my presence represented a substantial interruption to their daily routine. In such cases, interruptions into testing were the norm. On one memorable occasion, a family member entered the room during the meditation task, and expressed concern that the participant was apparently asleep and exhausted by testing. I and the participant were able to reassure them that the participant's eyes were closed only as part of the mindfulness exercise.

In future similar studies, I would strongly recommend similarly involving the carer (when they are present for testing) in an initial discussion of the logistics of the appointment, in order to allay any concerns, and reduce the amount of distraction and interruption that may occur.

Clinical concerns in the research context

Although participants had been briefed that the study was not designed to individually assess or aid their memory difficulties, it was understandable that the testing process led some to ask questions and express concerns about their performance, in the context of their known memory problems and dementia diagnosis.

It was helpful to have considered the possibility of this occurring ahead of time as part of the parent study's protocols. I was able to respond to queries in a general way, including giving basic and sensitive feedback on tests such as the ACE III, and encouragement about accessing further support from sources such as the memory service, GP, or local dementia adviser service. I learnt to be prepared with contact details to facilitate this, since the person with dementia not infrequently (and understandably) had not retained the memory of their contact at the memory service, or the nature of support they could facilitate.

Being prepared in this way would be sensible for any research involving people with dementia, where there is a possibility for some that participation may elicit concerns which suggest clinical support could be helpful.

Conclusion

A range of factors related to the biopsychosocial nature of dementia as a condition affected the current study in terms of recruitment, consent and data collection. Anticipating such challenges and planning how they are best dealt with or mitigated would be a sensible part of designing future research with this population.

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Appendices

Appendix A: Original confirmation of ethical approval



NRES Committee London - City Road & Hampstead
Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: [REDACTED]
Facsimile: [REDACTED]

16 May 2014

Dr Joshua Stott
Senior Clinical Tutor and Joint Admissions Tutor
University College London
Research Department of Clinical, Educational and Health Psychology
University College London
Gower Street London
WC1E 6BT

Dear Dr Stott

Study title: Exploring cognitive mediation ability in people with dementia: the factors that influence it and effects of difference in ability
REC reference: 14/LO/0554
IRAS project ID: 147241

Thank you for your letter of 07 May 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 Vice-Chair.

We plan to publish your research summary wording for the above study on the HRA 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 REC Assistant Miss Marjolein Groot Blumink, nrescommittee.london-cityroadandhampstead@nhs.net.

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 favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett [REDACTED] the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		01 May 2014
Evidence of insurance or indemnity		26 July 2013
GP/Consultant Information Sheets	1	24 April 2014
Other: CV - Joshua Stott		
Other: CV - Lucy Gore		
Other: Scientific Critique of Aim 1		05 February 2014
Other: Scientific Critique of Aim 2		08 October 2013
Participant Consent Form: Clinical Stage 1	3	24 April 2014
Participant Consent Form: Clinical Stage 2	3	24 April 2014
Participant Consent Form: Control Stage 1	3	24 April 2014
Participant Consent Form: Control Stage 2	3	24 April 2014
Participant Information Sheet: Clinical Stage 1	4	24 April 2014
Participant Information Sheet: Clinical Stage 2	4	24 April 2014
Participant Information Sheet: Control Stage 1	4	24 April 2014
Participant Information Sheet: Control Stage 2	4	24 April 2014
Protocol	2	17 February 2014
Questionnaire: Cognitive Mediation Questionnaire		
Questionnaire: Reed and Clements Assessment		
Questionnaire: Thoughts/feelings/behavioural differentiation assessment		
Questionnaire: Emotion Recognition Test		
REC application		04 March 2014
Response to Request for Further Information		07 May 2014
Summary/Synopsis	1	17 February 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed

guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

14/LO/0554	Please quote this number on all correspondence
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We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely



pp
Mr Hari Jayaram
Vice Chair

Email: [Redacted]

Enclosures: "After ethical review – guidance for researchers" [\[SL-AR2\]](#)

Copy to: *Suzanne Emerton*
Dr Tumi Kaminskas, North Central London Research Consortium

Appendix B: Confirmation of ethical approval for substantial amendment to the study



Health Research Authority

NRES Committee London - City Road & Hampstead

Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Tel: [REDACTED]

06 July 2015

Dr Joshua Stott
Senior Clinical Tutor and Joint Admissions Tutor
University College London
Research Department of Clinical, Educational and Health Psychology
University College London
Gower Street London
WC1E 6BT

Dear Dr Stott

Study title: Exploring cognitive mediation ability in people with dementia: the factors that influence it and effects of difference in ability
REC reference: 14/LO/0554
Amendment number: Substantial Amendment 1
Amendment date: 17 April 2015
IRAS project ID: 147241

The above amendment was reviewed on 19 June 2015 by the Sub-Committee in correspondence.

Ethical opinion

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Interview schedules or topic guides for participants [MBAT script]		
Notice of Substantial Amendment (non-CTIMP) [including more routine clinical data, addition of mindfulness]	Substantial Amendment 1	17 April 2015
Other [Sections of original submission affected by proposed amendments]		
Participant information sheet (PIS) [Clinical PIS Stage 1 CB]	5 (clean)	10 April 2015
Participant information sheet (PIS) [Clinical PIS Stage 1 CB]	4-5 (tracked)	17 June 2015
Validated questionnaire [CAMS R questionnaire with instructions]		

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

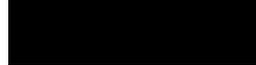
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

14/LO/0554:	Please quote this number on all correspondence
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Yours sincerely



Dr Koula Asimakopoulou
Acting Alternate Vice Chair

E-mail: 

Enclosures: List of names and professions of members who took part in the review

*Copy to: Dr Tumi Kaminskas, North Central London Research Consortium
Portfolio Suzanne Emerton*

Appendix C: Script for Meditation Breath Attention Task (MBAT) (Frewen et al., 2008)

What I'd like you to do first is just to sit at your chair quietly, and simply focus your mind on your breathing. I know that you may have had to rush to get here, and may not be feeling very much at ease. So please just take a few moments and relax your mind and body before we get the study started. It's important for you to feel relatively relaxed before we begin with the actual meditation. So please just focus on your breathing and allow yourself to relax.

[pause 2-3 minutes]

Okay, if you are ready now and feeling relaxed enough to begin, we'll get started...

What I'll ask you to do first is to close your eyes. This might be a little awkward at first, but don't worry, this feeling should soon subside. [Note: Participants eyes remain closed now for the duration of the exercise]

Now, and for the duration of this exercise, please begin to breathe both in and out through your nose. Please do not breathe through your mouth. I'll let you get used to this process now for a few breaths. [pause 5-10 seconds]

Now please focus your attention on your breathing, and notice *how* you are breathing. [Not expecting an actual answer:] Are you breathing slow or fast? Where do you notice your breath? Is it in your chest or your abdomen? Just bring a gentle interest and inquisitive nature into the process of your breathing.

[pause approx 5 seconds, then appropriately paced...]

Let's observe our breathing process together now, from inhalation to exhalation. Notice where your inhalation starts, at the nostrils. Now observe, if you can, your breath travel down your nasal passage, and down into your lungs. Observe it there, and then observe the moment when the inhalation ends and the exhalation begins. Observe your breath travel up again now and out your nose.

[pause approx 5 seconds]

We will now do this again for 3 breaths, counting silently to ourselves before each breath. Let's practice...

[instructions are delivered slowly, as a means of pacing participants' breathing...]

Say silently to yourself, "1". And now, observe your breath as you breathe in through your nostrils, observe your breath travel down into your lungs, observe the moment when the inhalation ends and the exhalation begins, and observe your breath now travel up again and out your nose.

[pause 2-3 seconds]

Now say silently to yourself, "2". And now again, observe your breath as you breathe in through your nostrils, observe your breath travel down into your lungs, observe the moment when the inhalation ends and the exhalation begins, and observe your breath now travel up again and out your nose.

[pause 2-3 seconds]

Now say silently to yourself, “3”. And now once more, observe your breath as you breathe in through your nostrils, observe your breath travel down into your lungs, observe the moment when the inhalation ends and the exhalation begins, and observe your breath now travel up again and out your nose.

[pause 2-3 seconds]

Now please continue to count your breaths, on your own, observing your breathing process in this way for a total of ten breaths, beginning again at 1 and ending at 10. Begin by saying silently to yourself, “1” and observe the process of your breathing through the inhalation to the exhalation. Please try to keep your breath slow and relaxed.

[pause approx 45-60 seconds, saying at approx 20 seconds: “Please just continue breathing in this way, keeping your eyes closed throughout, including when you have finished observing your tenth breath...”]

Okay, I will assume now that you are done... Now you may have found this somewhat easy, or you may have found it difficult to keep your attention focused on your breathing process. That’s okay. It’s very normal to eventually become distracted by thoughts while trying to attend to your breath; almost everyone gets distracted eventually and this is okay. It’s simply a normal part of the nature of the human mind.

In fact the task that we will now be doing is one that is designed to measure how well you are able to stay focused on your breathing, and not become too distracted by various thoughts and feelings that you might have during meditation.

What you should do during this next meditation is just to sit silently, staying focused on the process of your breathing, but this time **WITHOUT** counting your breaths. Just observe each breath, from inhalation and exhalation, as we have been doing. This meditation will be for [time in minutes, in our study this was 15 minutes].

If at any time during the meditation you find that your attention wanders to thinking about something, daydreaming about the future or remembering something from the past, or you experience a feeling or an emotion starts to come up, that’s okay, there’s no need to judge yourself or get upset about this. Simply when you notice this happens, gently re-focus your attention, as best you can, back to your breathing.

To measure how well you are able to keep your attention focused on your breathing, at several points during the 15 minute meditation, you will hear a chiming tone like this [make sound]. At these times, please raise your [right/left] hand if at that time your attention was focused on your breathing, and your [left/right] hand if you were distracted and focusing on thoughts, memories, emotions, or other things [counterbalance hand raising order]. Don’t worry about remembering which is left and which is right though, I’ll repeat those instructions each time the chime rings.

If you notice your attention wanders at times when the bell hasn’t just rung, you don’t have to raise your hand. At these times, just gently re-focus your attention, as best you can, back to your breathing. You only have to raise your hand to indicate whether your attention is on your breathing at the times when the bell is rung, and not at other times.

Okay, we will start the meditation now. Please begin again to focus your attention toward the process of your breathing. Observe your breath as you breathe in through your nostrils, observe your breath travel down into your lungs, observe the moment when the inhalation ends and the exhalation begins, and observe your breath now travel up again and out your nose. Continue to do this now, until you hear the first bell, keeping your eyes closed throughout. Remember, you don't need to count this time. Just focus on your breathing...

[Bell is chimed at 3 minute intervals. At these time points, after chiming the bell, say: "Now, keeping your eyes closed, please raise your [right/left] hand if you were focusing on your breathing, and your [left/right] hand if you were distracted or were focusing on thinking, remembering something, or paying attention to feelings or emotions."]

[Record responses for each participant as a repeated measure]

[Then say: "Okay, now return your focus to your breathing. Observe the process of your breathing for each breath through the inhalation to the exhalation, trying to keep your breathing slow and relaxed."]

[Repeat for chimes 2-5. After fifth chime say: "Thank you. You have now completed the mindfulness meditation exercise, and can open your eyes."]

Meditation Breath Attention Score for each participant is simply the sum of the number of times the participant indicated his or her attention was focused on his or her breathing during the meditation exercise.

Appendix D: Cognitive and Affective Mindfulness Scale, Revised (CAMS-R)

CAMS-R

People have a variety of ways of relating to their thoughts and feelings. For each of the items below, rate how much each of these ways applies to you.

For each question choose from the following alternatives:

1 = Rarely/Not at all

2 = Sometimes

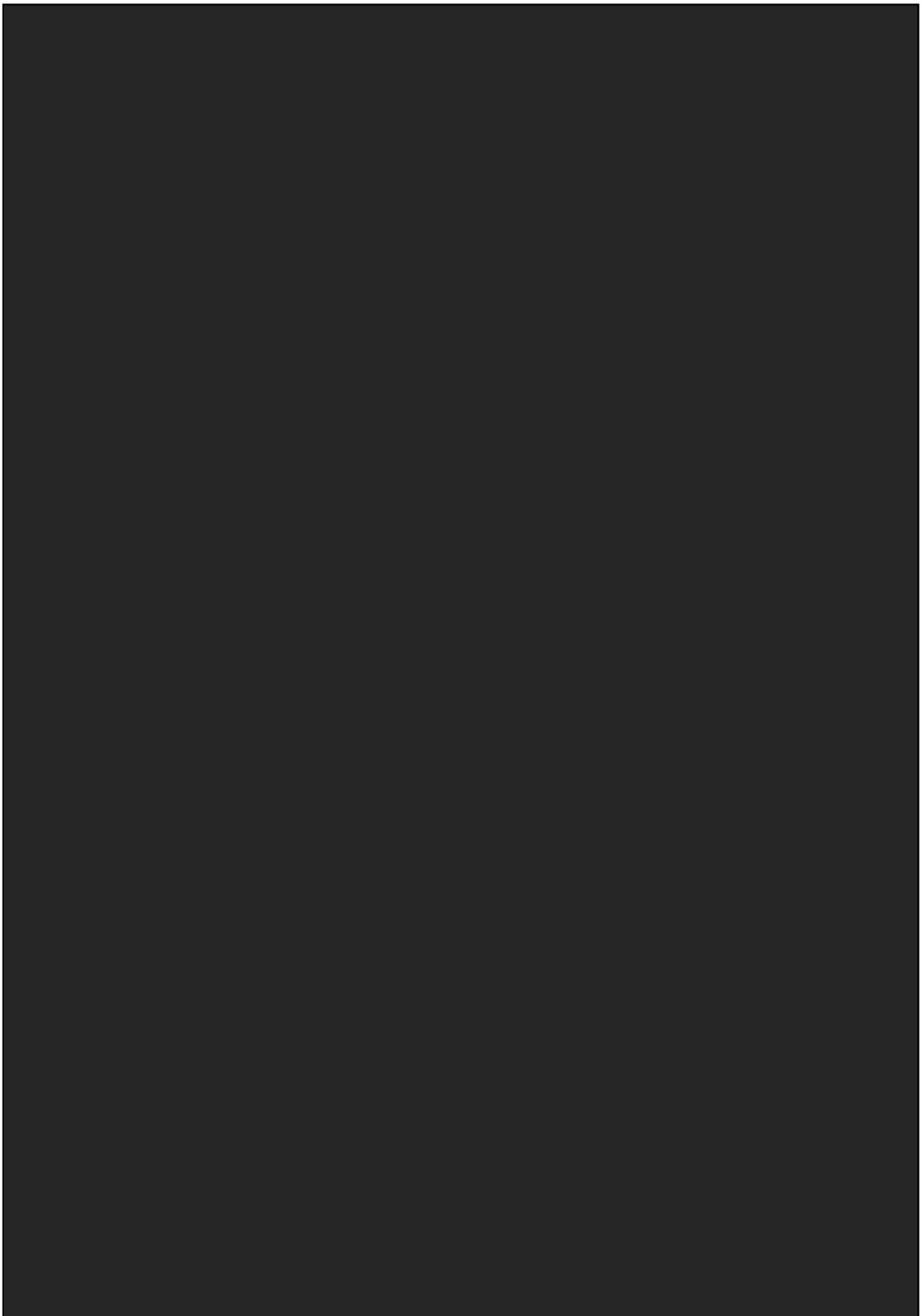
3 = Often

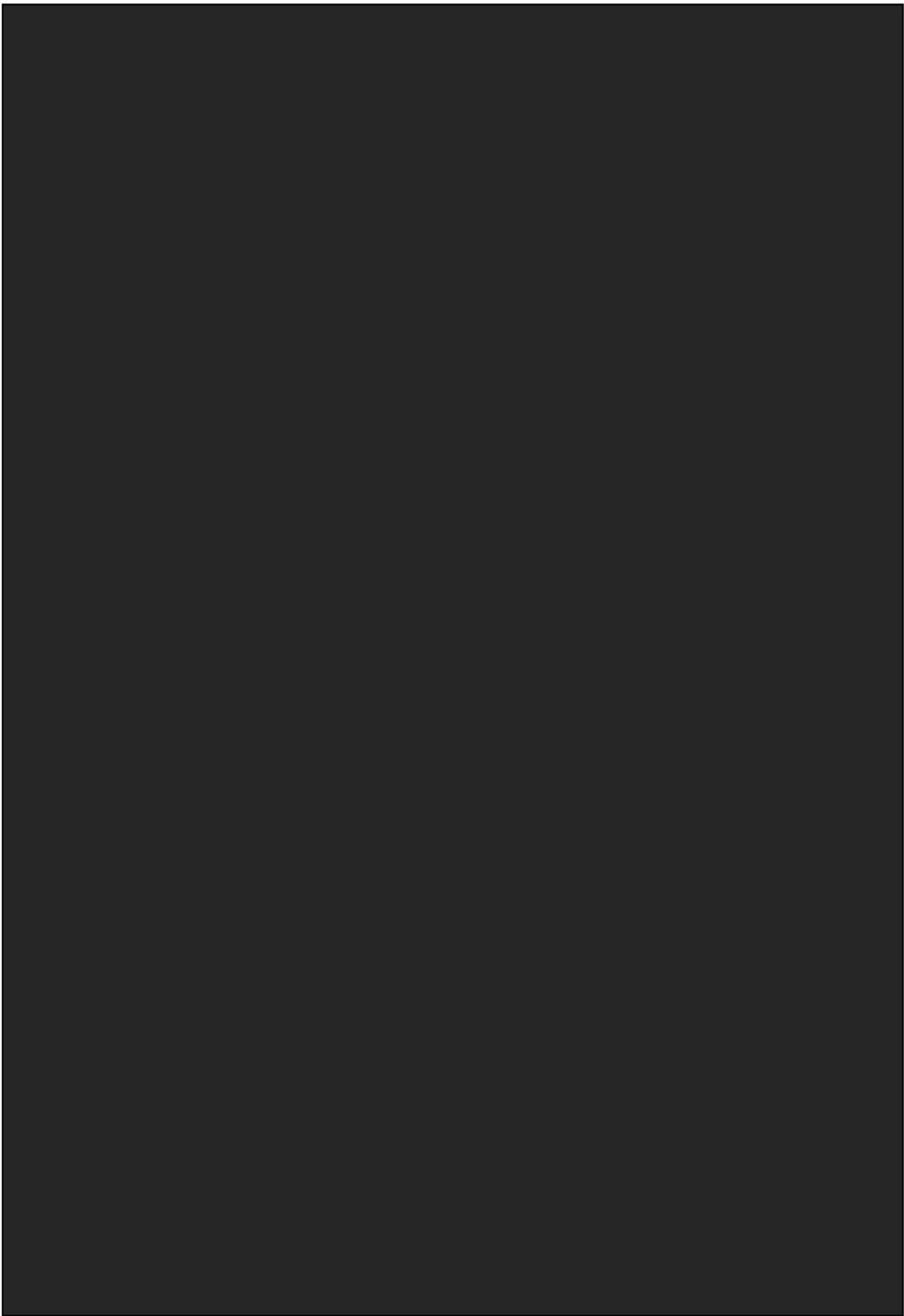
4 = Almost always

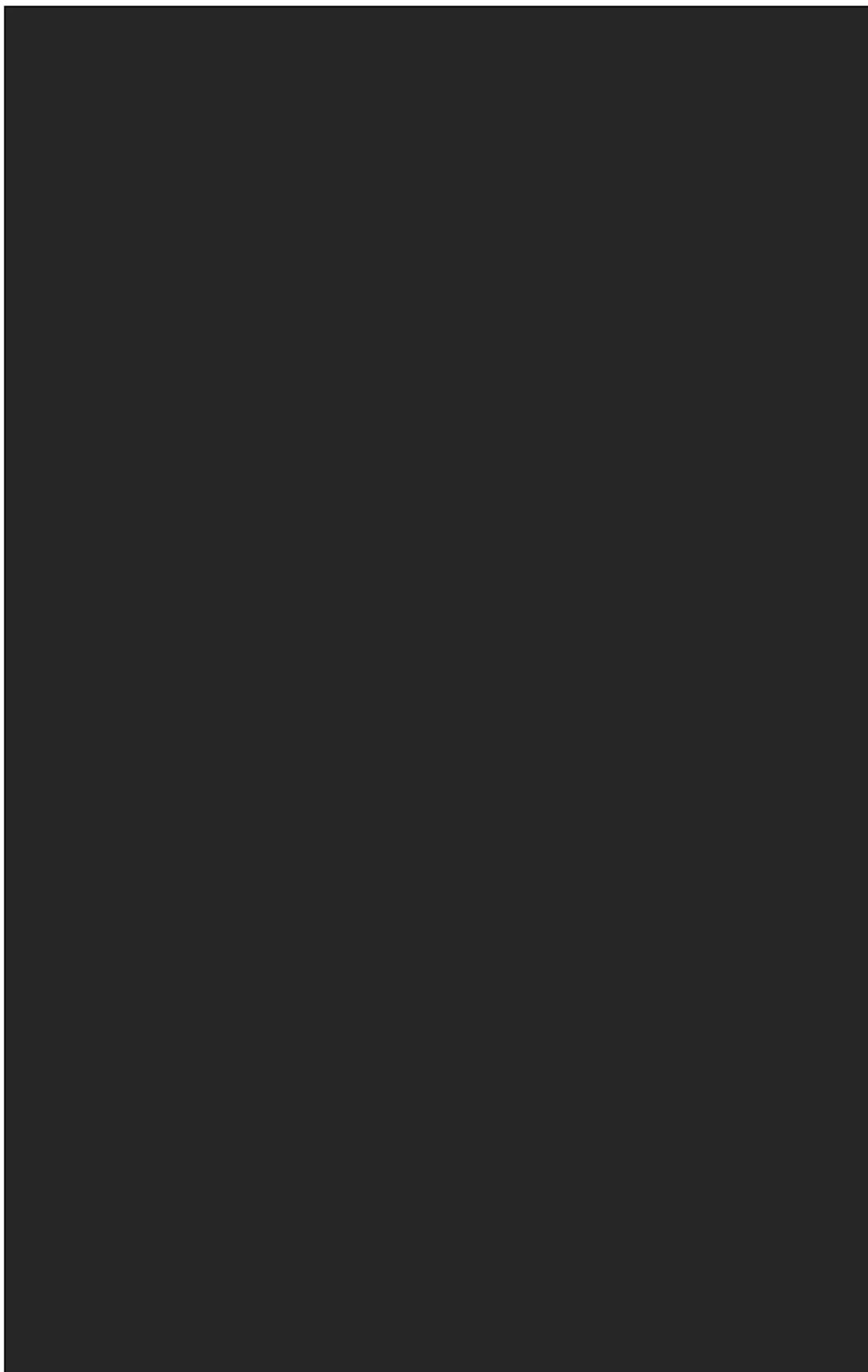
		Rating
1	It is easy for me to concentrate on what I am doing.	
2	I am preoccupied by the future.	
3	I can tolerate emotional pain.	
4	I can accept things I cannot change.	
5	I can usually describe how I feel at the moment in considerable detail.	
6	I am easily distracted.	
7	I am preoccupied by the past.	
8	It's easy for me to keep track of my thoughts and feelings.	
9	I try to notice my thoughts without judging them.	
10	I am able to accept the thoughts and feelings I have.	
11	I am able to focus on the present moment.	
12	I am able to pay close attention to one thing for a long period of time.	

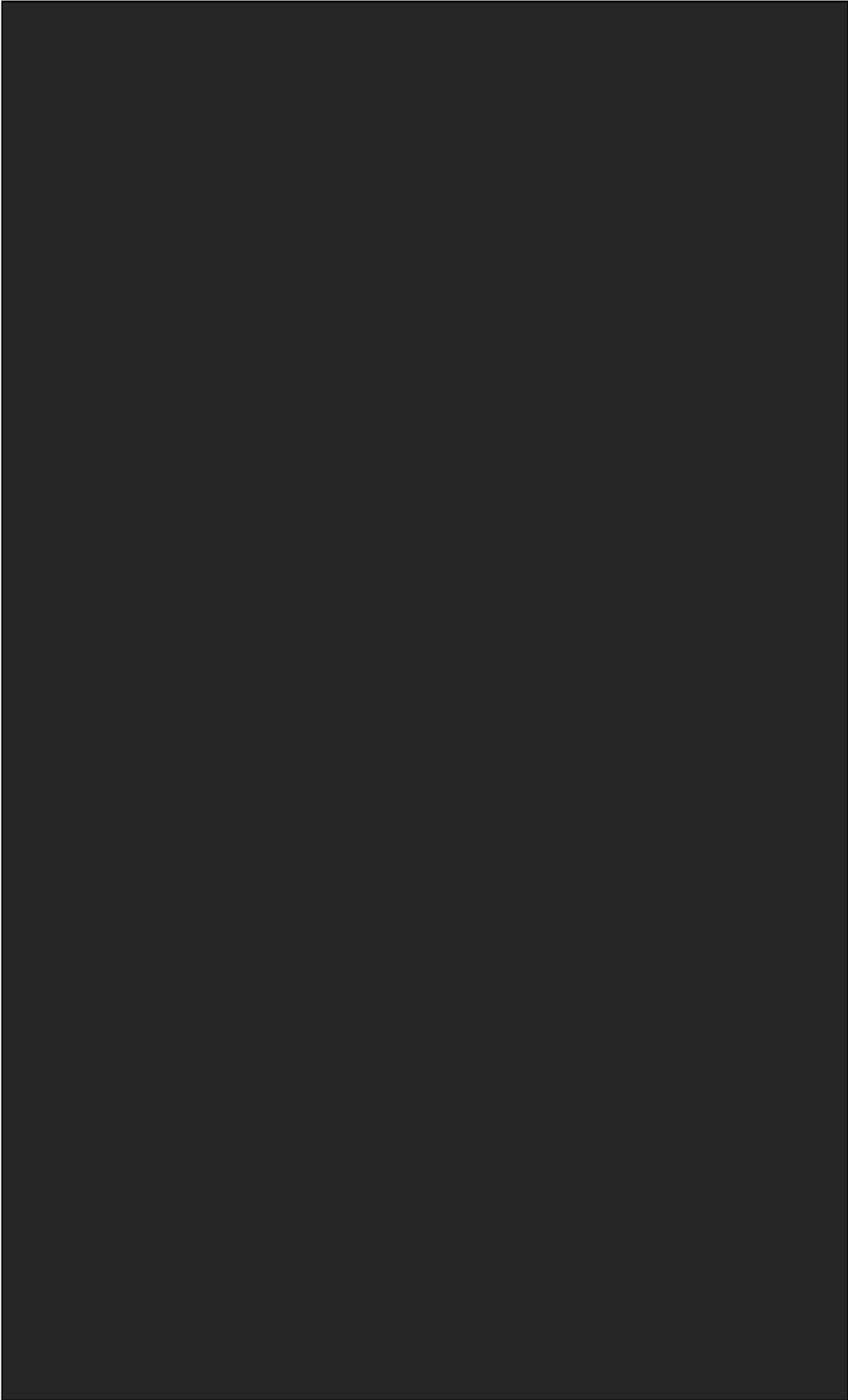
Appendix E: Trail Making Test (TMT) Parts A and B

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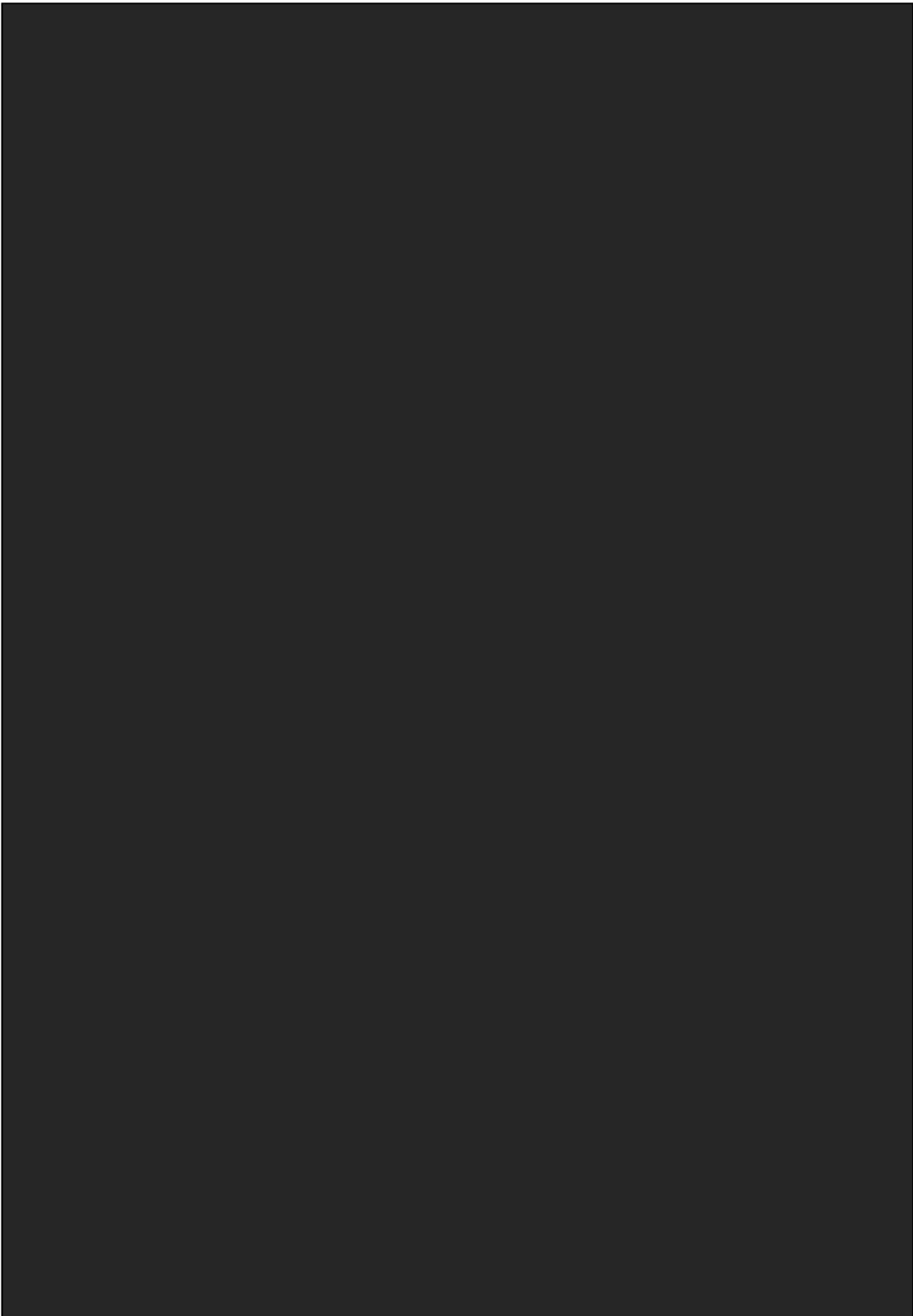


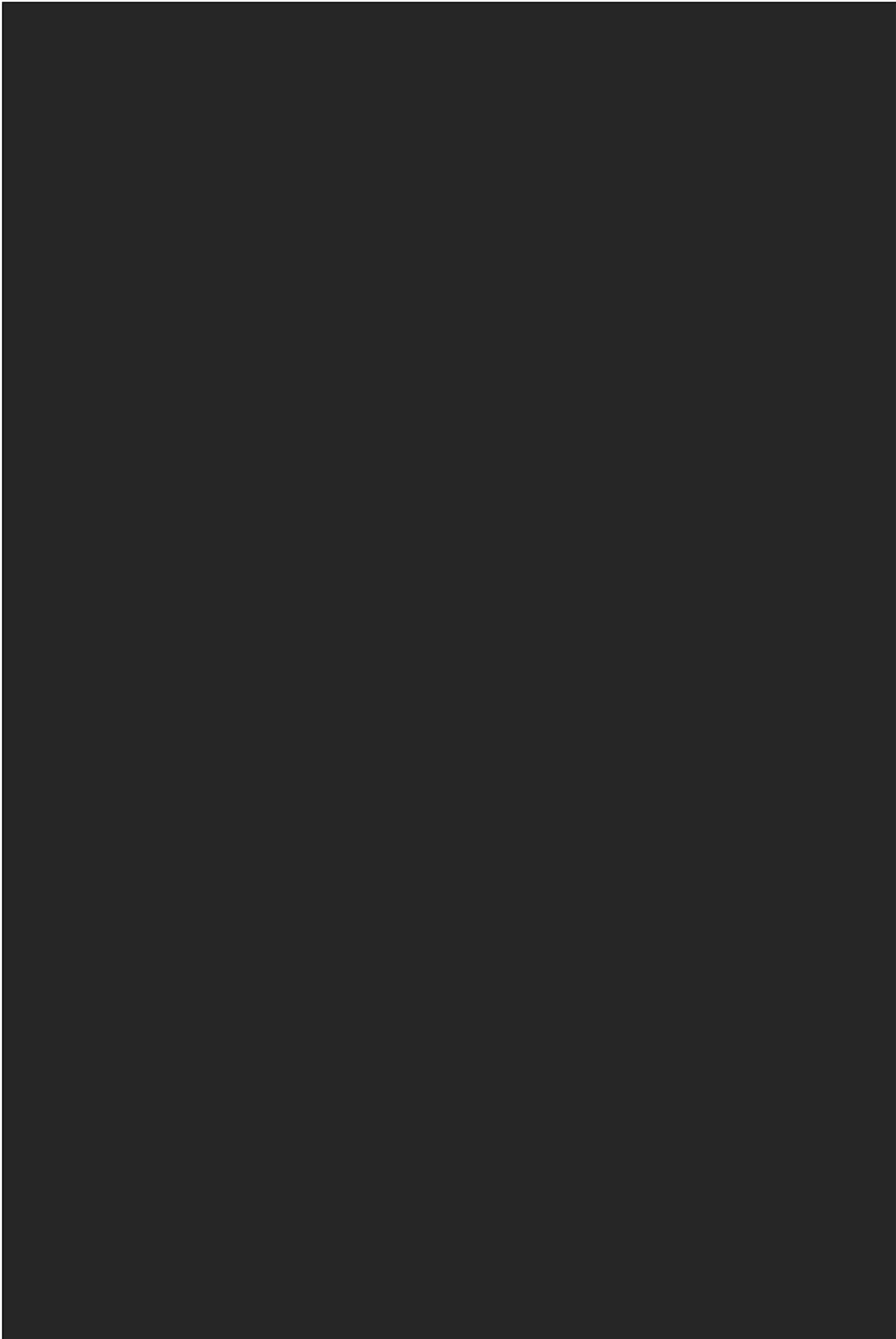


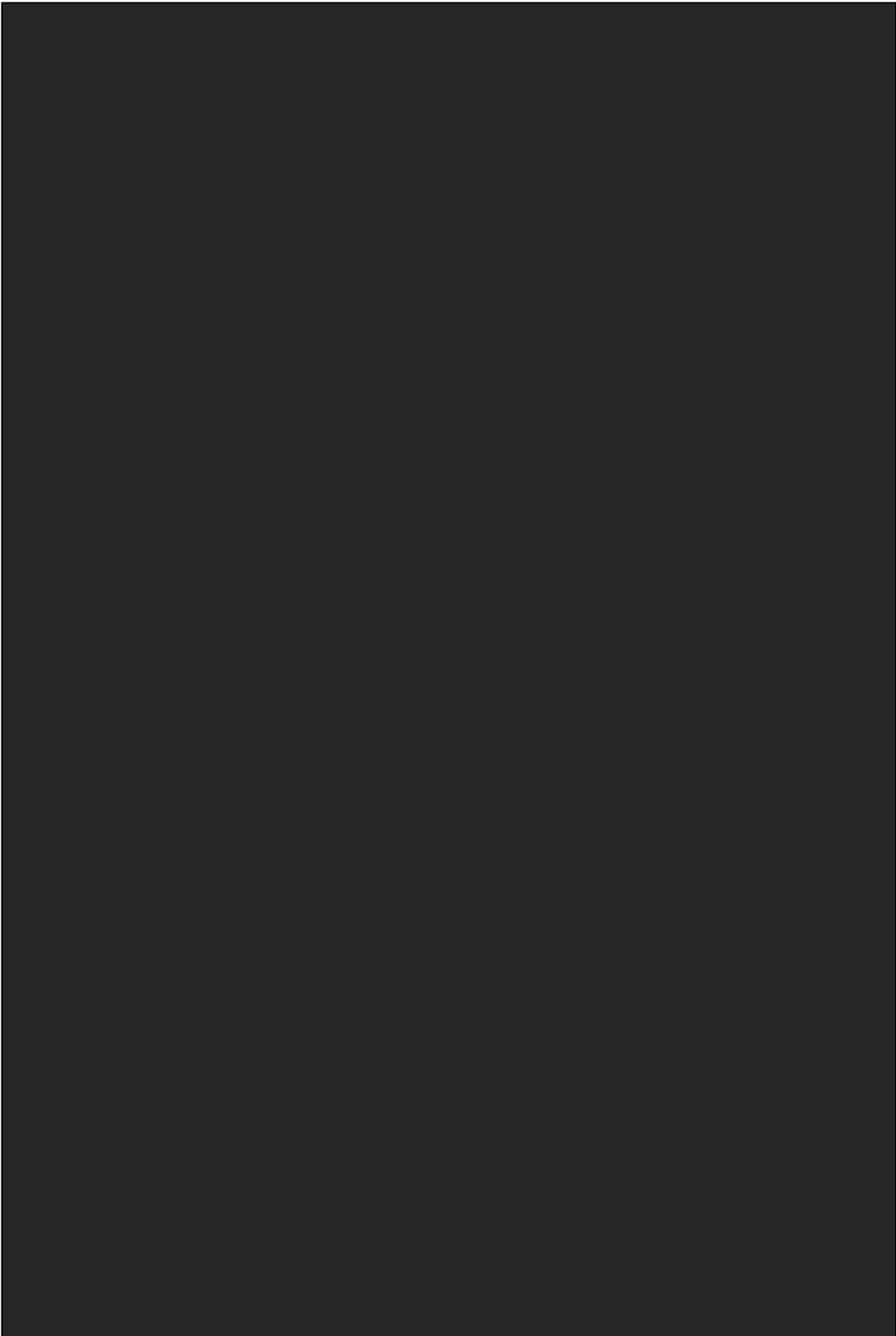


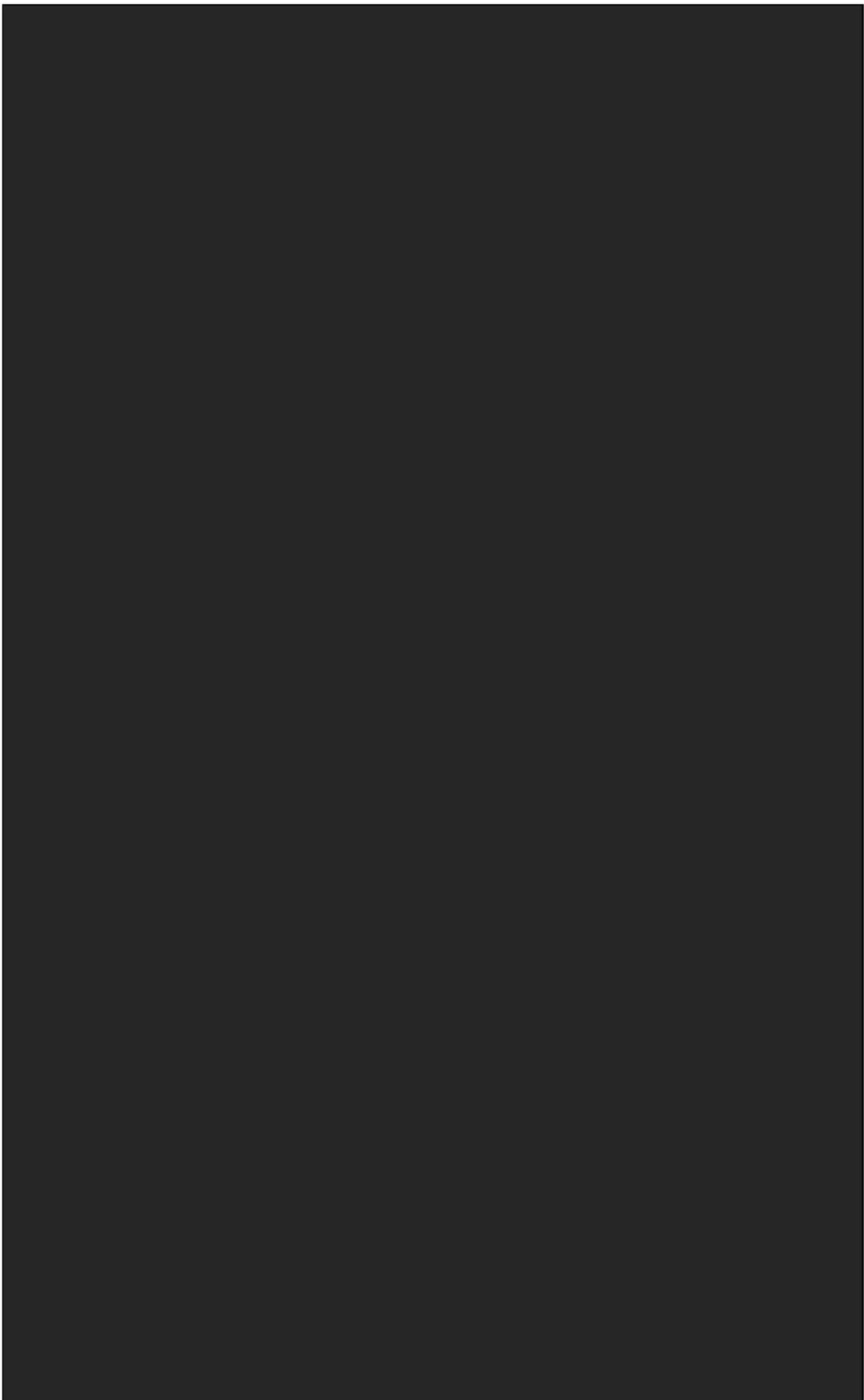
Appendix F: Addenbrooke's Cognitive Examination III (ACE III)

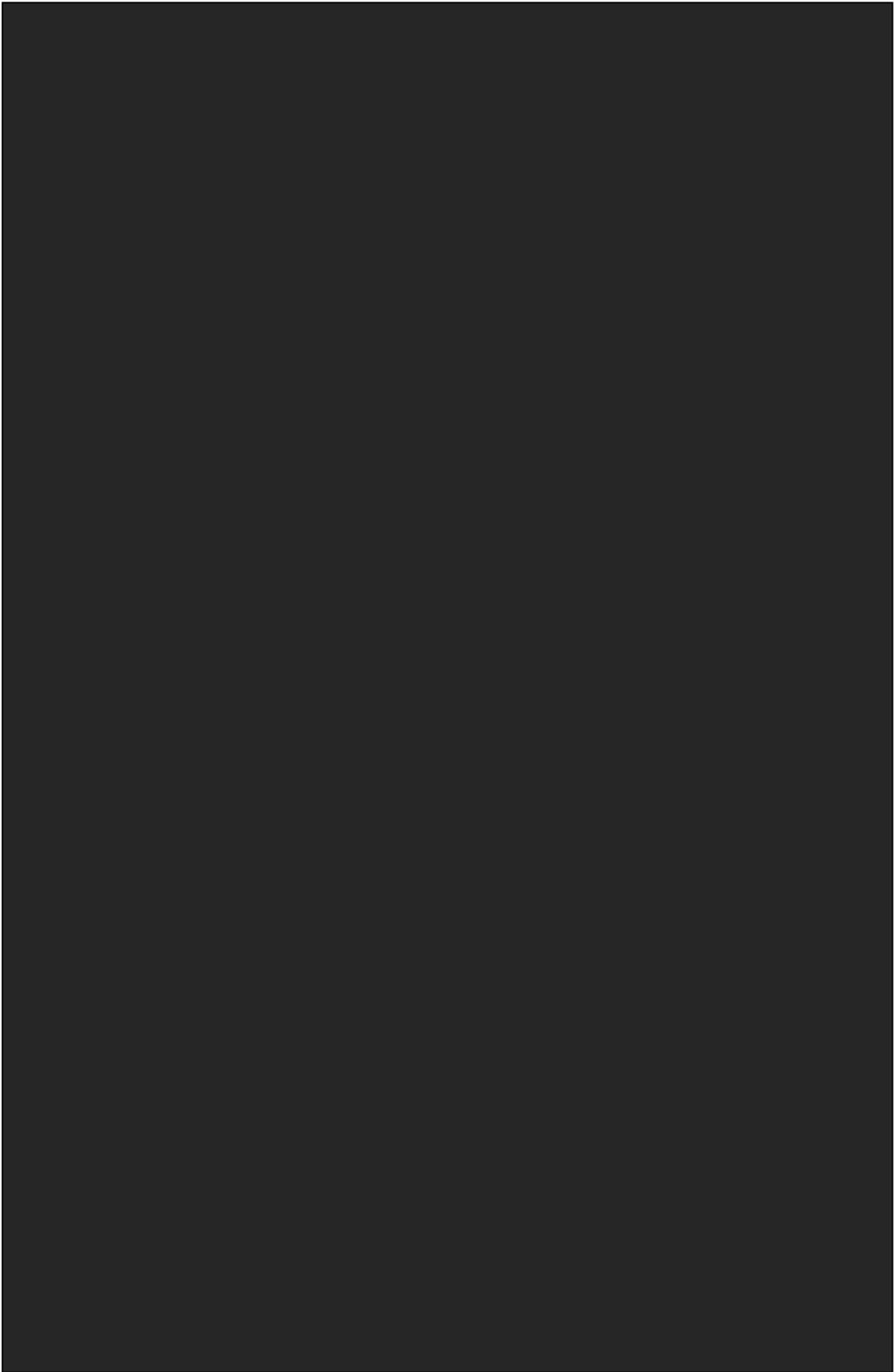
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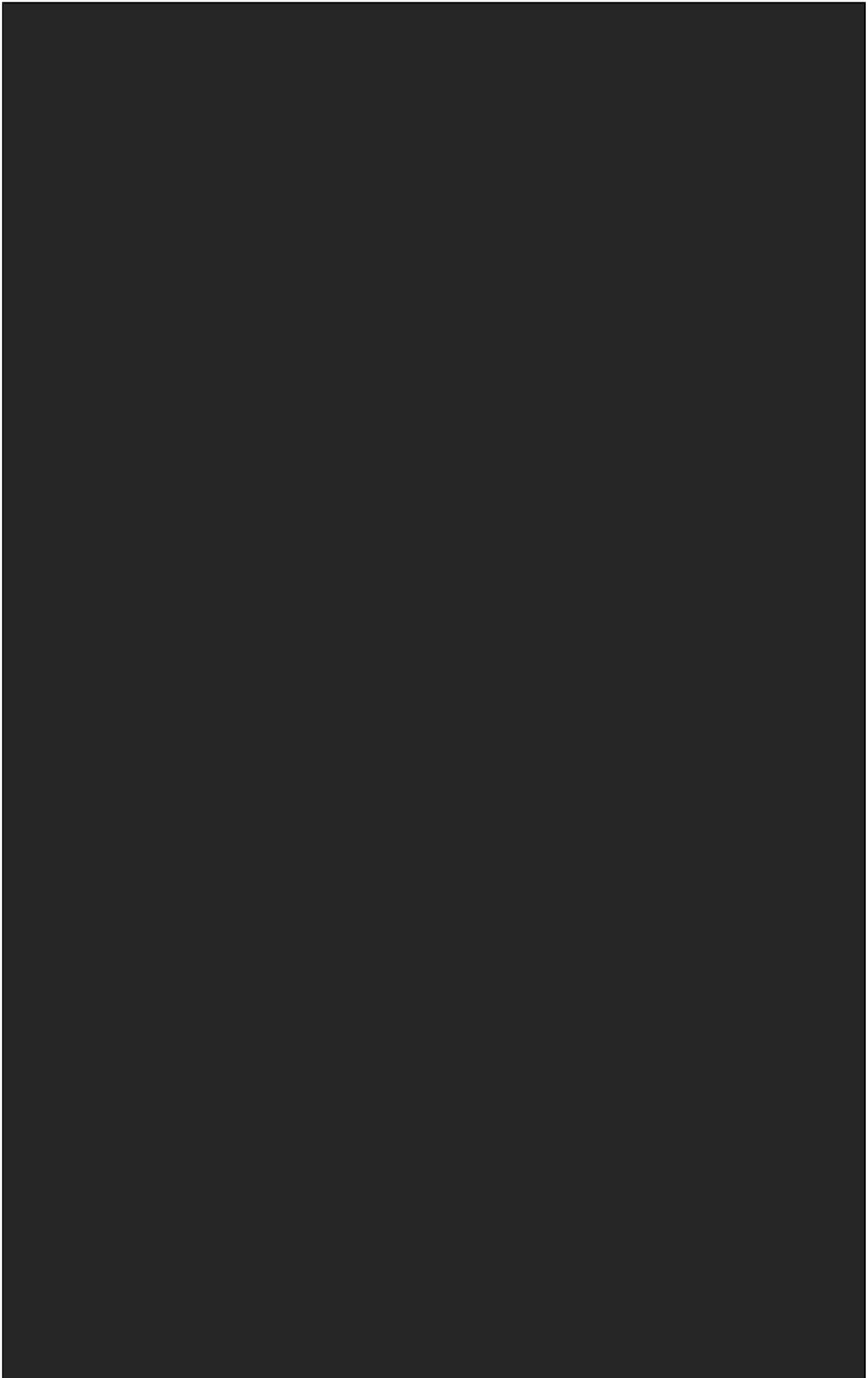
Appendix G: Hospital Anxiety and Depression Scale

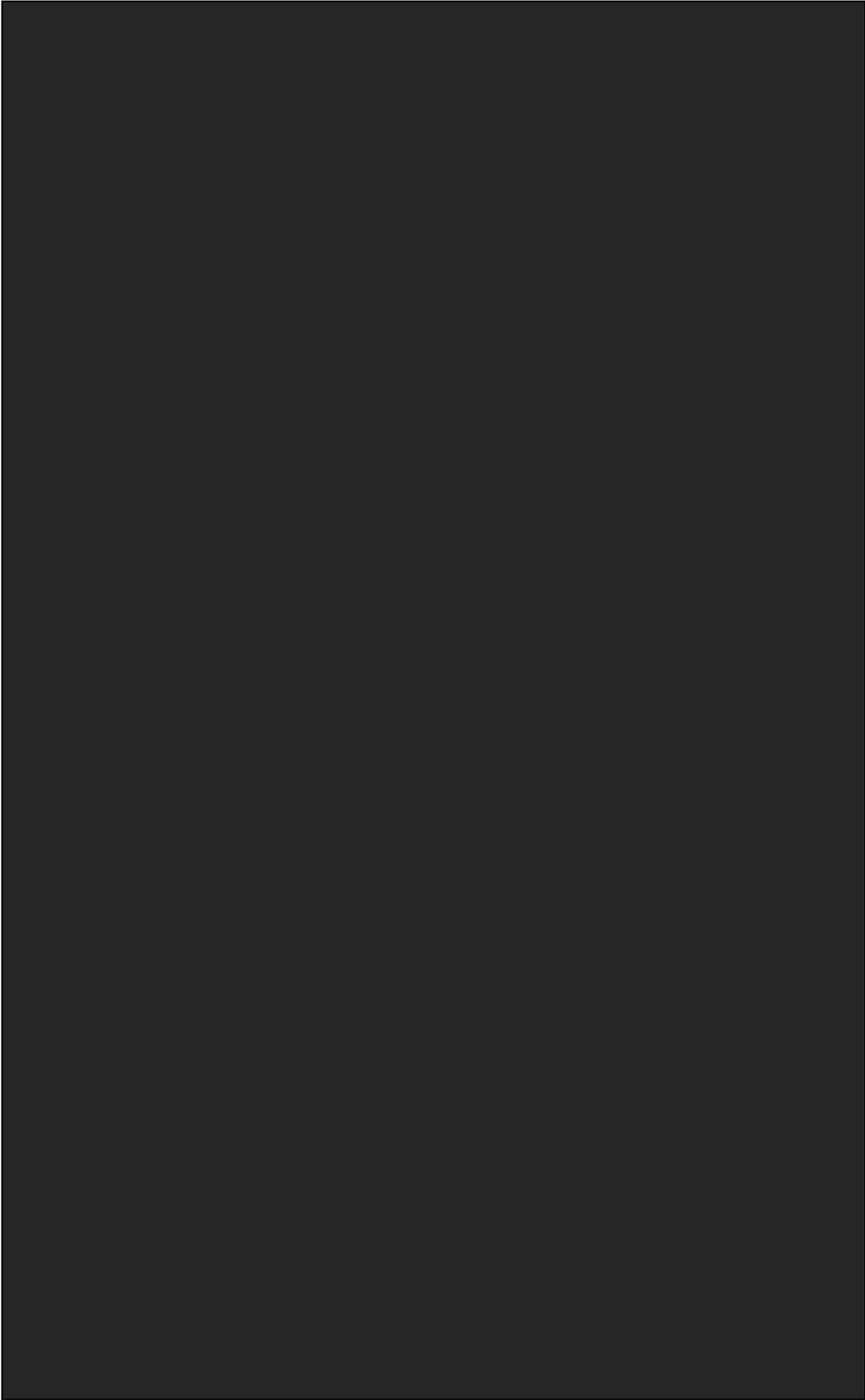
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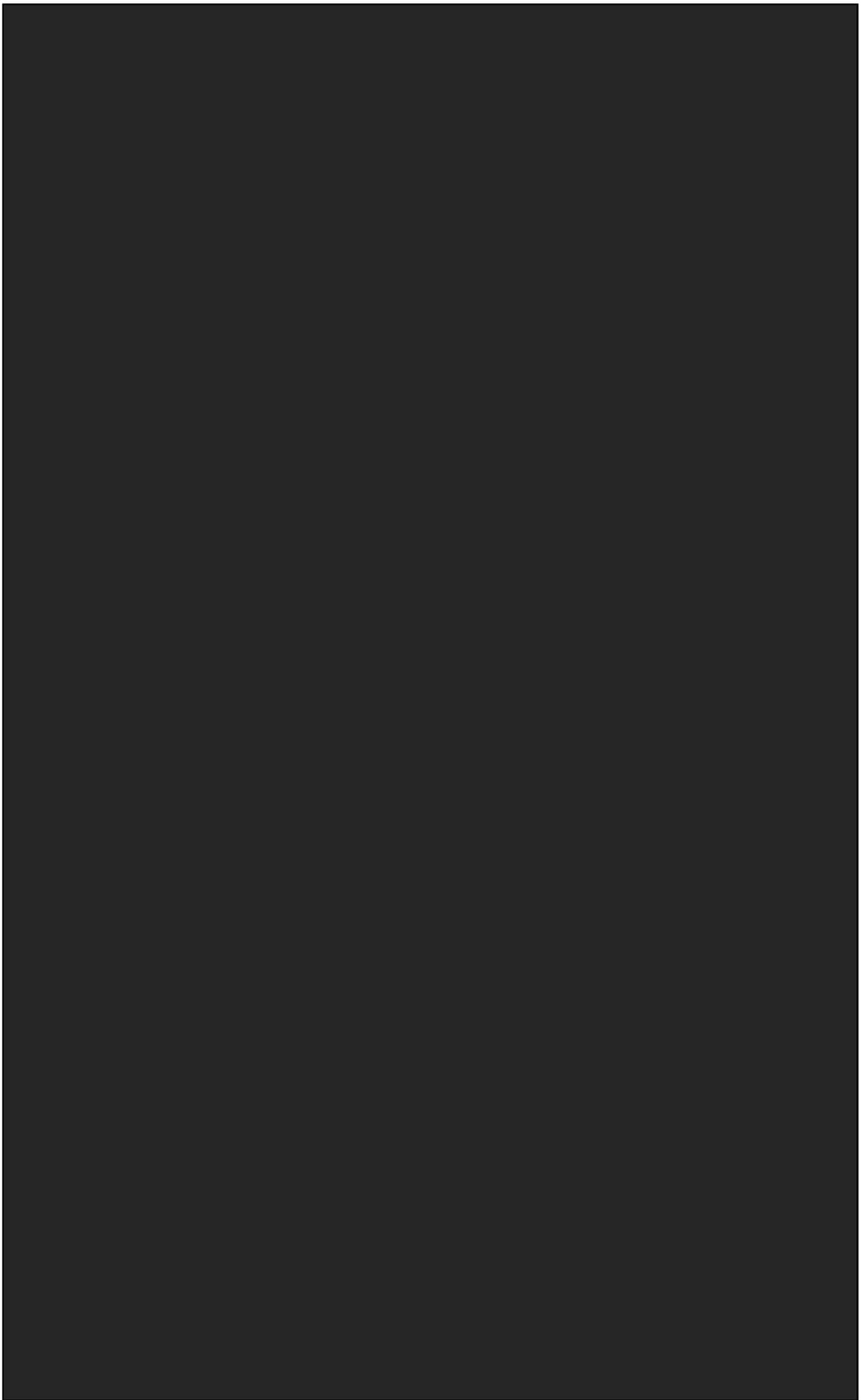
Appendix H: Test of Premorbid Functioning (TOPF)

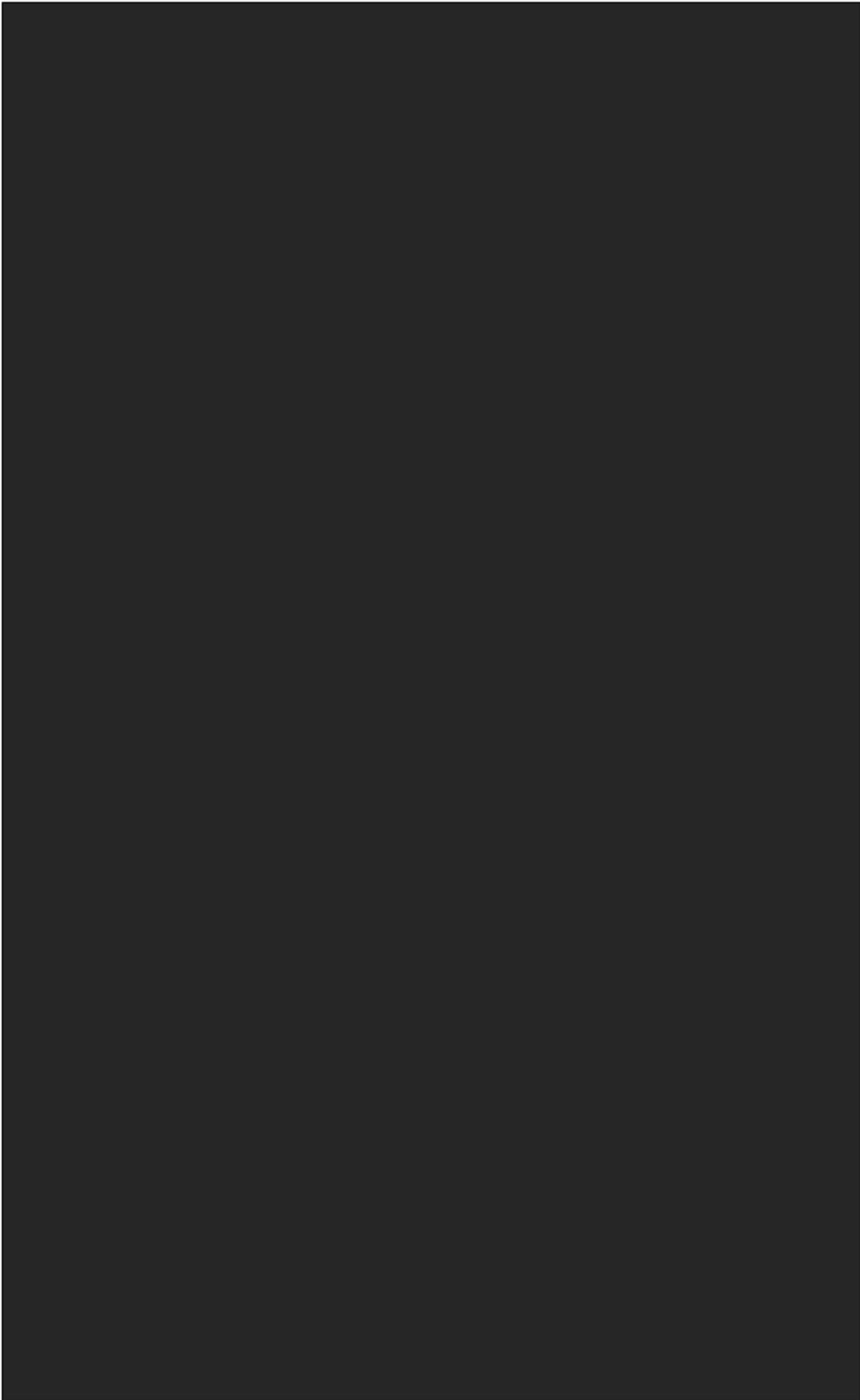


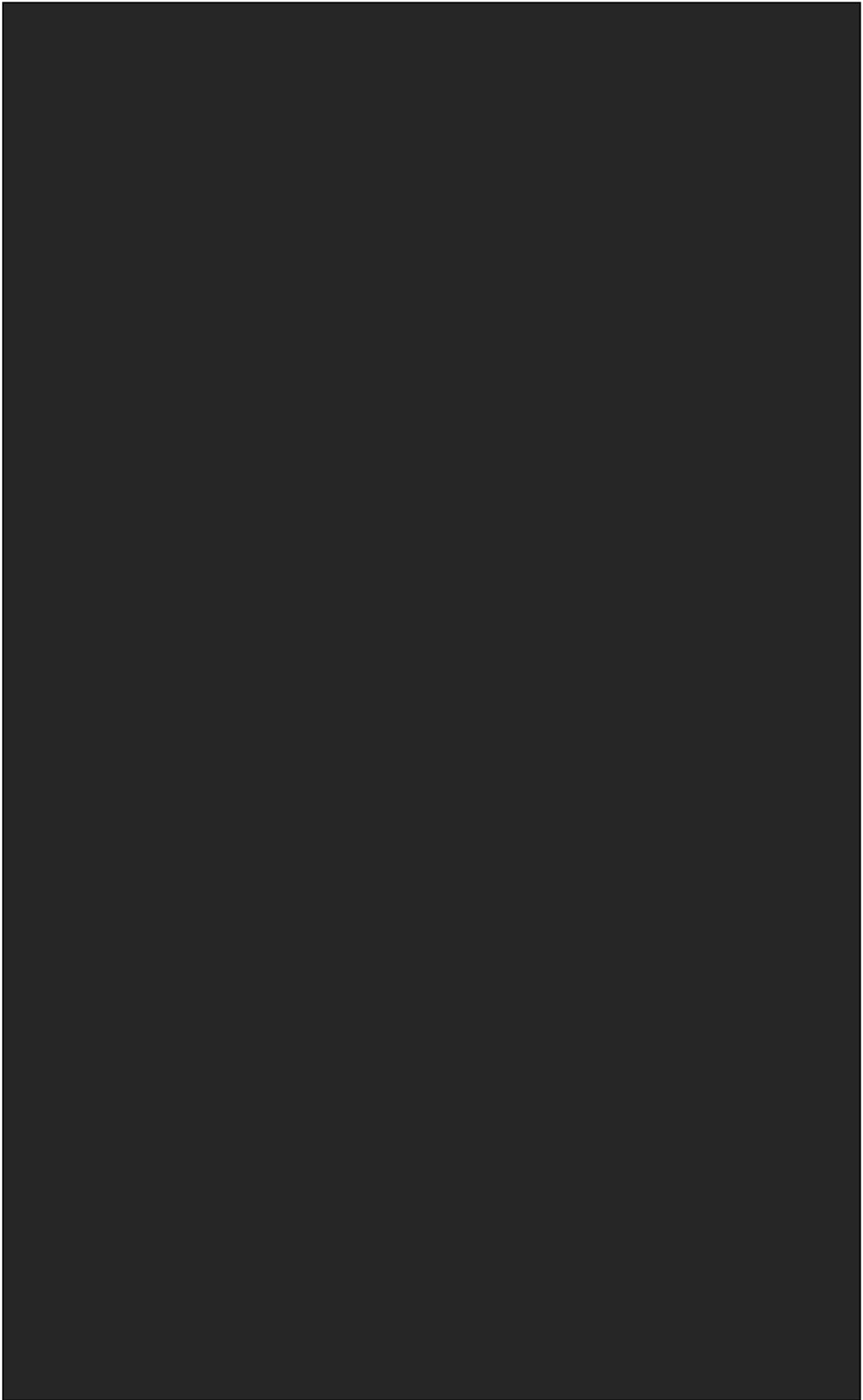
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Appendix I: Patient information sheet

RESEARCH DEPARTMENT OF CLINICAL,
EDUCATIONAL AND HEALTH PSYCHOLOGY



Stage 1 Participant Information Sheet- Clinical Sample

Can people with memory difficulties and dementia do 'Cognitive behaviour therapy' (CBT)?

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. This will take 10 minutes. Talk to others about the study if you wish. Part 1 will tell you the purpose of this study and what will happen to you if you take part. Part 2 will give you more detailed information about the conduct of the study. Ask us if there is anything that is not clear.

PART 1

What is the purpose of the study?

We are researching therapy for people with dementia or memory difficulties.

The main reason for doing this study is that people with dementia/memory difficulties can often feel quite depressed or anxious. Sometimes they are offered a type of counseling called CBT to help them with this. However, elements of CBT can be quite difficult for some people to understand. The aim of this study is to see how easy it is for people with dementia/memory difficulties to understand the different parts of CBT.

Why have I been invited?

You have been invited because you are over 50 and have problems with your memory or dementia. We are inviting some people who have memory difficulties or dementia and some people who don't take part in the study so that we can look at differences between them.

Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You can change your mind at any time and withdraw from the study. This will not affect your care.

What will happen if I take part?

You will meet with a researcher for one to one and a half hours. The researcher will meet with you in a place of your choosing, generally our clinic or your home.

Expenses

Participants who travel to the clinic for the research will be reimbursed for the full cost of their journey.

What will I have to do?

The research will involve filling in some questionnaires and doing practical and pencil and paper tasks to look at memory and other abilities.

Clinical Information Sheet Stage 1 (Student Study)
Version 5 (10/04/2015)

What are the possible disadvantages and risks of taking part?

We will be giving you some questionnaires as well as practical and pencil and paper tasks. While we don't think it is likely, this might make you feel worried or distressed. If this were the case you could stop the research at any time. We would also discuss with you what sources of support are available and direct you to them. You may have questions about your current clinical care from the service or your current diagnosis. We cannot offer any clinical advice during the research but we will direct you to someone who can answer any questions.

What are the possible benefits of taking part?

We cannot promise the study will help you but we hope the information we get from this study will help improve the treatment of people with dementia and memory difficulties. Some people have also told us they enjoy the process of doing the questionnaires and tasks.

What happens when the research study stops?

After you have taken part the researcher may ask you if you are interested in taking part in the second stage of this study. It will involve another hour of testing either at your home or at the clinic where you will complete questionnaires and a short interview about a recent life event. Information sheets about the second part of the study will be provided at the end of the research session to help you decide whether to take part. You will have time to take this away and think about your decision. A smaller number of people are needed for this second part of this study so when we have enough people for stage 2 we will stop asking people if they want to take part in this.

If you are interested in how you have done on the questionnaires and tasks then we can provide you with individualised feedback. You can contact Dr Joshua Stott on [REDACTED] or Catherine Bousfield on [REDACTED] if you want this.

You and all other participants will be invited to a feedback session once the study is completed. At this session, we will present what we have found and answer questions you may have about the research.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2**What if relevant new information becomes available?**

If the study is stopped for any reason, we will tell you and arrange your continuing care.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time and this will not affect your usual care. We will discuss with you whether you want all of your information withdrawn from the study.

What if there is a problem?

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If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you (please see harm section below). Please ask your researcher if you would like more information on this.

Harm

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your researcher, please make the claim in writing to Dr Joshua Stott who is the Chief Investigator for the research and is based at UCL. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

If you suspect harm is the result of the National Health Service and wish to make a formal complaint, you can do this by conducting the Patient Advice and Liaison Service who can offer advice on the best service to address your complaint. They can be contacted on pals.cnw1@nhs.net or 020 3214 5773.

Will my taking part in this study be kept confidential?

All information, which is collected, about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised. We will keep this data stored securely for 5 years and it will only be look at by the research team.

If you decide to take part in the study we will write to your GP to let them know about your involvement in the study. We will explain in the letter what participating in the study will involve and that you have made an informed decision after being made aware of what it will involve and your rights as a participant.

What will happen to the results of the research study?

The results of the research may be published in scientific journals. You will not be identified in any data or report unless you have given your consent

Who is organising and funding the research?

The research is organised and funded by University College London and Central and North West London NHS Trust.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the National Research Ethics Committee. This particular research has also been reviewed and approved by academic staff at University College London.

Further information and contact details

If you want further information about the study or have any concerns about it, please do contact Dr Joshua Stott on [REDACTED] or Catherine Bousfield on [REDACTED].

Clinical Information Sheet Stage 1 (Student Study)
Version 5 (10/04/2015)

Appendix J: Participant consent form



Patient Identification Number for this trial:.....

CONSENT FORM - Stage 1
Clinical Sample

Title of Project: Can people with dementia access Cognitive Behavioural Therapy (CBT)?

Name of Chief Investigator: Dr Joshua Stott

Name of Student Researcher: Catherine Bousfield

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 17/07/2015 (version 5) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my care or legal rights being affected.
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University College London or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4. I agree to my GP being informed of my participation in the study.
5. I agree to take part in the above study.

Name of Participant

Date

Signature

Name of Person
taking consent.

Date

Signature

Appendix K: Joint project submission declaration: declaration of overlapping projects

The D.Clin.Psy projects of Noor Habib and Catherine Bousfield and the PhD project of our supervisor Dr Joshua Stott contain overlapping data. This is a declaration that we have followed UCL guidance on overlapping research projects created by Norah Fredericson, Professor of Educational Psychology.

I am required to make a clear declaration that my thesis will 'make a distinct contribution to the knowledge of the subject and will afford evidence of originality as shown by the discovery of new facts and/or the exercise of the independent critical power.'

I confirm that my research questions are coherently different from those asked by my colleague Noor and my supervisor Joshua.

I also confirm that although the three projects have common data, they do not completely overlap.

As stated in my empirical paper, I collected all the data for my dementia sample, which is a subset of the data that Joshua Stott will be using for his dementia sample. The data I share with Noor Habib is that which she collected for the older adult comparison sample. This is used in my study for a clearly defined and limited purpose.

I am finally required to confirm that I agree for my thesis to be made available upon request to examiners of other theses and I confirm that I agree for this to happen.

The guidance states that my colleague, supervisor, and I sign this declaration to confirm the accuracy of the given information to our best knowledge.



Noor Habib
Trainee Clinical Psychologist



Catherine Bousfield
Trainee Clinical Psychologist

20/06/2016



Dr. Joshua Stott
Senior Clinical Tutor

